NIH NATIONAL CANCER INSTITUTE

Cancer Therapy Evaluation Program
Intellectual Property Option to Collaborators

IP Option effective April 1, 2011

A. The IP Option described in this Section A would apply to inventions that would be described in patent disclosures that claim the use and/or the composition of the Agent(s) and that are conceived or first actually reduced to practice pursuant to clinical or non-clinical studies utilizing the NCI CTEP provided Agent(s)("Section A Inventions"):

Institution agrees to grant to Collaborator(s): (i) a royalty-free, worldwide, non-exclusive license for commercial purposes with the right to sub license to affiliates or collaborators working on behalf of Collaborator for Collaborator's development purposes; and (ii) a time limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty bearing license for commercial purposes, including the right to grant sub licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the non-exclusive commercial license, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs. Collaborator(s) will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of a patent application or six (6) months of receipt of an invention report notification of such a section A invention. In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. If Collaborator elects to negotiate an

exclusive commercial license to a Section A Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention.

For all Section A Inventions, regardless of Collaborator's decision to seek a commercial license, Institution agrees to grant Collaborator a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution retains the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

B. The IP Option described in this Section B would apply to inventions not covered by Section A, but are nevertheless conceived or first actually reduced to practice pursuant to clinical or non-clinical studies utilizing the CTEP-provided Agent(s). It also applies to inventions that are conceived or first actually reduced to practice pursuant to NCI CTEP-approved studies that use non-publicly available clinical data or specimens from patients treated with the CTEP-provided Agent (including specimens obtained from NCI CTEP-funded tissue banks) ("Section B Inventions"):

Institution agrees to grant to Collaborator(s): (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; and (ii) a nonexclusive, royalty-free, world-wide license to (a.) disclose Section B Inventions to a regulatory authority when seeking marketing authorization of the Agent, and (b.) disclose Section B Inventions on a product insert or other promotional material regarding the Agent after having obtained marketing authorization from a regulatory authority. Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Invention.

C. The IP Option described in this Section C would apply to inventions made by Institution's investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, as a result of research utilizing the CTEP-provided Agent(s), unreleased or non-publicly available clinical data or Agent treated specimens outside the scope of approval granted by the NCI CTEP (Unauthorized Inventions):

Institution agrees, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to Unauthorized Inventions. Institution will retain a non-exclusive, non-sub-licensable royalty free license to practice the invention for research use purposes.

D. Institution Notification

Institution agrees to promptly and confidentially notify NCI CTEP (**NCICTEPpubs@mail.nih.gov**) and Collaborator(s) in writing of any Section A Inventions, Section B Inventions, and Unauthorized Inventions upon the earlier of: (i) any submission of any invention disclosure to Institution of a Section A, Section B, or Unauthorized Invention, or (ii) the filing of any patent applications of a Section A, Section B, or Unauthorized Invention. Institution agrees to provide a copy of either the invention disclosure or the patent application to the Collaborator and to NCI CTEP which will treat it in accordance with 37 CFR Part 401. These requirements do not replace any applicable reporting requirements under the Bayh-Dole Act, 35 USC 200-212, and implementing regulations at 37 CFR Part 401.