

Division of Cancer Prevention (DCP) Intellectual Property (IP) Option to Collaborators

Definitions:

1. “Affiliate” means any corporation or other business entity controlled by, controlling, or under common control with the Collaborator. For this purpose, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.
2. “Agent” or “Technology” is Collaborator's property and defined in the technology transfer agreement between NCI DCP and Collaborator.
3. “Collaborator” means a biotechnology, pharmaceutical, or nutraceutical company that provides a proprietary Agent or Technology for use in the NCI DCP-supported Study.
4. “Institution” means an NCI DCP funding recipient that utilizes a Collaborator's Agent or Technology under the scope of a funding agreement.
5. “Invention” means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act ([7 U.S.C. 2321](#) *et seq.*).
6. “Study” means DCP-supported clinical and associated non-clinical studies conducted by the Institution under the scope of a funding agreement with NCI DCP.
7. “Subject Invention” means an Invention that is conceived or first actually reduced to practice in the performance of the Study conducted by the Institution using Collaborator's Agent or Technology.

A. The IP Option described in this Section A applies to Subject Inventions that claim the use and/or composition of the Collaborator's Agent or Technology in patent disclosures (“Section A Subject Inventions”). Collaborator's Agent or Technology will be provided to the Institution by NCI DCP, as applicable:

Institution agrees to grant to Collaborator(s): (i) a royalty-free, worldwide, non-exclusive license for commercial purposes with the right to sublicense 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 sublicenses, 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 royalty-free, worldwide, 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 will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Subject 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 Subject Invention; the timing is based on whichever event comes first. In the event that Collaborator fails to notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section A Subject 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 Subject Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Subject 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 Subject 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 Subject Invention.

For all Section A Subject 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 Subject 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 applies to Subject Inventions not covered by Section A, but are nevertheless conceived or first actually reduced to practice by the Institution during the conduct of the Study. It also applies to Inventions that are conceived or first actually reduced to practice pursuant to NCI DCP-funded studies that use non-publicly available clinical data or specimens from patients treated with Collaborator's Agent or Technology (including specimens obtained from NCI DCP-funded tissue banks) (“Section B Subject Inventions”):

Institution agrees to grant to Collaborator a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Section B Subject Inventions for research purposes only. Institution retains the right to make and use any Section B Subject Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so. Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Subject Invention.

Institution Notification

Institution agrees to promptly and confidentially notify NCI DCP (ncidcppio2@mail.nih.gov) and Collaborator(s) in writing of any Inventions upon the earlier of: (i) any submission of any

Invention disclosure to Institution of an Invention, or (ii) the filing of any patent applications on an Invention. Institution agrees to provide a copy of either the Invention disclosure or the patent application to the Collaborator and to NCI DCP 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 U.S.C. 200-212](#), and implementing regulations at [37 CFR part 401](#).