Intellectual Property Option to Collaborator

Institution agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the Institution's principal investigator or any other employees or agents of Institution, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Drug (hereinafter "Institution Inventions").

Institution agrees to grant to Collaborator: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Institution Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Institution Inventions on terms to be negotiated in good faith by Collaborator and Institution.). Collaborator shall notify Institution, in writing, of its interest in obtaining an exclusive license to any Institution Invention within six (6) months of Collaborator's receipt of notice of such Institution Invention(s). In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Institution Invention, and Institution will be free to dispose of its interests in such Institution Invention in accordance with Institution's 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 Institution Invention, then for a period of six (6) months thereafter Institution shall not offer to license the Institution 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 shall have a period of thirty (30) days in which to accept or reject the offer.

Institution agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 USC 201(e), arising out of any unauthorized use of the Collaborator's Study drug and/or any modifications to the Study Drug, shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Institution will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Institution will cause to be assigned to Collaborator all right, title and interest in and to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Institution may also be conducting other more basic research using the Study Drug under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

Protection of Proprietary Data

"Clinical Data and Results and Raw Data will be provided exclusively to the NCI, the Collaborator, and the FDA, as appropriate. This provision shall not affect the investigators right to publish or present as described in the standard protocol language."

This statement ensures that data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI, the FDA, and the Collaborator. Furthermore, this addresses the needs of the Collaborator to have access to the patient records and raw data; it has no effect on the investigator's right to publish.

35 USC(e):
"(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d) (FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance."

NIH "Intellectual Property Option to Collaborator"

This is a provision being added to certain NCI awards. The original intent was to ensure that NIH funded researchers have access to promising investigational agents belonging to pharmaceutical companies ("Collaborators") for use in clinical trials. However, this provision has spread to non-clinical CRADAs and has even begun showing up in MTAs for researchers who are not funded by NIH.

Summary of provision:

- Definition of Invention: "whether patentable or not," "conceived and/or first actually reduced to practice."
- Agree to grant Collaborator a paid-up nonexclusive, royalty-free, world-wide research purposes license to Inventions.
- Collaborator gets a time-limited first right to negotiate an exclusive, royalty-bearing commercial license to Inventions, with a right of first refusal should negotiations fail.
- Collaborator gets ownership of inventions, patentable or not, arising out of unauthorized use of or modification to study drug.
- Clinical Data and Results and Raw Data to be provided exclusively to NCI, Collaborator and FDA, though this shall not affect the right to publish or present (though this does not show up in all agreements).

Implementation Issues:

- Not limited to clinical trials – has also been used in CRADAs and MTAs.
- Introduced in the middle of multi-year awards.
- Has been used even when no investigational agent is being provided or when the compound is an NIH compound.

Primary Agreement Issues:

- Should be limited to patentable inventions (consistent with Bayh-Dole).
- Should be limited to inventions that relate to the study drug.
- Six month election period + three month negotiation period + six month right of first refusal can result in inventions being tied up for 15 months.
- "Penalty clause" pre-determines an extreme remedy, i.e., *ownership* of inventions, for unknown and possibly nonexistent damages. **Note – this provision would seem to be in direct contradiction of 35 USC 202(f).**
- Proprietary data approach is internally inconsistent. Could prevent any disclosure of research results, including raw data, outside of a publication or presentation. Could affect patient care, as well as future academic collaborations.
- Overall approach seems inconsistent with NIH's own policies, especially the Research Tools Guidelines.