

NEGOTIATING IP RIGHTS IN CLINICAL TRIAL AGREEMENTS BETWEEN ACADEMIC MEDICAL SITES AND INDUSTRY

January 11, 2017

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Intellectual Property Rights – Industry Sponsored Clinical Studies

Generally, the position of industry regarding intellectual property rights in industry designed/sponsored clinical studies is:

It's our Concept...

It's our Product....

It's our Money....

So, it's all ours....

Definition of “Intellectual Property”

- Industry sponsors typically define “Intellectual Property” very broadly.

Example: Any discovery, invention, know-how, ideas resulting, arising from or related to the Clinical Study...

- It is critical that the definition be narrowed to include only those inventions discovered/conceived (or conceived and reduced to practice) in the performance of the Clinical Study.

General Guidelines

Industry Designed Clinical Studies

If the Clinical Study was (a) designed by the Industry Sponsor; (b) involves the Industry Sponsor's product (drug or device); and (c) is funded entirely by the Industry Sponsor, then it is reasonable to grant the Industry Sponsor all rights in inventions discovered in the performance of that Study.

General Guidelines

Investigator Initiated Studies

If the Clinical Study was not designed by the Industry Sponsor then various factors must be considered when deciding who shall own any Intellectual Property. Such factors include:

- Whose idea was it?
- Who designed the study?
- Whose drug/device is it?
- Who is funding the study?
- Who is the sponsor of the study?
- Who owns the background IP?
- Who funded the background IP?
- Are there any existing patents, licenses, material transfer agreements?

Options to Consider

Depending on the circumstances, the ownership of Intellectual Property may be as follows:

Institution owns the Intellectual Property, but grants Industry Sponsor:

- a non-exclusive, royalty-free license to use the Intellectual Property (but with no right to sublicense); and/or
- an option to negotiate an exclusive, royalty-bearing license to use the Intellectual Property for its business purposes

or

Institution and Industry Sponsor jointly own the Intellectual Property related to Industry Sponsor's drug/device; Institution owns all other Intellectual Property

or

Industry Sponsor owns the Intellectual Property directly relating to its drug/device and Institution owns all other Intellectual Property.

Institution's Retained Rights

The academic institution must always retain a non-exclusive, worldwide, royalty-free license to use Intellectual Property for its educational, non-commercial research, and patient care purposes.

Academic Institution Considerations

- Bayh Dole mandate to commercialize and share revenue with inventors
- Federal funding of background IP
- Is Industry Sponsor fully funding the Study (including full overhead) or only contributing drug/device
- Tax-exempt bond considerations
- Tax exempt status
- Conflicts of Interest

Industry Sponsored Study Unacceptable IP terms

“Any inventions or discoveries (whether patentable or not), innovations, suggestions, ideas and reports arising out of or in connection with the performance of the Study by Institution and/or Investigator shall be immediately disclosed to Sponsor, and shall be the exclusive property of Sponsor. Upon Sponsor's request, Institution and Investigator shall take all actions necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name with respect to any of the foregoing.”

Industry Sponsored Study

Acceptable IP terms

“Any inventions or discoveries (whether patentable or not) discovered by Institution or Investigator in the performance of the Study (“Inventions”) shall be promptly disclosed to Sponsor and Sponsor shall exclusively own any rights that Institution and Investigator may have in such Inventions, provided that Institution shall have a non-exclusive, royalty-free, irrevocable, worldwide license to use any Inventions for its educational, non-commercial research and patient care purposes. Upon Sponsor’s reasonable written request, Institution and Investigator agree to reasonably assist Sponsor in obtaining patent protection for any Inventions, provided that Sponsor reimburses Institution and Investigator for all reasonable time spent and costs incurred in providing such assistance.”

Investigator-Initiated Study

Acceptable IP terms (Option 1)

“Any discoveries or inventions (whether or not patentable) discovered by Institution or Investigator in the performance of the Study (“Inventions”) shall be owned by Institution. Institution hereby grants Sponsor an exclusive option to a worldwide, exclusive, irrevocable, royalty-bearing license to any Inventions involving the Study Compound (“Sponsor Inventions”) provided that Institution retains a non-exclusive, royalty-free, irrevocable, worldwide license to use Sponsor Inventions for its educational, non-commercial research and patient care purposes. Sponsor must notify Institution within six (6) months from the date of disclosure of any Sponsor Inventions of its intent to exercise such option, otherwise Institution shall be free to license Sponsor Inventions to a third party.”

Investigator-Initiated Study

Acceptable IP terms (Option 2)

“Any discoveries or inventions (whether or not patentable) discovered by Institution or Investigator in the performance of the Study which involve the Study Drug (“Sponsor Inventions) shall be promptly disclosed to Sponsor and shall be jointly and equally owned by Sponsor and Institution, provided that Institution shall have a non-exclusive, royalty-free, irrevocable, worldwide license to use any Sponsor Inventions for its educational, non-commercial research and patient care purposes. All other discoveries or inventions (whether or not patentable) discovered by Institution or Investigator in the performance of the Study (“Institution Inventions”) shall be owned exclusively by Institution.”

Investigator-Initiated Study

Acceptable IP terms (Option 3)

“Any discoveries or inventions (whether or not patentable) discovered by Institution or Investigator in the performance of the Study which involve the Study Drug (“Sponsor Inventions) shall be promptly disclosed to Sponsor and Sponsor shall own any rights that Institution or Investigator may have in such Sponsor Inventions, provided that Institution shall have a non-exclusive, royalty-free, irrevocable, worldwide license to use any Sponsor Inventions for its educational, non-commercial research and patient care purposes. All other discoveries or inventions (whether or not patentable) discovered by Institution or Investigator in the performance of the Study (“Institution Inventions”) shall be owned exclusively by Institution.”

Questions



Thanks!

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