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# Intellectual Property Provisions of Clinical Trial Agreements

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# What Will We Cover?

- IP basics
- Relevant IP in a clinical trial agreement
- Institution perspectives
- Sponsor perspectives
- Clinical trial agreement
- Negotiation tips



# What Types of IP Are We Concerned With?

- Patents
  - Exclude others from making, using, offering for sale or selling his/her invention in the U.S. or importing the invention into the U.S.
- Copyrights
  - Gives the owner the right to make copies of, distribute, adapt, perform and/or display creative works for a limited period of time
- Trade secret
  - Information that has economic value, not known to others and the owner takes reasonable measures to keep secret to afford economic advantage over others
  - Know-how



# Differences in Each Type

	Patent	Trademark	Copyright	Trade Secret
<b>Basis</b>	<ul style="list-style-type: none"> <li>• Article 1, § 8</li> <li>• Patent Act</li> <li>• Title 35 USC</li> </ul>	<ul style="list-style-type: none"> <li>• Commerce clause</li> <li>• Lanham Act</li> </ul>	<ul style="list-style-type: none"> <li>• Article 1, § 8</li> <li>• Copyright Act</li> <li>• Title 17 USC</li> </ul>	<ul style="list-style-type: none"> <li>• Uniform Trade Secret Act</li> <li>• Defend Trade Secret Act</li> </ul>
<b>Standards</b>	<ul style="list-style-type: none"> <li>• Have utility</li> <li>• Be novel and non-obvious</li> <li>• Sufficiently disclosed</li> <li>• Appropriate subject matter</li> </ul>	<ul style="list-style-type: none"> <li>• Symbol, words, names</li> <li>• Source of products/services that distinguishes it from others</li> <li>• Distinctiveness</li> </ul>	<ul style="list-style-type: none"> <li>• “Original” work fixed in a tangible medium</li> </ul>	<ul style="list-style-type: none"> <li>• Essential in the operation of a business</li> <li>• Kept secret to afford economic advantage over others</li> </ul>
<b>Duration</b>	20 years from date of filing	As long as it is being used and maintained	<ul style="list-style-type: none"> <li>• Author’s life + 70 years</li> </ul>	Until it becomes public



# Key Differences

- Patents: Right to **exclude** others, but NOT to practice your patent (i.e. dominating prior patent)
- Trade Secrets: No upfront cost, but loss of legal protection as soon as they become public, regardless of fault
- Copyrights: Right to display, copy, etc. AND right to exclude others from doing same



# IP in Clinical Trial Agreement

- What is the IP?
  - Drug or device-related
    - e.g., new use, new design, new dosing, new combinations
  - Disease related
    - e.g., biomarker, diagnosis parameters
  - Unrelated
    - e.g., protocol deviations
- How do we allocate ownership and responsibilities for that IP during the relationship?
  - Pre-existing
  - What is the study IP
    - Is it jointly developed?
  - What about the improvements



# What Is IP at Issue?

- Patents probably are the main concern
- How is it described in a CTA?
  - What is an invention?
    - Is it patentable?
  - Mechanism of identifying it
  - Inventorship and ownership rules
  - Process for procuring and process for defending it



# Ownership

- Jurisdictional
  - What rules are we following?
- What steps need to be in place to ensure proper transfer?
  - Employment contracts
  - Assignments
    - Chain of title



# Institution Perspectives

- Revenue
- Further research
  - Educational mission and institutional policies
- Publications
  - Preserve the right to publish the results of the study
  - If a state institution is acting as a service provider, there may be tax implications
  - Keep delays for review to a reasonable limit
  - If multi-site, preserving the right to publish separately
  - Copyright ownership in publications



# Sponsor Perspectives

- Improving current standard of care
- Protecting investments
  - Life cycle extensions
  - Freedom to operate
  - Confidentiality and access
  - Patent protection



# Sample: Institution Perspective

Institution and Principal Investigator have the right to publish or otherwise publicly disclose information gained in the course of this Agreement. .... Institution will submit any prepublication materials to Sponsor for review and comment at least \_\_\_\_days prior to planned submission for publication.

Sponsor shall notify Institution within \_\_\_\_days of receipt of such materials whether it desires Institution to file patent applications on any inventions contained in the materials; and, if Institution agrees to do so, Institution will proceed to file a patent application in due course.

Institution shall have the final authority to determine the scope and content of any publications.



# Sample: Institution Perspective(Cont'd)

Institution agrees that the Investigator will promptly disclose to its Intellectual Property Committee and to Sponsor any inventions, ideas, ....., whether patentable or unpatentable, which the Investigator, alone or jointly with others, may conceive, invent, produce, or reduce to practice during this Trial and which result from the Trial (herein referred to as “Inventions”). It is agreed that all Inventions and any information with respect thereto shall be subject to the confidentiality obligations set forth in ....

Any Inventions, as defined above, that originate solely with the Investigator, or any other Institution employee associated with this Trial (jointly or severally referred to as “Inventor”) shall be the property of Institution. If Inventor is a co-inventor with Sponsor, its agents or employees, Institution and Sponsor shall jointly own the Invention. Institution does hereby grant to Sponsor an exclusive option to acquire an exclusive, worldwide royalty-bearing license to any such Invention which results from the Study. Sponsor shall indicate its intention to exercise its option to license by notifying Institution in writing within \_\_\_\_ days of each Invention’s disclosure to Sponsor. If Sponsor decides to exercise its option, the terms shall be negotiated in good faith within one hundred twenty (120) days of the date the option is exercised, or until such time as the parties may mutually agree in writing.



# Clinical Trial Agreement (CTA)

- Major Terms
  - Payment
  - Confidentiality
  - Data ownership
  - **Intellectual Property**
  - Publication
  - Insurance coverage
  - Patient/data privacy
  - Indemnification



# Types of CTAs

- **Sponsor-Initiated Clinical Trial**
  - Sponsor – CRO MSA on Clinical Trial
  - Sponsor – Site/Principal Investigator (PI)
- Investigator-Initiated Clinical Trial



# Basis of Sponsor's IP Ownership

- **Sponsor-Initiated Clinical Trial**

- Drug development cost (investment)
- Drug product for clinical trial (material)
- Drug protocol provided (information)
- Payment for service (funding)



# Sponsor's Perspective – General Principles

- Sponsor should own all the inventions (patentable or unpatentable) generated during the clinical trial
- Institution/PI/CRO should assign all inventions resulting from clinical trial to Sponsor, but
- Institution/PI retain publication right, subject to
  - Protection of Sponsor's patent right &
  - Confidentiality provisions



# Sponsor's Perspective – Licenses

- Sponsor should obtain a license from the institution/PI/CRO on their pertinent background IP, improvement IP and joint IP (if any) for freedom to operate
- Institution/PI obtains license to use the sponsor's invention (subject to confidentiality provisions) for internal, non-commercial research and educational purposes



# Sponsor's Perspective – Copyright

- Sponsor owns **copyrightable works** generated from the clinical trial
- Institution and PI have the right to use copyrighted materials for educational and research purposes



# Sponsor's Perspective – Trade Secret

- Usually protected through the confidentiality provisions
- “Confidential information” may interfere with Institution/Investigator’s publication rights
- Remedy: a publication delay provision defining a reasonable period (30-60 days) for Sponsor to review the manuscript prior to submission



# Right to Information and Assignments

- Prompt disclosure of inventions and or discoveries
- Assignment of assignable rights and title in relation to IP rights and know-how, and assistance in filing and prosecution of patent applications
- Seek from both Institution and PI



# Assignments From Affiliates

- All other parties involved in conducting the clinical trial
- Examples: coinvestigators, staff physicians, residents, interns, and CROs or their employees



# Considerations / Negotiation Tips

- Set objectives prior to the negotiation
- Clarify roles of Site, PI, and CRO
- Identify potential types of IP at issue
- Set confidentiality rules
- Set ownership rules
- Set assignment rules
- Prepare for compromise when necessary



# Example of IP Clause (“Sponsor Loophole”)

- “Site assigns all discoveries or inventions that arise out of the performance of Services under this Agreement to Sponsor.”
- **Issue:** U.S. patent law does not recognize agency relationship with regard to inventorship.

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# MAGI Model CTA

- “Site represents and warrants that it has the authority to grant all of the rights granted in this Section, and that its potential Inventors are and will be obligated to assign their Inventions to Sponsor and will not enter into agreements with third-parties that would interfere with this obligation.” (MAGI: Model Agreements and Guidelines International)

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## Example of CTA IP Provision

All materials, documents, information, programs and suggestions initially provided to CRO by Sponsor or on behalf of Sponsor in connection with any Study shall be the exclusive property of Sponsor. (Sponsor's IP).....

Notwithstanding the above, Sponsor acknowledges that any CRO Property that is improved, modified or developed by CRO under or during the term of this Agreement shall be the sole and exclusive property of CRO. (CRO's IP)



# Example IP Provision – Sponsor-Revision

All materials, documents, information, inventions, proposals, programs and suggestions initially provided to CRO by Sponsor or on behalf of Sponsor or generated during the Services provided by CRO, research site, principal investigator, or any related third party, or any improvements thereof, in connection with any Study or the Study Product defined hereunder shall be the exclusive property of Sponsor.



## Example IP Provision – Sponsor-Revision (Cont'd)

Notwithstanding the above, Sponsor acknowledges that any CRO Property that is improved, modified or developed by CRO and that is not dependent on or related to Study Product or the Study under or during the term of this Agreement shall be the property of CRO, and CRO hereby grants to Sponsor a perpetual, irrevocable, worldwide, royalty-free, transferable license (with the right to sublicense) in connection with the development, use, manufacture and sale of the Study Product without any obligation whatsoever to CRO.



# Summary

- Addressing IP issues in a CTA: patent, copyright, trade secret, know-how, etc.
- Clarifying real-world issues
- Resolving IP ownership and license issues early
- Taking different perspectives and being flexible in negotiation
- Making necessary compromise and achieving business goals



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