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Five Intellectual Property Loopholes in Clinical Trial Agreements

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In a typical clinical trial agreement (CTA), the section dealing with intellectual property (IP) rights is often heavily negotiated by academic and other institutions.

Sponsors require clear and marketable title to the IP rights related to their study drug or device. Any ambiguity about these IP rights could lead to a future legal challenge affecting the licensing, marketing and/or sale of the drug or device. Therefore, sponsors are reluctant to relinquish any IP rights to a study site. However, sponsors should focus their attention on trials and sites that have more than a remote chance of generating IP.

Academic sites care about protecting their own intellectual property and want the ability to use the knowledge gained from a clinical trial for research, teaching and sometimes commercial purposes. While sponsors might view sites as contractors performing a service for hire, like any other vendor, sites often view clinical research as a collaborative process, in which both parties contribute their expertise and intellectual resources.

Phrases that sound perfectly reasonable may create problematic loopholes. The loopholes below are based on actual clinical trial agreements. Some of them are simplified and taken out of context, but they identify areas requiring close attention. Suggested language is drawn from MAGI's Model Clinical Trial Agreement, available at https://www.magiworld.org/standards.

Sponsor Loophole

> "Site assigns all discoveries or inventions that arise out of the performance of Services under this Agreement to Sponsor."

Issue: Under agency law, the employees (agents) of an employer (principal) are legally bound to the terms of an agreement entered into (signed) by the employer. However, U.S. patent law does not recognize this agency relationship with regard to inventorship. (See Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993) [patent right initially vests with the individual and not the employer].) If an employer/site failed to obtain an assignment from the employee/inventor, the above clause will be ineffective in transferring these IP rights to the Sponsor.

Remedy: During the site selection stage, sponsors should determine how sites handle IP assignments from their employees. At the CTA negotiation stage, sponsors should obtain a "Representation and Warranty" from the site that all of its employees, contractors and other personnel working on the study have assigned any IP rights to the site, paying particular attention to physician/investigators who are not site employees. Sponsors should make sure that sites appreciate the significance of their potential liability.

See MAGI Model Clinical Trial Agreement Article 7.2: "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."

Site Loopholes

1. "Sponsor grants Site a perpetual, non-exclusive, royalty-free license to use Inventions to perform the Study, for its internal educational, non-commercial research, and patient care purposes, and to comply with any applicable laws and regulations."

Issue: Just as sponsors need to ensure that a site has proper legal authority to transfer IP rights, sites need to ensure that the sponsor they are contracting with is capable of an effective transfer of IP rights to the site. With Big Pharma strategically partnering in the clinical development of biologics/compounds/devices with smaller sponsors, this loophole is becoming increasingly important. Determining joint ownership rights to the biologic/compound/device is not only important for purposes of the IP section but for other sections of the CTA as well, including but not limited to, indemnification and publication.

Remedy: "Sponsor Authority: Sponsor represents and warrants it is the owner of the Study Drug/Device/Biologic and that it has the authority to grant all of the rights granted in this Agreement."

2. "Sponsor shall own all right and title in the Study Drug and Protocol, except for a non-exclusive license to Site to use the Study Data for internal academic non-commercial research purposes."

Issue A: If the investigator or an employee of the site contributed to the design of the study, the site might want greater rights to resulting IP.

Remedy A: Depending on the circumstances, joint inventorship rights between the sponsor and site may be more appropriate than the limited license above.

Issue B: Is the study funded in whole in part by the federal government? If so, the Bayh-Dole Act requires the CTA to recognize the IP rights of the federal government to a non-exclusive license to any IP developed from federally funded research.

Remedy B: Include language addressing federal rights.

See MAGI Model Clinical Trial Agreement Article 7.9: "Other Funding: Site will not knowingly support the Study with any third-party funding that may adversely affect Sponsor's intellectual property rights under this Agreement. The Study falls outside the planned and committed activities of any U.S. government-funded project undertaken by Site and will not diminish or distract from the performance of such Government-funded Activities within the meaning of 37 CFR §401.1(a)(1). If any aspect of the Study Conduct is found to be Government-funded, Site will take all actions necessary to retain title to any Invention made under this Agreement, including those required by 37 CFR §401.14(c)(1), (2), and (3). If any Invention is controlled by federal law in accordance with 37 CFR §501.1 - 501.11, any license will be subject to the right of the U.S. government to retain an irrevocable, royalty-free right to use the Invention throughout the U.S. government."

3. "All writings, discoveries, inventions, ideas and other work product of any nature whatsoever, that are created, conceived or reduced to practice by Site out of the performance of Services under this Agreement, shall be considered "work made for hire" and owned by Sponsor. To the extent that the foregoing does not apply, Site assigns to Sponsor all intellectual property rights therein."

Issue: For sites operating as 501(c)(3) not-for-profit legal entities, the inclusion of 'work made for hire' language potentially jeopardizes the site's tax-exempt status under the Internal Revenue Code. (See IRS Regulation 501(c)(3)-1(d)(1(ii) [organizations prohibited from entering into transactions that result in a private benefit to another party].)

Remedy: Delete "work made for hire" language and add language that explicitly excludes it.

See MAGI Model Clinical Trial Agreement Article 7.5: "This Agreement is not a 'work made for hire' agreement under the copyright laws of any country."

4. "Site irrevocably appoints Sponsor as attorney-in-fact for the purposes of executing such documents as may be necessary or desirable to carry out the purposes of this IP section."

Issue: Powers of attorney are powerful documents and governed by state law. Granting this language will allow the Sponsor to take action at the USPTO without site knowledge or additional consent, in the event of a dispute.

Remedy: Instead, sites should contractually agree in the CTA to execute all documents reasonably necessary for the sponsor to secure ownership rights in the study IP at sponsor's cost and expense.

See MAGI Model Clinical Trial Agreement Article 7.7: "At Sponsor's request and expense, Site will execute, or cause to be executed by its Inventors, all documents and perform all acts deemed necessary by Sponsor to evidence Sponsor's ownership of Inventions, obtain patents in any country, and otherwise protect Sponsor's interests in Inventions."

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