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12 Publication Rights Loopholes in Clinical Trial Agreements

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Independent publication of clinical research results is a fundamental job requirement for academic clinical research investigators. These publications support the public service mission of their employers and protect the institutions' tax-free status. Corporate clinical research sponsors have very different motives. They pay sites and investigators to generate data on commercial products that will benefit the public when they eventually reach the market. If this data falls into the hands of their competitors, it may undermine the commercial rationale for investing in the research.

Reconciling these conflicting objectives in a clinical trial agreement (CTA) is challenging. It often requires compromises that please neither side. To make matters more complicated, publication language must be read in conjunction with the Confidentiality, Intellectual Property, Ownership & Use of Data, and Publicity sections of the CTA.

Study sponsors normally draft the CTA template. In searching for language that serves their interests and will also be acceptable to academic sites and investigators, they may include language that appears innocuous but creates loopholes that seriously compromise the needs of the site and investigator. The common loopholes below are based on actual clinical trial agreements. Many of them are simplified and out of context but identify areas requiring close attention. Suggested language is adapted from MAGI's Model Clinical Trial Agreement, available at http://www.magiworld.org/.

Common Loopholes

1. Investigator may publish Study results in reputable scientific journals.

   Issue: Investigator may want to present Study results in a scientific meeting or other legitimate forum.

   Remedy: Replace "journals" with "journals, scientific meetings, and other legitimate scientific forums."

2. Investigator may publish after the multicenter publication.

   Issues: There may be no multisite publication or it may be slow in coming. Actual publication may occur long after submission of a manuscript.

   Remedy: Add "Investigator may publish independently after the earlier of (a) submission of the multicenter article for publication by Sponsor; or (b) 12 months after the conclusion or early termination of the study or the study becomes inactive, as indicated by the substantial absence of subject and site monitoring visits."

3. Sponsor must approve publication.

   Issues: Sponsor approval of content contradicts investigator's independence. Sponsor may prevent publication by the investigator or anyone else. (See http://www.icmje.org/sponsor.htm).

   Remedy: Replace "approve" with "review and comment."

4. Sponsor may review publication and remove data, results and other information Sponsor deems to be confidential.

Issue: The standard for what information is confidential is subjective and under the Sponsor's control. Removing key information from a publication may severely damage its value and prevent publication. If the study's data and results are confidential information, there is nothing left to publish.

Remedy: Define "Confidential Information," specifying any exceptions for publications, such as results and supporting data.

5. Investigator may publish twelve months after database is locked.

   Issues: Database lock may be delayed by slow sites or delays by Sponsor. If results appear negative, Sponsor may never lock the database.

   Remedy: Specify maximum period of time that datalock (or any other requirement) can delay publication.

6. Investigator may publish after data, samples and reports are collected from all sites; multicenter publication is submitted; Sponsor reviews manuscript for confidential information and patentable inventions; and with reasonable extensions by Sponsor.

   Issues: A long string of delays can add up to years, making publication meaningless. The time period from submission to publication can be long.

   Remedy: Remove opportunities for delay, e.g., "study is complete" vs. "last subject visit." Shorten time periods and run them concurrently where possible, e.g., manuscript review both for Confidential Information and patentable inventions.

7. Authorship shall be determined by Sponsor; or Authorship shall be determined by number of patients enrolled at site; etc.

   Issue: Reputable journals subscribe to ICMJE's authorship guidelines or have their own policies governing authorship.

   Remedy: State that authorship will be determined by journal guidelines, or remain silent.

8. Sponsor shall own intellectual property created in the Study, including inventions, discoveries and copyrights.

   Issues: Sponsor ownership of copyrights gives it complete control of publications and authority to deny transfer of copyright to journals that require it.

   Remedy: Delete (or specifically exclude) Sponsor's ownership of copyrights on Investigator's publications and the data and results they include. Grant Sponsor use of Investigator's publications to the extent permitted by the journal.

9. Investigator may publish his/her site's results after the multicenter publication.

   Issue: Site's data, on its own, may not be statistically significant. Investigators should be able to independently analyze and interpret multicenter data.

   Remedy: Include language that authors of multicenter publications will be given access to all multicenter data, as required by ICMJE guidelines for authorship, sponsorship and accountability: "…as the persons directly responsible for their work, researchers should not enter into agreements that interfere with their access to the data and their ability to analyze them independently, and to prepare and publish manuscripts." (II.D.2)[1]

10. Investigator's data, on its own, is not statistically significant, so cannot be published independently without Sponsor's approval.

    Issue: Sponsor controls publication.

Remedy: Let the journal's editorial process determine significance by replacing text with "Publications will be published only in reputable scientific journals."

11. Investigator may not use Sponsor's name without Sponsor's approval.

    Issue: Scientific publications require use of Sponsor's name to explain the source of the data and funding.

    Remedy: Permit Investigator to use Sponsor's name to the extent required to meet requirements of journals, scientific meetings, and other legitimate forums.

12. Text missing: Sponsor will register the study as required by ICMJE guidelines and the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85).

    Issue: Over 500 medical journals, including JAMA, NEJM and Lancet, subscribe to the ICMJE guidelines, which require registration for many clinical studies before enrollment of the first subject. See also: Food and Drug Administration Amendments Act of 2007 (Public Law 110-85).

    Remedy: If Study should be registered, require Sponsor to register it per ICJME guidelines and Public Law 110-85.

Reference

1. The International Committee of Medical Journal Editors (ICMJE) makes its Uniform Requirements for Manuscripts Submitted to Biomedical Journals available at http://www.icmje.org/.

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