

## 18 Subject Injury and Indemnification CTA Loopholes

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The subject injury and indemnification sections of a clinical trial agreement are very complex. Phrases that sound perfectly reasonable may create loopholes that completely invalidate the protections. 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 drawn from MAGI's Model Clinical Trial Agreement, available at <http://www.firstclinical.com/magi/>.

### Common Loopholes: Subject Injury

1. Sponsor will pay Subject for the costs of treating his/her injuries.

Issues: Site may incur costs. Illness should be explicitly mentioned.

Remedy: Replace language with "Sponsor will reimburse Subject for his/her reasonable and customary diagnosis, care and treatment costs. Sponsor will pay Site and Investigator all reasonable and customary fees for standard-of-care diagnosis, care and treatment of the injury or illness. Sponsor will pay the fees of third-party providers and pharmacies to which Investigator delegates any diagnosis, care or treatment, subject to the above conditions."

2. Sponsor will reimburse Site for Institution's reasonable expenses for treating subject injuries.

Issues: Subject may incur costs outside the Site. Sponsor should reimburse Site based on its standard fees, not its costs. Illness should be explicitly mentioned.

Remedy: Replace language with "Sponsor will reimburse Subject for his/her reasonable and customary diagnosis, care and treatment costs. Sponsor will pay Site and Investigator all reasonable and customary fees for standard-of-care diagnosis, care and treatment of the injury or illness. Sponsor will pay the fees of third-party providers and pharmacies to which Investigator delegates any diagnosis, care or treatment, subject to the above conditions."

3. Sponsor will pay for unexpected and unforeseeable injuries caused by the Study.

Issues: Risks in protocol and informed consent form should not be excluded. Illness should be included.

Remedy: Delete "unexpected and unforeseeable." Add "and illness."

4. Sponsor will pay for costs of emergency medical treatment necessary to stabilize subject.

Issues: All diagnosis, care and treatment costs should be covered.

Remedy: Replace "emergency medical treatment necessary to stabilize subject" with "diagnosis, care and treatment of the subject."

5. Sponsor will pay for costs for treating an illness or injury that Site and Sponsor jointly determine to be caused by Study Drug.

Issues: The investigator has responsibility for determining adverse event causation. The subject may incur treatment costs without consulting with the site. There may

be costs incurred to diagnose an apparent illness or injury that turns out to be nonexistent.

Remedy: Replace "for treating" with "related to the diagnosis, care and treatment of." Replace "that Site and Sponsor jointly determine to be caused by Study Drug" with "due to participation in the Study."

6. Sponsor will pay for the costs of treatment if claims are not covered by the Subject's insurance coverage or other third-party payor.

Issues: Insurance coverage may require deductibles and copayments, which subject should not have to pay. Some sites believe that it is unethical to bill the subject's insurance carrier for the cost of treating clinical research injuries because it can negatively impact the availability and cost of coverage for the subject. The U.S. Centers for Medicare & Medicaid Services (CMS) has determined that a "clinical trial sponsor's agreement with trial participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such injury occurs... Therefore, Medicare will not make payment." (Letter from CMS Office of Financial Management, April 13, 2004)

Remedy: Delete "if claims are denied by the Subject's insurance coverage." Replace "treatment" with "diagnosis, care and treatment."

7. Sponsor will pay up to Five Thousand Dollars (\$5,000) per Subject.

Issue: Sponsor should pay all costs caused by participation in the study.

Remedy: Delete language.

### **Common Loopholes: Indemnification**

8. Sponsor will indemnify Institution and any agents and employees under the supervision of Investigator.

Issues: Investigator is not indemnified. Neither are personnel such as nurses, physicians, pharmacy and institutional board members who may not be under the investigator's supervision. Even if they bear no responsibility for a subject injury, they may still incur legal costs that should be covered by indemnification.

Remedies: Add ", Investigator." Delete "under the supervision of investigator"

9. Sponsor will indemnify... for any judgment awarded by a court of competent jurisdiction.

Issues: Defense costs may far exceed any award, and may be incurred even if the defense prevails. The parties may settle the claim.

Remedy: Replace "any judgment awarded by a court of competent jurisdiction" with "any and all third-party liabilities, including reasonable attorneys' and experts' fees and costs, arising from claims, actions and lawsuits."

10. Sponsor will indemnify... for any bodily injury.

Issues: Injuries may be psychological or be based on an unanticipated claim such as "dignitary harm." Defense costs may far exceed any award, and may be incurred even if the defense prevails.

Remedy: Replace "bodily injury" with "any and all third-party liabilities and expenses, including reasonable attorneys' and experts' fees and costs, arising from

claims, actions and lawsuits for property damage, personal injury, or death due to a Subject's participation in the study."

11. Sponsor will indemnify... for any injury not related to a claim of indemnitee's negligence.

Issues: This language waives indemnification even if the site's negligence was only 1% responsible for the injury. Most subject injury litigation will claim negligence by the site and investigator, whether or not anyone was negligent, so the site will incur defense costs, even if it was not negligent. Normally, the indemnitor covers the defense costs, which are later allocated after a court judgment or as part of a settlement.

Remedy: Delete "not related to a claim of indemnitee's negligence." Or replace "not related to a claim of" with "to the extent it is not caused by." (However, note that the determination of negligence comes late in the process.)

12. Sponsor will indemnify... for any claim directly caused by administration of the drug.

Issues: "Administration of the drug" can be interpreted to include only the actual administration of the drug, and not its later effects. Some injuries may not be direct, or the definition of "direct" may be argued to exclude, for example, interaction with another drug. Injury may also be caused by study procedures and use of study equipment.

Remedy: Replace "directly caused by administration of the drug" with "resulting from administration or use of Study Drug according to the Protocol or Sponsor's written instructions." Add "or proper performance of any Study test or procedure, or use of any equipment or supplies provided by Sponsor."

13. Sponsor will indemnify... for any injury directly caused by defect/malfunction of the device.

Issues: "Directly caused by defect/malfunction of the device" excludes injuries known to be caused by the investigational use of a device that is non-defective and functioning as intended in the investigation. Additionally, some injuries may not be direct, or the definition of "direct" may be argued to exclude, for example, interaction with a magnetic field.

Remedy: Delete "directly caused by defect/malfunction of the device."

14. Sponsor will indemnify...provided that the Study is conducted in accordance with the Protocol, all written instructions delivered by Sponsor, all laws and regulations, accepted standards of medical and clinical practice and GCP Guidelines.

Issues: Language conditions indemnification on site's compliance with regulatory and other matters that may have nothing to do with causation of an injury. The noncompliance may even relate to a different subject. Even if noncompliance contributes to an injury, it may be only part of the cause, so there should be partial indemnification. The protocol and other documents may conflict with one another.

Remedy: Replace "provided that the Study is conducted in accordance with the Protocol, all written instructions delivered by Sponsor, all laws and regulations, accepted standards of medical and clinical practice and GCP Guidelines." with "to the extent that the potential liability was caused by any indemnitee not conducting Study in accordance with..."

15. Sponsor shall have the sole right to select defense counsel, direct the defense, settlement, or other disposition of any claims, and indemnitees shall cooperate in the

defense of any claim, including but not limited to providing documents and witnesses for purposes of pre-trial preparation, discovery, and/or trial.

Issues: This language allows the sponsor to settle claims that impose costs on the site and investigator, such as possible loss of malpractice insurance or a medical license. It does not allow the site to waive indemnification and defend itself.

Remedy: Add: "However, any indemnitee may elect to defend itself and waive its indemnification rights for any particular claim. This waiver does not apply if a Court of competent jurisdiction orders an indemnitee to retain its own counsel. Sponsor may not effect any compromise or settlement of a third-party claim without indemnitees' consent, and indemnitees have no liability with respect to any compromise or settlement of any third-party claim effected without its consent, except if (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claim that may be made against the indemnitee; (b) the sole relief provided is monetary damages that are paid in full by sponsor; and (c) the compromise or settlement includes, as an unconditional term, the claimant's or the plaintiff's release of the indemnitee, in form and substance satisfactory to the indemnitee, from all liability in respect to the claim."

16. Sponsor will indemnify... provided that Sponsor is notified within 5 days after the claim is made.

Issue: Site may not become aware of a claim within five days because delivery of notice may be absent or defective, or the recipient may be on holiday.

Remedy: Replace "that Sponsor is notified within 5 days after the claim is made" with "Site notifies Sponsor promptly upon becoming aware of any claim or reasonable likelihood of a potential claim of indemnification rights under this Section." Or, add "However, Site's failure to promptly notify Sponsor of the claim will not relieve Sponsor of its indemnification obligations unless such delay or failure to notify actually prejudices Sponsor's ability to defend the claim or suit."

17. Sponsor will indemnify... provided that Site immediately provides Sponsor with complete written documentation of all the facts and details related to the claim.

Issue: The site does not have access to all the facts; some are in the possession of the sponsor or third-parties. It will take time for the site to document the facts and details related to the claim that are in its possession. It may overlook a fact or consider it unimportant. The claim may be very broad and require court intervention to narrow its scope.

Remedy: Replace "Site immediately provides Sponsor with complete written documentation of all the facts and details related to the claim" with "Site cooperates fully, at Sponsor's reasonable expense, in the defense or settlement of any claim, action or lawsuit."

18. In consideration of submission to Sponsor of a complete report of the results of the Study, Sponsor will indemnify...

Issues: Research sites do not normally provide reports on studies. Failure to provide a report did not cause the injury; there are other appropriate remedies for the sponsor if the site were to breach a contractual obligation such as providing a report. The term "complete" is undefined. The site may not have access to information about the entire study. A complete report may have to wait until the study is complete. Completion of the report may require action by the sponsor or a third-party, which may not be forthcoming.

Remedy: Delete "In consideration of submission to Sponsor of a complete report of the results of the Study."

No example is provided in this article, but the subject injury and indemnification sections should be consistent between themselves and with the informed consent form.<sup>1</sup> Any inconsistencies create potential loopholes. For example, if the informed consent form provides reimbursement for treatment costs, but the clinical trial agreement excludes cases in which the subject bears responsibility for the injury, the site may be obligated to pay those costs.

## **Reference**

1. "Treatment Reimbursement in Informed Consent Forms and Clinical Trial Agreements", Norman M. Goldfarb, Journal of Clinical Research Best Practices, May 2006

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