

Boilerplate Provisions in Clinical Trial Agreements

By Tara Cowell

The term "boilerplate" can refer to any standardized provision in a contract. Boilerplate provisions are more important than they might seem — the "boilerplate" name refers to the thick slabs of steel used to construct high-pressure steam boilers that wreak havoc if they explode.

Boilerplate provisions generally appear near the end of a contract but can be quite mischievous if ignored. Many of them serve as a road map for administration of the contract. Classic examples include the choice of law, notice, force majeure, and assignment provisions.

In this article, we will discuss 13 boilerplate provisions commonly found in U.S. clinical trial agreements (CTAs) between Study Sponsors and Investigative Sites (and Investigators) (the "parties" to the contract). We will explain their importance and identify issues that can arise if they are not properly drafted and negotiated for the business arrangement at issue. The provisions discussed in this article include survival, notice, governing law & jurisdiction, publicity & use of name, integration, amendments, assignment, delegation, relationship of the parties, third-party rights, severability, non-waiver and force majeure. Sample text is drawn from the MAGI Model CTA, available at <http://www.magiworld.org>, which contains extensive sample provisions and commentary.

Survival (MAGI Model CTA 12.5)

A survival clause usually refers to or lists specific provisions that the parties want to continue even after the termination or expiration of the agreement. The following is an example of a severability provision:

"Sections 4, 5, 6 and 8 of this Agreement will survive the completion, expiration, termination or cancellation of this Agreement."

Rights and obligations which by their nature should survive or which this Agreement expressly states will survive will remain in full force and effect following termination or expiration of this Agreement. The parties will cooperate with each other during and following termination or expiration of this Agreement to safeguard subject safety and continuity of treatment, and to comply with all applicable laws, rules, and regulations.

In lieu of a survival provision, the parties may elect to include a specific statement in each of the sections affected, such as:

This section shall survive the termination or expiration of this Agreement.

The parties should carefully review each term in the Agreement to determine which provisions should continue to "live" even after the contract ends. Some examples of provisions that should survive beyond the contract term are confidentiality, record retention, payment and indemnification.

Notice (MAGI Model CTA 13)

The notice provision can be broken down into three parts: First, how must notice be provided under the contract? Second, to whom must notice be given? Third, when must

notice be given? CTAs often run for multiple years, and there are some provisions that have requirements lasting into the decades, such as confidentiality and record retention. It is therefore critical that the notice provision be drafted in this context.

When determining how notice must be given, consider modes of delivery that will continue for the long term. The hard-copy mail system is always an important mode to allow, but consider facsimile and email. Which fax number would be appropriate? Whose e-mail address would be utilized? The parties must ensure that those modes of delivery will be received or important notices may be missed. If the parties agree to allow facsimiles or emails for notices, they should utilize a general-delivery or departmental (e.g., legal department) facsimile number and email address that are not tied to a particular employee, who may not be with the entity in six months, to say nothing of 10 years later, when a notice might be sent.

The same issue applies when determining to whom notice should be given via standard mail. The address should be a central corporate address, and the individual responsible should be listed by title rather than name.

If an organization moves or individuals who have been listed in agreements leave the organization, it is critical that notification of the change be provided as directed in each affected contract. Without the notification, important notices may be misdirected.

When notice is required, it is typically stated throughout the agreement because different events create different levels of urgency. For example, the termination provision might require 30 days written notice of termination, while a material protocol violation might require five days. Other than specific notice obligations like these, any formal communication with the other party should be delivered in accordance with the notice provision.

Governing Law & Jurisdiction (MAGI Model CTA 14.1)

Governing law (choice of law) is a contractual provision whereby the parties designate the state law that will govern any disputes arising out of their agreement. It is typically drafted as follows:

The laws of New York govern this Agreement, without regard to conflict-of-laws provisions.

Since the sponsor typically provides the draft clinical trial agreement, the state listed will most often be the home state of the sponsor. The language in the example above means that New York law will govern any dispute between the parties. Conflict-of-laws refers to that part of the law in each state, country or other jurisdiction that determines whether, in dealing with a particular legal situation, its law or the law of some other jurisdiction will be applied.

If the Site is located in Nebraska, it will have little or no familiarity with New York law. If a dispute arises, it may need an attorney in New York. Conversely, the Sponsor, with numerous sites throughout the country, does not want the laws of multiple states governing one study. In rare cases, one party might actually prefer the laws of the other party's state, or the parties could pick a third state as neutral territory. Some state institutions cannot agree to be governed by the laws of a different state, but can typically agree to remain silent (see below).

A court in one state can apply the laws of a court in a different state, so the state (and county) of jurisdiction (choice of forum) is a separate issue than the state of governing law. Litigating in the other party's state is even more burdensome than using the other state's law. The following is an example of jurisdiction language:

The Courts of _____ have legal jurisdiction.

Since CTAs are seldom litigated and this provision can be very contentious, it is common for the CTA to “remain silent” on governing law and jurisdiction. The effect of remaining silent is to agree that a court or arbitrator will decide these issues, if and when a dispute arises. In simple terms, the court’s determination will look to notions of substantial justice and fair play for the parties involved — in other words, where it is fair for the dispute to be litigated and for justice to prevail. The court will examine questions, such as: where the relevant activities occurred; where the witnesses are located; and to what extent each party will be burdened by the location of the suit. The court will most likely choose that forum’s law and jurisdiction.

Publicity & Use of Name (MAGI Model CTA 14.2)

The publicity & use of name provision states that neither party will use the name of the other party for commercial or other unauthorized purposes without the other party’s consent.

With the enactment of recent laws like the Sunshine Act and Food and Drug Administration (FDA) requirements around the use of www.clinicaltrials.gov, it is important to include a caveat like “except as may be required by law” so that legally required disclosures are excluded from the requirement to obtain consent. The provision may also include specific exceptions like the following examples:

- (1) Sponsor may, without prior consent, identify Site as the entity that conducted the Study, and identify Investigator as conducting the Study at the site. This paragraph does not apply to information of Subinvestigators or other study personnel.
- (2) Site and Investigator may, without prior consent, disclose their participation in the Study (including the name of the sponsor, name of the study, protocol number, funding amount, and any information available in a public registry) as required by law, Court order, or state regulation; or in (1) C.V.s, (2) their website, (3) industry directories, (4) brochures and marketing materials, (5) internal reports, (6) publications and presentations, (7) grant applications to non-commercial funding sources, (8) government reports and filings, and (9) conflict-of-interest reports. This paragraph applies to Subinvestigators and other study personnel.

Integration/Entire Agreement (MAGI Model CTA 14.3)

The integration clause is sometimes referred to as the entire agreement clause. This provision typically states:

This Agreement represents the complete understanding between the parties. No prior oral or written agreements or understandings have been relied upon.

This Agreement, together with any attachments or exhibits, sets forth the entire understanding among the parties about the Study. Any prior agreements, promises or representations, whether oral or written, such as agreements of confidentiality, have no force or effect. Any modification or waiver to this Agreement must be in writing and signed by all parties to this Agreement. However, IRB-approved changes to the Protocol are incorporated by reference into this Agreement, subject to agreement on appropriate Budget modifications.

This clause means that if a provision is not written in the Agreement, it won’t be enforced. Parties cannot rely on verbal promises or earlier memorandums without incorporating those

terms or documents into the Agreement. For example, if the Site signed an earlier confidential disclosure agreement (CDA), the CDA usually expires when the CTA is signed.

Amendments (MAGI Model CTA 14.3)

The amendments provision defines the ways in which the terms of the agreement can be modified. Standard amendment clauses state that the parties may amend the agreement in a writing (i.e., a written document) signed by the parties. However, CTAs often contain avenues for the sponsor to amend the protocol without requiring the written agreement of the Site and/or Investigator. Sponsors argue that this power is necessary to manage a multi-site study. However, sites will want to ensure that the CTA contains language that would require an amendment to the budget, if necessary, if there is any change to the protocol.

Assignment (MAGI Model CTA 14.7)

In legal terms, an assignment refers to the transfer of the rights and responsibilities of a party in a contract to another party. For example, a Sponsor does not want to sign a CTA with one site and then find out that a completely different site will be conducting the study. A typical assignment provision states:

Any party may assign this Agreement to an Affiliate or in connection with the merger, consolidation or sale of all or substantially all of its assets, upon 20 Days' prior written notice to the other party, provided that the Affiliate or acquirer agrees to assume all responsibilities and obligations under this Agreement. Any other assignment of this Agreement, and the associated rights and obligations, requires the prior written consent of the other party. If Site or Investigator terminates this Agreement, it will assign to Sponsor its contracts with subcontractors, if any, so Sponsor can continue Study without that party.

Due to the sometimes complicated corporate structure of sponsors and sites, there may be additional language in the assignment provision that allows for an assignment to other related corporate entities without the consent of the other party. If such additional language is included in a CTA, the parties should learn more about the related entities to ensure that they will be protected against a potential assignment to an entity without the resources, financial or otherwise, to live up to that party's obligations under the agreement.

Delegation (MAGI Model CTA 14.8)

Delegation refers to the transfer of authority or obligations from one person or party to another. This provision may be used to allow the Sponsor to delegate responsibilities for administering the clinical trial to a contract research organization (CRO). If a CRO is involved, the parties need to be aware of which responsibilities the Sponsor is delegating to the CRO under the agreement. A delegation provision may also be used to set forth the ability of the Site or Investigator to delegate duties to others. The following example specifically permits delegation of Investigator responsibilities:

Site may delegate Investigator duties under this Agreement according to Section 3.6. Investigator may delegate his/her duties under this Agreement according to Section 3.8. The parties may delegate other duties under this Agreement to third-parties, provided, however, that: (a) such third parties perform such duties in a manner consistent with this Agreement, and (b) the delegating party remains fully responsible for such third parties' performance under this Agreement.

Relationship of the Parties (MAGI Model CTA 14.9)

The relationship of the parties is defined by first identifying the parties and then specifying their relationship.

Identification of the parties is usually addressed in the introduction to the CTA. A Sponsor's template may arrive at a Site as a two-party agreement, but if the Investigator is not an employee or agent of the Site, she or he may need to be a separate party to the agreement. Without careful analysis of who the parties should be, the Investigator might not be legally bound by the CTA and the Site could be liable for the actions of an independent Investigator over whom it has no control.

If the Investigator is a Site employee, he or she may not want to incur the legal liabilities of a CTA signatory. In this case, the Sponsor and/or Site may still wish the Investigator to be aware of the agreement's contents so he or she will comply with them. In this case, the Investigator can sign the CTA under the words "Acknowledged by," which does not create the binding obligations of a regular signature on a contract.

The Independent Contractor provision is another important way the parties state their relationship in an agreement. This provision will clarify that the parties are not intending to become employer and employee, or create an agency relationship. (A legal agent is someone who can act on another party's behalf. A party to whom power is delegated is acting in its/his/her own legal capacity.)

Site is an independent contractor to Sponsor, and not a partner, agent, employee, representative or joint-venturer of Sponsor. Investigator {is/is not} Site's {employee/subcontractor/owner/principal}. Except as set forth in this Agreement, no party, or its employees, agents or subcontractors, has any right or authority to bind or act on behalf of another party.

Third-Party Rights (MAGI Model CTA 14.10)

A third-party rights section will clarify whether the parties intend for anyone not a party to the CTA to have rights under the agreement. Someone with these rights is called a "third-party beneficiary." If a CRO is contracting with a Site on the behalf of a Sponsor, the contract may specify the Sponsor as a third-party beneficiary under the agreement, providing the Sponsor with contract rights despite the fact that it is not a party to the agreement.

If the Sponsor is the contracting party, the third-party rights provision will commonly state that there are no third-party beneficiaries. This will provide some protection if, for example, a study subject sues the Sponsor based on the subject injury provisions in the CTA. Such language would state, "This Agreement creates no legal rights for any third-party."

Severability (MAGI Model CTA 14.11)

There are times when a law or regulation may change in the middle of a contract, or some provision in the contract turns out to be illegal or unenforceable. Such an event could make some provisions or even the entire contract invalid or unenforceable. A severability clause ensures that courts don't "throw out the baby with the bath water." It will allow the rest of the contract to continue while just invalidating the term at issue. When the unenforceable or illegal term is the foundation for other provisions of the contract, the severability clause should explain how to address the void, since a foundational term cannot simply be removed from the CTA. For example, the provision may state that the parties will negotiate to revise the contract if the illegal or unenforceable term is foundational to the CTA.

A typical severability clause might state:

If a court of competent jurisdiction finds any provision of this Agreement legally invalid or unenforceable:

- (a) Such finding will not affect the validity or enforceability of any other provision of this Agreement.
- (b) The parties will negotiate to revise the provision to make it valid and enforceable. If the parties cannot agree on such revisions, the Agreement will be performed in the absence of such provision. If such performance is impossible, this Agreement will terminate upon 20 Days' written notice by one party to the other party.

Non-Waiver (MAGI Model CTA 14.12)

Although this provision is often called the "waiver" clause, it really acts as a "non-waiver" clause. This provision maintains the enforceability of a provision even if a party excuses (explicitly or implicitly) the other party's non-compliance with that provision on one or more occasions. Non-waiver provisions are often drafted as follows:

The failure by one party to require performance of any provision shall not affect that party's right to require performance at any time thereafter, nor shall a waiver of any breach or default of this Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

In case of breach or default of this Agreement, the Parties may pursue all contractual and other remedies, both legal and equitable. Any waiver of a provision of this Agreement will be in writing. Failure to enforce any provision will not constitute a general waiver of that provision.

For example, a CTA might require safety reports from the Site to be provided to the sponsor on the fifth day of each month. However, the Site is consistently late with the safety reports, submitting them around the 15th day of each month. After a year, the late data prevents the Sponsor from filing an accurate governmental report on time, thereby incurring significant penalties. If the Sponsor then attempts to terminate the agreement for breach, the Site will not be able to claim that the Sponsor accepted the late reports and, therefore, the Site was not required to provide them in a timely fashion. In other words, the fact that the Sponsor chose not to enforce the timeliness of the reports does not constitute an amendment to the CTA.

Force Majeure (MAGI Model CTA 14.14)

Force majeure literally means "greater force." These provisions excuse a party for non-performance under the contract for matters out of its control, such as a natural disaster or a strike. A flood may make it impossible for the Site to continue conducting the study in a practical timeframe. Contracts do not always contain force majeure provisions, but sites and investigators should consider including a force majeure provision to protect themselves in case a "greater force" affects their ability to perform under the agreement.

Conclusion

CTAs are complicated documents. Most parties focus on the indemnification, insurance and subject injury provisions, but the boilerplate provisions should not be overlooked. They usually are not the most important points in a negotiation, but ignoring them invites abuse by the other party or parties.

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