Clinical Trial Agreements at Community Hospitals

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Most community hospitals are not the site of clinical studies or investigations. Rather, they devote themselves entirely to the care of patients using approved drugs, devices, and procedures. Some, however, do host clinical trials of drugs or devices conducted under FDA oversight or research projects designed to increase knowledge about therapies available to patients. In that case, they will be proceeding under a clinical trial agreement entered into with the study sponsor, either the manufacturer of the drug or device or the independent funder of the research. This article explores issues relevant to community hospitals that are negotiating clinical trial agreements with study sponsors.

Usually, the sponsor presents a proposed clinical trial agreement to the hospital for signature before the study begins. Such agreements tend to be formulaic, covering certain common areas. Sponsors often provide them as fixed templates that do not allow for discussion or negotiation. It would be wrong, however, for hospitals to think that they therefore must accept them as presented. A hospital that is knowledgeable about clinical trial agreements and their functions can obtain changes that will protect its own interests and make the clinical trial run more smoothly.

The first area of concern involves the contracting parties themselves. Clearly, the sponsor (usually the drug or device manufacturer or other funding source for the study) and the hospital are interested entities. However, sponsors are not always formal parties to clinical trial agreements involving their own products. Many work through so-called "contract research organizations" or "clinical research organizations" ("CROs") that administer the research project, including working with the hospital that will be the site of the investigation and the investigators who will be responsible for carrying it out. Where a CRO is involved, it, rather than

the sponsor, may be the contracting party, with the sponsor mentioned in the agreement as having stated rights with regard to the study and its results. This is acceptable, as long as the sponsor is prepared to assume ultimate responsibility for the drug or device. This can be accomplished through a separate indemnification agreement by which the sponsor undertakes to compensate the hospital for any liability resulting from injuries due to defects in the design or manufacture of the investigational drug or device or to defects in the study protocol.

A second question concerns the role of the principal investigator and any sub-investigators. Sponsors often present community hospitals with agreements that place responsibility on the hospital for all aspects of the study, including medical decisions that are the province of the investigators. These include such matters as choice of study subjects, compliance with the study protocol, and production of accurate results. Such agreements stem from sponsor familiarity with institutions such as universities and research foundations that focus on, or are devoted entirely to, clinical investigations. In that case, the investigators are employees of the institution, which oversees the research program closely and takes full responsibility for its conduct, including the work of the investigators. Agreements arising from this context are usually between the sponsor (or CRO) and hospital, with the principal investigator mentioned as a person who will be performing the duties on the hospital's behalf but and who is under the hospital's control. The principal investigator then acknowledges the agreement at the end. Community hospitals should require that such agreements be amended to include the principal investigator as a separate party, responsible for conducting the study in accordance with the sponsor's protocol and performing associated medical tasks. The hospital's role is to support the study through its clinical trial coordinator and other staff, including registering patients, providing the premises, equipment, and supplies for their treatment (including any drug or device received from the manufacturer for use in the study), and maintaining and disclosing the study results as appropriate. In the past, study sponsors have resisted this bifurcation of duties between the hospital and principal investigator, seeking to impose all of the responsibilities for the study on the hospital. However, most now accept that hospitals and investigators have different roles and responsibilities and therefore should be separate parties to the clinical trial agreement. Many now have clinical trial agreement templates that name the sponsor, hospital, and principal investigator as separate and independent parties.

Beyond these basic considerations, a community hospital should focus on the following provisions in clinical trial agreements with which they are presented:

- Confidentiality. The sponsor will almost always include a confidentiality clause to protect the proprietary information that it shares with the hospital and principal investigator. The hospital should make certain that the definition of confidential information excludes patient medical records and protected health information, given the special rules to which those materials are subject under HIPAA and state confidentiality laws. Furthermore, if the hospital has any interest in disseminating the study results, it should ensure the confidentiality provision does not restrict its publication rights. Lastly, the hospital's confidentiality obligations should not extend to information that is: (1) already in the hospital's possession at the time of disclosure, (2) part of the public domain or that later becomes part of the public domain through no fault of the hospital, (3) received from a third party hav-

ing no obligation of confidentiality to the sponsor; (4) independently developed by the hospital without the use of confidential information received from the sponsor, or (5) required by law or regulation to be disclosed. The hospital should always carve out these five exceptions from the confidentiality provision in a clinical trial agreement.

- **Publication.** Often the hospital will want to publish the results of the study. Even if it is unsure whether it ultimately will want to do so, the hospital should preserve its future publication rights in the agreement. To accomplish this, the hospital should include several safeguards in the agreement. These should provide that, prior to publication, the hospital will send the manuscript or presentation to the sponsor, which will have 30 days to review and comment on it. The sponsor will be limited to: (1) determining whether any confidential information will be disclosed in the publication, (2) verifying technical accuracy, and (3) identifying any potentially patentable technology discussed in the publication. The sponsor should never have the right to edit or approve the contents of the publication. The agreement should provide that, if the sponsor does identify any patentable technology, the hospital will provide it with extra time, such as an additional 60 days, to file a patent application.

- **Intellectual Property.** The hospital should protect any intellectual property that it develops during the course of the study. The sponsor will seek rights to as much of the intellectual property as possible. The hospital for its part should seek to narrow the sponsor's rights to what is "directly related" to the study drug or device and "reasonably anticipated" by the protocol or study instructions. Because it may find discoveries or developments emanating from the study to be useful, the hospital should include a statement in the agreement granting it a royalty-free license to use any inventions that result from the performance of the study. The hospital should also negotiate rights to inventions that are developed solely by the principal investigator or by it and that are not "directly related" to the study drug or device and "reasonably anticipated" by the protocol or study instructions.

- **Termination.** Many clinical trial agreements contain a termination clause permitting the sponsor, but not the hospital or principal investigator, to terminate without cause. Hospitals should revise this provision to state that any party may terminate the agreement without cause, upon 30 days' written notice (or whatever amount of time is viewed as adequate) to the other parties. Additionally, the hospital should ensure that any party can immediately terminate the agreement if (1) it is requested to do so by a governmental or regulatory authority or (2) it determines that termination is necessary for the safety of the study subjects. Lastly, the hospital should ensure that, when the agreement terminates, it will receive payment for all work performed up until the date of termination and for any non-cancellable obligations incurred in accordance with the agreement.

- **Indemnification.** The indemnification provision is to ensure that the hospital is protected against any claims for damages that are not due to its own acts or omissions. The hospital will first want to make certain that the sponsor will indemnify all the appropriate parties that could be named in any such claim, including the hospital and its directors, officers, employees and agents. Additionally, the hospital should ensure that the sponsor indemnifies it for bodily injury and property damage caused by (1) the administration of the study drug or product, (2) the proper performance of the procedures required by the protocol and/or sponsor's instructions, (3) any defect in the design

or manufacture of the study drug or device, and (4) the unauthorized disclosure of a study subject's protected health information. As previously noted, the sponsor may not always be a party to the agreement where a CRO is involved in administering the study. In those instances, the hospital should require the CRO to indemnify it for (1) and (4), while sponsor should enter into a separate indemnification agreement with the hospital agreeing to indemnify it for (2) and (3). Finally, the hospital should never agree to indemnify sponsor or CRO for any acts or omissions emanating from their own negligence or willful misconduct.

In conclusion, community hospitals that undertake clinical trials or investigations are entering a specialized world that is more familiar to drug and device manufacturers, funding agencies, research foundations, and academic medical centers. The clinical trial agreement that defines the relationship between the study sponsor and the hospital is likely to be a foreign document, filled with impenetrable descriptions of rights and duties. Hospitals confronted with such documents should have a basic understanding of the underlying legal considerations and be prepared to negotiate changes to any template with which they are presented to ensure that their interests are protected.

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