CLINICAL TRIALS AND SOVEREIGN IMMUNITY

The King can do no wrong.

When conducting human clinical trials, drug and medical device sponsors should be aware of the crucial difference between choosing a state-chartered or federal clinical facility rather than a privately operated clinic or hospital: the issue of sovereign immunity. This difference can create a major risk for the sponsor while protecting the sovereign rights of a state or federal facility.

Drug and Medical Device discovery companies conduct their human clinical trials at many different types of clinical sites. These clinical sites may include clinics and hospitals or university hospitals that are operated under a state or federal charter. A typical clinical trial agreement (CTA) in the United States divides the indemnification responsibilities between the sponsor and the clinical site. The sponsor typically assumes responsibility for claim activity caused by its product – the test device or drug. The clinical site accepts the medical professional liability risk that it may create through medical negligence in administering the protocol treatment or through deviation from the written protocol. Depending on the details of the contract, the clinical site may also agree to be responsible for willful misconduct, breach of contract, violation of intellectual property rights and other negligent acts.

Generally, CTAs include a mutual indemnification clause where the parties agree to indemnify each other based on attributable negligence. The CTA will also contain an insurance clause that provides a financial backstop for some of the activities when the parties agree to mutually indemnify.

But what if the sponsor’s contract is with a clinical site operated by a state or the federal government? The clinical site may refuse to indemnify the sponsor by claiming protection under sovereign immunity, thus potentially transferring the clinical trial professional liability risk and other claims of negligence back to the sponsor.

Sovereign immunity is a carryover from English law that held that “the King can do no wrong” and, therefore, cannot be sued for negligence. The Eleventh Amendment to the U.S. Constitution allows the federal government and states to assert sovereign immunity as a defense against any liability claims. The sovereign immunity rights have been challenged over the years at both the state and federal levels. In many instances, a particular state’s sovereign immunity has been modified to recognize more modern legal theories, while other states hold firmly to their traditional immunity status. It is important for drug sponsors to know and understand the sovereign immunity statutes in every state in which they are conducting clinical trials if the trial site is a state or federally operated institution that can claim sovereign immunity.

In some instances, this issue will be a point of discussion during the negotiation of a clinical trial agreement. The drug sponsor will ask for indemnification and the clinical institution will push back that they are protected by sovereign immunity and will not agree to indemnify the sponsor for the clinic’s negligence nor provide evidence of insurance. The clinic may opine that state or federal laws prohibit them from entering into indemnity agreements. If the sponsor agrees to a contract without the clinic’s indemnification for negligent treatment, what additional risk are they accepting? If a trial subject is injured
by the clinic's staff, who will be responsible if the injured party brings suit?

Let’s assume that a trial subject, injured by an employee of the clinical site (not caused by the trial drug), sues both the clinical site and the sponsor. The clinical site successfully asserts it sovereign immunity rights leaving the sponsor to defend itself. The sponsor’s clinical trials policy covers the sponsor if the product directly causes the injury and has an exclusion for “direct patient care.” This type of policy would probably defend the sponsor, but if the sponsor was ultimately required to pay for the injuries caused by the clinic’s employee (medical professional negligence), the sponsor would have no insurance coverage for this loss.

It is probably more common that the issue of sovereign immunity is not discussed during the negotiation of a clinical trial agreement, and the state-run institution signs an agreement with indemnification language. Typically the institution may ask for language in the agreement that says “in signing this agreement, the institution is not waiving its right to claim any exemptions, privileges and immunities as may be provided by law.” Be aware that this simple language may allow the institution to assert sovereign immunity resulting in the setting aside of any obligation to indemnify the sponsor or settle the claim of an injured trials subject. Courts have also held that “those dealing with the state are charged with knowledge of immunity,” so ignorance of state sovereign immunity will probably not be a useful defense.

Many states have modified their sovereign immunity statutes to allow claims under certain circumstances. In some states, where you are allowed to bring suit, your awarded damages may be capped to a dollar maximum that can be significantly lower than would have been awarded had the suit been against a private company under the same circumstances. Many states allow claims as a result of medical injury. You must be aware of the specifics of each state’s sovereign immunity laws.

WHAT ARE PRUDENT RISK MANAGEMENT STEPS?

- If you are contracting with state-chartered institutions, know the sovereign immunity statutes in those states.
- Examine your contracts to see if the issue of immunity is specifically addressed when necessary.
- When practical, contract with a private clinical site that is not protected by sovereign immunity.
- If you are the sponsor, modify the medical professional services language in the clinical trials policy to allow for vicarious medical professional liability to be included in coverage.

In some instances, a U.S. federal government agency will collaborate with drug companies and/or hospitals. The NIH has several initiatives where they provide the research drug that is to be tested (i.e., a vaccine or a biodefense drug) to a sponsor or directly to the clinical sites. In these instances, the federal government will claim sovereign immunity and may also require that the clinical site be responsible for any injury to a trial subject while participating in a government-sponsored trial. The clinic not only retains the risk for its own professional liability but also accepts the product liability exposure. A hospital professional liability policy usually does not intend to cover this exposure, so a separate risk transfer program must be contemplated by the collaborator and the clinical site.

- Avoid adding the institution as an additional insured on the sponsor's policy.
- Avoid accepting the negligent acts of the institution in the CTA.

CONTACT

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