

The Legal Liability of the Institutional Review Board[†]

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Introduction

On July 25, 1988, the El Paso Institute for Medical Research and Development and the El Paso Center for Clinical Research asked us, two personal injury lawyers, to be on their Institutional Review Board (IRB). Those on the board were not given a specific charge. Our IRB serves an urban area with a Hispanic majority, many of whom speak only Spanish. Our board approves drug and nondrug studies. The members of the board are volunteers with varied backgrounds. Although we are not on the IRB specifically to give legal advice, our training as lawyers gives us a unique perspective on issues with which IRBs grapple daily.

Liability

In our increasingly litigious society, anyone who volunteers to serve in any capacity should be aware that he or she may be brought into a court of law to answer for negligent acts. This is not always a realistic concern, but it is becoming more relevant when considering invitations to work with a committee or institution that may become responsible to individuals who suffer personal injury.

Obviously, an IRB is not exempt from these concerns. When approached about serving on an IRB, the first question an individual is likely to ask is "What is my personal liability?" There is rarely a clear answer to this query.

[†]The views expressed in this paper are solely those of the authors and not of the El Paso Institute.

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In considering regulations about IRBs, the FDA discussed whether regulations should grant IRBs limited liability in case of malpractice suits. They responded that

the FDA lacks the authority to grant limited liability to IRBs or their members. The authority resides in Congress and in the state legislatures. Although it is impossible to limit liability or to ensure against lawsuits, the agency believes that the chances of a successful suit against an IRB or any of its members are greatly diminished if the IRB has complied with these regulations and any applicable state law in reviewing proposed research (1).

This quotation illustrates that it is possible for the IRB or its members to be brought into litigation, depending on the laws of the governmental entity involved.

As a practical matter in research involving drug trials, the entities most likely to risk litigation are the investigators and the drug companies. These "deep pockets" usually have assets or insurance sufficient to pay damages, thus, an injured party will not have to search for others to sue. However, if a situation arises in which the drug company takes the position that its protocol was modified or the IRB failed to perform its duties properly, or the investigator indicates that the IRB did not take appropriate action upon advisement of problems with a piece of drug research, a litigant may be left without any choice but to sue the IRB and its members. In these circumstances, a litigant would be foolish not to attempt to secure remedies against the IRB and its members.

How can an IRB protect itself from the potential liability that may exist for the actions it takes? There is no way to completely protect an IRB from lawsuits. However, an IRB can take several steps to provide assurance that litigation will be as painless as possible. First, the IRB should make certain that sufficient insurance is available to pay for any injuries to drug-study participants caused by negligence. Each investigator should have adequate insurance coverage to pay for individual negligent acts that cause damages.

Today, many medical providers believe that it is more economical to do without liability coverage than to pay the high premiums associated with coverage. In the research setting, we believe an IRB is acting irresponsibly if it fails to require an investigator to maintain minimum coverage for negligent acts. The amount will vary from community to community. It should be sufficient to pay damages to an injured participant if the drug company refuses to pay. For instance, the company might allege that its protocol was not followed. It is important that participants in a drug study are pro-

tected. The IRB should address whether there is sufficient money to pay for injuries suffered by drug-study participants. We believe that few IRBs consider the insurance issue. Those involved in drug studies assume that the drug company will ultimately be responsible for any damages suffered by an injured participant. This does not necessarily follow. If the drug company can raise the defense that the investigator was negligent by doing something outside the protocol approved by the drug company or that the IRB did not properly monitor the study, the drug company will likely have sufficient insurance and assets to cover damages. The IRB should require proof of adequate coverage. The IRB can also purchase its own insurance. Given the voluntary nature of IRBs, it may be impractical to require a board to purchase insurance unless the drug company pays for it. The best approach is for the IRB to be sure that the other parties in the drug research chain are adequately insured.

Second, to prevent liability to the IRB in a drug study, the drug company should be required to indemnify the board for its acts involving the study. Such a written indemnity would require the drug company to pay for all damages, costs, and attorney's fees arising from any litigation against an IRB. We have found that when we asked for an unconditional indemnity from drug companies, they will only provide indemnity with limitations. One such limitation is that all procedures are carried out according to the drug company's protocol. Another limitation is that indemnity will be forfeited if the investigator or anyone employed by the investigator is negligent. This causes significant concern, as IRBs should have freedom to modify the protocol to protect the rights of the subject. In so doing, the IRB could void any indemnity. In order for the IRB to operate effectively, it must function in an environment where protection is provided by the ultimate sponsor of the drug study. The opposing argument to this is that an IRB will act more prudently when it realizes there is potential exposure to liability. Possible exposure to liability is not conducive to gaining and retaining of experienced and qualified IRB members. If drug companies can reduce the fear of litigation in the minds of the IRB members, such as by providing full and unconditional indemnification, an IRB will be able to take a more meaningful review role in the drug research process.

This discussion of the liability of IRBs is mainly academic, as we were unable to identify any cases in which an IRB has been named as a party to litigation. However, we believe that an IRB or its members can be sued, at least in our jurisdiction. IRB members can feel some sense of security when drug-study sponsors are reputable drug manufacturers, because the protocols and informed consents have been reviewed by the drug company and by other IRBs.

Additionally, there is the added security that the FDA maintains strong compliance requirements to make certain that abuses do not cause significant damage. Overall, the FDA's belief that lawsuits are unlikely against an IRB is probably accurate for IRBs who comply with all the requirements set out in FDA regulations and who are careful and dutiful about the reviews performed.

Police Role vs Ethical Review

In debating the FDA's rules and regulations for IRBs, comments suggested that IRBs are being forced into a "police role" as opposed to an "ethical review in an atmosphere of trust and cooperation" (2). The FDA stated that the

FDA disagrees with the comments. There is no requirement that IRBs treat investigators with less cooperation than in the past. However, it is up to the IRB to assure itself, by whatever method it deems appropriate, and to assure FDA that the rights and welfare of human subjects are being protected. FDA encourages IRBs and clinical investigators to cooperate and interact with each other in a non-adversarial manner. Nevertheless, FDA considers it an appropriate requirement that IRBs develop procedures to determine whether there is a need for verification from sources other than the investigators, that there has been no material change in certain protocols since their previous review. Verification is not required by FDA but should be an available avenue when, in the opinion of the IRB, verification provide necessary protection for subjects involved in greater than minimal risk research (3).

This comment raises the query, can an IRB, essentially composed of volunteers, put itself in a position of not relying solely upon investigators' representations? In private research settings, this is a troubling question. For instance, it is unrealistic to expect an IRB to make surprise visits to research institutes, to be present for interviews of prospective participants, or to require the videotaping of such interviews for later review. If this approach were in effect, individuals could be discouraged from serving on an IRB. There is, however, a concern that in any study involving more than "minimal risk," a careful verification be required if an IRB is to be absolved of negligence. The standard of care required of an IRB would be that of "a reasonably prudent IRB in the same or similar circumstances." The regulations do not require this type of "police activity." We believe that the FDA's expectations, as reflected in their comments, extends the role of the IRB far beyond that of any "reasonable IRB."

Uniformity

Establishing minimum requirements for an IRB and then insisting that an IRB represent the community standards of its locale creates a paradox. The acceptability of the same protocol in different localities could create a liability problem. Though we are moving toward national standards in malpractice litigation, the question remains for drug testing whether an IRB that draws its subjects from a university environment, such as medical students, has a different obligation than an IRB that draws from a population of mainly non-English-speaking, lower economic-status individuals. The FDA, on January 27, 1981, issued the following statement:

One comment stated instead of uniformity among IRBs there will probably be diversity because each IRB will be able to establish its own regulations within the loose Federal framework. FDA agrees that each IRB will be able to establish its own procedures within the Federal framework, which represents minimum standards of protection of human subjects than those required by those regulations. As stated previously, FDA does not believe that it should provide detailed directions to IRBs on how they are to comply with these regulations. How the IRBs meet the general standards should be left to each individual IRB and institution (4).

Is it a paradox to say that an IRB will be able to avoid liability by following federal standards, yet state that nonuniformity is expected?

A study by Jerry Goldman, PhD, and Martin D. Kats examined the issue of inconsistency and IRBs (5). Their study took identical research protocols and submitted them to 32 IRBs at major universities. Each protocol raised serious ethical issues, contained flaws in scientific design, and provided incomplete consent forms. Twenty-two IRBs participated in the investigation, and the study revealed completely inconsistent results. Their findings were that "IRBs seemed to behave in ways that defied any pattern." Goldman and Kats stated, "our evidence supports the conclusion that IRBs approve inappropriate investigations and inhibit appropriate investigations. Deficient protocols may be modified, but only the most glaring problems are identified. These findings cast doubt on the adequacy of IRB decision making and the effectiveness of relevant regulations."

As lawyers, the study itself raises a concern about whether standards used to judge an IRB's conduct can be anything but retrospective. Each IRB will obviously deal with ethical and moral issues

in a different way. If we have learned anything as a melting pot society, it is that there are some things on which we can all agree and some things about which none of us can agree. Unless you are dealing with research design protocols that are so heinous as to be analogous to those used in the concentration camps of Hitler's Germany, IRB members will not be able to agree that all ethical concerns are met adequately.

Drug studies that use placebos are especially troubling in that part of the group suffering from some sort of ailment or problem will not receive any treatment when such treatment is potentially available. What if the volunteer participates because he or she cannot afford to seek medical care anywhere other than the research setting?

In our opinion, the IRB should not be the only group with whom responsibility for the approval and disapproval of research protocol lies, nor should the IRB merely be a rubber stamp of protocols brought before it. The IRB serves as a check in the system of human experimentation, particularly in drug trials with multiple investigators involved, multiple IRBs involved, the sponsoring drug company involved, and the FDA involved. Although this system at first blush may seem to err on the side of excessive bureaucracy, the chance for disaster is less likely with this system of checks and balances.

Specific Informed Consent

With specific minimum requirements for informed consent involved in any drug-study protocol, these standards are clearly minimum requirements and an IRB should be free to add any additional protections it believes necessary to protect the research population. State laws should be examined to ensure compliance, as federal regulations do not pretend to establish anything but minimum requirements.

Selection of Subjects

Another troubling issue in medical research is the proper method for selection of subjects for participation in medical research. The regulations state that the "selection of subjects should be equitable." The regulations further state "that in making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted" (6). In a commentary regarding this particular section, the term equitable was dubbed ambiguous and in need of further explanation. The FDA responded:

FDA disagrees with the comment. Special subgroups of the population should not have to bear a disproportionate amount of the risks of research that benefit others. The subjects of an investigation should not come from any particular group simply because it is convenient for the investigator to draw from that group. Scientific design and alternate human subject populations should be considered in assessing whether the selection of subjects is equitable. For example, the IRB should require that the investigator justify the proposed involvement in the study of hospitalized patients, of other institutionalized persons, or of disproportionate numbers of racial or ethnic minorities or persons of low socioeconomic status (7).

In a private research setting for a drug study, where is an investigator to get research subjects? Often an investigator will review his or her patient base, selecting exclusively from that group. Other times, advertisements are placed in newspapers. Clearly an IRB should evaluate all advertisements and make sure that they are placed in different types of media and circulated throughout a specific area. It would be improper, for example, for an advertisement to circulate only in a local non-English newspaper. As part of its review, an IRB should ask for an analysis of the ethnic and socioeconomic background of the patients, included in the study.

Conclusion

IRBs are an integral part of drug research studies. With our court system increasingly resolving disputes, the possibility that IRBs may be a party to litigation along with the large drug company increases. IRBs can lessen risks by requiring insurance and indemnity protection from drug companies and investigators, and by following the FDA's rules and regulations both in substance and in spirit.

References

1. *Fed. Reg.* (1981), **46:17**, 8961, para 13.
2. *Fed. Reg.* (1981), **46:17**, 8967, comment 65.
3. *Fed. Reg.* (1981), **46:17**, 8967, comment 66.
4. *Fed. Reg.* (1981), **46:17**, 8967, comment 64.
5. Goldman, J. and Kats, M. D. (1982) *JAMA* **248**(2), 197.
6. 21 DFR, Section 56.111 (3) (4/1/91 edition).
7. *Fed. Reg.* (1981), **46:17**, 8967, subsection 88.

Recommended Readings

Rostoff, A. J. (1981), *Informed Consent*, Aspen Systems Corp, Rockville, MD.
President's Commission on the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *The Official IRB Guidebook*, available from the Office of Protection of Research Subjects, U.S. Dept of Health and Human Services.