Law and Ethics in Medicine

Trials and Tribulations of the IRB Member

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Abstract
Clinical research is vital to advance medical knowledge and to test the efficacy and safety of new drugs and devices. The oversight of clinical research is entrusted to the institutional review board (also known as the research ethics board), whose primary purpose is to assure the protection of the rights and welfare of human research subjects. However, recent research scandals have led to questions about the effectiveness of this board and its members, as well as their liability in lawsuits filed over research-related deaths and injuries. This paper examines the present working conditions for institutional review board members in Canada and the United States, and the troubling new threat of claims of negligence against them.

The institutional review board (IRB) or research ethics board as it is known in Canada, is the independent body charged with regulating the ethical conduct of research involving human subjects. Often referred to as the “first line of defense” in patient protection,¹ the IRB is the only body that evaluates the moral as well as the scientific implications of a proposed research protocol.² While the importance of this function to the clinical research process is undisputed, the specific roles and responsibilities of the board and its members are poorly defined.³ The vague accountability of IRB members has become the subject of much discussion within both the medical and legal communities.

“Frustrated and Disillusioned”
In recent years, the IRB and its members have been faced with unprecedented challenges. Biomedical science is advancing rapidly, and the number of clinical studies is increasing exponentially.⁴ The ballooning workload combined with the growing complexity of the protocols has put significant strain on the IRB and its members. Caught between conflicting interests of research subjects, investigators and study sponsors, IRB members must contend with a “pressure-cooker atmosphere”⁵ in striking a balance between safeguarding study participants and permitting the progress of potentially life-saving research. The expanding involvement of commercial sponsors⁶ has complicated matters further, introducing new conflicts of interest that must also be assessed. IRB members are overwhelmed and overburdened with their many obligations.⁷ The situation has reached “crisis” proportions”.⁸,⁹

Adding to the mounting tension experienced by IRB members have been the spate of high profile incidents involving the deaths or injuries of research subjects, and the allegations of misconduct that have followed.¹⁰-¹² IRBs have frequently borne the brunt of the criticism in subsequent investigative reports, as well as in the mainstream media and academic literature. IRB members have understandably become “frustrated and disillusioned”,⁹ “weary of reading repeatedly that public opinion...sees them as largely incompetent”.⁹ Since 1998, the United States’ Office of Human Research Protection (OHRP; the agency responsible for oversight of IRBs in the U.S.), has suspended or restricted research at over a dozen institutions due to IRB inadequacies, including such prestigious institutions as Duke¹³ and Johns Hopkins.¹⁴ A report by OHRP concluded that IRBs review “too much, too quickly, with too little expertise”,⁷ and that the entire system was “in jeopardy”.⁷ Though there is no equivalent to the OHRP in Canada, Canadian IRBs have not escaped criticism¹⁵,¹⁶ or calls for reform.¹⁷,¹⁸ On both sides of the border, research-related deaths and injuries have landed IRBs or their sponsoring institutions in court.¹⁹,²⁰ However, it was not until 2001 that any lawsuit named IRB members as individuals. A complaint filed on behalf of subjects who had participated in a cancer clinical trial at the University of Oklahoma Health Sciences Center named twelve IRB members individually as defendants.²¹ The IRB members were accused of negligence in their duties.²¹

Legal Liability of the IRB Member
Though the 1978 U.S. National Commission for the

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Protection of Human Subjects’ Report and Recommendation: Institutional Review Boards clearly states that IRB members may be held personally liable “for malpractice or negligence in discharging their IRB functions,” the 2001 claim filed against the University of Oklahoma Health Sciences Center IRB members is believed to be the first. Interestingly, the primary document governing research ethics board function in Canada makes no reference to the legal liability of individual members. The University of Oklahoma Health Sciences Center case came as a shock to IRB members across North America. Those who serve on the IRB are volunteers who receive no payment or other inducement for their work, and as one IRB member put it, “neither do they get much thanks, though complaints are common enough.” IRB members face enormous pressure from researchers, sponsors, institutions, and patients and their families to approve protocols quickly without imposing any restrictions or requesting any modifications. They must also make difficult judgment calls about complicated protocols for which there are no precedents and no clear instruction from any guidelines currently in use. As one case study points out, “in the case of many judgment calls...there is no definitive ‘right’ answer.” These decisions require “a fair exercise of intelligence and discretion on the part of IRB members,” and are made in good faith. Finally, Harold Edgar and David Rothman observe, “the quality of an IRB’s work depends to an inordinate degree on the conscience and commitment of its volunteer members.” While no one would suggest that IRB members be exempt from accountability, the idea that they may be held personally liable for any injury or death resulting from research they approved is unsettling.

Why were the IRB members accused in the University of Oklahoma Health Sciences Center case? In an interview, the plaintiffs’ attorney Alan Milstein’s rationale was that “federal regulatory agents made specific reference to the inadequate job that the IRB did.” Leonard Glantz, professor of health law at Boston University School of Public Health, described the tactic of naming everyone even peripherally involved in a lawsuit as common practice among plaintiffs’ attorneys. “It’s a strategy that causes more people to be upset, and therefore encourages institutions to settle quicker.” But why now? The National Commission’s Report stating that individual IRB members could be held personally liable was published in 1978, and several lawsuits have been filed against IRBs and their parent institutions since then. How have individual IRB members stayed under the radar for so long? Why did 23 years elapse before IRB members were named in a complaint? It may be that IRB members were viewed as being unlikely to have “deep pockets” as compared to the parent institution. Another possibility is that the plaintiffs’ attorneys were reluctant to file a claim they felt they had little chance of winning; many authors in the academic literature have expressed serious doubt that a claim against an IRB member could be successful. To understand why, it is necessary to look at the elements of a negligence claim.

Negligence

In both Canada and the U.S., the elements for a claim of negligence include duty of care, breach of standard of care, loss or injury, and causation. Establishing that there is a duty and standard of care for IRB members would seem to be the most problematic of the elements for a plaintiff. Do individual IRB members have a legal duty of care to individual research subjects? The IRB as a body has the responsibility to protect the rights and welfare of research subjects, but the relationship between individual IRB members and individual subjects is comparatively indirect. Defining an individual IRB member’s standard of care would prove even more challenging. It is well known that the standard of performance between IRBs is highly variable. The standard between individual IRB members would seem to be even more so. IRB members necessarily come from different backgrounds and experience levels. As such, one would expect different levels of comprehension of a research protocol, particularly for community members of the board. Employing the “reasonable man” standard, it is easy to foresee that the opinion of a “reasonable IRB member” who is a physician may differ from that of the “reasonable IRB member” who is a social worker or lawyer or layperson. Finally, establishing the causation element of a negligence claim may also prove to be difficult in some cases, given that clinical research by definition involves risk, and many participants in clinical research are already in failing health.

The Future for Claims Against IRB Members

What defense is available to the IRB members who find themselves named in a lawsuit? In the U.S., it is left to the individual institution to decide whether or not to provide liability coverage to its IRB members. Similarly, a Canadian IRB member may seek indemnity from the institution he or she serves. It remains to be seen whether the University of Oklahoma Health Sciences Center will indemnify its IRB members, should the case progress. This complaint was recently dismissed on jurisdictional grounds by a federal district court in Oklahoma. The plaintiffs may now choose to pursue a federal appeal, or take their case to state court. While the outcome of this particular case has yet to be decided, the legal strategy of naming individual IRB members as defendants appears to have caught on. In the past year, at least two more cases have been filed in the U.S., although to date there have been no similar cases in Canada.

Consequences

Many fear that the emergence of IRB members as a new legal target is symptomatic of a trend toward increased litigation in clinical research, one that will negatively impact all partners in the process. The threat of liability will undoubtedly serve to discourage individuals from becoming IRB members, particularly if there are no clear provisions for liability insurance. This would seem especially true for the most qualified potential IRB members, who would arguably have the “most to lose.” The present situation may also result in IRB members...
performing reviews so rigorous that valuable research is delayed unduly, or rejected outright if the IRB member fears it poses even minimal risk. Calls for IRB reform in recent years propose standards of practice to help define the IRB members’ specific roles and responsibilities, and the legal framework in which they should be operating. However, others warn that once this happens, legal liability will be inevitable. IRB members across North America will be watching closely to see how the cases presently before the court are resolved, and what implications they will have for the current system of clinical research review. Until then, “members should remain good citizens trying to do their best”.

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References
44. A search of the Canadian legal databases Quicklaw (www.quicklaw.ca) did not retrieve any relevant cases.