Lawsuits Against IRBs: Accountability or Incongruity?
Pressure is mounting to hold researchers and research institutions accountable for the protection of human subjects. When subjects or their family members believe they have been injured, they are increasingly willing to file lawsuits. Recent cases indicate that institutional review boards (IRBs) and their members may be pulled more and more into the legal fray.

The Gelsinger case
On September 17, 1999, 18-year-old Jesse Gelsinger died while participating in a Phase I clinical trial testing a new approach to treatment of ornithine transcarbamylase deficiency (OTC), a rare metabolic disorder. Although infants affected by the severe form of OTC die shortly after birth, Gelsinger suffered from a relatively mild form. It appears undisputed that the cause of Gelsinger's death was not the disorder itself, but multiple organ system failure triggered by the virus used to carry new genetic material into his system. The first wave of news stories portrayed the experiment as a team effort in a noble cause with a tragic outcome. That portrayal changed, however, as information emerged about financial conflicts of interest and problems in the way the research was conducted.

On September 18, 2000, the Gelsinger family filed suit, seeking actual and punitive damages from the trustees of the university, lead investigator Dr. James Wilson, sponsor Genovo, Inc., former medical school dean Dr. William Kelley, and Dr. Arthur Caplan, a bioethicist, among others. The complaint alleged, in essence, that the researchers used a virus known to be more dangerous than other vectors because they held patents on that kind of virus and stood to gain financially from its use. The complaint asserted that possible conflicts of interest were not disclosed to the subjects.

According to the complaint, the informed-consent process was also defective in conveying risks and benefits. As alleged in the complaint, Gelsinger believed that the risks were “minimal” and that the potential benefits were “enormous,” whereas, in reality, the risks were significant, and the potential benefits were suspect and more likely to accrue to the researchers than to the subjects or infants affected by OTC.

The researchers also allegedly altered the consent form approved by the U.S. Food and Drug Administration (FDA) by deleting information about the deaths and illnesses of monkeys in prior animal studies. Other allegations concerned failures to adhere to eligibility criteria, good scientific and clinical practice, and FDA requirements regarding monitoring and reporting of adverse events. The causes of action in the complaint included wrongful death, assault and battery linked to a lack of informed consent, and common law fraud and misrepresentation linked to deficiencies in the informed-consent process.

Interestingly, the IRB that reviewed and approved the protocol was not named as a defendant. Caplan, the bioethicist, did become a target, owing to his role in the decision to use relatively healthy adult volunteers, rather than dying infants, as subjects. According to the complaint, Caplan was “consulted to determine the ethical complications surrounding the OTC gene transfer experiment.”

Mark A. Rothstein serves as the section editor for “Currents in Contemporary Ethics.” Professor Rothstein is the Herbert F. Boehl Chair of Law and Medicine at the University of Louisville School of Medicine in Kentucky.
Caplan and Kelley were subsequently dismissed from the suit. A settlement by the remaining parties was announced on November 3, 2000, and its details have not been publicly disclosed.¹¹

The Robertson case

In July of 2000, a federal shutdown of research at the University of Oklahoma Health Sciences Center-Tulsa brought attention to another clinical trial. On January 8, 1997, the IRB at the Center approved a protocol for a Phase I study of a cancer vaccine, with Dr. Michael McGee as the lead investigator. The target of the vaccine was melanoma, a virulent form of skin cancer. Many of the patients who enrolled in the study had advanced disease, had been unresponsive to standard therapies, and had been given prognoses in the range of two to six months to live.¹² According to news reports, ninety-four subjects actually received the vaccine, and twenty-six died during the course of the study.¹³ None of these deaths has been attributed to the vaccine itself.

The vaccine experiment attracted the attention of federal regulators, the media, and, ultimately, lawyers—not due to a highly visible death, but rather due to the activity of Cherlynn Mathias, the nurse coordinator assigned to the study. Reportedly, Mathias repeatedly advised McGee, Dr. Daniel C. Plunket (the IRB chair), Dr. Kevin Donovan (the consulting bioethicist), and administrators of problems with quality control, patient care, reporting of adverse events, and adherence to the study protocol.¹⁴

The reports began in December of 1999, when Mathias made formal presentations to the head of the department of surgery and the director of the office of research. These presentations appear to have triggered the engagement of outside consultants to conduct an audit. This audit resulted in a highly critical report, which found violations of good manufacturing practice, good clinical practice, and FDA requirements.¹⁵ On April 3, 2000, McGee sent a letter advising subjects that the trial was closing due to an inadequate supply of the vaccine. At this time, neither the subjects nor the FDA was advised of safety concerns. Soon afterwards, Mathias approached federal regulators with her concerns.

On June 12, 2000, an investigator with the federal Office for Human Research Protections (OHROP) notified the university of its receipt of serious allegations of noncompliance with human subject protections. The investigator summarized the OHROP’s findings, including both McGee’s failures to supply documents or information to the review board as well as Plunket’s unilateral retroactive approval of deviations from IRB-approved criteria for the enrollment of subjects. In addition, a number of findings reflected on the IRB as a whole. For example, many subjects were terminally ill, and hence “vulnerable,” yet the board “failed to ensure that additional safeguards were included in the study.”¹⁶

With regard to the informed-consent form, fault was found with the description of the purpose of the trial, the scientific basis for the trial, and risks and side-effects. More globally, the OHROP found that the review board “regularly” failed to satisfy requirements for continuing review for “essentially all” research protocols. It also found that the board often appeared “to lack sufficient information to make the determinations required for approval of research,” such as information on subject recruitment and enrollment, subject selection, privacy and confidentiality protections, and additional safeguards for vulnerable subjects.¹⁷ In addition to the investigation conducted by the OHROP, the FDA conducted its own investigation.

On January 29, 2001, a number of subjects and subject representatives, including Dawanna Robertson, filed a lawsuit seeking actual and punitive damages.¹⁸ The defendants include twelve individuals identified as members of the IRB—not only Plunket and Donovan, but also a number of members not mentioned by name in the allegations of misconduct. Interestingly, despite the serious allegations reported in the media and reviewed in the complaint, other subjects expressed faith in McGee and the vaccine and sought FDA permission to continue treatment.¹⁹

The number of causes of action in the Robertson complaint greatly exceeds the number in the Gelsinger complaint, and several are derived from international human rights law rather than standard medical malpractice or tort law. For example, the Robertson complaint charges the defendants with “breach of the right to be treated with dignity.” Lengthy quotations from sections of the Nuremberg Code and the Declaration of Helsinki concerning biomedical research are followed by an assertion that “common law has recognized such standards as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial.”²⁰

In the negligence count, the IRB defendants, individually and as a group, are charged with failing to exercise reasonable care in accordance with the accepted practices and procedures of institutional review boards, failing to follow and abide by guidelines set forth by various governmental agencies, and acting negligently per se, with the plaintiffs’ injuries a direct and proximate result. The IRB defendants are not named in the informed-consent count.

The Wright case

In March of 2001, Seattle’s Fred Hutchinson Cancer Research Center joined the ranks of institutions under fire for their treatment of human subjects. The Center has a national reputation as a pioneer in bone marrow transplantation. A bone marrow transplant is a potentially curative treatment for some cancers, but the treatment kills a significant number of patients. Patients are given extremely high doses of chemotherapeutic agents, which destroy the immune system as well as cancer cells. In an allogeneic transplant, the patient is infused with donated bone marrow as the foundation for a new immune
In the 1980s, Becky Wright traveled to Seattle for treatment of her leukemia under Protocol 126.21 As with Jesse Gelsinger, Wright died, and she died as a result of the treatment rather than her underlying disease. However, Wright was not the first of Protocol 126’s subjects to die during its long history.

In early 1981, Protocol 126 was first presented to the Center’s IRB; the protocol was presented under the patronage of Dr. E. Donnell Thomas, a co-founder of the Center and a recipient of the Nobel prize.22 During a meeting held on January 20, 1981, IRB members expressed concerns about the protocol, including the appropriateness of a jump from mice to human beings, the plan to enroll patients who would be expected to do well with standard therapy, and the misleading and incomplete discussion of risks and alternatives in the informed-consent form. These concerns were prefaced and followed by comments that suggested the board members were unclear about their responsibilities.23 Despite the members’ objections on this occasion, the IRB later approved the protocol.

Dr. John Pesando joined the staff at the Center in 1982 and the IRB shortly thereafter. As an IRB member, he was involved in the continuing review of Protocol 126. For Pesando, as the deaths mounted, stopping the study became a personal crusade.24 In 1991, Pesando took his concerns outside, writing to members of Congress, federal and state regulators, and later the Office for Protection from Research Risks (OPRR), the predecessor to the Office for Human Research Protections. In 1993, the OPRR opened an investigation. The president of the Center responded by sending a twenty-four page letter denying all charges.25

The investigation apparently fell prey to prejudgment by top-level officials at the National Institutes of Health, staff turnover, and the number of research scandals competing for regulators’ attention.26 A 1995 report by J. Thomas Puglisi, chief of the compliance oversight branch of the OPRR, concluded that Pesando’s charges were “unsubstantiated” and that it is the function of the IRB to establish whether risks are reasonable in light of anticipated benefits, with no second-guessing from the OPRR.27 A year later, the state began its own inquiry, but it was derailed when the investigator who was assigned to the project changed jobs.

At the urging of Pesando and a family member of a patient, the Seattle Times initiated an investigation and eventually published a series of articles. On March 26, 2001, a class action lawsuit was filed on behalf of the Wrights and “all others similarly situated.” Neither the IRB nor any of its members has been named as a defendant.

The development of protections

For over fifty years, the need to protect human subjects participating in research has been widely recognized. During the past thirty years, the federal government has regulated biomedical and behavioral research involving human subjects. Regulation, however, has followed a long and checkered history of research abuses. In fact, the history of research involving human subjects has been described by ethicists Ruth Faden and Tom Beauchamp as one of “progress propelled by scandal.”28

The evolution of the regulation of human biomedical research began in 1947, when the Nazi Doctors Trial brought to light the many atrocities that occurred in the name of science during World War II. At the conclusion of the trial at Nuremberg, the judges of the American military tribunal issued a verdict incorporating ten principles for the conduct of research involving human subjects, including the principle that “the voluntary consent of the human subject is absolutely essential.”29 Despite the powerful, if not legal, force of these principles, as well as the public’s awareness of the atrocities of the Holocaust, ethical abuses continued.

The next regulatory advance occurred in 1966 when the Public Health Service developed a policy requiring peer review of all research that held possible risk to human subjects.30 Two years before, in 1964, the World Medical Association had adopted the Declaration of Helsinki, providing guidelines for physicians conducting biomedical research on human subjects.31 These advances occurred following a series of exposés. In 1963, it was revealed that patients at the Jewish Chronic Disease Hospital were injected with live cancer cells without consent. In that same year, at the Willowbrook School, a residential institute for mentally disabled children, patients were infected with hepatitis to study the period of infectivity in advance of testing for a vaccine. And, in 1966, Dr. Henry Beecher published a ground-breaking survey of twenty-two examples of ethnically questionable research.32

In 1974, the National Research Act was enacted, resulting in regulations for the protection of human research subjects. “With the new regulations, the IRBs — rather than principal investigators — became responsible for determining whether potential research subjects are ‘at risk,’ and if so, whether the risks outweigh possible benefits to them and the importance of the knowledge to be gained from the research.”33 The Act came about largely in response to the Tuskegee Syphilis Study, in which approximately 400 African American men with syphilis were left untreated to try to gain a scientific understanding of the progression of the disease.34 Although the study had been ongoing since the 1930s, it was not until a 1972 newspaper story about the research that the public became aware of the deficiencies of the study.

The National Research Act also led to the establishment of the OPRR and
the National Commission for the Protection of Human Subjects. The Commission was charged with examining the problems in human subjects research and suggesting guidelines for the protection of human subjects. In 1978, it released a draft of the seminal Belmont Report, laying out the basic ethical principles guiding research involving human subjects: respect for persons, beneficence, and justice.

In 1981, the U.S. Department of Health and Human Services (DHHS) (then the Department of Health, Education and Welfare) revised the regulations for protecting human subjects found at 45 C.F.R. § 46 and, in 1983, added Subpart D to provide additional protections for children participating in research. The FDA also issued regulations. In 1991, the regulations at 45 C.F.R. § 46 were adopted by fifteen other federal agencies and became known as the Common Rule, and the FDA adapted its own regulations largely to comport with the Common Rule.

Recent reports
While the federal regulations have not changed dramatically since 1991, the past several years have seen much more attention focused on their effectiveness as well as the effectiveness of IRBs. For example, in its 1995 report, the Advisory Committee on Human Radiation Experiments questioned the adequacy of the reviews being done by institutional review boards. In that same year, the General Accounting Office issued a report that found several factors hampering the performance of review boards. A 1998 report by the Department of Health and Human Services Office of the Inspector General, Institutional Review Boards: A Time for Reform, concluded that "the effectiveness of IRBs is in jeopardy." The report went on to delineate six challenges for these boards:

- minimal continuing review of approved research;
- conflicts that threaten their independence;
- little training for investigators and board members; and
- not giving much emphasis to evaluating effectiveness.

Why the backlash now?
Why are IRBs suddenly facing so much criticism? What has changed since their inception in 1974? The answer is "a great deal." At the time the institutional review board process was developed and the federal regulations were implemented, research typically involved a single investigator at one institution with a circumscribed group of subjects. In the last decade, research has assumed a vastly different form: multicenter trials with centers located all over the country, even the world, with many investigators and numerous subjects. Further complicating the picture is the increased commercial sponsorship of research, influenced by the passage of the Bayh-Dole Act in 1980. With corporate sponsorship, protocols are often dictated by the sponsor. In fact, in testimony before the Committee on Government Reform and Oversight, Deputy Inspector General George Grob acknowledged that "IRBs feel pressure to accommodate these sponsors who are looking for quick turnaround of their research and for whom time is money." A heavy workload, including both initial reviews and continuing reviews (performed at least annually), has made it nearly impossible for even the most committed and informed IRB to discharge its responsibilities under the current federal regulations. The average board has gone from reviewing about 40 protocols per year to reviewing more than 300 per year. Some of the larger research institutions have seen even more profound changes. At Duke University, for example, in 1974, 400 protocols were reviewed; currently, at least 2,200 protocols are reviewed annually, and research brings in over $100 million per year. At the University of California at San Francisco, protocols increased from 100 in 1966 to nearly 4,000 in 1999.

Since the 1998 report from the Office of the Inspector General, the "IRB crisis" has been a priority issue for federal regulators. Over the past two years, the OPRR/DHRP has stepped up its enforcement efforts. From April 1997 to May 1998, the OPRR conducted only one on-site investigation, whereas between June 1998 and March 2000, the agency conducted ten on-site investigations.

During this two-year period, institutional review boards have been under close scrutiny not only by federal regulators, but by the public. In 1999, the OPRR took a hard-line approach with several prestigious academic institutions by restricting or suspending their "Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects," a document stating the institution's commitment to upholding human subjects protection regulations, and their policies and procedures for meeting these regulations, for all research. By restricting or suspending this document, the OPRR essentially halted research at a number of institutions. According to one professional at an institution with a suspended Multiple Project Assurance, "[a] prolonged delay in new research would cost the hospital millions of dollars in federal and private grant money and inflict immeasurable harm on its prestige.

Institutions such as Mount Sinai School of Medicine, City University of New York, and Duke University were issued suspensions requiring them to revamp their review process and re-review hundreds, if not thousands, of protocols in order to have their assurance reinstated. The tremendous publicity given to these actions and to Jesse Gelsinger's death has begun to change the landscape of the institutional review of research. What was largely an unknown and unpublicized process has become front-page news, and the pub-
lic, from which research subjects are drawn, has begun to demand accountability.

In April of 2000, the Office of the Inspector General released a status report finding some improvement in the enforcement of federal regulations for human subject protection. Since then, the OHRP has been relocated to the Office of the Secretary of Health and Human Services, instead of being subsumed under the National Institutes of Health, which oversaw the previous OPRR. The new agency also has a larger staff than it did before, enabling more active oversight and education of institutional review boards and investigators. Additionally, the OHRP has created a website providing access to educational materials, training modules, information about assurances, and a detailed list of the agency’s most common findings of non-compliance.

However, the 2000 report found that most of the Inspector General’s 1998 recommendations have not yet been implemented. The report concludes by acknowledging that “IRBs alone cannot do the job and that in various subtle ways IRBs are expected to carry too much of the burden.”

IRBs as defendants

Despite the recognition that too much responsibility has been laid upon them, IRB members — both individually and as a board — may be exposed to legal liability for any failures, deliberate or otherwise, associated with the human subjects research they are charged with approving and monitoring. The Robertson case illustrates this danger.

At least one news account suggests that the legal strategy pursued in Robertson is “unprecedented.” But with all the reasons in its favor, one may wonder why it took this long.

To begin with, when asked to explain why individual IRB members were named as defendants, attorney Alan Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, the New Jersey law firm involved in all three lawsuits, told a reporter, “[federal regulatory agents made] specific reference to the inadequate job of supervision that the IRB did.” Government reports highlighting the current deficiencies in the review process and specific investigations documenting areas of non-compliance provide fodder for plaintiffs’ attorneys, which they can use to support charges against particular review boards.

More generally, one legal scholar suggests that the decision to sue IRB members is consistent with a general practice among plaintiffs’ attorneys to cast the net as wide as possible, at least initially. “It’s a strategy that causes more people to be upset, and therefore encourages institutions to settle quicker.”

But suing IRBs and their individual members is not without its challenges. A number of factors, including uncertainties about the existence of a duty of care and the applicable standard of care, converge to make IRBs less than ideal defendants. On the other hand, although suits against IRBs and their members may not be successful in winning large monetary awards, or even favorable verdicts, naming IRB members as defendants may be a way of intimidating them and undermining their credibility should they be called to testify.

Duty of care

One of the most likely causes of action in a research-related lawsuit, as illustrated in the cases discussed above, is negligence. The elements of a claim for negligence include duty, breach of the applicable standard of care, loss or injury, and causation. The threshold question, then, is whether an IRB or its members have a legal duty to exercise care that extends to individual human subjects.

Courts have held that an institution may be liable for non-compliance with standards for informed consent established under federal regulations. A Multiple Project Assurance or other assurance to which the institution is a party is another possible source of institutional obligation. An IRB is simply one of the means through which an institution meets its obligations to protect subjects as a class. While the “primary purpose” of an IRB’s review may be “to assure the protection of the rights and welfare of the human subjects,” IRB members have only the most indirect relationship to actual subjects. Courts generally employ concepts such as “reasonableness” and “foreseeability” and weigh considerations of public policy in assessing whether a duty of care exists.

Standard of care

A standard of conduct may be “established by a legislative enactment or administrative regulation which so provides.” The federal regulations arguably set forth the standard of conduct to which IRBs should be held. Codes of conduct and professional guidelines may also be considered. In the context of research involving human subjects, a number of codes exist, including the Nuremberg Code and the Declaration of Helsinki. Whether a court will accept these codes as evidence of the standard of conduct for IRBs remains to be seen.

The difficulty in determining a reasonable standard of conduct for individual IRB members is compounded as a result of their diverse backgrounds and experience. The federal regulations require review boards to be composed of both scientists and non-scientists and to include at least one community member. Implicit in this requirement is an understanding that not all IRB members will understand all aspects of a particular protocol under review. It seems wrong, moreover, to hold all IRB members, especially community members, to the same standard as health professionals on the board.

Causation and damages

The remaining elements of a negligence action may present problems in particular cases. For example, causation and
damages may be difficult to establish in cases involving terminally ill subjects. The applicability of peer review protections must also be considered. While IRBs serve a different function from traditional peer review committees, these protections may apply to IRBs if the state’s peer review statute is broad enough. If this is the case, the protections afforded peer review may shield IRBs and their members from liability — as well as shield IRB records and documents from discovery or admission into evidence. For example, an Illinois court held that an IRB qualified as the type of committee covered by the state peer review statute and would not be required to disclose documents requested by the plaintiffs.63 Also, from a purely practical standpoint, suing an IRB and its members is unlikely to bring in resources beyond those of the institution since they are unlikely to have “deep pockets.”

Policy considerations for extending liability, or not

From a public policy perspective, the major question is whether the fear (or fact) of legal liability will lead to more responsive and more accountable review boards.

In defense of legal liability

“[I]t is a sorry reflection of the postmodern values of some researchers, clinicians, and even members of ethics committees that they accuse those seeking to improve [research] practice of increasing their own legal liability. The law, after all, is one medium through which society ultimately holds all its citizens to account.”64 Legal liability is a perfectly ordinary means for ensuring that people and institutions meet their responsibilities. Also, given the slow pace of the response to recommendations from internal and external critics of the IRB system, lawsuits may be one of the few ways of expediting the needed changes, as fear can often be a motivating force.

As evidenced by accounts of the Wright case, IRB members are often torn between protecting subjects from harm and their concern over damaging relationships with colleagues. The threat of liability may strengthen their commitment to protecting subjects even at the expense of their relationships with colleagues. For example, awareness of the then-breaking research scandal at the UCLA Medical Center seems to have strengthened the resolve of review board members in the first review of Protocol 126.65

Finally, exemption from liability should require some strong justification: “In a legal system that couples responsibility with liability, immunity … would be inappropriate.”

Against legal liability

One commentator has noted that “IRBs up to this time have not attracted the attention of tort law. And if this process of dealing with oversight of IRBs has an unfortunate consequence that it is used as a mechanism for attack by tort law, IRBs will be in real trouble.”66 Some would argue that lawsuits are an arbitrary way of setting and enforcing standards. Since lawsuits are factually specific, they may not produce the best general rules. In addition, with regard to health care generally, studies have shown a lack of correlation between negligent treatment and malpractice claims.68 Furthermore, some assert that fear is more likely to discourage people from becoming IRB members than motivate them to become more diligent board members. As one executive director of an IRB has put it:

Why would I even want to risk the chance of being named in a lawsuit? … With the amount of research done at any major research university or academic medical center, there will be people who have adverse events and there will be people who die. If the default is as soon as that happens the IRB gets sued, there will be no more IRBs and there will be no more research because you can’t do research without IRBs.69

Finally, IRBs may become so risk-averse that no research passes muster. It should be noted, however, that boards may also face lawsuits from investigators if, for example, they block or delay research in a way that damages an investigator’s career and reputation.

Recommendations:
less criticism, more assistance

The focus during the past several years has been on the problems with IRBs. Each critical report, however, has recognized that board members are overtaxed through no fault of their own. The time has come to stop criticizing an underresourced, largely untrained group of volunteers and instead find solutions to the identified problems. Is liability the answer? It seems unlikely. Given our experience with IRBs, we believe that the prospect of being hauled into court whenever a clinical trial goes badly will likely discourage those who are most qualified (typically those who have the most to lose) from participating on an IRB. At the same time, a blanket exemption from liability would not be an appropriate response either; clearly boards need to appreciate the gravity of their role in protecting human subjects. While other organizations and committees are engaged in the broader task of developing recommendations for system-wide reform, we present here a non-exhaustive list of recommendations specific to IRB liability.

1. Define the role of the IRB more clearly. Should a review board be a guarantor of the ethical conduct of research, as suggested in the Robertson complaint, or should it be but one component of a process for bringing to the surface and addressing some problematic features of research? We add our voices to the chorus arguing for the lat-
ter. While we believe that institutions are responsible for policing conflicts of interest and using audits or other means to detect fraud on the part of researchers, these duties should be carried out through mechanisms other than the IRB.

2. Increase the resources devoted to IRBs. Resources that must be provided include education, full-time staff, and financial support. Greater efficiency in operation could result from a number of the innovations described below.

3. Relieve local IRBs of tasks that are peripheral to their role and/or exceed their capabilities. For example, a strong case has been made for using central IRBs for multicenter trials and for using specialized data monitoring committees more frequently for continuing review of complex protocols.

4. Strengthen other parts of the accountability framework. This recommendation has three parts: requiring certification and accreditation; providing whistle-blower protections; and disseminating information to the public.
   
   (a) Certification and accreditation. The Applied Research Ethics National Association (AREN) has designed a voluntary certification program for IRB members or would-be members that requires passing an exam. The exam covers the history of research, principles of bioethics, codes, and standards. Additionally, Public Responsibility in Medicine and Research (PRIM&R) has proposed a voluntary accreditation plan for institutions. Also following this trend, a recent Institute of Medicine report presents the arguments for accreditation and offers detailed recommendations for implementation.

   (b) Whistle-blower protections. Although we cannot address the subject at length here, the importance of whistle-blowers and whistle-blower protections should be clear from the descriptions of the Robertson and Wright cases.

   (c) Information to the public. While the OHRP has expanded its website to include common findings of non-compliance and information about investigations, even more information could be offered to the public.

5. Specify the nature of liability for IRBs and help members contain this liability. To the extent that private suits for damages have a place in the accountability framework, then legislators and judges should fashion a standard of care that considers the interdisciplinary and collaborative nature of the work performed by a review board. The standard should also take into account the background and experience of the particular board member. Furthermore, the standard should be more procedural than substantive, as "[t]hese decisions are often not black-and-white cases but rather require professional judgment." A minimalist procedural standard would hold IRB members responsible for proceeding in good faith and investing sufficient time and energy to arrive at a sound judgment.

Universities or other research sponsors should contain liability for IRB service in a manner consistent with practice in other areas. Universities, for instance, could offer insurance coverage or indemnification to IRB members. Although this step would not eliminate the threat of a lawsuit or liability, it could reduce participants' concern over financial loss. Current industry practice in this area is unclear; for example, the university in the Robertson case would not comment on whether the institution's insurance policy covers IRB members. However, insurance is routinely provided to those who serve on corporate boards, and it should also be provided routinely to those who serve on review boards.

Another way to limit liability for IRB service in a manner consistent with practice in other areas would be to provide immunity for community members who serve on review boards. Community members are selected precisely for their lack of entanglement with the institution, so they are unlikely to benefit in any tangible way from their service. Furthermore, they often have very little power in relation to the institutionally connected members. A law exempting community members from liability would be analogous to existing laws protecting volunteer health-care professionals, absent bad faith and the like.

6. Increase the rewards for service on an IRB. There are several creative ways to implement this recommendation. For instance, universities can recognize the value of IRB service with professional rewards, such as release time and tenure credit, and consider paying members for their time. Payment may come in the form of buying out a percentage of an academic's or clinician's time. A university can also reward IRB service with moral support. For instance, it may be demoralizing to be overwhelmed with work (especially paperwork that seems to have no real connection to protecting human subjects) and to realize that one has little or no institutional backing when confronting a colleague over a protocol.

7. Work to change the institutional culture. The ultimate goal is to integrate protection of human subjects into conceptions of good science and good medicine, so that reviews are seen as part and parcel of the process rather than an obstacle to research.

References


4. Gelsinger v. Trustees of the University of Pennsylvania (Phila., Cnty. Ct. of C.P. filed September 18, 2000), available at <http://www.sskrplaw.com/links/healthcare2.html>. Dr. Steven Raper, Dr. Mark Batshaw, the Children's Hospital of Philadelphia, and the Children's National Medical Center were also named as defendants.
The financial arrangements were complicated. According to the complaint, Wilson had founded Genovo, the private, for-profit biotechnology company that sponsored the research, and he controlled a significant share of its stock. The university received a 5 percent ownership stake in Genovo in lieu of upfront funding of the gene therapy (or, more accurately, gene transfer) research program. The university, Kelley, and Wilson held or had applied for patents in vectors of the kind employed in the research. Id. at 2–3.


7. Ginsberg, supra note 4, at 5.

8. Id.

9. There may also have been problems with subject recruitment. According to Joanne Silberner, "volunteers had been recruited through an Internet site that presented overly optimistic information about the study." J. Silberner, “A Gene Therapy Death,” Hastings Center Report, 30, no. 2 (2000): 6.

10. In an interview with a reporter, one of the plaintiffs’ attorneys suggested that Caplan also helped write the informed-consent form. D. Nelson and R. Weiss, “Penn Researchers Sued in Gene Therapy Death: Teen’s Parents Also Name Ethicist as Defendant,” Washington Post, September 20, 2000, at A3. See also B. Gose, “Penn, Doctors, Ethicist Named in Suit Over Gene-Therapy Death,” Chronicle of Higher Education, September 29, 2000, at A34. Caplan’s name was also, however, omitted from the informed-consent-related counts in the complaint.


15. Letter from N.K. Hausmann to M. McGee and T. Broughan, regarding GMP and GCP Audit of OU-Tulsa Melanoma Vaccine IND Sponsorship and Clinical Study Conduct (March 16, 2000) (on file with authors).


17. Id. at 13.

18. Robertson, supra note 14.


22. Thomas never served as principal investigator, however.

23. Id., “I know that we are not constituted to review substantive research issues, but we should be sure that such a review has taken place.... In terms of the consent form, I think if the purpose of the Human Subjects Review Committee is to actually make sure the patient is fully informed, it should include in the consent the risk of GVHD [graft-versus-host disease] in the patients.” Minutes of the Fred Hutchinson Cancer Research Center, Human Subjects Review Committee (January 20, 1981) (on file with authors).


27. Letter from J. Puglia to R.W. Day, regarding Conclusion of Evaluation of Compliance with Assurance M-1008 with Regard to the Complaint Filed by John M. Pesando, M.D., Ph.D. (September 5, 1995) (on file with authors). According to the Seattle Times, the OPPR failed to interview IRB members, study investigators, Hutch officials, subjects, subjects’ families, or outside experts. Wilson and Heath, supra note 24.


33. Bell, Whiton, and Connelly, supra note 30, at 12.


39. Id.


47. Id. at 8.
53. Id.
55. V. Fouibuster, “Clinical Trial Patients Sue IRB Members,” American Medical News, February 26, 2001. Lawsuits have been brought against IRBs as entities before, albeit rarely. For example, the Boston University institutional review board, among others, was sued in connection with an experimental surgical procedure. The case eventually settled. See R. Saltus, “BU Medical Center Sued for $3.25M Over Surgery,” Boston Globe, May 12, 1994, at 26.
56. Fouibuster, supra note 55.
57. Id., quoting Leonard Glantz.
59. 21 C.F.R. § 50.102(g) (1990).
60. Restatement (Second) of Torts § 285.
61. State laws and regulations concerning protection of human subjects in research may also be cited as evidence of a standard of care where federal regulations do not apply. See, e.g., Protection of Human Subjects in Medical Experimentation Act, Cal. Health & Safety Code § 24170 et seq. (West 2000).
65. Preface your statement that this is what UCLA is in trouble for so be careful.... Unfortunately, these protocols are a hot potato in terms of what is happening at UCLA. It would behoove the investigators to have a meeting with this committee to answer some of the questions raised. So if there are any questions from the public in the future, we will have looked into the matter....” Minutes of the Fred Hutchinson Cancer Research Center, Human Subjects Review Committee, supra note 23.
69. Fouibuster, supra note 55, quoting Gary Chadwick, executive director of the institutional review board at the University of Rochester.
71. The FDA, for example, plans to disseminate extensive safety data to the public for the subset of clinical studies involving gene therapy or xenotransplantation. See 66 Fed. Reg. 4688–706 (January 18, 2001).
72. Fouibuster, supra note 55, quoting David Korn, senior vice president for biomedical and health sciences of the Association of American Medical Colleges.
73. Simply being named as a defendant in a lawsuit is always a negative. In addition, usually by policy and sometimes by law, beneficiaries are not protected against personal liability for actions taken with malicious purpose, in bad faith, or in a reckless manner.
74. Fouibuster, supra note 55.