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Essay—Memoir

TALES OF INFORMED CONSENT: FOUR YEARS ON AN INSTITUTIONAL REVIEW BOARD†

by
“Bartolo”††

FROM FEBRUARY 1987 until January 1991 I served on the institutional review board of a hospital as its volunteer attorney member; “community lay representative, lawyer” was my official designation. What follows is a memoir of that service. To preserve privacy, I have suppressed the name of the hospital and of other institutions, and have given pseudonyms to all those it was necessary to mention by name.

This is not a law review article in the ordinary sense of the term. It cites few cases, statutes, regulations, and refers only occasionally to secondary sources. Instead, my personal experiences and reactions to the experiences of others dominate the work. One could attempt to affiliate this subjectivity with the recent “narrative turn” in legal scholarship, but that seems presumptuous to me.

I hope that a reader could use this memoir of my work on an institutional review board for a few simple purposes. Of perhaps greatest importance is what my experience has to say about an institutional review board’s oversight of the process of informed consent. The following contains documents that may aid other boards and board members in discharging this oversight duty. My account may also be important to those who have served, or who are about

† Several colleagues read an earlier version of this article, and I thank them (albeit anonymously) for their many helpful comments. I feel constrained to mention that I did not show the manuscript to anyone with whom I had served on the institutional review board, and that the editors of *Health Matrix*, one of whom has served on another institutional review board in a different state, were unable to verify the events described here.

†† The author, who holds two law degrees, has been a full-time teacher at law schools in the United States since the mid-Seventies.

to serve, in such a position. Finally, the adventures of a lawyer among physicians and other health-trained professionals may be interesting to those in any of these disciplines.

* * *

In late 1986 a former law student, whom I will call Barbarina, telephoned my law school office for assistance. Barbarina had been an outstanding student and a favorite of mine. After graduation she had remained in town and eventually became the chief financial officer of a community children's hospital. On the phone, after an enthusiastic renewal of acquaintance, Barbarina indicated her problem: There were two hospital committees required to have attorney members that currently had no such members, an ethics panel and the institutional review board; did I have any suggestions?

Barbarina generally described the work of the two committees. The ethics panel, which considered discontinuation of life-sustaining treatment and other similarly weighty issues, tended to meet in crisis circumstances. I immediately thought of one of my law school colleagues who had a strong interest in right-to-die cases for the ethics panel and suggested to Barbarina that she contact that person.

Placing someone on the institutional review board was a more difficult matter. The board ("IRB," as she called it) met more regularly—but only once a month—to approve any hospital research project involving human subjects, including approval of the informed consent form given to the research subjects. Both of the school's torts teachers were familiar with the law of informed consent and therefore would be likely candidates. But one had already been on the IRB—his resignation several months before, I was told, had created the current vacancy—and the other was probably too busy to take up another responsibility. I said I would talk to the torts teachers and then get back to Barbarina.

The conversations with my torts colleagues were predictable. The former member said he had resigned because of concern over his personal liability for board decisions—a comment that would trouble me throughout my service on the IRB.¹ The other torts teacher professed interest, but did not want to take time away from teaching, a full slate of off-campus presentations, and family.

About a month after her original call, I telephoned Barbarina to report my lack of success in finding an attorney member for the

1. See, e.g., Allan Reider, *Potential Liability for Institutional Review Boards and Bioethics Committees*, HOME CARE ECON., Fall 1987, at 119.

institutional review board. After a brief pause, Barbarina responded, "What about you, Bart?" From the outset I had thought that she might be interested in having me as a committee member, but I had avoided the subject. Now that it was out, I quickly listed reasons why I was unqualified for the job: My main teaching area, criminal law, bore no relation to the work of the IRB; I had never even taken a course in medical jurisprudence; I was not a member of any state bar. Barbarina brushed these disclaimers aside, saying she was sure that I could do the work.

Of course, this was gratifying to my ego, and I began to sell the idea to myself. I had always enjoyed working with professionals from other disciplines,² and the chance to meet regularly with physicians, nurses, and hospital administrators began to appeal to me. More importantly, there was a relationship between the review of informed consents and my other principal teaching responsibility, legal research and writing. I already spent much of my time reading the written work product of law students—memos, briefs, and law review notes and comments—and could sharpen whatever skills I had acquired in this process by applying them to another type of legal writing: informed consent forms. So by the end of our second telephone conversation, I was telling Barbarina that I would likely take the IRB position.

Further reflection only interested me more, so I was happy to receive a letter in late February 1987 from the chairman of the IRB—Dr. Sarastro—thanking me for agreeing to serve on the board and inviting me to drop by his office before the next meeting. Enclosed in the letter was a four-page handout of guidelines for the IRB. Regarding board composition, the guidelines indicated that the board should have at least five members, that one-third to two-thirds of the membership should be "scientists," that at least one member should be "a representative of the community," and that membership by an attorney and a minister was "recommended"; appointments were for a year, and "[a]lthough some turnover of membership is desirable, the membership should be relatively stable from year to year in order to enhance the experience and introduce stability into the standards of the IRB."³

2. A year or so before, I had commenced what has turned out to be an extensive collaboration with a psychology professor.

3. For a discussion of IRB membership requirements and procedures, see George J. Annas, *Ethic Committees: From Ethical Comfort to Ethical Cover*, HASTINGS CENTER REP., May 1991, at 18; Dale L. Moore, *Recurrent Issues in the Review of Medical Research on Human Subjects*, 1 ALB. L. J. SCI. & TECH. 1, 11 (1991).

The board guidelines also included two separate lists of criteria for evaluating research projects (formally labeled "protocols") involving human subjects—the second pertaining to protocols involving children—which I subsequently learned were taken directly from the applicable federal regulations.⁴ The criteria bristled with mandatory but open-textured terms like "appropriate," "equitable," "the safest procedures consistent with sound research design," and "reasonable in relation to the anticipated benefits." The board guidelines also required informed consent forms that "minimize the possibility of coercion or undue influence" and "communicate[] in language that is understandable to the subject."

Also in Sarastro's first letter was a four-page set of "Guidelines for Investigators," directed toward those supervising research, with a five-page attachment, a blank "Human Research Protocol Form." Though there was no sample informed consent in the attachment, the investigator guidelines devoted almost two pages to the informed consent form, beginning with "Experience has shown that many applications are defective with respect to the informed consent." The investigator guidelines listed the federal requirements:

A fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;

A description of any attendant discomfort and risks reasonably to be expected;

A description of any benefits reasonably to be expected;

A disclosure of any appropriate alternative procedures that might be advantageous to the subject, if applicable;

An offer to answer any questions concerning the procedures;

An instruction that the person is free to withdraw consent and to discontinue participation in the project or activity at any time, without prejudice to him or herself;

A promise that all information which refers to or can be identified with a particular subject will remain confidential.⁵

The investigator guidelines also contained a lot of advice: "Use language that lay people can understand." "Be as explicit as possible in stating the risks and benefits." "In general, informed consents

4. 45 C.F.R. pt. 46 (1990) (same language as in 1986). See also 21 *id.* pts. 50, 56 (1991) (same language as in 1986).

5. The last item contained an additional explanation in parentheses: "That is, that such information will not be disclosed, except with the consent of the subject or a legally authorized representative, and as may be necessary for the review committee to fulfill its legal responsibilities for annual review of the project."

drawn up by pharmaceutical firms are inadequate for our purposes." "The fact that a particular consent form was judged adequate in another institution does not necessarily mean that it will be acceptable here."⁶

Skimming these guidelines gave me a sense that I was getting involved with a fairly sophisticated operation, with relatively strong internal procedures. A few days before the second Wednesday in March, I received at the law school a packet from the hospital's Quality Assurance Department, which had administrative responsibility for the IRB. The packet included a meeting agenda—approval of previous minutes, three annual reviews of research protocols, three new protocols, and one item for discussion (a protocol recently discontinued for lack of an annual review request)—and supporting documents for most of the agenda items.

The documents were rather formidable. Two of the annual review documents contained a memo indicating the current status of a previously approved project (in both cases, there were no new subjects in the project and little or no activity—a common situation, I learned rather quickly). Attached to each of these memos was a copy of the informed consent—eight double-spaced pages in one case and four pages in the other.

The other annual review document was in a form with which I soon became quite familiar. As most of the physicians in the hospital were also affiliated with a local university's medical school (not connected in any way with my law school), which had its own IRB, many of them chose to submit the university IRB forms to the hospital IRB. The university renewal form was a four-page bureaucratic array of lines and boxes to be completed by the investigator. The directions were short and to-the-point (for example, "Give your current assessment of the risks and benefits based on the results," above a two-inch-by-seven-inch box). The form ordered the investigator to attach an informed consent only if it had been revised. (Like the other renewals in my March 1987 packet, this document indicated little activity and no revision of the informed consent.)

The protocols for new research projects were in general more detailed. The first was only three single-spaced pages long (including informed consent)—such brevity was rare, I discovered soon

6. Another caveat — which was largely ignored throughout my service on the IRB — read, "If Spanish speaking subjects will be involved in the study, a Spanish version of the consent form should be provided for review by the Committee." See *infra* notes 30 & 33.

enough—but everything about the protocol put me off: its title, “Use of physostigmine salicylate (Antilirium) as a stimulus for growth hormone release”; its relentless use of medical jargon (the following phrases are all from the first paragraph, meant to be introductory: “GH radioimmunoassay,” “endogenous GH secretion,” “adrenergic, dopaminergic, cholinergic, serotonergic, histaminergic and gamma aminobutyric acidergic neurons”); and its equally confusing use of medical shorthand (“[B]aseline samples will be taken at -30, -15, and 0 minutes. At 0 minutes 0.02 mg/kg up to 1.0 mg will be given I.M.”). Rather than try to wade further through this, I retreated to the informed consent, to discover that the research involved a drug injection, followed by the taking of blood samples at fifteen-minute intervals over four hours—a relatively simple protocol. Thus I learned early on that reading the informed consent was the best way to understand a protocol, and probably the only way for those like me without medical training.

Though sponsored by a hospital doctor, the other two new protocols originated with a Japanese corporation that wanted to experiment with human tonsils obtained through routine tonsillectomies conducted at the hospital. I could not imagine how this might be controversial, and concluded from the first packet that while the work of the IRB might be tedious, it did not seem to be particularly contentious.

I met with Dr. Sarastro before the meeting. My first impression of him was that he was cordial in a distant sort of way; my attempts at ingratiating humor produced candid but unresponsive glances as frequently as they brought chuckles. After a few minutes of point-less conversation, Sarastro led me across an enclosed walkway to a neighboring building, down an elevator to the basement, around a corner and past a cafeteria, to the designated conference room. I knew then why Dr. Sarastro had asked me to meet him in his office before the meeting; I never would have found the meeting room on my own.

After being introduced to the other board members (about ten people that day, out of a membership of around fifteen), I kept pretty quiet. I thought that I should learn the ropes before I became an active participant. So I watched as the IRB approved the minutes of the last meeting—it surprised me that the minutes were distributed at the beginning of the meeting and collected at the end;

apparently, a hospitalwide policy, but still pretty uptight to me⁷—and then gave rather close scrutiny to the three renewals, requiring minor amendments in their informed consents (spelling corrections and word substitutions for clarity).

The same attention was given to the new protocols, which were also approved. Though it was arguable that research with discarded tonsils did not need IRB approval, the group determined for reasons I did not then understand to retain some review of the activities of the Japanese research institute. Occasionally in this discussion I noticed the peculiarly careful and indirect tone that professionals employ when they want to raise a concern without being explicit about it. But I did not catch what their concern was.

Because I had been so reticent at my first meeting, I determined that I should show my good faith at the second meeting by bringing a handout of legal materials relevant to the work of the IRB. Besides, finding the correct provisions would require looking at the *Code of Federal Regulations*, a source with which a teacher of legal research should be familiar. After a few false starts, I located the relevant statutes⁸ and regulations,⁹ which produced a more sizable packet than I had expected. Nevertheless, I asked the faculty secretarial office to reproduce twenty copies at school expense, and brought them to the next meeting.

The agenda for the April meeting included the two renewals modified at the March meeting, plus several new items. I read the supporting documents on these new items with a closer eye, flagging questionable areas based on my limited experience at the earlier meeting. For examples, one renewal form said that an informed consent was enclosed, when it was not, and a new protocol contained no informed consent form. But the most interesting parts of the agenda were six requests from Dr. Selim, the hospital's leading specialist in pediatric cancer. Each request involved a research protocol from a nationwide consortium of pediatric oncologists in which Dr. Selim participates; the consortium conducts numerous parallel research projects at hospitals around the country. The consortium protocols on the agenda—two new, one for annual review, and three to be amended—came with lengthy supporting documents (with unfathomable tables and flowcharts) and informed consents, all produced by the consortium's central office.

7. During my last year on the IRB, the chairman relaxed this policy, apparently unilaterally.

8. 42 U.S.C. § 289(a) (1988) (same language as in 1986).

9. 21 C.F.R. pts. 50, 56 (1991). See *supra* note 4.

Buffaloed by the protocols themselves (one was twenty-six pages, single-spaced), I turned to their informed consents. Though somewhat more illuminating, they too were disappointing. The consent forms used terms that would be unfamiliar to a patient—or, the more common situation at a children's hospital, a patient's parent—even one with an advanced education: "dose limiting toxicities," "intrathecal injections," "bone marrow aspiration," "histopathological material," and "bilateral wedge, testicular biopsy." Not only were these terms opaque, but in many cases their opacity hid what in reality were rather serious procedures and consequences.

Each informed consent also contained a sly attempt to limit liability: "In the event of a research-related injury, I understand that participation has been voluntary." This language surprised me, for whatever consortium employee drafted the consent forms should have known that any such attempt would be ineffective: The federal regulations regarding informed consent specifically prohibit using the consent form to limit the patient's legal rights in any way.¹⁰ These provisions thus distinguish human research informed consents from the informed consents between doctor and patient that typically play a role in medical malpractice litigation.

My best recollection of the April 1987 meeting is that I kept my mouth shut as the other IRB members gave a gingerly treatment to the consortium protocols. The general impression I had was that the group was dissatisfied with the informed consents, but was willing to acquiesce in their approval because the consent forms were being used nationwide, and because they were important to Dr. Selim's work, which in turn was important to the hospital.¹¹

By the second meeting, I had begun to identify the principal players among the IRB members. Dr. Sarastro, as his no-nonsense manner implied, ran a tight but fair meeting. He recognized everyone who wanted to speak, but usually exerted light pressure to move on. The principal discussant among the other board members was Dr. Ottavio, a pediatric endocrinologist in his mid-forties. Ottavio had his own research protocols (in the consideration of which he took no part, pursuant to board rules), and so brought an investigator's perspective to the IRB meetings. But tempering this possi-

10. 21 C.F.R. § 50.20 (1991); 45 *id.* § 46.116 (1990).

11. One marker of Dr. Selim's importance was that unlike some other investigators, Selim never attended an IRB meeting during my time on the board. Barbarina later told me that while he had a wonderful bedside manner, especially with very ill children, Selim had a very low tolerance for bureaucracy.

ble bias was an uncommon empathy for the worried parents of sick children. I liked Dr. Ottavio almost from the moment I met him.

Somewhat less vocal than Ottavio were Zerlina, a risk manager, and Reverend Nettuno, the hospital's chaplain. Zerlina had no discernible medical training, but she was not afraid to express her opinions. I admired Zerlina's spunk, as I admired Reverend Nettuno's compassion. A bearish middle-aged man, Nettuno championed the rights of patients, frequently implying his disdain for the way doctors (and lawyers) failed to relate to them as human beings.

While most of the other IRB members were silent or absent—for example, the community representative—a few occasionally contributed to the discussion: two nurses, one older, with the air of a shop steward, and the other somewhat younger and much more tentative; and Basilio, the hospital administrator. Basilio's manner was military: He did not really care what the policy was, as long as it was being followed, to the letter.

Most of the members appeared to appreciate my statutes-and-regulations handout (though I doubt any of them except Zerlina read it), and I was soon asked to do a little more research. Because of the hospital's connection with the local university, a state-supported institution, the hospital's consent form referred to a specific statute regarding state liability for injuries received during research; board members had the impression the statute was relevant to the work of the IRB, but had no idea what the provision said. It turned out that the statute was the state's general waiver of sovereign immunity and of course said nothing about human research or informed consent. I was surprised by the legal ignorance of a group of very intelligent people. Why couldn't they have looked up the statute themselves? They seemed awed by the incantatory power of legal references; we don't know what it means, just that we have to include it.

During my first few months on the board, I also did some research on the legal and ethical background of institutional review boards. Reverend Nettuno circulated some articles on the role of a hospital IRB, and Dr. Sarastro made available a set of videotapes that documented the history of the legislation requiring IRB's. From these sources and some others I found,¹² I learned of the atrocities that had been committed in the name of science—for ex-

12. See, e.g., NATIONAL COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH* (DHEW Publication No. (OS) 78-0012, 1978).

ample, a project in which the venereal disease of predominantly poor black men went untreated for decades¹³—and of the public, scientific, and legislative responses on learning of such events. Though it was difficult to compare such depraved “research” with injections and blood tests, or harvesting discarded tonsils, this study made me more aware of the underlying reason for the IRB and for participation in it by people like me.

So when I received the packet for the May meeting, which contained several protocols with informed consents that were unsatisfactory to me (some from Dr. Ottavio and some from Dr. Selim), I decided I had to speak up. Part of my thinking was that as an outsider, I could take potshots without risking my status in the institution—I had none—unlike virtually all the other members of the IRB, who were economically dependent on the hospital to one degree or another. Further, I began to feel obliged to play the gadfly; I owed it to the patients and their parents and to the other members of the IRB.

Despite my legal training, this role was not one I took to easily. I had never practiced law, so I had never sharpened my skills at being obdurate. Even as a law teacher, I had eschewed the confrontational “Kingsfield” style, opting for a more relaxed classroom. But at the meeting I cleared my throat and launched into an overheated attack on various defects in the informed consents: use of medical jargon, other defects in clarity, and spelling and grammar mistakes. My outburst was calmly received, and Dr. Sarastro managed to soothe me by responding to some of my concerns. In return, I softened my demands, and all of the protocols were approved with minor revisions in the informed consents. While recognizing that I had been coopted, I thought I had made a dent.

* * *

Over the next several months I continued to play my role. I was expected to find fault with most of the informed consents, and I usually lived up to this expectation. Sometimes I adopted a questioning, “I really don’t know what I’m talking about, but” tone; sometimes I was more derisive. And usually I had some support, from Zerlina, Reverend Nettuno, or one of the nurses—either seconding my comments or adding criticisms of their own. But our efforts produced only trivial amendments (which Dr. Sarastro be-

13. See Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, HASTINGS CENTER REP., Dec. 1978, at 21.

gan to handle on his own, rather than bringing them back to the board).

Some of the more extreme defects I complained about during my first year on the IRB included an informed consent that ended in its middle; either no one had bothered to finish the form, or no one had bothered to check the copies that were distributed to the review board. On another occasion the research protocol listed sterility as "a likely complication" of one of the drugs to be administered under the protocol, yet the informed consent made no mention of this potential side effect.

One of the requests for annual renewal during this period read in its entirety: "Registrations: One. Patient died an early death due to drug toxicity." Given this outcome, I wondered why the research was being continued. And one physician, using the university annual renewal form, answered the questions exactly as written below:

Describe the experience of these subjects, i.e., benefits, adverse effects, withdrawals from research.

The natural history of Transposition of the Great Arteries with medical surgical intervention has been reviewed. A compilation of results is available to date. Since the review is observational, no affect [sic] has been noted on the subjects.

What are the results of the research? Detail as applicable: - for Continuing Review include results to date. . . .

Results of the research indicate that the first year survival following medical surgical treatment is excellent in transposition. The arterial switch operation has the highest mortality rate. The Senning operation is next. The Mustard is least. There are many soddleties [sic] and complexities under study at this time.

Give your assessment of the risks and benefits based on the results.

Current assessment of the risks and benefits: The date [sic] are yet incomplete and have not influenced our treatment of patients at this time.

Detail any new information that has come to light since the last IRB review of this project which may relate to this subject's willingness to continue participation.

New information has been voluminous and a copy of this will be lent to the I.R.B. at th [sic] time of review.

No explanatory material accompanied the renewal request. Because of the evident vacuity and sloppiness of the request, I told the other board members that it was "the kind of document a plaintiff's attorney would kill for."

Despite these few problems with annuals renewals, the IRB was devoting the bulk of its meeting time to the informed consent forms,

with most of them going back to the researchers for some amendment. Attempting to short-circuit this process, Dr. Sarastro asked me to draft proposed guidelines for the forms, to be distributed to researchers before they submitted anything to the IRB. I was pleased with the assignment, and went through the informed consents I had seen during my brief tenure, noting what I liked and what I disliked. After again consulting the applicable federal regulations, I drafted the following guidelines and sent them to Sarastro, with a request for input; I was flabbergasted when he sent them on to the IRB membership with no changes at all.

Elements of an Informed Consent Form

- 1) Each informed consent form should begin with a heading containing a short title of the study and indicating the sponsoring institution(s).
- 2) The first sentence should indicate the signer's consent to participate in the study. Example: "I, _____, willingly agree to allow my child, _____, to participate in this study to assess" This description of the study in this sentence should be brief.
- 3) The next sentence(s) of the form should describe the underlying condition that qualifies the subject for participation in the study. Because it is assumed that this condition is already well known to the signer, this description may use technical terms otherwise unacceptable in an informed consent form. If this assumption is incorrect, technical terms should be avoided.
- 4) The next paragraph(s) of the form should describe, in layman's terms, the procedures that will be followed in the study. Use of layman's terms means that all procedures, including routine ones, should be described, in terminology understandable to a person of no more than ordinary intelligence with no special knowledge of medicine.
- 5) The next paragraph(s) of the form should indicate, in layman's terms, the risks of participation in the study, including the potential side effects of all therapies to be employed.
- 6) The potential benefits of the study, both generally and specifically to the participants in the study, should be included in the form. Once again, the description should be in layman's terms.
- 7) The form should include a statement that participation in the study is voluntary, that the subject may refuse to participate or withdraw at any time, and that neither refusal nor withdrawal will result in any penalty or loss of benefits. Alternative procedures available to a nonparticipating subject should be described, in at least general terms.
- 8) A statement indicating the degree of confidentiality to be accorded study results should be included.

9) The form should include the following sentence: "In the event that physical injury occurs as a result of these procedures, treatment for injury of my child will be available at [the h]ospital. I understand, however, that I will not automatically be provided with reimbursement for medical care or receive other compensation."¹⁴

10) The form should indicate the names and telephone numbers of those principally responsible for the study, along with a statement that these persons may be contacted for additional information about the study, both before and after signing the form.

11) The form should conclude with a statement that the signer has read all of the consent form, has had the opportunity to ask questions and to receive answers, and has decided to consent to participation in the study. There should also be an acknowledgment of the fact that a written version of the consent form will be provided to the signer.

12) There should be signature lines, with accompanying lines for dates of signature, for the parent(s) or legal guardian of the subject, the subject (if appropriate), and the principal investigator.

Outside counsel for the hospital had previously recommended the specific language in item 9. IRB members, especially Basilio who as chief administrator dealt directly with the hospital's law firm, considered its inclusion essential. After a perfunctory discussion, the IRB approved the guidelines.

While the guidelines had little immediate impact on the researchers, I was surprised when they seemed to change the behavior of some of my IRB colleagues. At one meeting after their distribution, I indicated that I had no problems with a particular informed consent, and we were about to move on in the agenda when Zerlina, the risk manager on the board, launched into a detailed analysis of the form, noting many problems I had missed. Chagrined at my oversight, I was also pleased; I felt partially responsible for energizing her, either by precept (through the guidelines) or by example (through my continual carping over the preceding months).

* * *

1988 brought a few new members to the IRB. One of the nurses on the board left and was replaced by Despina, whose attitude to the IRB's work was quite practical. Also new, or perhaps just noticed by me, was Pedrillo, head of the hospital's pharmacy. Pedrillo seemed painfully shy. He rarely participated in the discussions, and when he did, he seemed frustrated at his inability to express himself as clearly as he would have liked.

14. My proposed guidelines contained the full name of the hospital.

Dr. Alfonso was the most notable of the new members. He came from the hospital's immunology department, which performed a lot of bone marrow transplants. The informed consents received from immunology were quite good, except for their overly sophisticated language. I had derived many of the recommendations in the guidelines from them, as well as from those submitted by Dr. Ottavio. At one meeting Dr. Alfonso let it slip that he was primarily responsible for drafting the immunology consent forms. Alfonso, who cast the image of a connoisseur of good food and wine, was certainly a connoisseur of good writing.

While Alfonso knew how to write acceptable informed consents, he was deeply skeptical of the IRB process. He would erupt every few meetings with the criticism that no piece of paper can assure adequate communication between physician and patient. He felt that true informed consent involves a conversation over several hours, if not days, and that the IRB was merely creating another paperwork hoop for doctors to jump through. I usually chimed in that these requirements were for the unethical practitioners, those who cared not at all about patient communication or patient rights. The IRB imposed minimum standards which good physicians should routinely exceed. Because my rejoinder never satisfied Dr. Alfonso, we repeated this exchange several times during our tenure on the board.

Another of Alfonso's complaints was the cost of the paperwork. Under hospital policy, each department's budget included copying; a single research proposal, if submitted to both the hospital and university IRB's, might involve well over 1000 pages of copies. Surprisingly, the board spent considerable time discussing the problem of excessive copying, which I deemed one of the costs of doing research. When someone seriously suggested that incomplete applications be distributed—some IRB members would get the research protocol, while others would get the informed consent—I put down my foot. I certainly was not going to vote favorably on any research protocol I had not read; the prospects for civil liability were just too high. Raising the twin specters of litigation and liability scares most people, especially those in the medical field. And it usually stops the conversation, as it did in this instance.

Institutional liability was almost as great a concern as personal liability. In discussing one research protocol involving an experimental surgical device, board members thought that the company making the device should indemnify the hospital. The company refused and indicated that it had entered into an indemnity agreement

with only one hospital in the nation, a prestigious institution with which the company strongly desired to work. The implication was that our hospital was not in this category.

Our researcher intended only "compassionate use" of the device. This means the device could be used in only a few extreme cases where no other therapy appeared likely to succeed. While not true research, compassionate use was nevertheless subject to the IRB process. Asked to research the potential liability of the hospital and its employees during compassionate use of an experimental device, I referred the matter to my student assistant at the law school. He eventually gave me a twenty-one-page handwritten memo on the subject.

Although my student assistant was bright, he was an outsider to the IRB process. He misunderstood what I wanted and the memo was largely irrelevant. What struck me most about the memo, though, was how specialized my knowledge of institutional review boards had become in little more than a year on the job. My legal questions were so narrow that I could not even sensibly convey them to an intelligent law student. If he had sat with me through the monthly meetings, he would have understood my questions in a moment. But he had not, and it was as if I was asking him to analyze the behavior of an aboriginal tribe. So I realized that it took insiders to evaluate the IRB process.

* * *

Throughout my service on the IRB the hospital fretted about the regular visits from Food and Drug Administration inspectors; any deficiency noted by these inspectors could result in serious problems for the hospital. So when an FDA inspector suggested in March 1988 that the resumes of IRB members needed to be on file with the hospital, we all submitted our resumes. When the inspector said the IRB should have recorded votes on each research proposal, Dr. Sarastro began taking recorded votes. And when the FDA said the IRB needed better guidelines on emergency review and on conflicts of interest, we spent the better part of one meeting redrafting Sarastro's proposed guidelines.

The FDA had even more suggestions three months later. First, the IRB needed a policy for determining which research projects required review more frequently than every year. Second, the board "[n]eed[ed] to insure that [it was] applying the appropriate considerations in regard to the informed consents." When Dr. Sarastro circulated these FDA suggestions to the board, his only amplification of the latter remark was to append copies of the applicable fed-

eral regulations.¹⁵ The board acted on the first suggestion, but the second was referred to me.

Closer review of the applicable regulations caused me to make several changes in the previous guidelines.¹⁶ I added a number of specific requirements mentioned in the regulations: to indicate the purposes of the research and its expected duration, to label as "ex-

15. 21 C.F.R. § 50.25 (1991).

16. The revised guidelines read as follows:

Elements of an Informed Consent Form

1) Each informed consent form should begin with a heading containing a short title of the study and indicating the sponsoring institution(s). Subheadings for the various parts of the form indicated below are strongly recommended.

2) The first paragraph should indicate the signer's consent to participate in the study. Example: "I _____ willingly agree to allow my child, _____, to participate in this study to assess" This description of the study should specify that the study involves research and should explain the purposes of the research and the expected duration of the child's participation in the study.

3) The next paragraph(s) of the form should describe, in lay terms, the procedures that will be followed in the study. Use of lay terms means that all procedures, including routine ones, should be described in terminology understandable to a person of no more than ordinary intelligence with no special knowledge of medicine. All experimental procedures should be identified as such.

4) The next paragraph(s) of the form should indicate, in lay terms, the risks of participation in the study, including the potential side effects of all therapies to be employed.

5) The potential benefits of the study, both generally and specifically to the participants in the study, should be included in the form. Once again, the description should be in lay terms.

6) The form should include a statement that participation in the study is voluntary, that the subject may refuse to participate or withdraw at any time, and that neither refusal nor withdrawal will result in any penalty or loss of benefits. Alternative procedures available to a nonparticipating subject should be described.

7) A statement indicating the degree of confidentiality to be accorded study results should be included. This statement should specify that the Food and Drug Administration may inspect the study records.

8) The form should include the following paragraph: "In the event that physical injury occurs as a result of these procedures, treatment for injury of my child will be available at [the h]ospital. I understand, however, that I will not automatically be provided with reimbursement for medical care or receive other compensation. For further information on this subject, please contact [Basilio, the hospital administrator] at [his hospital telephone number]."

9) The form should indicate the names and telephone numbers of those principally responsible for the study, along with a statement that these persons may be contacted for additional information about the study, both before and after signing the form.

10) The form should conclude with a statement that the signer has read all of the consent form, has had the opportunity to ask questions and to receive answers, and has decided to consent to participation in the study. There should also be an acknowledgment of the fact that a written version of the consent form will be provided to the signer.

11) There should be signature lines, with accompanying lines for dates of signature, for the parent(s) or legal guardian of the subject, the subject (if appropriate), and the principal investigator.

I put Basilio's name and telephone number in section (8) merely to tweak him. The IRB changed this portion of the guidelines to recommend contacting the hospital's Quality Assurance/Risk Management Department.

perimental" the use of any such procedures, to acknowledge that FDA officials may have access to the research records, and to identify a person to contact regarding reimbursement of research-related costs. I also removed the requirement of discussing the patient's underlying condition, to which the federal regulations did not refer. There were also some new stylistic touches—most notably, a suggestion to use subheadings, and removal of some sexist language in the guidelines themselves (substituting "lay" for "layman's").

There were complaints among IRB members about the increased size of the guidelines and the consequent lengthening of the consent forms. But it was difficult to argue against items specifically required by applicable regulations. The board approved the new guidelines with the most significant change being the addition of a section on paying the cost of the research: "A clearly defined statement as to the cost of the study. If the costs are not covered by usual reimbursement mechanisms, the responsibility of the subject and family must be defined."¹⁷

Another apparent response to the FDA's suggestion regarding the hospital's informed consent process was to seek the opinion of outside counsel. Outside counsel turned out to be Cherubino, a former student, who was a senior associate at one of the "better" local firms. Cherubino's three-page letter was rather superficial, but I supposed that his problem was the same as my student assistant's: Though Cherubino could read the regulations as well as I, he lacked the insight that comes from actual involvement in the process.

Another problem was Cherubino's writing style. His letter became the butt of a lot of sarcastic comments about why lawyers write in an incomprehensible way. My response was to sheepishly admit that I had been one of Cherubino's legal writing teachers. While most IRB members would have ignored the letter, the hospital administration insisted on implementing one of Cherubino's recommendations—that informed consents include the following language:

I am aware that [the h]ospital does NOT provide emergency room care. In the event that physical injury does occur as a result of these procedures, emergency treatment should be sought at the nearest facility and if appropriate, additional follow up treatment will be available at [the h]ospital. For further information on this subject, please contact the Quality Assurance/Risk

17. This language became section (12) of the revised guidelines. See *supra* note 16. I did not draft this section.

Management Department at [the h]ospital, [that department's telephone number].

While I felt there were many ways to improve this language, what offended me most about it was the "NOT"; capitalizing and underlining the word reeked of lawyers. But the hospital administration had paid good money for the language, and was determined to use it, "NOT" and all.

* * *

In the summer of 1988 Dr. Sarastro surprised us by announcing that he was leaving the hospital to become dean of a medical school in another state. Though I had never been close to Sarastro, his announcement made me realize that I had come to rely on his steady guidance of the IRB. I worried that a different personality in his successor could change the IRB, and thus change a setting that I had grown to enjoy.

Dr. Ottavio presided as interim chair for a month and then we met our new leader, Dr. Figaro. Figaro was quick when Sarastro would have been deliberate, glib when Sarastro would have been reticent. While new to the IRB, Dr. Figaro was a member of the immunology group and he had participated in many Dr. Alfonso's research projects. One of Dr. Figaro's first acts was to ask the IRB if it objected to having his father, a retired physician, sit on the board. The request surprised me mildly, but like the other members, I thought one more opinion would be helpful.

Figaro's initial months as chairman were relatively uneventful. The board discussed whether it had to review a research project that included only a questionnaire. (It seemed a little strange to require the language beginning "In the event that physical injury occurs as a result of these procedures"; one wag asked how injury was likely to occur—"from a broken pencil, maybe?") Another meeting saw a discussion of a recent California intermediate appellate court decision,¹⁸ holding that a research participant had a property interest in a valuable medical product that the researchers had developed from the patient's removed body parts. The IRB also devoted considerable time to preparing an orientation packet for new members.

Preparing the packet made it apparent that the hospital had several inconsistent policies regarding the IRB. For example, an undated set of policies I had never seen before required that all board

18. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494 (Cal. Ct. App. 1988), *aff'd in part, rev'd in part*, 793 P.2d 479 (Cal. 1990). See *infra* text accompanying notes 37-38.

decisions be unanimous. This practice was never followed during my time as a member. The same document mandated distribution of the paperwork on each research project two weeks prior to the monthly meeting. In actual practice, the Quality Assurance Department tried to get the IRB paperwork out a week before the meeting, but I rarely received my packets more than five days in advance.

The board ironed out these inconsistencies, but a few were more intractable. For example, hospital policy required that one of the participants be a psychologist. However, I had never attended an IRB meeting which included the hospital's psychologist, a hospital employee who was supposedly a member of the board. Basilio's resolution of this problem was simple: "He's my employee. I'll order him to come." Another hospital policy indicated that at least one-third of the board members should be "scientists." This minimum could be met only if the nurses and other medical nonphysicians on the board fell into this category. During a meeting I asked Despina if she considered nurses like herself scientists, and she bluntly answered, "No." The hospital solved this problem, probably inadvertently, by increasing the number of physicians on the IRB.

* * *

Expansion in the IRB's membership came soon after the beginning of 1989, and it changed the board dramatically (though not as dramatically as it would be changed two years later). Most of the new physician members¹⁹ were Figaro's contemporaries, perhaps a decade younger than Drs. Ottavio and Alfonso: Dr. Ferrando, a male, who spoke with an accent that was difficult to follow at times; Dr. Almaviva, an extremely pleasant woman; and Dr. Susanna, who had recently relocated to the area with her lawyer husband from a university hospital in another state. A few months before, Dr. Figaro had circulated that hospital's informed consent guidelines for comparison purposes, and now I guessed who had given them to him.

Dr. Titus, one of the new members, did not fall into the same age bracket as his cohorts. In contrast to the other new members, he was old enough to have treated one of the secretaries at my law school when she was a child. Two other secretaries had taken their now teenage children to Titus, and they all spoke warmly of him. I

19. There was also a new community representative, the mother of one of Dr. Ottavio's patients, who was much more active in IRB affairs than her predecessor had been. The new community representative remained on the IRB until the fall of 1990, when she withdrew for personal reasons.

too would get to know and appreciate Dr. Titus a great deal, because of a new organizational plan for the IRB introduced in February 1989.

The packet sent to me for the February meeting was unusually thin; it contained only one research project. The skimpy individual reading assignments were the result of dividing the board into three-person subcommittees and asking each subcommittee to consider only one project. The subcommittees were to convene fifteen minutes prior to the board meeting. The subcommittees were then expected to present their decisions for ratification by the full IRB.

This reorganization of the committee's work pattern incensed me because I felt it was yet another ploy to reduce copying costs. Nevertheless, I dutifully met with the other members of my subcommittee: Pedrillo, the hospital pharmacy supervisor—finding him occasioned my first and last trip to the hospital pharmacy—and a new board member, a physician who never made it to the subcommittee meeting, and who attended only a few IRB meetings before quitting.

Later at the board meeting, I reintroduced my concern about voting on research projects when I had read neither the protocol nor the informed consent. I once again raised the liability issue, for it was easy to envision how a good attorney would cross-examine an IRB member who had given such a blank check to his colleagues.

Other board members soon expressed dissatisfaction with the new procedure, and I had the feeling that Dr. Figaro had been skeptical about it from the start. By meeting's end we had a new "new procedure": The subcommittees would remain, with the members of each subcommittee receiving full documentation on each research project assigned to it, but instead of getting nothing, the rest of the IRB would receive a short-form description of the project (usually the university IRB cover sheet) and the informed consent. Of course, this did not fully satisfy the concern I had voiced. But not getting the research protocols was a minor loss to me, as I rarely understood them anyway.

The next month when my quite thick packet arrived, I found that my subcommittee now had two new members. One was Dr. Titus. Despite our different backgrounds, Titus and I had roughly the same anxieties about research involving children and about the process of informed consent. The other member, another new physician on the IRB, never made either a subcommittee or a board meeting. Titus and I continually had trouble finding a reliable third

member for our group so we simply had our subcommittee "meetings" over the phone.

Titus seemed awfully mercurial to me. One month he would be astounded at the medical risks to which researchers planned to expose children—a project involving spermatic cord injections particularly set him off—while the next month his approach would be much more permissive. Regarding consent forms, he was just as likely to condemn all the ones we were to review as "too complicated," as to accept them all with a wry but weary smile. Dealing with Dr. Titus, like other physicians, reminded me that consistency was the hobgoblin of legal minds and that other professions had different sacred cows.

Titus' lack of consistency was frustrating at first because it was so hard to pin down the sources of his dissatisfactions (which I had to do in order to explain them to the rest of the board, on the few occasions when Titus could not attend the board meeting²⁰). But ultimately I grew to enjoy the physicians' lack of consistency, as compared to lawyers, because it seemed more interesting, more human, and more real.²¹

* * *

Reality in a different form hit the IRB in the first half of 1989. Switching to the subcommittee system—which was intended to save meeting time, as well as paper—was itself a time-consuming process: The board spent parts of some meetings discussing the subcommittee system, and thus fell behind in its business. So we lengthened the meetings. Adjourning at 5:00 became out of the question; 5:30 or 6:00 was far more common. But still much of February's work ended up on the March agenda, and much of March's on the April agenda.

Then in May a thunderstorm struck: annual reviews of thirty-four of Dr. Selim's projects for the national consortium of pediatric

20. Considering our inability to hold a third subcommittee member, Dr. Titus' absence meant that there was no medical professional present at the IRB meeting who had reviewed the protocols assigned to our subcommittee. Approving research projects under these circumstances made me very uncomfortable, and I occasionally suggested delay. But typically I would acquiesce to the board's desire not to make researchers suffer because of the absences of other board members.

21. Dr. Figaro's father also provided many vivid examples of what struck me as inconsistency. First he would fume about research defects that seemed minor to me, but later he would offer apologist explanations for oversights that were inexcusable in my opinion. I could never predict what would set him off, and was glad that we rarely sat on the same subcommittee. But I greatly enjoyed our social chats (he and I had a habit of arriving early for the IRB meetings, and would talk over the cookies and soft drinks the hospital provided), in which he was unfailingly warm and engaging.

oncologists. These assignments came as an addition to the IRB's usual workload. Later I heard that Selim had allowed a lot of paperwork (like applying for IRB annual reviews) to slide, and so feared that a forthcoming consortium inspection would jeopardize his participation in that group.

This deluge of renewal requests raised the old problem of the consortium's consent forms, which the hospital had previously allowed Dr. Selim to use.²² But as the board had developed more specific standards for informed consent, the consortium consent forms became less and less acceptable. Discontent at the forms, compounded by discontent with the volume of the renewals, produced a revolt: Though we approved the renewals requested, the IRB served notice that it would no longer accept the consortium's informed consent forms. In the future Dr. Selim was going to have to produce forms that followed the board's guidelines.

Most board members sensed that Selim himself would never do this work. Thus in June when Figaro introduced a new IRB member, a member of Dr. Selim's staff named Papagena, there was little surprise. Her task, which was soon to become a major responsibility, was to act as emissary between Selim and the IRB.

We were already overburdened by this flood of work. However, in the first half of 1989 the IRB took on new assignments. In March the board split into two large subcommittees, one to address policies and procedures and the other to focus on informed consent. Dr. Ottavio chaired the former subcommittee, which was to study interaction with the university IRB and standards for exempt research and expedited review.²³ Dr. Figaro asked me to chair the informed consent subcommittee, and I requested Dr. Susanna as a co-chair. The primary mission of the informed consent subcommittee, as stated in a list of "Issues to be Addressed," was to "[d]evelop standardized content/verbiage for Informed Consent. (Put on floppy disk & make available to researchers)."

Dr. Figaro's initial plan was to devote some of the scheduled IRB time to meetings of these major subcommittees. But as the IRB meetings grew longer, it became apparent that this plan was

22. The IRB had previously required only minor modifications in the consortium's consent forms—most notably, shoe-horning the "I am aware that [the h]ospital does NOT provide" language into the margins of the consortium docket.

23. Dr. Ottavio's subcommittee reported back in November 1989 with detailed recommendations regarding "Emergency (Compassionate) Review." As I recall, the IRB approved these recommendations with minor changes. The board also revamped its protocol amendment form at approximately the same time.

not going to work. So even though none of us wanted to commit more than one afternoon a month to the IRB, the subcommittees began to meet in between the monthly board meetings. The first informed consent subcommittee meeting was on May 17th. While the subcommittee had almost a dozen members, the most active were Dr. Susanna, Dr. Almaguiera, Dr. Figaro's father, Reverend Nettuno, Despina, and Zerlina (who was not even officially a subcommittee member).

For this meeting I made a open-ended list of "my conception of the work facing the subcommittee," under general headings such as where in the consent form standardized language would be appropriate, how to encourage use of lay language in the portions where standardization was impossible, and a catchall for miscellaneous headaches like use of "he/she" and "I/my child." Though I had my own ideas of how a standardized form should look, I did not want the other members of the subcommittee to feel that I was jamming something down their throats.

It was apparent from our first meeting that we were all pretty much patient-centered. For example, we wanted informed consent forms that a person with a seventh grade education could understand without much assistance from the doctor or nurse who might be trying to get the patient to sign. I think we all sensed that there were others on the board (I thought of Dr. Alfonso and of Basilio) who would not agree with this goal, but we all seemed determined to pursue it.

The subcommittee work progressed well throughout the late spring and summer of 1989. I prepared a memo of the actions taken at the May 17th meeting, which I distributed along with photocopies of the chapter of Rudolf Flesch's *How to Write Plain English*²⁴ that explains the Flesch Readability Chart, a device for scoring the comprehensibility of English prose by grade level. Dr. Susanna presided at a subcommittee meeting on May 31st, and produced her own summarizing memo. After a third meeting on June 21st, the subcommittee had a six-page list of guidelines for drafting an informed consent. Then we set about the task of actually drafting the standardized language.

The other subcommittee members were more than happy to let Dr. Susanna and me split the task of initial drafting. She took the first half of the informed consent—where there would be a lot of variation, because of the need to describe the particular research

24. RUDOLF FLESCH, *HOW TO WRITE PLAIN ENGLISH* 20-32 (1979).

and its risks and alternatives—and I took the last half, where virtually all the consent forms would be identical (for examples, “Paying the Costs of the Research,” “Physical Injury Resulting from the Research,” “Confidentiality,” and so on).

Drafting language for the last half of the informed consent was more difficult than I expected it to be. I had models for all the sections I drafted (many of them from Dr. Alfonso’s informed consents), but they were all more complex than the subcommittee wanted. So I spent hours “dumbing down” the language: splitting sentences into shorter and shorter ones, substituting short words for long ones. When I had finished, I scored parts of the document on the Flesch Readability Chart, and was very disappointed to find that most of the sections I had drafted required a reader with a twelfth grade education.²⁵ Though I knew it was possible to simplify the language further, I mailed my draft to Dr. Susanna—and went on vacation.

Sometime after my vacation (and hers, I believe), I received Susanna’s corrections of my sections and the draft of her sections as well. Because I had very few suggested changes for her draft, we merged the two halves and presented them to the subcommittee at a meeting in September. After contrasting the “rubberstamp” nature of the IRB years before with what it was becoming, the subcommittee made minor changes in the proposal, and forwarded it to the board in October.

Surprisingly enough, the IRB made few changes in the document. Dr. Alfonso did not complain (much) about the additional burden on researchers, and Basilio did not mourn the passing of the “*NOT*” language (which I had excised, in a fit of self-satisfaction). The board added some language here and there, rearranged some portions of the proposed draft, and appended a three-page glossary of lay language (which we drafted by individually submitting suggested terms and their simplified replacements to Dr. Figaro).²⁶

25. Several months later a computer analysis of the form finally approved by the IRB indicated that it was readable by a person with a tenth or eleventh grade education.

26. The glossary read as follows:

5 ml	One Teaspoon.
Acromegaly	A condition in which excessive growth of soft tissues & bones occurs as a result of excessive secretion of growth hormones.
Adolescent	Young adult.
Allergic Reaction	Fever, chills, rash, nausea, difficulty breathing, or low blood pressure.
Alopecia	Temporary loss of hair.
Anorexia	Loss of appetite.

But the form ultimately approved by the IRB—in December 1989, after postponing consideration because of the press of business at

Antibody	That substance in the blood that blocks the activity of other substances and helps fight infection.
Antidote	A remedy that counteracts something undesirable.
Antiviral	A substance that fights viruses.
Aplastic Anemia	A disease when bone marrow fails to produce normal blood forming cells.
Arrhythmia	Irregular rhythm of the heart.
Aspiration	Removal with a syringe.
Assess	Find out.
Bacteria	Germs.
Biopsy	Removal of a small piece of tissue.
Bloodwork	Blood studies.
Bone Marrow	The body's "factory" that makes the blood cells.
Bone Marrow Aspiration	A needle is put into bone in order to remove marrow (blood forming cells).
Cannula	Tube or needle.
Catheter	Plastic or rubber tube.
Central Line, Broviac	A plastic catheter placed, under general anesthesia, in a large blood vessel which goes to the heart.
Chemotherapy	Anti-Cancer drugs.
Colon	Large intestine.
Cytomegalovirus (CMV)	A virus infection.
Decontaminated	Germ Free.
Device	Instrument.
Dysfunction	Impairment or disturbance in functioning.
Enzyme	A substance that causes the breakdown of a naturally occurring chemical in the body.
Graft vs. Host Reaction (GVHR)	Cells of the transplanted tissue react against the tissue of the recipient.
Hematuria	Bloody urine.
Hepatic Dysfunction	Liver doesn't work correctly.
Hepatitis	Liver inflammation.
Hyperpigmentation	Darkening of normal skin color.
Hypertension	High Blood Pressure.
Hypopigmentation	Loss of normal skin color.
IV Push	Give quickly through a small needle into a vein.
Immuno Function	The defense system of the body.
Immunosuppressive Agents	Something that prevents the defense system of the body from working.
In Vitro	In test tubes.
Inadequate	Too low, not enough.
Inflate	Open up.
Injection	Shot, given through a needle.
Interdermal	Given just beneath the skin.
Interferon-gamma	A substance that is naturally present in the human body which is used by the body to strengthen its ability to fight infections.
Intravenous	Given through a small needle put into a vein.
Irradiation	Exposure to high doses of radiation.
Leukopenia	A decrease in the white blood cells in the body which increases the tendency for infection.
Local Anesthesia	Numbing medicine.
MRI Scan	A type of X-ray exam.
Meningitis	Infection of the lining of the brain.
Milligram	1/28,000th of an ounce.
Monitor	Watch, observe.
Myocardial Damage	Injury to the heart muscle.

the two previous meetings—was quite close to what the subcommittee had proposed.

* * *

Because most of the research projects at the hospital involved children, who could not give legally valid consent,²⁷ the form addressed itself to the parent of a research subject. After a standardized description of research and informed consent (lifted from language appearing in virtually all of Dr. Alfonso's informed consents), the first half of the form contained directions for describing the research and its risks, benefits, and alternatives:

Neurotoxicity	Causing damage to nerves (should explain what the patient will experience)
Non-pathogenic	Does not cause disease.
Osteoporosis	Weakening of the bone caused by a loss of minerals.
Palliative	To provide relief without curing.
Perforate	Tear.
Performed	Used — do.
Photosensitivity	Sensitivity to light.
Platelets	Cells that help the blood clot, prevent and correct bleeding.
Primary	Original
Proteinuria	Protein in the urine.
Random	Picked by chance.
Recumbent	Lying flat on back.
Recurrent	Returning.
Red Blood Cells	Carry oxygen.
Regime	Plan.
Reimbursement	Payment.
Relapse	Disease recurrence
Remission	Return to a disease free state
Retinitis	Eye infection.
Sensor	Able to read.
Sodium	Salt
Sterility	Inability to have children.
Subcutaneous	Given under the skin, into the fatty tissue.
Syndrome	Condition.
Therapy	Treatment.
Thrombocytopenia	Low number of cells that help the blood clot.
Toxicity to Peripheral Nerves	Numbness, tingling
Transient	Temporary
Venipuncture	Blood test.
White Blood Cells	Fight infection.

27. The informed consent subcommittee spent considerable time discussing whether it was psychologically advisable to seek the assent of the child, even though such assent was legally irrelevant. The IRB ultimately decided to add a child's assent form to the standardized informed consent, but with an option to forgo obtaining assent, provided that the researcher gave a written reason for exercising the option. *See infra* note 28. But the board never definitively determined when the child's assent was necessary. *See infra* text proceeding note 40.

INFORMED CONSENT

Title of Research Study: _____
 Principal Investigator: _____
 Co-Investigators: _____

CLINICAL RESEARCH AND INFORMED CONSENT

"You are being asked to allow your child to take part in a clinical research study. The doctors at [this h]ospital study the nature of disease and try to develop better methods of diagnosis and treatment. This is called clinical research. In order for you to decide whether you should agree to allow your child to be part of this study, you should understand enough about its risks and benefits to make an informed decision. This process is known as informed consent."

"This consent form contains detailed information about the clinical research study which the person doing the research will discuss with you. Once you understand the study, you will be asked to sign this form if you agree to have your child take part in it. You will be given a copy of this form to keep as a record."

INVITATION TO PARTICIPATE IN STUDY

"You are being asked to consent to your child's participation in a clinical research study called _____." [insert title of research study]

"The purpose of this study is _____." [explain purpose, in lay terms]

"You are being asked to consent to your child's participation because _____." [explain why subject is being recruited, in lay terms]

"It is expected that there will be about _____ [insert approximate number] persons taking part in this study." (If approximate number of participants is unknown, delete the sentence).

DESCRIPTION OF THE RESEARCH STUDY

a) Give a concise description of the research protocol, in lay terms. Include all tests and procedures to be performed, types and amounts of radiation, medications to be given, special diets to be followed, and so on. Describe any discomfort to be expected, and what will be done to minimize it.

b) Any experimental drugs, devices, or procedures must be clearly identified as experimental. State whether a placebo or randomization will be used, by following these examples.

Placebo statement: "In order to test the effectiveness of _____, your child will be selected to receive either _____ or a placebo (inactive compound), which will look the same as the drug. Neither you, your child, nor your child's doc-

tor will know which one your child is taking until after the study, but this information will be available to your child's doctor in an emergency."

Randomization statement: "Your child will be randomly selected to receive one of two different treatment plans. This is similar to a flip of a coin, and your child's chances of receiving either treatment are about the same."

- c) Explain whether the study involves inpatient or outpatient care, and the expected duration of each. If there are contingencies that will alter the duration of the study, these should be noted.

Inpatient/outpatient statement: "Your child's doctors expect that your child will be in the hospital for about ____ weeks, but he or she may need to stay longer. After that, your child will be seen as an outpatient (in the office or clinic) about once every ____ weeks for the next ____ months."

POTENTIAL RISKS

- a) Describe reasonably foreseeable risks, side effects, or discomforts, whether physical, psychological, or social, in lay terms. Parents and patients should be warned that the underlying condition may not improve, or may worsen, during participation.
- b) If there is potential risk to a fetus, now or in the future, a statement regarding the risks of pregnancy must be included. The following are examples of fetal risk statements:

"The effects of _____ [drug, device, or procedure] on an unborn child are not known, and it is not known whether _____ [insert one: "taking this drug," "using this device," or "undergoing this procedure"] now can have effects on unborn children in the future. If your daughter becomes pregnant while participating in this research study, it may be harmful to the unborn child. If your daughter does become pregnant, you should contact one of the doctors involved in this research study immediately."

Or: "_____ [drug, device, or procedure] is known to cause serious birth defects in unborn children. If your daughter becomes pregnant while _____ [insert one: "taking this drug," "using this device," or "undergoing this procedure"], it may be harmful to the unborn child. If you daughter does become pregnant, you should contact one of the doctors involved in this research study immediately."

POSSIBLE BENEFITS OF THE RESEARCH

- a) Describe the possible benefits to the individual of participation in the study. When there are no anticipated benefits for the individual, describe the potential benefits to science from the collection of information.

ALTERNATE PROCEDURES OR TREATMENTS

a) Describe alternate approaches, such as standard therapy (if any), other experimental therapies (if any), similar therapy not part of a research protocol (if possible), or no further therapy (if appropriate to the condition).

PAYMENT FOR PARTICIPATION

a) State whether the participant will be paid or reimbursed. Explain whether the payment is contingent on completion of all or part of the study.

Payment statement: "You will be paid for each blood sample that your child gives."

Or: "You will be paid after your child completes all the tests in this study. If he or she completes only half the tests, you will be paid only _____."

Unlike the first half of the form, the second half contained mostly standardized language, with relatively few options for individual variation:

PAYING THE COSTS OF THE RESEARCH

"You will be responsible for paying any hospital costs of your child's participation in this research project. Hospital costs include items such as physician visits, drugs, tests, and procedures while your child is a patient in the hospital."

"You will also be responsible for paying any outpatient costs of your child's participation in the research. Outpatient costs include items such as physician fees, clinic visits, drugs, tests, and procedures performed while your child is not a patient in the hospital."

a) Use where appropriate: "You will be provided a written list of procedures required because of the research study. These are tests that would not be done as part of routine medical care for your child's condition. Some of these procedures may result in added costs. One of the persons in charge of the research will discuss these procedures and their costs with you."

b) If any of the foregoing costs will be absorbed by someone other than the patient's family, indicate these arrangements and modify the preceding paragraphs.

"The costs mentioned above may or may not be covered by your insurance. A financial representative of [the h]ospital is available to help you regarding cost and payment. That person may be reached at [the telephone number of the hospital's admission office]."

INJURY RESULTING FROM THE RESEARCH

"Your child might suffer some injury from participating in this research. If injury occurs while your child is a patient in [the h]ospital, the hospital will provide treatment for the injury."

"Injury may occur while your child is not a patient at [the h]ospital. If this occurs, please be aware that [the h]ospital does not provide emergency room care for outpatients. Therefore, your child should be brought to the emergency facility nearest to you. If additional treatment is needed, it will be available at [the h]ospital."

"You may or may not be responsible for paying the costs of treatment for injuries to your child that result from participating in this research. For further information on this subject, please contact the Quality Assurance/ Risk Management Department of [the h]ospital, at [that department's telephone number]."

CONFIDENTIALITY

"Your child's research and hospital records will be kept confidential. However, agents of the United States Food and Drug Administration have the right to inspect the records of research done at [the h]ospital. This includes the research involving your child."

a) Use where appropriate: "Also, companies that provide drugs or devices to be used in research frequently reserve the right to inspect research records involving their products. In this research project agents of _____ [insert company name(s)] will have the right to inspect the research records."

"The results of this research may be published. Published reports will not include your child's name or any other information that would identify your child."

VOLUNTARY PARTICIPATION

"Your decision to allow your child to participate in this research must be completely voluntary. You are free to choose either to let your child enter the research study or to keep your child out of the study. There will not be any penalty or loss of benefits for you or your child if you decide not to allow your child to participate."

"Before you make your decision, one of the persons in charge of the research will give you a chance to ask any questions you have about the research study. Do not sign this form unless you have had this chance to ask questions and have received satisfactory answers to your questions."

RIGHT TO WITHDRAW

"Even after agreeing to allow your child to take part in this research, you may withdraw your child from the research at any time. If you do decide to withdraw your child from the research, there will be no penalty or loss of benefits for you or your child. After withdrawal, your child will be offered available care that suits your child's needs and medical condition. Before withdrawing your child from this research, you should notify one of the persons in charge of this research that you wish to withdraw. This notice will allow that person or someone else supervising the research to inform you if there are medical risks of withdrawal."

NEW INFORMATION ARISING DURING THE RESEARCH

"During a research project, new information regarding the risks and benefits of the project may become known to the persons in charge of the research. Also, they may get new information about other possible treatment. If at any time during this research project the persons in charge of it learn of any such new information, they will tell you about this new information."

"New information may convince the persons in charge of this research that it is not wise to continue the research. If this occurs, the research project will be stopped. Or, the new information may show that your child should no longer participate in the research. If this occurs, the persons supervising the research will stop your child's participation in it. In either case, your child will be offered available care that suits your child's needs and medical condition."

PERSONS TO CONTACT

"The persons in charge of this research are the investigator and co-investigators listed on the first page of this form. Whenever you have questions about this research project, you may contact one of them at _____ [daytime phone number, other than [the hospital's] general switchboard number] or [the hospital's general switchboard number]."

"If you have questions about your rights as the parent of a research participant, or about the rights of your child, you may contact a representative of the Institutional Review Board of [the hospital]. That person can be reached at [the telephone number of the hospital's IRB chairman]."

At the close, to heighten the sense of the consent's importance, the form switched from "you" to "I" in identifying the research subject's parent:

CONSENT

By signing this form I agree that:

- 1. I have fully read this informed consent form.
- 2. I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- 3. I have been given a copy of this informed consent form, which is mine to keep.
- 4. I freely give my consent to have my child participate in the research project outlined in this form, under the conditions indicated in it.

Signature of Parent or Legal Guardian	Date
Signature of Parent or Legal Guardian	Date
Signature of Investigator	Date
Signature of Witness	Date

THIS RESEARCH PROJECT/STUDY HAS BEEN
REVIEWED BY THE . . . HOSPITAL INSTITUTIONAL
REVIEW BOARD FOR THE PROTECTION OF HUMAN
SUBJECTS.²⁸

When the IRB finally adopted the form, I felt a sense of anticli-

28. The form ended with the following addendum regarding the child's assent, *see supra* note 27:

If possible, assent from the participating child should be obtained. The research study should be explained to the child in words the child can understand, with a parent and a witness present. The child will indicate assent by signing this form. If the child's assent cannot be obtained, the reason should be listed on this form and the parent and witness should acknowledge this reason by signing the form.

CHILD'S ASSENT

"I agree to be in the study explained to me by _____."
[insert name of investigator or co-investigator giving explanation].

Signature of Child	Date
Signature of Parent or Legal Guardian	Date
Signature of Investigator	Date
Signature of Witness	Date

"_____ [Insert name of child] is unable to give assent for the following reason(s):

Signature of Parent or Legal Guardian	Date
---------------------------------------	------

max. In one way, the form's adoption was the culmination of all the work I had done at the hospital, and I was quite proud of it. But it was only a piece of paper—and an overwhelming bureaucratic one at that. My "accomplishment" would undoubtedly affect the lives of those who did research at the hospital—and those on whom research was done—but whether it would actually improve anyone's lot was an open question.

* * *

Through the long gestation of the approved form, the principal work of the IRB continued. One project, considered while I was vacationing but deferred to a later meeting, particularly drew my ire. The informed consent contained what was labeled a "HOLD HARMLESS CLAUSE," purporting to waive the patient's right to sue the hospital or any of the researchers, who were affiliates of the hospital but not its employees. In urging the deletion of this clause, I pointed out that the applicable federal regulations specifically stated that nothing in an informed consent could limit the rights of the research subject.²⁹ The bland reaction of the physicians on the board was that the researchers' malpractice insurer insisted on this language. Because I would not take this for an answer, Dr. Figaro deferred consideration of the project a second time.

In the interval between meetings, I had a number of twisted thoughts about this matter. At one point, I considered dropping my objection; leaving the ineffective language in would lull the insurance company into erroneously thinking it was protected—and the eventual liability would serve them right for being so insistent. But the same language might also convince a gullible (or principled) patient that there was no legal recourse. Another solution I envisioned was to put the waiver of rights in a separate document, where the federal regulations regarding IRB informed consent would not apply. But I was loath to help insurance companies figure out an effective way to get patients to waive their rights.

When the matter came up again, I registered my displeasure with language so loud and long that Barbarina—who as chief financial officer did not attend the IRB meetings, but apparently read their minutes—telephoned me about it. We had not talked at

Signature of Investigator

Date

Signature of Witness

Date

The model for this assent form was part of an informed consent submitted to the IRB by a nurse studying the effects of music (administered by headphones) on the pulse, blood pressure, and temperature of child patients.

29. See *supra* text accompanying note 10.

length since I joined the IRB, and this conversation gave me the chance to say that despite my occasional flareups (like the one that occasioned her phone call), I greatly enjoyed my work on the board.

Another topic that occupied board time in the last half of 1989 was a research project involving "Escherichia coli replacement therapy in the treatment of chronic inflammatory bowel disease." The project required patients first to submit to complete obliteration of bacteria in the intestinal tract (by antibiotics) and then to effect their replacement by drinking a solution containing new bacteria. Asking research subjects to "drink shit," as one board member put it, was more than most of the IRB was willing to do. The board deferred the project the first time it came up. At the next meeting the physician who was most interested in the project came to discuss it—still a relatively rare event—and brought with him a bottle of the solution, offering to drink it himself. Even this did not convince the board, which continued to express many reservations about the project—which ultimately was withdrawn.

The attitude of board members to this doctor surprised me. He and his research drew snickers, and they were not entirely caused by the bizarre nature of his project. For some reason, unknown to me, he was not quite worthy of the respect and deference the IRB members usually showed their colleagues. I thought of similar responses I had seen from my law school colleagues—humoring those professors with a reputation for competence, while making life hard for those with the opposite reputation—and wondered if the comparison was apt.

Another example of this apparent disparity was the solicitude with which the IRB had treated Dr. Selim. It was the latter half of 1989 before the board finally received from Selim informed consents drafted by someone on his staff, rather than by the national consortium of pediatric oncologists. Selim's staff member Papagena was responsible for this change, and the rest of the board was so happy that we thanked her profusely and overlooked the few deficiencies the forms still contained.

Still behind in its work, the IRB met twice in August 1989 (in addition to subcommittee meetings, major and minor). One and a half to two hours continued to be the typical meeting length, but some members were oblivious to the need to keep the agenda moving. Dr. Ferrando in particular tended to drone on and on in his lilting accent, focusing on minute problems in the research protocol and the informed consent; he gave thoroughness a bad name.

At one meeting in late 1989 Ferrando and his subcommittee

members, Despina and Zerlina, were particularly exhaustive. They directed most of their attention at one of Dr. Alfonso's projects, taxing him for (among other things) using informed consent language that was too difficult in some spots and too superficial in others. Alfonso did not take the criticism well, and began to sputter about the futility of trying to explain complicated medical procedures in a few pages of very simple prose.

Of course, I had heard this from Dr. Alfonso before. But it had new meaning for me that day, because I thought that the subcommittee members were going too far, that they were asking researchers to do more than was necessary. For the first time I wondered if my harping on informed consent for all these months had created a monster.

* * *

What was to be my final year on the IRB opened in typical fashion, with the introduction of new members. Zerlina had taken a risk management job at another hospital in the area (as she left her last meeting she told me that I had "made a difference"; it is the accolade of my board membership that I most prize). Her replacement was Blonde, another risk manager. Because new construction at the hospital had allowed staff expansion, Reverend Nettuno had a new assistant, to whom Nettuno surrendered his IRB position. The assistant chaplain participated diligently in the board meetings, but he never seemed to get the hang of it. (Six months later the hospital psychologist followed the lead of the chaplain. The psychologist's assistant, a quiet woman with alert eyes, was less active than the assistant chaplain, but seemed to understand more of what was going on.)

There were two new nurses, whom I never really got to know, and two new physicians, only one of whom regularly attended meetings: Dr. Guglielmo, a young pulmonary specialist, who quickly fell into step with his friends, Drs. Susanna, Almaviva, and Ferrando. The other new health professional who became an IRB regular was Dr. Osmin, a researcher with a Ph. D. but not an M.D., whose husband was the chief physician-in-charge at the hospital.

Dr. Osmin was a veteran of research projects at the university hospital, and frequently criticized those aspects of our IRB process that were inconsistent with the university IRB's procedures. For example, she complained about the length of our meetings, saying they would be shorter if we would insist on attendance by one of the investigators on each project (as the university did). My thought was exactly the opposite: Whenever we had one of the investigators

in the room, the process of explanation and defense inevitably lengthened the meeting.

Dr. Osmin's emphasis on the university IRB was ironic, because during that same time period former patients at a university-affiliated hospital sued the university (among others), alleging inadequate informed consent prior to research.³⁰ The lawyer filing the complaint was reputable, so I copied a few newspaper articles about it and circulated them to board members. At a subsequent meeting Dr. Susanna wondered aloud why we should consider following the example of a board whose oversight of informed consent was the subject of a lawsuit.

To tell the truth, Dr. Susanna and I had another reason for wanting to diminish the authority of the university IRB among our board colleagues. Because so many of the hospital's doctors did research at the university as well, the approval of the draft informed consent, on which she and I had worked so hard, remained contingent on our form jibing with the requirements of the university. We feared that the university IRB, sensing a turf battle, would demand something different from our form, and thus undo all our previous effort.

Thus it was a great relief to learn that the head of the university IRB, to whom Dr. Figaro had sent our form for comment, had only a few, relatively minor suggestions for change. I revised the form to reflect most of these changes, which the board approved in February 1990. But a few months later Figaro announced that the head of the university IRB had not realized that she was "officially" commenting on our form—she thought we were merely interested in her personal opinion—so the issue of conformity between the two boards remained unresolved (and still does, as far as I know).

Thinking that the informed consent form had cleared its final hurdle, the IRB set about the task of enforcing its adoption. It was relatively easy to require that new research projects adhere to the form, but the considerable number of project renewals proved much more vexing. Researchers complained that having to extensively revise existing informed consents was a colossal (and often pointless³¹) burden, and frequently sought temporary "reprieves" from the requirement. For example, Dr. Alfonso—whose informed con-

30. Part of the alleged inadequacy in the informed consent was the lack of forms in Spanish. See *supra* note 6 and *infra* note 33.

31. Frequently, research projects continued with existing patients, and thus required regular review, but were not open to new patients, so that revising the informed consent was arguably unnecessary.

sents continued to use phrases like "high-grade encapsulated bacterial pathogens," "semi-permanent catheter," and "pre-transplant preparative regimen"—was a frequent requester of reprieves.

Dr. Selim had found another way of dealing with the new form. Apparently, he assigned two secretaries to translate, with the help of Papagena, the pediatric cancer consortium's informed consents into the hospital's form. Whenever Selim had an item before the IRB—virtually every month—the two secretaries would attend and dutifully jot down our many suggestions for changes.

Physicians who had neither Alfonso's temerity nor Selim's manpower found a third way of dealing with the requirement: They simply ignored the IRB. One month Dr. Figaro reported that he had earlier notified the investigators on thirty-four projects that their requests for review were overdue (some by as much as a year); however, over two months later, only seven had replied. Equally as alarming was the fact that the IRB had no mechanism for assuring compliance with its suggestions when a project was "approved, with changes"—which had become our usual disposition, with the changes usually in the informed consent. For all we knew, researchers were ignoring our indicated amendments.³²

The board's concern regarding these matters heightened when we received another opinion letter from outside counsel, again from Cherubino. Quality Assurance had asked, among other things,³³ whether the hospital and its researchers might be liable for research pursued with lapsed IRB approval. Cherubino's answer (once one waded through a thicket of statute and regulation recitations) was an emphatic yes.³⁴ (I wondered whether individual IRB members might also be liable; I doubt I was the only board member who considered this question.) Cherubino's letter probably contributed to the hospital's decision to hire a full-time secretary for the IRB, one of whose responsibilities was to "bird dog" projects through the application and renewal processes.

32. Or they were ignoring the protocols the IRB had approved. At one meeting during 1989 or 1990, one physician on the IRB apologized because a patient in one of his projects had received drug therapy for many days beyond the maximum indicated in the research protocol. Except for self-reporting such as this, the board had no way of knowing when such deviations occurred.

33. The hospital also wanted to know whether it was required to provide written translations of informed consents for patients who did not understand English. See *supra* notes 6 & 30. Cherubino indicated that a written translation was legally preferable to using an interpreter, the hospital's usual way of dealing with the problem.

34. Dr. Figaro later told me that he had golfed with Cherubino soon after the hospital had received his letter; Cherubino had laughingly told Figaro that he loved to write letters to the hospital, especially for fees in the four-figure range.

When researchers did use the new form, a few problems quickly appeared. Some physicians slavishly copied the form—down to its quotation marks and interlinear instructions to researchers, which were never intended for the final product. Others poked fun at the form's relentless emphasis on lay language. After his reprieves ran out, Dr. Alfonso submitted an informed consent that began:

The sickness that the doctors call "severe combined immunologic deficiency disease" (SCID) has been found to be due to the baby's being born with no way to kill bad germs. For this reason, the baby is puny and will have lots of bad infections. If the baby is not treated right, the chances are that the baby will die from a bad infection during the first year of life. There is more than one kind of SCID, but babies with all kinds of SCID can't fight bad germs. They have poor immunity. This poor immunity is due to the thymus gland's not working right. The thymus gland is in the chest and certain white blood cells called, "T-cells," go through the thymus gland to be able to fight bad germs.

Though not quite so classic a putdown, the rest of the informed consent continued in approximately this fashion (e.g., "Research is the way in which scientists try to find out new things.").

When I first read this offering, my inclination was to be angry. I felt what another IRB member said at the meeting: "I think we're being made fun of." But when I had cooled a bit, I considered the ridicule somewhat justified, and more important, it had produced a more easily comprehensible document—even if that was not Alfonso's primary intent. As I recall, the board approved the informed consent with few changes.

Beside causing problems for the researchers who used it, the new form caused problems for some IRB members. One difficulty to which I fell prey was skimming through sections that I assumed were copied directly from the form, and thus running the risk of missing a variation. At one meeting, after my superficial discussion of a project assigned to my subcommittee, Dr. Susanna politely asked what I thought of the change in the "Paying the Costs of the Research" section. As I looked at the section and noticed the disparity for the first time, I considered trying to bluff my way through my oversight. But I quickly decided that truth would be more instructive—and I probably could not have pulled off the bluff anyway. So I confessed my error and then segued into a pious discourse on the ease of missing something crucial in the informed consents.

Another problem that the form posed for the IRB arose when its provisions seemed inapplicable to the specific research under

consideration. For example, for research that involved only a telephone survey and a blood sample, some board members thought that it was silly to include in the informed consent language regarding the costs of inpatient and outpatient treatment. Such costs were not possible, or so the argument ran, and therefore the language was irrelevant. I found myself resisting this contention, but for no good reason, other than maintaining the integrity of the form: If a deviation from the form was allowed in this case, it made it that much easier to argue for a deviation in a less appropriate situation. But the inflexible conservatism of this view shocked me, and I guessed that my main motivation was a simple desire to protect my work product from any attack, justified or not.

* * *

As 1990 progressed, the IRB meetings again began to lengthen. After relatively short agendas at the beginning of the year, there were twenty items on the agenda in April, twenty-six in May, twenty-eight in June, and twenty-seven in July. Most of the additional items were Dr. Selim's projects from the national consortium of pediatric oncologists. Though Selim's informed consents now followed the prescribed form, they still had a number of defects. Many were inordinately complicated, with different options among alternating courses of chemotherapy and radiation, sometimes extending over years; the side effects of the various drugs usually took pages to describe. A minor defect, but one that got on my nerves, was the look of Dr. Selim's informed consents: Until I complained, his forms invariably came to us looking like fifth generation copies of poorly printed documents. Beside being difficult to read, they said to all who saw them—including patients—"This is not an important piece of paper."

Though the IRB was going through its share of difficulties, I felt that it had reached a plateau. There was a core membership—Figaro, Susanna, Almagiva, Ferrando, Despina, Papagena, and I—with a clear vision of the mission of the IRB: to use informed consent to protect the rights of patients. A slightly larger group—Ottagio, Titus, Figaro's father, Pedrillo, and Guglielmo and virtually all the other new members—shared that vision, if somewhat less clearly. Even the board's holdouts—Alfonso, Osmin, Basilio, and Blonde—occasionally subjected research projects and their informed consents to the close scrutiny I thought was necessary. With the administrative support of a full-time secretary, who first appeared at the August 1990 meeting, the IRB was on the verge of becoming a potent force in the hospital.

August was also the occasion of my service on yet another subcommittee. Two months earlier, in considering a project that involved research on excised tumors, Dr. Titus had questioned whether the patient would retain any interest in the "cell lines" that such research might produce. The IRB had discussed this issue before,³⁵ and I finally saw its relevance to the discarded tonsil research that the board had considered at my very first meeting³⁶: Marketing medical products developed from removed body parts could be quite lucrative, and the patient at least should know whether he has any interest in such a product. I offered to look into the legal question and report back to the IRB.

After some perfunctory research, I circulated a short memo, suggesting that the following language be added to the informed consent form, under "PAYMENT FOR PARTICIPATION": "Add where appropriate: 'Tissues taken from you, including blood and other fluid samples, may be used in the creation of new medical products. You may or may not have a financial interest in any such product.'" While the rest of the board was considering this language, the California decision that had sparked the first discussion of the issue was modified on appeal.³⁷ Though the California Supreme Court rejected the research subject's claim that he had a property interest in any product made from his body parts, the court did hold that the researchers had a "fiduciary duty" to inform the patient of any financial interest the researchers would have in such potential products.³⁸ Dr. Figaro's father and I both circulated newspaper accounts of the decision. Though this out-of-state decision was not binding on the hospital, the case did seem to underscore the need for some reference to the problem in an informed consent.

The issue, and my proposed resolution of it, apparently caused a stir at the hospital sufficient for Dr. Figaro to ask Dr. Susanna and me to meet with two hospital physicians interested in the question. This subcommittee met in August, just before the scheduled IRB meeting. Blonde also attended the meeting, as a representative of Quality Assurance/Risk Management.

The interested doctors, one of whom was new to the hospital and reportedly quite eminent in his field, initially resisted any no-

35. See *supra* text accompanying note 18.

36. See *supra* text following note 7.

37. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990). See *supra* text accompanying note 18.

38. *Id.* at 485.

tion of informing patients that their discarded body parts might be valuable. But they did not understand that Susanna and I were talking about including such information only in research-related informed consents. Their main concerns, it appeared, involved other hospital documents—the general medical treatment consent form and the consent for autopsy, for examples. Though Susanna probably agreed with me that these documents ought to contain similar information, that issue was beyond the bailiwick of the IRB, and we did not pursue it. (I did wonder why these doctors were so interested in the question; was it an aversion to increased paperwork, or something more?)

With their concerns satisfied, the physicians helped Susanna and me redraft the language, producing: "Tissues taken from you, including blood and other fluid samples[,] may be used in the making of new medical products. The persons conducting this research do/do not have a financial interest in any such product. You may or may not be entitled to receive profits from this product." In October (after a deferral from the September meeting, because of another long agenda), the IRB voted to add this language to the informed consent form.

Another topic before the board in October 1990 was AIDS. Several of the research projects at the hospital involved aspects of treatment for acquired immune deficiency syndrome,³⁹ but the project up for consideration in October, from Dr. Selim, dealt instead with transmission of the AIDS virus. The project required completion of questionnaires by and blood tests on hemophiliacs and their household members; the questionnaires included detailed inquiries about sexual practices.

Board members had two separate questions. First, if the blood tests revealed that a patient was HIV-positive, would the hospital be under any legal compulsion to report that information to public health officials—and if it was, should that be mentioned in the informed consent (which said only that the research subject's "confidentiality will be protected to the fullest extent allowed by law")? Second, would a parent's consent to participate in the research bind a sexually mature child—and would the parent be able to see the child's answers, especially those relating to sex acts?

39. For example, earlier in 1990 the board had considered a project from Dr. Alfonso for pediatric AIDS patients who had not responded to treatment with AZT. The IRB approved the project, but only after insisting that the informed consent use the term "AIDS," rather than euphemistically referring to use of an "antiretroviral drug because your child has experienced substantial deterioration despite AZT treatment."

The IRB deferred consideration while both questions were investigated. The first was a straightforward question of law, and as a new member of my county's "AIDS Coordinating Council," I had access to materials that gave a quick answer: Under state statutes, the hospital had to report cases of full-blown AIDS to state public health officials, but not mere instances of HIV-positivity. The second question really asked when it was necessary, legally and ethically, to get the child's agreement. The board had frequently discussed this matter, and had made decisions as far as individual projects were concerned, but had never adopted an across-the-board policy.⁴⁰

At the November meeting the IRB accepted the "fullest extent allowed by law" confidentiality language (though its opacity and open-endedness bothered some of us), and determined that assent by children over thirteen was necessary, in addition to their parents' consent. We also agreed that a child's responses would be kept confidential, even from the child's parents. There was no real effort to develop a comprehensive policy on child assent; perhaps case-by-case decisionmaking was the best method of dealing with the problem.

Curiously enough, another research project on the November 1990 agenda raised roughly similar issues. Dr. Monostratos, whose name meant nothing to me, assisted by Dr. Osmin and Dr. Osmin's husband, wanted to compare the "immunological competency" of babies born to cocaine-addicted mothers with those born to nonaddicted mothers, through analysis of blood samples taken at birth, three months, and six months. As in the study of AIDS transmission, this research raised questions of mandatory reporting and confidentiality. The hospital was legally required to report any newborn whose blood tests disclosed a controlled substance, so participation in the study could expose the mother to criminal prosecution⁴¹—a fact that I thought should be considered in evaluating the research project and the confidentiality section of its informed consent.

Other IRB members had a different concern. With unusual cir-

40. See *supra* note 27.

41. In 1990 an appellate court in one state had upheld the conviction of a mother for delivering a controlled substance to her child, through the umbilical cord. *Johnson v. State*, 578 So. 2d 419 (Fla. Dist. Ct. App. 1990). Similar prosecutions were pending in other states. See generally Rachel M. Nicholson, Note, *No (Pregnant) Woman Is an Island: The Case for a Carefully Delimited Use of Criminal Sanctions to Enforce Gestational Responsibility*, 1 HEALTH MATRIX 101 (1991).

cumspection, a few board members pointed out that the research protocol was sketchy about how the researchers were going to determine which mothers were "addicted"; the mere presence of cocaine in the mother's or child's bloodstream would not necessarily evidence addiction. Because she was not the principal investigator, Dr. Osmin could not clarify this obscurity, which I saw as a "garbage in, garbage out" problem: Without a clear definition of addiction, the study would prove little—all the while exposing its participants to possible criminal sanctions. The IRB deferred consideration of the project so that Dr. Monostratos could define what she meant by addiction.

A third item of interest on the November agenda was a seemingly innocuous project that involved cardiac catheterization at the hospital of patients who had received an experimental drug at another area hospital. Figaro had given the project preliminary approval under expedited review, but Basilio was apparently upset that the researcher (who was not a hospital "regular") had not gotten administrative clearance as well. When Basilio said some things about the hospital's trustees being the ultimate decisionmaker and how the IRB just made recommendations to the trustees, I spoke up. Of course the hospital, through its trustees, could decide not to implement a research project approved by the IRB—the outcome Basilio was recommending for this project. But the trustees could not legally decide to implement a project the IRB had disapproved; in this respect, I lectured him, the federal regulations controlling research with human subjects made the IRB superior to the hospital's trustees. Basilio professed shock at this assertion.

I knew that the last half of my comment was irrelevant to the project before the board, but I wanted to upset Basilio's smug assertion of administrative authority. At the time, my rationalization was that I did not want to let Basilio go uncorrected, in order to avoid setting some sort of precedent—even though precedent seldom commanded much respect at the IRB. Despite my outburst, Dr. Figaro and others were able to paper over the dispute, by simply approving the proposed project and letting the hospital administration decide whether the research would ever actually be carried out.

* * *

As I prepared for the December 1990 board meeting (which was to be my last), I thought that perhaps I should try to mend fences with Basilio, whose job after all made a hierarchical, bureaucratic perspective unavoidable. However, the agenda for the meeting of-

ferred little controversy (and therefore little opportunity for solidarizing with anyone). The agenda did have a curious cover sheet, with a bare-bones outline of the meeting, "Happy Holidays" in large ornate Christmas script, and the following at the bottom: "All information discussed at the Institutional Review Board Meeting is confidential and information shall be shared only with those professionals who are involved with the Board." I wondered where that came from.

Among the first to arrive for the December meeting, I made polite chit-chat as the members straggled in. When Dr. Susanna entered, she threw her packet on the conference table in disgust. Susanna was never one to keep her dissatisfaction bottled up, and I assumed she had had another trying day at the hospital. From across the room I said something to her like "That bad?," and she turned to me and responded, "Haven't you heard?" I did not understand her response and was mumbling something as Dr. Figaro entered the room.

Figaro quickly began the meeting by announcing that we would not be covering the agenda today, as some other matters had come up. Specifically, he had been informed by the hospital's incoming chief of staff—Dr. Monostratos—that she was unhappy with the IRB's performance, especially the length of its meetings, that beginning in January the IRB would have a new chairman, and that while the new chairman would come from the ranks of the current board members, a large number of the other members would be new.

Some board members, like Dr. Susanna and Basilio, were not surprised by these announcements (though my guess is that they had received advance word from different sources). But most of us were shocked. There followed a few minutes of incredulous questions, during which Dr. Figaro maintained an air of restrained anger and disappointment; as an example of his restraint, he specifically refused to indicate who the new chairman would be, though he clearly knew the name.

The vast majority of those present were unhappy with the wholesale replacement of the board. (Those who were not unhappy were keeping their own counsel.) While we all had better things to do with the time we devoted to IRB work, no one liked being dumped so unceremoniously. At one point Dr. Guglielmo facetiously suggested that we reconsider Dr. Monostratos' research project. Not in a facetious mood, Dr. Figaro observed that those who wanted to register their disagreement with the action should draft

and sign a joint letter of protest to the hospital's board of trustees. Several members, including me, agreed to participate.

At the close of the meeting, Blonde reminded us that IRB proceedings were confidential (answering my question about the agenda coversheet). After the meeting, Basilio remained talking to several hangers-back, including Figaro, Susanna, Blonde, and me. Basilio was being very conciliatory, saying that there had been some sort of terrible misunderstanding. When I learned (from Dr. Susanna, who was talking to Blonde and me) that Dr. Monostratos was responsible for appointing only the physician members of the board, and that Basilio appointed the other members, including me, I moved into his knot of conversation and said that I very much wanted to continue my membership. He responded that for the sake of continuity, I should stay on the board. As I left the hospital, I thought it was ironic that Basilio, whom I had abused so recently, would be the one to save my position on the IRB.

Over the next few days I had many telephone conversations: one with Barbarina (who expressed the same sort of solicitude as Basilio); several with the IRB secretary, who was acting as the main contact person, through the hospital fax machine, regarding the letter of protest (worried, I told her to be careful not to get fired); and one with Figaro (who decided, for security reasons, that I should fax my edit of the draft letter to his private office, rather than to the hospital). Over the phone, Figaro seemed in something of a funk, which I thought—but did not say—he should snap out of; after all, his fall as the hospital's IRB chairman was not the end of the world.

From one of these calls I learned that Dr. Titus had originally agreed to chair the board in the coming year, but had withdrawn his agreement in light of the furor at the hospital over Dr. Monostratos' actions. This fact was confirmed to me by Monostratos herself, in a very curious telephone conversation. One day, out of the blue, she called me at my office, saying that we should talk. Over the phone, she portrayed herself as surprised by complaints that she was exercising her power to appoint new IRB members. She said that this unexpected outburst was forcing her to take over the board chairmanship herself, a task she really had no time for. She considered the letter of protest (which had not yet been mailed) as an act designed to subvert her rightful authority. Her conclusion was that she did not think that she could work with me on the IRB.

Perhaps she was trying to get me not to sign the letter, in order to save my position on the board. But the offer was not that clear, I really could not break my promise to Figaro or Susanna, and be-

sides, I had Basilio's implied commitment to retain me. So I told Dr. Monostratos that she should withhold judgment on the letter until she had read it, and that I stood ready to work with her and anyone else on the incoming IRB. Later that day I called Basilio, giving him the gist of my conversation with Monostratos (he was surprised to learn that she planned to chair the IRB) and reiterating my willingness to work with her and the new board.

Five days after the December meeting the letter of protest was mailed to Dr. Monostratos. It read as follows:

We, the members of the [h]ospital Institutional Review Board, have a number of concerns regarding the recently proposed changes in the leadership and membership of the committee.

As you know, the IRB is charged with the responsibility of reviewing all protocols involving research at [the h]ospital. According to the federal mandate for IRBs, this review focuses on the protection of the rights of research subjects and thus is especially directed at the process of informed consent. Also, the "science" of each study is reviewed to ensure that any potential risks to subjects are outweighed by the information or potential benefits to be derived from the study.

As you may be aware, the number and complexity of the protocols submitted to the IRB for review over the past few years has grown exponentially. Membership on the committee has also grown to meet this ever increasing demand. Under Dr. [Figaro]'s leadership, the IRB has developed a subcommittee system designed to enhance the organization and efficiency of the committee. This subcommittee system has succeeded primarily because the committee members have confidence in each other's high standards of critical review, allowing for a streamlined yet thorough review of each of the many protocols submitted. In this way, the investigators and research subjects all benefit.

It is our understanding that the criticisms of the current IRB include the following:

1. Length of IRB meetings.
2. Investigators are not invited to meetings.
3. [P]rotocols [from the consortium of pediatric oncologists] should be handled by a subcommittee.

We are concerned that none of these criticisms had been brought to the attention of the IRB chairman or committee members prior to our being informed of the proposed changes in leadership. In answer to some of the above concerns, we would like to advise you of the following:

1. The meetings are held monthly and generally last 2 hours, although some may last longer. Most of the members stay the entire length of the meeting, which indicates that we are committed to our work on the IRB and do not have a serious concern about meeting times.
2. Whereas individual principal investigators are not generally

invited to attend IRB meetings, they are usually well represented by the members of the IRB, who often are co-investigators in the protocols submitted. When this is not the case, investigators have been invited to discuss their projects at IRB meetings. Additionally, designated representatives for the [consortium] protocols routinely attend IRB meetings to facilitate review and revision of [consortium] protocols.

3. As already mentioned, protocols are reviewed by a subcommittee of three IRB members and then presented to the entire committee for further discussion. This holds true for the [consortium] protocols, which are generally reviewed by the same subcommittees, who have developed a degree of fluency with these complex projects. Again, this was instituted in order to enhance the efficiency of the IRB's work, and to facilitate the work of the [consortium] investigator.

Given these facts, we believe there is no rational or logical basis for the proposed sudden changes in IRB membership or leadership. If there were substance to our alleged inadequacies, we believe they should have been brought to the attention of the committee and that we should have been given the opportunity to discuss them and make any necessary changes. We are concerned that the proposed changes to our committee would be a disservice to the institution, the investigators, and above all, to the patients we serve.

We strongly urge you to reconsider any changes in the membership or leadership of the Institutional Review Board at this time. Any of us would be happy to discuss with you any further concerns you may have.

Copies of the letter went to the hospital's president, board of trustees, and medical staff executive committee, and to Basilio.

Only six IRB members signed the letter, five physicians and me. (According to Figaro, pressure was brought to bear on some of the other nonphysicians on the board, each of whom was an employee of the hospital.) Along with the expected signatures—Drs. Figaro, Susanna, Almaviva, and Guglielmo—I found one that was totally unexpected: Dr. Alfonso. And I was sad to see Dr. Ottavio's name missing from the list.⁴²

A few days after the letter of protest was mailed, I left town for Christmas vacation. On returning after New Year's, I found in my campus mailbox a brief letter of thanks from Dr. Figaro, apparently sent to every member of the IRB.⁴³ There was nothing else in my

42. At first sight of the letter I was surprised that Dr. Ferrando's name was missing, but later I recalled that he was a junior member of Dr. Monostratos' hospital practice group. There may have been an analogous reason for Dr. Alfonso's signature: Figaro was a junior member of Alfonso's practice group.

43. I would like to extend my sincere thank you for the long hours you have spent serving on the Institutional Review Board at [the h]ospital.

mail regarding the IRB: no packet for the January meeting, and no letter indicating definitively whether I was still on the board.

As it was uncommon for the hospital to send reappointment letters, I was in some doubt about my status. So I called the IRB secretary, who informed me, in her best attempt at a cheery voice, that I was no longer a board member and that I would soon be receiving an explanatory letter from Dr. Monostratos. The letter, dated January 4th, arrived the next day:

This letter is in reply to yours of 12/17/90. I appreciate your concerns over the proposed changes in the format and membership of the Institutional Review Board. I have likewise been concerned about the many negative comments which I have received regarding this Committee. Scientists at this institution have complained that it may take over 6 months to have a protocol approved. Investigators on the faculty of the [u]niversity . . . must also have their protocols approved by the University's IRB. This can only be done after a letter of approval is received from the [hospital] IRB. Therefore, there may be up to a one year delay in implementing some protocols. The Committee has been described to me as cumbersome and obstructive to research. Some investigators have stated that they choose not to initiate research projects or participate in nationwide studies at [the hospital] because of difficulty and delays in dealing with the IRB. In addition to these concerns voiced by investigators, I have some concerns about the format of the Committee.

My concerns about the length of meeting times are two. One is that meetings which last over 1 - 1 1/2 hours consistently usually are trying to cover too much material. The possibility of subcommittee or more frequent meetings should be considered in such a case. My other concern is that the Committee members have advised me that much of the meeting time is spent re-writing Informed Consent forms. Frequently there were lengthy discussions regarding simple changes in wording.

Invitation of principal investigators to IRB meetings is a common courtesy and expedites review of protocols. Co-investigators are not always aware of every aspect of the protocol and therefore may not be able to answer every question raised. It is unfair to the researcher to have the final decision on a protocol delayed because he/she was not invited to a meeting to answer all questions.

The [national cancer consortium] protocols are a specialized

The most important ingredient for any of our committees is the caliber and dedication of the individuals who give of their time. I view the efforts of each individual committee member as critically important to the successful functioning of the Institutional Review Board.

I hope you have a wonderful Holiday and a Happy New Year.

Thank you again for your participation.

The letter was dated December 26th.

group of national protocols. These protocols have been extensively reviewed for scientific merit on a national level. Therefore they do not require the same type of review as other protocols. A *true* sub-committee (not a project review committee) could be set up to evaluate these protocols separately from the main IRB meeting. The minutes of this sub-committee meeting would then be presented to the full Committee.

As past Chairman of the Committee for Human Values and Ethics, I am well aware of the need for the Informed Consent. This should be the case not only for patients involved in research protocols but also for any patient receiving treatments at [the h]ospital. A research protocol is made up of more than an informed consent. I feel that it is also important to have the scientific value of every protocol evaluated. The skill to do this type of evaluation does not come with a medical school diploma, it usually requires graduate school or post doctoral research experience. Therefore, most physician members appointed to the Committee for the next year have such experience. The informed consent forms will continue to receive intense scrutiny with more lay input in the wording of these forms.

As past Chairman (1981-1985) and founder of the IRB at [the h]ospital, I am well aware of the duties and responsibilities of this Committee. Based on the information provided, major changes in the format and direction of the IRB seemed indicated. I felt this would most easily be accomplished by a change in Chairman and membership. The anger and lack of critical self evaluation reflected in your letter appear to make this a wise decision.

As Chief of Staff for 1991 I have the responsibility for the actions of this and other committees. The Hospital Bylaws state that the Chief of Staff is "accountable to the Board of Trustees in conjunction with the Executive Committee for the quality and efficiency of clinical services and performance within the hospital. . .". Given this responsibility, it is only appropriate that the Chief of Staff has the right to appoint committee chairmen and members. It can also be noted in the Rules and Regulations of the Hospital that terms of committee membership for physicians are for one year. Your attempt to undermine the authority of the position of Chief of Staff is based entirely on conjecture and speculation. The implication that the IRB will be unable to function in your absence is both illogical and presumptuous. The IRB is not the only committee for which I have recommended major or minor changes for this year. However, it is the only committee which has responded to such recommendations in the manner which you have chosen.

My decision to restructure the IRB was made only after a great deal of thought and discussion with many people. Therefore, I have no plans to change my decision. If you had requested, I would have been happy to have discussed this matter with you.

According to Dr. Figaro, there is a sign on Dr. Monostratos' desk that says, "I don't get mad, I get even."

Monostratos had sent copies of her letter to all those we had copied with our letter, including Basilio. Still supposing that he had control over my situation, I telephoned Basilio. His tone was still conciliatory, but he denied having any authority over the question of my reappointment. He laid all responsibility at Dr. Monostratos' feet, saying that she had even recruited a new attorney member (whose name I never learned).

That day I also called Barbarina. As in our conversation just after the December meeting, she expressed respect for Dr. Monostratos' skill as a physician but some doubts about the way she was handling the wholesale change in IRB membership. (Beside Dr. Titus, only one other previous member was retained; I never learned who it was.) My call to Barbarina ended with her saying that she had the ear of the hospital president, and I inferred that she was planning to speak to him about my situation. I do not know whether she did, because that conversation was the last contact I ever had with any administrator at the hospital.

Now it was my turn to be in a funk. I was angry that the hospital had discarded me in so cavalier a fashion, and longed for some sort of revenge. I took the language of Dr. Monostratos' letter and mentally elaborated it into a coup d'etat by the hospital's researchers, who would now merrily go about putting patients at risk. Someone should be warned of this, I thought, and I began drafting in my head a letter to the Food and Drug Administration. Over a few days this plan for vendetta developed a new aspect: I would also release the letter to the local newspapers, which surely would be interested in this power grab by physicians in high places.

It was Dr. Figaro who brought me to my senses. When I called him—to get the name and address of the proper federal official to contact—he suggested that a letter to the FDA would accomplish little, other than making Dr. Monostratos angry, and thus running the risk that she would lash out at the former IRB members at the hospital. Of course he was right, I told him—I was trying to make a mountain out of a very small molehill—and then I shifted the conversation into general ruminations about our time on the IRB. I carried this on for too long, and Figaro ended the conversation with an abrupt "Take care!" His curtness stung a bit, but I quickly realized that he was right about that too: It was time for both of us to close this minor chapter in our lives.

A month or so later I ran into Dr. Titus at the intermission of a

concert. After we traded appreciative comments about the orchestra, I mentioned the IRB, forcing him to discuss it. As I expected him to, he apologized about "the way things were done" and the misconceptions that some people had had about the board's work. Then he paused, gave me his sad smile, and added: "You know, the meetings take just as long."

* * *

I waited six months to begin writing this memoir, primarily because I wanted to overcome as much of my vindictiveness as possible. My feelings toward my work on an institutional review board are now quite ambivalent. I understand better, and appreciate more, the overt criticisms of Drs. Alfonso, Osmin, and Monos-tratos, and the implicit criticisms of Dr. Selim. And I am less convinced of the paramount importance of informed consent, in which I, Drs. Figaro and Susanna, and many others so fervently believed.

I remain impressed with all the health care professionals I encountered while a board member. Though flawed, as all we humans are, they showed wisdom, compassion, determination, and spirit. After six months, I still miss them.

POSTSCRIPT

When I showed an earlier draft of this work to several colleagues and friends,⁴⁴ a few objected to the lack of recommendations for change. They thought that I should try to identify weaknesses in the IRB process and ways to avoid them. One of the most intelligent of these critics was Marcellina, a physician and former medical examiner who had gone to the law school where I teach, and who was now representing doctors and hospitals in a nearby community, as well as serving on an IRB. Unlike the other objectors, Marcellina offered some possible recommendations.

First of all, she had doubts—and correctly thought that I did too—about the ability of "hypereducated" people to write for a seventh grade audience. Her solution to this problem was technological: a computer program that scores written material for readability, while providing suggestions for improvement (she even sent me several printouts from the program, comparing a few excerpts from documents in my memoir to her revisions of the excerpts.)

Initially I was surprised that Marcellina had not seen reference to the use of a similar computer program, though I quickly realized

44. See *supra* first asterisk.

that reading the footnotes closely⁴⁵ is probably too much to ask of a reader. Because of this previous use, I was familiar with the computer program Marcellina described, and consider it helpful—up to a point. Such programs are much better at identifying a readability problem than they are at showing a solution. In the final analysis, it takes a lot of human labor to produce writing that patients can understand. The various documents in this memoir may perhaps provide some starting points for that difficult work.

Marcellina also bemoaned the fact the IRB members and those who submit research projects to IRB's rarely receive any training. Consequently, the board members either do nothing, suffer burn out from work overload, or alienate enough of the hospital power structure to be discharged; for their part, the researchers become either contemptuous or frustrated. Required training for all concerned was Marcellina's recommendation for solving this problem.

But there was little in the way of training that could have prepared me for my experience as an IRB member. As previously noted,⁴⁶ it is difficult to give a meaningful explanation of the work of an IRB to someone who is not already familiar with that work. On-the-job training, either as a board member or as a researcher subject to board review, seems required. About all that can be done beforehand is to gain a general understanding of the issues with which IRB members grapple—another service I hope this memoir provides.

Regarding the potential power struggle between researchers and the board that reviews their work, Marcellina recommended that IRB members invoke the power of external agencies, such as the state boards that regulate medical professionals. The power of these boards to revoke or condition medical licenses is a saber that a "savvy" board, as she put it, could rattle at appropriate times to curb overzealous researchers.

Again, my experience makes be dubious. Certainly those of us on the IRB who championed patient interests could have been more savvy, but I do not think the outcome would have been any different. The destiny of a hospital IRB is to be a marginal body, and any board that seeks more influence than this will fail, sooner or later. The unsurprising lesson of my IRB service is that there is a limit to what can be accomplished within any power structure, especially one peopled with professionals. But a board member willing

45. *See supra* note 25.

46. *See supra* text preceding note 15 (discussing the work of my student assistant).

to work within those limits can accomplish quite a lot. That is another point I hope this memoir underscores.

As I thanked Marcellina for her comments, I thought to myself that I was not likely to use them. But a few months later, when the editors of *Health Matrix* recommended adding a postscript indicating “how things could be better” on an IRB, I thought again of her suggestions, and I think that they point the way to improving the IRB process. But like all specifics, they tell only a part of the story.

This week I wrote this postscript, in November 1991, I ran into Dr. Titus, once again at a concert. I was pleased to see him, and enthusiastically wished that he convey my greetings to all those I knew at the hospital. He misunderstood my comment, pointing out in a good-natured fashion that there were few persons on the current IRB whom I knew. Then he added that he had decided to leave the board at the end of the year—“just too many other things to do,” he said. He was moving on, and as the concert intermission was about over, I had to be moving on, too.

