

An IRB Public Member's Education

By Jerry Rabow

The author is a public (non-affiliated, non-scientist) member of a human subject medical research institutional review board ("IRB") for a major hospital and research center. He recounts what he learned from his experience as a minority voice in a review of the risks and benefits of a research proposal.

I am now in my fourth year as a public member¹ of a human medical research institutional review board ("IRB") at a major hospital and research center. When I joined the IRB, I had been retired for a decade from my career practicing law. While I had been busy and productive during my retirement, I had been looking for an opportunity for additional volunteer service to the general community. A friend who was a member of the IRB on which I now serve convinced me to apply for a public-member vacancy on the IRB. (The institution regularly has a minimum of two public members on each of its IRBs).

The institution uses a substantive, in-depth interview process before accepting new public member volunteers. A substantial training program then follows, including formal written and online training materials, as well as informal sessions with some of the institution's experienced public members. But these steps merely began my education as a new public member. It took 10 or so IRB meetings over the course of a year to even begin to understand how to efficiently prepare for the new matters assigned to me as a "secondary reviewer." (My IRB assigns each new research application for review and reporting to both a physician member for primary review and a public member for secondary review. Although only the physician member can draw on medical expertise, both reviewers review and report on all aspects of the applications.)

Moreover, I had to develop a personal workflow for reviewing and evaluating the other new studies, amendments, continuations and adverse event reports that were assigned for review to other members of the IRB. It took me considerable time to appreciate the interpersonal aspects of my particular IRB, including getting to know the professional staff, doctors (many conducting important research themselves), and other professional healthcare members of the IRB. Working as an "equal" with such qualified people was a bit intimidating.

Despite all of the training for my role, I began my participation with substantial doubts as to how effective and meaningful my service would be. Federal law mandates the presence of at least one public member like me, so was my participation merely a legal formality to be tolerated by the other members? Who in that room of 15 or so doctors, pharmacists, nurse supervisors, radiation safety experts, social workers, and other healthcare professionals would bother to listen to me, a retired attorney with a liberal-arts education?

Some of these early misgivings were resolved when I observed my IRB in action. First of all, I learned that the medical professionals who volunteered for the IRB shared a deeply felt belief in the critical importance of medical research. In contrast with many of the professional, corporate and charitable boards and committees that I have advised or participated in, these IRB meetings did not become venues for territorial disputes, status squabbles, or ego trips. Instead, every aspect of the IRB's functioning was dedicated to solving problems so research could proceed in a manner that would advance science, while protecting the interests of the research participants and society at large.

The format of the meetings supported these objectives. The Chair balanced the practical need for brevity with the goal of allowing full discussion of any problematic aspects of a research proposal. Everyone was encouraged to express his or her views, which were always granted a respectful and thoughtful hearing by the other members, even when those other members were experts on the specific medical issue being discussed. My erroneous questions and comments were gently corrected with the same measure of respect.

The true test of the system came during my second year of membership on the IRB. We were reviewing a clinical study to evaluate the effectiveness of a new procedure for bariatric (weight loss) surgery.² The FDA (U.S. Food and Drug Administration, whose regulatory jurisdiction includes matters like new surgical uses of medical devices) had already approved the general protocol design being submitted, including the attempt to meet the agency's "gold standard" of a double-blind, placebo-controlled experimental design.³

As applied to the proposed surgical technique, this meant that the control (placebo) group would be subjected to a sham procedure that would include a period of general anesthesia during which the surgeon would insert an instrument down the participant's throat, so that the participant would experience post-procedure discomfort consistent with having undergone the actual bariatric surgery.

In addition, both groups would receive the same post-operative instructions required for bariatric surgery patients, including strict rules governing the volume, frequency, speed and content of meals. They would also receive warnings of possible serious injury from disregarding these rules.

As one of its duties, the IRB must make an independent assessment of the relative likelihood of risks and benefits of the proposed research. Among other things, if the risks and costs to the participant (including physical or psychological injury, discomfort, financial cost, time and inconvenience) are not outweighed by the likely benefits to the participant or to the advancement of medical knowledge for the benefit of others, then the IRB cannot approve the proposed research, regardless of the willingness and consent of the prospective participants.⁴

I was the secondary reviewer on this study. In my report to the IRB, I raised the following issues:

- Participants in the control group would be subjected to the admittedly small, but real, health risks of general anesthesia for the sham surgery.⁵ And, since members of the control group would be drawn from the population of seriously overweight individuals who qualified for bariatric surgery, and who may have other health problems, the anesthesia risks might be higher for them than for the general population.
- Control group participants would be subject to substantial discomfort and inconvenience from the post-surgical eating restrictions for the 12 months of the study.
- Participants would be drawn from a psychologically vulnerable population (seriously overweight individuals who had tried and failed other methods of weight loss, such as diet, exercise and counseling). Assuming that the placebo effect and eating regimen would not secure long-term weight loss for the control group, individuals randomized to the sham surgery might experience stress and disillusionment from yet another personal "failure" — the inability once again to lose weight despite attempting to adhere to the prescribed eating regimen.
- Low self-esteem of the participants could also make them especially vulnerable during the consent process, due to societal views that are often openly critical of people who are seriously overweight (based, I believe, on the erroneous view that all

obesity is a consequence of ignorance or lack of willpower). Taken together with the participants' past failed attempts to lose weight, these special vulnerabilities to psychological pressure to solve their obesity problems raise the question as to whether their signature on any ICF could be relied upon as signifying truly voluntary informed consent, at least in the absence of special consent procedures.

- After the surgery, all of the participants, aware of the possibility that they might have received only the sham surgery, might be tempted to find out whether they really were still capable of eating larger portions without feeling any different. Such experimentation risked injury or reversal of the potential benefits to participants who had received the real surgery. It could also unblind participants, leading control group members to not follow the eating regimen or drop out of the study, thereby weakening the experimental design.

As always, the other IRB members respectfully listened to my comments and a full discussion followed. The details of the discussion are not significant here. Some IRB members agreed with one or more of my points. Others supported the study as designed, pointing out that obesity had become a major health problem. Thus, progress in scientific knowledge in this area was extremely important for public health — a factor directly affecting our risk/benefit analysis. Moreover, it was observed that the FDA had already approved the research design for a sham surgery control group in this multi-site study. Therefore, as a practical matter, disapproval by our IRB probably would not result in any substantial redesign of the research, but would only prevent our institution from participating in research that would be done elsewhere, possibly by less-experienced surgeons.

Because of the variety of views expressed, the Chair permitted the discussion to go on about 20 minutes longer than usual. When all members had had an opportunity to express their views, the 15-member vote on the matter was almost evenly divided, with a one- or two-vote majority in favor of approving the application.

If that had been the end of it, I would have felt fully supported by the group in our deliberations. Although some of the doctors discounted the seriousness of the anesthesia risks I had raised, no one challenged or even showed any irritation with a retired attorney raising that type of medical issue. No one in the group expressed any impatience with the Chair's allocating the additional time for a full airing of the matter, although it contributed to an especially long meeting. And, of course, the fact that the vote had been such a close one relieved my personal anxiety about whether my concerns were reasonable.

What happened next, however, was eye-opening. Immediately after the vote was announced, one of the physicians who had just voted to approve the application expressed discomfort that the vote on such a significant issue had been so closely divided. She requested permission to change her vote on the basis that such a slim majority did not reflect an adequate consensus. Several other members who had previously voted in favor of the application then made the same request. On a revote, the application was disapproved by a wider margin than the approval in the initial vote. After further discussion, the IRB voted to request resubmission of the application after some substantial clarifications and modifications were made.

The point of this article is not to examine the merits of a specific protocol. Instead, I have described this meeting because it taught me how, with the appropriate attitude by the Chair and medical members of an IRB, the role of the public member does not have to be restricted to the non-medical aspects of proposed research, such as the wording of the ICF or impact on the community. A public member can make meaningful contributions on any issue, fulfilling the spirit as well as the letter of the requirement for participation by a non-scientist member in every aspect of an IRB's decisions.

Notes

1. Under federal law, all human subject research proposals must be initially approved and thereafter monitored by an IRB. (45 CFR 46.109 (a) and (e)) Every IRB must have at least five members. At least one member must be a non-scientist member (a member whose primary concerns are in nonscientific areas, i.e., not a physician or other healthcare professional). (45 CFR 46.107 (c)) A non-scientist member must be present as part of the greater-than-50% quorum of members attending any regular IRB meeting. (45 CFR 46.108 (b)) Also, at least one member of the IRB must be non-affiliated (an independent member not employed by, significantly compensated by, or having other potentially conflicting financial relationships with the institution served by the IRB). (45 CFR 46.107 (d)) These two requirements can be, and often are, fulfilled by the same individual member. The applicable statutes do not provide a term to describe such a dual-status member. In the literature, terms commonly used include independent non-scientist member, community member, and public member. Because the term "community member" could be taken to imply a special role in representing the interests and concerns of a specific community (e.g., a racial, national, local, socioeconomic or religious sub-group) rather than the general public, this article will use the term "public member" to describe the non-affiliated, non-scientist IRB member.
2. Bariatric surgery generally involves surgically creating or implanting some physical restriction limiting the effective size, capacity or function of the digestive tract, commonly through the excision, suturing or external banding of part of the stomach or intestine.
3. In a double-blind study, neither the participants nor the investigators know which of the alternative medications or procedures being compared in the study have been assigned to which of the participants. A double-blind study design minimizes distortions in the experimental results that could otherwise be due to the expectations of participants or investigators. In a placebo-controlled study, some of the participants receive an intentionally ineffective drug or procedure (a "placebo," like a sugar pill) in order to compare their results against those of participants who receive the actual experimental drug or procedure being tested.
4. 45 CFR 46.111 (a) (1) and (2).
5. According to the American Society of Anesthesiologists, at the present time, the chance of a healthy patient suffering an intraoperative death attributable to anesthesia is less than 1 in 200,000 when an anesthesiologist is involved in patient care.
<http://www.asahq.org/For-the-Public-and-Media/Press-Room/Anesthesia-Fast-Facts.aspx> [May 15, 2011]

Author

Jerry Rabow is an author, IRB member, and retired attorney. Contact him at jerryrabow@gmail.com.