

## A Relatively Paperless IRB

Most IRBs generate and send many documents, conduct most communication at their meetings and by letter to investigators, and have an immense paper documents to store on a long-term basis. I chaired an IRB that had none of these problems, that reviewed protocols, communicated and resolved problems quickly and effectively, and had a target turn-around time (assuming the protocol was approved) of 4 days or less. The key to this effective operation was the use of on-line communication. (On-line communication does not necessarily mean on-line reviewing of protocols. Protocols that could not adequately be reviewed on a monitor screen are printed out – or at least those portions that would require careful study were printed out.)

*Background:* This IRB is a major committee within a private research corporation/think tank. It follows the basic principles set forth in the Belmont Report and federal requirements for informed consent, risk assessment, and so on. The corporation does no medical research, only social/behavioral studies of how people respond to prototypes of the electronic devices being invented or to ideas about such new concepts. However, there is research on children of all ages as well as adults, in lab and field settings. There are ethnographic field studies of how people live (how their homes are organized and how the family would use a specified new gadget). Some research subjects are employees of the organization. Some studies include continuous videotaping of people in unobtrusive ways. Hence there are the usual concerns to protect children and the rights of parents, to protect privacy and ensure confidentiality, to make sure people understand what they are getting into and to respect their autonomy. In research on teenage individuals or groups, there are many of the usual concerns about learning more than we care to know about drug use, and other such activities. In some other ways, the corporation is different (e.g., there are major intellectual property concerns that most university IRBs do not get involved with). But those differences need not concern us here.

The IRB began by studying current practices and principles of protecting human subjects and writing a document for internal use, which slightly resembled a combination of the Belmont report, and the basic OPRR requirements of IRBs (in miniature, of course). The corporation has an internal web and HSC has a web site on it. The document appears on the internal web site for all employees to see. However, THE IRB does not assume researchers will read it. Like the Belmont Report and Federal Regulations, it is a foundation that was agreed to, that keeps THE IRB from arbitrarily mutating into different practices, and to which THE IRB can refer researchers as appropriate. Like the issues that any IRB deals with, The IRB too must evolve as cultural and research issues evolve. The IRB's internal web site contains various policy addenda, checklists, prototypes of consent statements for a range of purposes or types of subjects, and a template that may be used for submitting protocols.

The IRB meets face-to-face at least once a month for 2 hours. As problematic protocols come up, or unusual questions arise in the course of the month, these items often find their way onto the meeting agenda. Meetings are devoted mostly to policy issues, development of committee or web-site documents dealing with those issues, housekeeping details such as decisions about updating web site documents, nominating or mentoring new members (the 10 person committee includes 9 employees and an external chair and consultant (myself), etc. The IRB has developed a "Slippery Slope Referral System" which it updates as needed. Members serve for 3 yr terms, with 1/3 rotation each year. The IRB also plans educational activities – e.g., in a series of panels for Friday afternoon forums, outside experts will present positions on evolving issues of privacy and technology.

As the corporation develops new lines of research, two or more members of the IRB meet with any new research or development groups to tell them about the IRB, how to submit protocols, and how to get help from members in doing so. All IRB members are always available in person, by phone or on line to help researchers who are planning a protocol.

Now for the main paperless part: All protocols, consent statements, questionnaires, screeners, etc. are submitted by researchers as e-mail attachments to an email message addressed to the IRB, which reaches all 10 IRB committee members. (Even members who are traveling usually travel "wired" so that their reviewing can be done whether they are in Pittsburgh, London, or Palo Alto.) the IRB members generally log on to their email at least once a day.

My internal counterpart (internal chair) assigns each protocol to four members, but all the IRB members are invited to participate in the review. (No IRB member who would have a conflict of interest with a given protocol ever reviews or participates with that protocol.) Both the Internal and External Chair give serious attention to every protocol. The Internal Chair assigns a Primary Reviewer to each protocol who serves as the conduit for communicating with the researcher, and as the leader of the discussions evaluating the protocol. The Primary Reviewer immediately emails back to the researcher saying something like: "I will be your primary reviewer. If you have any questions, please address them to me." If the Primary Reviewer sees any obvious omissions or problems, he or she mentions to the researcher that these are sure to be issues that the committee will raise, and perhaps the researcher can clarify them now to avoid delay. Other members of the IRB who have additional concerns are likely to raise them the same day the researcher emails the protocol.

The IRB seeks to respond to every protocol in 4 business days or less. Every IRB member receives every other the IRB member's communication about the protocol. Every IRB member is encouraged to comment, question, suggest, etc. However only the 4 assigned reviewers are required to vote, though any IRB member may comment that they would approve, or approve if such and such a condition were met, or would require that something be radically changed, etc. No comments by members outside of the assigned 4 are ever ignored. The IRB has become quite creative in finding good methodological or procedural solutions to the problems it sees. We work very hard to be user friendly to investigators without ever ignoring the rights and interests of subjects.

Typically there is one or more iteration of communication between the IRB and the researcher before the IRB gives its final decision. A member may even visit with the researcher or inspect the research site (equipment, etc.), to clarify things for the rest of the IRB or to give advice on how to solve the ethical issues the IRB has raised. Most of the time the IRB can give approval or conditional approval within 4 days or less.

The IRB has worked hard to make sure all its communication and relationships with its clientele are very collegial. We emphasize that we welcome any suggestions on ways to make the IRB more user friendly. The IRB has always had the total backing of the President of the corporation, and any serious violations of IRB requirements are to be reported to him (which has happened a couple of times). With his total backing and his emphasis on collegial relationships, the IRB is taken seriously but is not seen as the "ethics police." The president serves as the final authority and has emphasized that violating the requirements of the IRB is a good way to get fired.

*Document storage:* The IRB has a document storage file (electronic). Each application has its own file within that larger file. On the protocol, applicants are to give that particular study a unique 2 word name (not the name of their whole on-going project). All of the documents (protocol, consent form(s), screeners, questionnaires, etc.) are stored in the electronic folder under the name of that study. Folders are organized according to the name of the over-all project in which they occur. Another way to do this, more appropriate to a university the IRB, is to organize folders according to date or alphabetically according to last name of PI; in either case the word processing software will organize the files alphabetically or by date as desired. Often the IRB gives conditional approval. Our archivist makes sure the requested additional documents arrive and files them appropriately, keeping the files up to date. Files are backed up daily. The actual signed consent forms are hard copy, of course, and are kept under lock in the PI's office, where they would be available for inspection by the IRB if the IRB so requested.

