ABCs of IRBs

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Some issues are so important and so pressing that APS members could not even wait for the convention to begin before they began discussing them. One such issue is Institutional Review Boards (IRBs), which was the topic of a pre-conference symposium moderated by Barbara Spellman, University of Virginia, and Jeffrey Cohen of the federal Office for Human Research Protections (OHRP).

The IRB symposium covered the spectrum of IRB procedures and pitfalls. A group of almost fifty gathered to be part of this interactive program, which devoted as much time dedicated to Q and A as to the more formal presentations. “I asked someone why they were coming to this workshop,” said Spellman. “And their answer was, ‘I’m mad as hell, and I’m not going to take it anymore!'” quoting Peter Finch’s infamous rant in the movie, *Network.*

“The issue of IRBs and IRB regulation in human subject research is one we need to address as a field,” said APS Executive Director Alan Kraut in his introductory remarks. “Where does behavioral science fit in this issue?”

The symposium began with a nuts and bolts introduction by Cohen and his colleague George Pospisil. They made one point very clear: if you want to understand human subject protection, you have to read the Belmont Report.[1]

“No one, from a university president to an IRB administrator, should even be involved in any research of any kind involving human subjects unless they have read and understood it,” said Pospisil, who is with OHRP’s education division. The report is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. Pospisil noted that “The Belmont report has three basic ethical principals: Respect for persons, beneficence, and justice.”

Cohen tackled the issue of risk and harm in behavioral science research involving human participants. “Psychological risks are real risks,” he began. “They are real risks for the participants in research, and are no less serious than physical risk.” Cohen pointed out that it is the responsibility of the IRB to identify risks, determine that these risks are minimized, and determine that subjects are adequately informed. Such risks include emotional distress, psychological trauma, and invasion of privacy.

Cohen also addressed the issue of informed consent. “The consent procedure should empower the

subjects to make their own determination about risk," he emphasized. Cohen then added that risk should be explained in terms that subjects could relate to, and that the consent process should not do more harm than the research.

Cohen's final comments focused on the subject of applying the so-called "Common Rule"[2] to behavioral research. It lays out procedures and guidelines for IRB review of research protocols, expedited review, and the protection of special populations in research. "The Common Rule provides sufficient flexibility for IRBs to effectively and efficiently review non-biomedical research," Cohen pointed out. "Written informed consent is not necessarily appropriate for all research … IRBs have considerable flexibility and authority to modify or waive consent requirements and should not hesitate to do so." He added that IRBs need to be more aware of what research can be considered exempt or expedited under the common rule.

When Things Go Wrong

Carol Prescott of Virginia Commonwealth University was able to offer a unique perspective on the IRB process in her presentation "Third Party Subjects in Behavioral Research." VCU's human subject research was sanctioned by OHRP in 1999. She cited a now well-known study on twins. Problems began when the father of a participant in the study opened a letter to his daughter, and discovered that the questionnaire called for answers to questions about the subjects' parents. More specifically, the survey inquired whether the father ever suffered from depression, or had abnormal genitalia. After the father complained to OHRP and the university that he should have been consulted before questions about him were asked, all human subject research at VCU was temporarily suspended, and the IRB was disbanded.

The basis of the father's complaint was threefold: He was not given a choice about whether information about him was being collected, he questioned the security of the information, and he questioned the accuracy of the information. OHRP, in its investigation, found the IRB member training to be inadequate, as well as insufficient documentation of operating procedures and protocol modifications.

With this background, Prescott addressed the question on everyone's mind: Could suspension of human subject research happen to your university? The answer, said Prescott, is yes, if the proper procedures are not in place.

"In [the VCU] case, no subjects were harmed and no confidentiality was violated. The primary investigator was fully compliant with all the existing IRB rules and regulations of the institution. It was really a failure at the institutional level."

Third party research is critical to behavioral science, and as a result, Prescott believes that the VCU example is an important one. In order to fully understand such studies as genetic epidemiology or molecular genetics, sometimes you have to ask about the disease status of other relatives. But this raises other questions: When are third parties to be considered "subjects," and therefore entitled to the same protections as primary participants? The answer is, when they are "readily identifiable" based on the information gathered about them.

Perhaps the most striking information from Prescott's presentation was the story of the changes made by the university following the OHRP investigation. Two IRB support staffers became nine. One panel with 20 members became three panels with 50 members. And an annual budget of $40,000 became $750,000

– all in order to increase compliance.

An Ounce of Prevention

In his presentation on "Making IRBs More User Friendly," Louis Penner, chair of the University of South Florida IRB, emphasized four guiding principals: Protect research participant rights, facilitate research and research careers, ensure compliance with federal regulations, and protect the interests of the institution. "We can do these four things in such a way that they compliment each other, not get in each other's way."

Other suggestions from Penner included better training and education for IRB staff, IRB members and administrators being more accessible to researchers, and being more flexible. "I became an IRB chair because protocols were being submitted to our IRB when I was an IRB member, and were taking three to five months to be approved." While this may not seem like a long time to some, Penner pointed out the potential snags. "If you're a graduate student, and you don't begin research by the fifth week of the semester, kiss that semester good-bye. The time period [for review] is simply unacceptable – we could do better."

Also of importance, said Penner, is understanding the guidelines for what constitutes "risk," "informed consent," and knowing what should go before the full board.

In order to expedite the review process, the University of South Florida IRB operates a kind of "triage." Every protocol submitted to the IRB is first reviewed by two board members, in order to ensure that the investigators have dotted each "i" and crossed each "t," so to speak. If they have not, the protocol is sent back to the investigator. This way, the entire IRB does not have to spend valuable time reviewing a protocol that is not ready to proceed. When the protocol does make it through triage, the IRB chair then categorizes the research.

The Future of Research?

Robert Kraut addressed an issue that is fairly new to research, but can be controversial: Online research. This type of research can have many benefits, Kraut pointed out, such as reduced costs, and access to larger and more diverse populations. "The Internet is providing lots of opportunities for improving and changing the ways we do research," he said.

But online research presents a new array of concerns to many traditional IRB issues, such as obtaining documented informed consent, ensuring confidentiality, and regulating participation by minors. Internet research also poses difficulties in assessing reactions, and in the vulnerability of data in transit and storage. In order to navigate an online research protocol through an IRB, the investigator must be able to preserve confidentiality and demonstrate informed consent on behalf of the participants. "There's less control over the research setting," Kraut noted. "You can't guarantee debriefings or follow up when the research has ended." Other concerns are data quality, including difficulties in trying to prevent multiple participation and bogus responses.

Notes

1. On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie

the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to be followed, to assure that such research is conducted in accordance with those principles. The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years.

2. In the Code of Federal Regulations (CFR), Title 45 section 46, lies the U.S. government standard for protection of human participants in all types of research conducted by federal agencies:

This policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research.