

PRIM&R's 2016 Advancing Ethical Research Conference

By Norman M. Goldfarb

Public Responsibility in Medicine & Research (PRIM&R) held its annual Advancing Ethical Research Conference in Anaheim in November 2016. This article discusses a small selection of interesting observations from a small selection of sessions, since the conference offered up to 25 concurrent sessions.

50 Years after Beecher's Bombshell: Where Are We Now, What Have We Learned?

Alexander M. Capron, Barbara E. Bierer, Susan E. Lederer, David H. Strauss, Alexander M. Capron

In 1966, Henry Beecher's New England Journal of Medicine article discussed 22 cases of clinical studies with, to put it kindly, questionable ethics. He discussed three pillars of human subjects protection: informed consent, responsible investigators, and peer (i.e., IRB) review. Over the past 50 years, the clinical research enterprise has substantially strengthened all three pillars, but much work remains to be done. Informed consent is far from satisfactory, with rather dismal levels of understanding and ever greater intrusion of institutional, rather than participant, protections. Investigators, in general, have become much more knowledgeable about their responsibilities, but education on ethics and regulatory compliance is far from comprehensive. IRBs are prone to mission creep and over-focusing on the expanding legion of rules (doing things right rather than doing the right things).

Implementing NIH Single IRB Policy Using the National Center for Advancing Translational Sciences (CTSA) Program

Barbara E. Bierer, Michelle A. Culp, Valery M. Gordon, Ann Johnson, Emily Sheffer

The NIH has mandated the use of a single IRB for NIH-funded clinical research. In response, 62 CTSA members have joined together to create the SmartIRB initiative. Initially, Johns Hopkins, University of Utah, and Vanderbilt University IRBs will perform reviews for consortium members. SmartIRB has created a standard reliance agreement and is now creating software to facilitate communications between referring and reviewing institutions.

Any healthcare facility or IRB with an FWA number can join SmartIRB. In addition, reviewing IRBs must be AHRPP-accredited. Referring IRBs must be accredited or pass a quality assessment by a qualified external party. Eventually, any qualified IRB will be able to review any study from willing IRBs, so SmartIRB could be the framework for all sorts of consortia and network reviews. Reviewing IRBs will use their own software, forms and business processes. NIH has issued guidance on allowable budgets for IRB reviews, but further clarification will be required.

Schulman IRB has already joined SmartIRB, and more independent IRBs are sure to follow. It remains to be seen how the competition between local and independent IRBs will play out.

Presentation of the Research on Medical Practice Results

Benjamin S. Wilifond

The Research on Medical Practices (ROMP) study on the attitudes of IRB professionals about randomization and informed consent collected responses from 601 PRIM&R members, among others.

About 80% of PRIM&R members said that randomization of study participants or research sites should always trigger IRB review. Forty-four percent believe that collecting and analyzing patient data to test hypotheses for generalized knowledge should always trigger IRB review. Twenty-six percent said that the intention to publish the results should always trigger IRB review. Risk vs. benefit was not considered in this question.

Thirty-one percent of respondents said it is unethical for a patient's clinician to obtain consent, while 10% said that only a patient's clinician should obtain consent. Respondents were equally divided on who should obtain consent: the patient's clinician, an investigator not involved with the patient's care, or a study coordinator not involved with the patient's care.

Innovations in Public Perceptions of Research and Risks: Simultaneous and Sequential Study Enrollment Among 34,237 Clinical Trial Patients and Patients' Motivation for Duplicate Enrollment

Jonathan Rabinowitz

The researchers found an apparent frequency rate of unpermitted multiple enrollments ranging from 4.8% in Western Europe to 8.6% in North America to 14.1% in India, based on birthdate, sex, height and weight. Many of the offenders said they believed the exclusion criteria did not apply to them. Medical treatment and monetary gain were probably the primary motives.

Return of Individual Results – Complex Considerations for a Not-So-Simple Request: Perspectives from Scientists, Subjects and Regulators

Michelle Griener, Michele Russell-Einhorn, Mark E. Sobel

HIPAA says clinical researchers must release research data to study participants. CLIA says only CLIA-certified labs can release data to patients, and data must be from validated tests. Labs that perform testing for clinical research studies often are not CLIA-certified and often use unvalidated tests. So, clinical researchers are damned if they do and damned if they don't, with the potential for significant monetary and other penalties either way. CMS says "no problem" — get CLIA certification for your lab and validate your tests. But CLIA certification and test validation are costly and time-consuming to obtain and maintain. The best course of action appears to be to *not* release data, despite potentially significant health implications for study participants and the possibility of harsh media coverage.

Precision Medicine Initiative

Ysabel Duron, Nancy E. Kass, Pearl O'Rourke

The Precision Medicine Initiative ("All of Us") is preparing to enroll 1 million participants in a registry. The data, including medical records and genetic data, will be available to academia, industry and "citizen scientists" for legitimate inquiries. Diversity in the study population is a major focus, with an emphasis on real engagement and participation "on their own terms."

Things That Keep Institutional Officials (IOs) Up at Night

Lois Brako, Suzanne M. Rivera

This session focused on how an IO should handle a crisis like suspension of Federalwide Assurance, loss of accreditation, data breach, or media exposé on a human injury or death. In the short term, addressing concerns about patient safety is paramount. Attention then turns to building a crisis-management team and empowering it to act. Finally, damage to the institution's reputation can be mitigated and systemic improvements made.

True Stories from the IRB and Their Impact on IRB Operations

Elizabeth L. Hohmann, James Riddle, Susan L. Rose, Elyse I. Summers

IRBs at major research institutions see head-scratching issues every day. For example, a resident was discovered to be performing hip X-ray fluoroscopies without training or a dosimeter badge. The problem was remedied but, a month later, the IRB discovered the same problem in a different lab in the same department.

A theoretical physicist submitted an application to the IRB for a time-travel study. The consent form included a caution not to eat meat for three days prior to the study visit. Why? Because when the study participant travels back in time, the meat might turn back into an animal. You can't make this stuff up...

All levity aside, IRBs cannot make any assumptions about the conduct of clinical research. Do all the training and auditing you want, but researchers will still find ways to do ignorant or stupid things. Be prepared to keep calm and take remedial action. And remember, outsourcing IRB reviews does not mean these problems will go away.

Author

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