PRIM&R’s 2019 Advancing Ethical Research Conference

By Norman M. Goldfarb

Public Responsibility in Medicine & Research (PRIM&R) held its annual Advancing Ethical Research Conference in Boston in November 2019. This article discusses a small selection of interesting observations from a small selection of sessions, since the conference offered up to 23 concurrent sessions.

The Seven Habits of Highly Effective and Flexible IRBs

Jeffrey A. Cooper, MD, MMM, Vice President for Process and Strategic Improvement, WIRB-Copernicus Group
Jonathan M. Green, MD, MBA, Director, Office of Human Subjects Research Protections, National Institutes of Health

IRBs have a specific role: protecting participants in clinical research studies according to SOPs defined by the head of the human research protection program. This “organizational official” sets the compliance culture, is a respected liaison to the investigators, promotes the responsible conduct of research, and assumes all HRPP responsibilities not granted to the IRB. These responsibilities include overseeing the review and conduct of human research, ensuring compliance with ethical and legal requirements, creating policies, establishing training problems, ensuring the IRB operates independently, acting on allegations regarding human research, implementing monitoring programs to ensure compliance, investigating and remediating systemic problems, appointing and removing IRB chairs and members, determining which study events constitute unanticipated and problems that involve risks to subjects or others, determining whether any non-compliance is serious or continuing, limiting or conditioning investigator research privileges, and suspending, terminating or disapproving research. It’s a big job and not one the IRB should attempt to do.

The IRB’s authorities are specific to individual studies: review, approval, requirement to modify, disapproval, suspension, termination and observation. They should not be deciding what research has to be reviewed by the full board, determining whether non-compliance is serious or continuing, reviewing and approving SOPs, barring use of data, requiring destruction of data, prohibiting publication, or sanctioning investigators. These authorities are reserved to the organizational authority and his or her staff, which includes the IRB staff.

Why Informed Consent Doesn’t Work and Why the Revised Common Rule Won’t Fix It

Quincy J. Byrdsong, EdD, CIP, CCRP, Associate Vice President for Research Administration, WellStar Health System
Stephanie S. Cargill, PhD, Associate Professor, Center for Health Care Ethics, Saint Louis University

A 2015 review of 103 studies found that 67-78% of subjects understood the study aims, the ability to withdraw, the risks and the benefits. These are appalling comprehension rates, and there had been no significant improvement in 30 years. A 2019 study found that multimedia, enhanced consent forms, extended discussions and testing/feedback had little or no impact. The revised Common Rule requires a section on “Key Information,” which probably won’t have much impact either because we are using the wrong communications
model: one-way transmission instead of two-way interaction, along with other issues like the context and relationship between the parties.

To really improve comprehension, allow sufficient time, let the subject take the consent form home for review, encourage questions, check understanding frequently during the process, refer frequently to the document, promote the subject’s autonomy, and remember that consent is a continuing process.

Navigating State Law Differences in the Era of Single IRB (sIRB) Review

David G. Forster, JD, MA, CIP, Chief Compliance Officer, WIRB-Copernicus Group
Michael J. Linke, PhD, CIP, IRB Chair; Professor, Internal Medicine, University of Cincinnati College of Medicine, Adjunct Professor, University of Cincinnati

Unlike local IRBs, central IRBs and, now, single IRBs (sIRBs) have to worry about variations in state laws. These laws are numerous, can be hard to find, might be impossible to definitively interpret, and are subject to change. They can apply to age of consent, legally authorized representatives, informed consent, privacy, genetic data, biosamples, prisoners, STD and mental health research, IRB minutes, and other areas.

Implementing the Key Information Requirements of the Revised Common Rule — Perspectives on Early Approaches

Susan Z. Kornetsky, MPH, Senior Director Clinical Research Compliance, Boston Children's Hospital
Sariah Fuller, Community Member, University of Utah
Holly A. Taylor, PhD, MPH, Research Bioethicist, Department of Bioethics, Clinical Center, NIH

Key information must be concise, focused and of keen interest to study subjects (an interesting chicken and egg problem).

No Federal guidance is available to answer the following questions related to informed consent under the revised Common Rule: What are the changes to the general requirements for informed consent? Are there changes to the basic elements of informed consent? Are there changes to the additional elements of informed consent? Are there changes to the conditions for waiving informed consent by the IRB? What are the new flexibilities to the requirement for informed consent for screening, recruiting, or determining eligibility? Are there changes to the requirements for documenting informed consent? What changes have been made to the definition of legally authorized representative? What consent form must be posted? Does the posted informed consent have to be reposted after every change to the form? Are social, behavioral, and educational (SBER) research studies also required to post an informed consent form? Where should consent forms subject to the revised Common Rule's posting requirement be posted?

Author

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