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Vol. 6, No. 10, October 2010 "Can You Handle the Truth?"

"Ethical Issues in Clinical Research: A Practical Guide"

Bernard Lo, 2010, 292 pages, Wolters Kluwer, $59.95

Review by Norman M. Goldfarb

"Ethical Issues in Clinical Research: A Practical Guide" is a gem of straightforward and concise information about numerous ethical issues that arise in clinical research. The book makes it clear that ethics cannot be separated from the day-to-day activities in clinical trials.

Each topic includes an analysis of the issues, answers to important questions, regulatory citations, and a case study for discussion. The book provides the following advice for contacting potential subjects:

HOW MAY ELIGIBLE PARTICIPANTS CONTACTED?

After researchers identify eligible participants, they must next determine how to contact them to invite them to participate in the study. When contacting eligible participants, researchers need to explain how they were identified.

RESEARCHERS CONTACT ELIGIBLE PARTICIPANTS

As previously discussed, because of increasing concerns about confidentiality and privacy, many IRBs do not allow researchers to contact patients with whom they have no existing relationship. Although an IRB might allow researchers to identify eligible participants from hospital records without obtaining their permission, it might require researchers to contact them only through the treating physician or clinic director.

USE OF INTERMEDIARIES TO CONTACT PATIENTS

One option is for treating physicians or their staff to personally approach patients about the study and invite them to participate. However, this approach may raise other problems. Busy clinicians may have little time to discuss a research project or may forget to do so. Thus, few participants may be recruited. In addition, there is a potential for undue influence because patients may find it difficult to decline requests from their treating physician and office staff, on whom they depend for care. Another approach is for the treating physician or director of the clinic to cosign with the researcher a letter to eligible participants explaining the study and stating that the research team will contact them. Alternatively, the clinic receptionist or nurse may ask permission for the researcher to speak with patients.

HOW SHOULD FIRST CONTACT BE MADE?

Participants may view certain means of contact as a greater violation of their privacy. A letter from a researcher describing a study may be regarded as less intrusive than a telephone call because it does not require a response or interaction. Hence it is respectful for the first contact to be a letter to eligible participants to briefly describe the study and to inform them about how additional contact will occur and offer a means to prevent it.

AFTER INITIAL CONTACT, WHAT SHOULD BE DONE?

Opt-in Strategy

After sending a letter to eligible participants, researchers should make additional contact only with those who return a postcard or make a telephone call giving permission to be contacted about the study. Having participants give permission for further contact maximizes their privacy and confidentiality, and is preferable when the study concerns a sensitive condition. However, recruitment rates may be much lower than they would be with an opt-out strategy. Moreover, persons who take the initiative to contact researchers may not be representative of the target population of the study in clinically important ways. Thus an opt-in strategy may lead to bias and lack of generalizability.

Opt-out Strategy

Researchers can send eligible participants an introductory letter saying that they will call about the study, unless the person makes a phone call or returns a postcard refusing contact. The participant therefore has the burden of taking steps to avoid further contact. The rationale is that the vast majority of persons who do not reply are willing to be contacted. Compared to an opt-in strategy, this approach usually leads to higher participation rates and thus more rapid completion of the research.

Recontact nonresponders. Under an opt-out strategy, researchers usually want to try again to contact prospective participants whom they are unable to reach but who have not refused contact. Such persistence increases response rates and therefore enhances the generalizability of the research findings. However, some people who do not want to he contacted again may fail to return a postcard or telephone call indicating this. They may consider it an invasion of privacy if researchers continue to try to reach them. They may also feel upset that they have to do something to keep from being bothered. Thus researchers should set limits on the number of attempts to contact nonresponders.

Oversight of research staff. Research staff who contact participants or respond to participants' inquiries need appropriate training and supervision. The principal investigator must develop scripts for these discussions and obtain IRB approval for them. Front-line staff should practice role-playing and observing several conversations with participants before holding interviews themselves. Senior investigators should conduct an ongoing review of interviews with front-line staff.

ELIGIBLE PARTICIPANTS CONTACT RESEARCHERS

If persons interested in the research project contact the investigators, there are no concerns about confidentiality and privacy. For example, people may respond to an advertisement about the study.

The book consists of 28 chapters in six sections:

- Ethical and Regulatory Background
- The Researcher-Participant Relationship
- Responsible Conduct of Research
- Vulnerable Participants
- Ethical Issues in Specific Types of Research

The book is available in bookstores.

Reviewer

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