“Silent Partners: Human Subjects and Research Ethics”

By Rebecca Dresser, 2017, 302 pages, Oxford University Press, $28.00

Review by Norman M. Goldfarb

“Silent Partners: Human Subjects and Research Ethics” provides a thorough review of the ways clinical researchers can ignore the perspectives of research participants, the resulting negative consequences, and some of the ways the situation can be improved. The book points out that a clinical trial is not just a test of a drug or device; it can also be a difficult and exhausting trial for the study participants.

The book includes two unique chapters. One discusses portrayals of clinical research in fiction. The other, which discusses rule-breaking by study participants, includes this excerpt:

Although subject rule-breaking in later-phase trials often goes unnoticed, some investigators take measures to detect it. These measures allow researchers to compare subjects’ reports about their study behavior with objective indications of that behavior. In one example, investigators in an asthma study gave subjects inhalers that (unbeknownst to the subjects) were equipped to record the dates and times that medication was released. Almost one-third of the subjects “dumped” all or most of the medication at least once before meeting with study staff, revealing their failure to use the inhalers as directed. Those subjects withheld this information from the researchers. In another study, the pill containers that subjects returned to researchers indicated that 92% of subjects were taking the study drug as directed, but blood tests revealed that only 70 percent of subjects had actually done so.

Rule-breaking can be a particular problem in later-phase trials comparing investigational drugs with drugs already in medical use. Patients entering trials are often dissatisfied with their current treatments and hope they will be assigned to receive a new and potentially better one. They don’t want to be assigned to control groups receiving standard treatment or a placebo. And as one researcher put it, “people allocated to less desirable control conditions where they feel deprived of their preferred treatment...may lose heart, or act up.” This phenomenon is most likely to occur in nonblinded trials, but “even when participants do not know their treatment group, they often guess or suspect, correctly or incorrectly,” which drugs they are receiving.

Patients in this situation disregard a variety of research requirements. Some enter trials with the specific intent to drop out early if their symptoms don’t improve within a certain time. Some share drugs with other study subjects to ensure that each person receives at least some of the preferred one. During the early years of the HIV/AIDS epidemic, desperate patients admitted to both of these actions, as well as to “frequent cheating, even bribery, to gain entry to studies.” Researchers have observed similar behavior in other trials. So-called contamination occurs when “participants assigned to a control condition try to gain access to or adopt elements of the intervention condition.” For example, cancer survivors assigned to the control group in an exercise study were found to actually be exercising at the same level as the intervention group.
According to one review, "Research demonstrates that many clinical trial participants are overestimating their adherence and not providing the study investigators with honest self-reports." Estimates are that up to 30% of trial subjects fail to take study drugs as directed. One expert suggests that the rates could be even higher: "There is considerable anecdotal evidence, if not hard data, that most patient-subjects are not fully compliant."

The book includes nine chapters:
- Subject Perspectives: The Missing Element in Research Ethics
- Personal Knowledge and Study Participation
- The Everyday Ethics of Human Research
- The Hidden World of Subjects: Rule-Breaking in Clinical Trials
- Participants as Partners in Genetic Research
- Terminally Ill Patients and the "Right to Try" Experimental Drugs
- Embedded Ethics in Developing-Country Research
- Research Subjects as Literary Subjects
- How to Hear Subjects

Reviewer
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