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## Exploiting a Research Underclass in Phase 1 Clinical Trials

Carl Elliott, M.D., Ph.D., and Roberto Abadie, Ph.D.

In November 1996, the *Wall Street Journal* reported that Eli Lilly was paying homeless alcoholics from a local shelter to participate in safety testing of new drugs at its trial site in Indianapolis.<sup>1</sup> “These individuals want to help society,” asserted Lilly’s director of clinical pharmacology. The subjects, however, said they took part for easy money and free room and board. Although Lilly reportedly offered the lowest per diem in the business, it managed to attract poor subjects from all over the country.<sup>1</sup> The medical director of the local Homeless Initiative Program said Lilly had created a “shadow economy” of paid human subjects.

Today, the Lilly episode seems like an early warning about an emerging set of ethical problems. Over the past decade, clinical trials have moved from universities to private testing sites, the pressure to recruit subjects quickly has intensified, and ethical oversight has been outsourced to for-profit institutional review boards (IRBs). Payment to subjects has escalated,

creating “shadow economies” in cities throughout North America and elsewhere. In 2005, Bloomberg Markets reported that SFBC International, a contract research organization, was paying immigrants to participate in drug trials under ethically questionable conditions in a dilapidated Miami motel. A few months later, nine apparently previously healthy subjects at an SFBC subsidiary in Montreal contracted latent tuberculosis during a trial of an immunosuppressant. In 2006, six healthy subjects required intensive care in a phase 1 trial of a monoclonal antibody at a London facility run by the contract research organization Parexel. For all the ethical debate over these cases, however, few commentators have addressed the most troubling question: Is it ethically problematic to pay poor people to test the safety of new drugs?

Paying study subjects is not a new practice, but neither is it uncontroversial. According to regulators, payment should not be so high as to become an “undue

inducement,” lest subjects enroll in risky, unpleasant, or degrading trials against their better judgment. But this standard gives IRBs little practical guidance: a sum of money that the wealthy can easily resist may be very tempting for poorer people. Keeping payments low, however, seems unfair to the poor, who submit to trials precisely because they need the money. And whether or not such people are being unduly induced, the larger question is whether they are being exploited.

To exploit people is to take unfair advantage of them, but there is no consensus that current trial arrangements are unfair. Defenders of the status quo argue that people who enroll in trials have agreed to their conditions, that they get paid enough to make it worth their while, and that they are made better off by the arrangement. Nevertheless, there are good reasons to believe that poor subjects are being exploited.

First, poor people are less likely than wealthier ones to get access

to the drugs in question, if and when they are approved. Volunteers are unlikely to have full-time employment or, therefore, to have health insurance. Placing the burden of safety testing on the poor appears to contravene article 19 of the Declaration of Helsinki, which states that medical research is ethically justified only if there is a reasonable chance that the population in which it is conducted will benefit from the results.

Second, the U.S. oversight system is not well equipped to monitor a highly competitive, market-based, multinational research industry. The Office for Human Research Protections has no jurisdiction over privately sponsored studies, and the Food and Drug Administration inspects only about 1% of clinical trials.<sup>2</sup> IRBs, the most important bodies charged with protecting subjects, were designed primarily to review trial design, risk–benefit ratios, and informed-consent documents. Recent research scandals — which have been uncovered largely by investigative reporters rather than regulators — have concerned a very different set of issues: fraud, conflicts of interest, unfair payment practices, and unsafe or degrading trial conditions. Such problems are magnified still further when studies are conducted at private testing sites and reviewed by for-profit IRBs that are financially dependent on research sponsors.

Third, even though the purpose of phase 1 trials is to test whether new drugs are safe, most sponsors apparently do not provide free care or treatment for subjects who are injured in these trials. In fact, no agency is even tracking injuries in phase 1 trials, much less the long-term health of people who volunteer for many trials over a period of years. A recent study commissioned by the Department of Health and

Human Services showed that only 16% of academic health centers provide injured subjects with free care. None compensate injured subjects for pain and suffering or lost wages.<sup>3</sup> Although no comparable data are available for private research sponsors, there is little reason to believe that private sponsors are much more generous<sup>4</sup>; indeed, many include disclaimers in their consent forms indicating that subjects retain responsibility for their own medical care.

Most of these problems can be seen as consequences of the transformation of clinical research into a business. Many subjects in phase 1 trials today see their participation as a job.<sup>5</sup> They must pay taxes on their trial income, and sponsors often require them to sign a form acknowledging their status as “independent contractors.” The payment has become high enough to make participating in trials more lucrative than holding a minimum-wage job, even if subjects abide by the requirement that they wait 30 days between trials. Yet subjects get none of the rights or benefits that come with a good job, such as workers’ compensation, the right to unionize, disability benefits, or health insurance. Subjects whose livelihoods depend on trial income are often reluctant to drop out of trials that turn out to be risky or unpleasant, especially if they have traveled some distance to the trial site and have invested a substantial amount of money in accommodations while waiting to enter the trial. Subjects have little incentive to be truthful about their medical history or health status because known medical problems may preclude their participation in a study. Nor do they have anyone to go to with complaints. Many say they are reluctant to complain to sponsors about poor conditions for fear

of being excluded from future trials. For similar reasons, they are reluctant to go to a lawyer, even if a trial goes seriously wrong.<sup>4</sup>

Without actually intending to do so, policymakers have allowed participation in clinical trials to become something very close to a job. Sponsors call subjects’ payments “compensation” to suggest that they are merely reimbursing participants for expenses and inconvenience, even as they fill studies with unemployed people who depend on trial income to make ends meet. They refer to paid subjects as “volunteers,” implying that participation is a freely chosen act of altruism, whereas most subjects indicate that they take part in trials for the money. Regulators allow sponsors to use money to attract subjects but do not require them to provide the kinds of benefits that subjects would demand if they had more power. The result is what one Philadelphia trial subject describes as “a mild torture economy.” “You are not being paid to do something,” he explains. “You are being paid to endure.”<sup>5</sup>

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