

The Right to Participate in Research

We were conducting a pilot study in an area of the U.S. that had a large Hispanic population. I must emphasize that this was a “very” pilot project, funded entirely by our department. The data being gathered were extremely preliminary and would not benefit research participants in any way. In fact, it would probably be more correct to say that this was a “pre-pilot” study although it was approved by our IRB, of course.

The problem occurred when Hispanic, would-be enrollees started showing up in our research offices without a consent form. This would occasionally happen because the informed consent translator would not be available, and the participants would be sent directly to research. But when that happened, we had no one available in the research unit to go over or “translate” the Spanish consent form into something the participants could understand. (Many of them were illiterate.)

Because this became increasingly problematic, we decided to exclude Hispanics from the study altogether. A member of our research team was disturbed by this, however, saying that we were denying this population a possible “benefit.” Furthermore and intuitively, the wholesale exclusion of Hispanics certainly sounded discriminatory.

I continue to wonder about this. Is there a *right or a duty* to participate in research? Was our exclusion of Hispanics in this study ethically defensible?

Expert Opinion

The recruitment of adequate and representative groups of trial participants can be extremely challenging. A 1984 study that is still quoted found that 34 percent of 41 randomized controlled trials in the U.S. recruited less than 75 percent of their planned samples.¹ Recruitment problems are particularly acute among minority groups. A 2004 study by Murthy and colleagues found that Hispanics and Blacks were under-represented in National Cancer Institute (nonsurgical) treatment trials for breast, lung, colorectal or prostate cancer from 1996-2002.² The elderly were particularly under-represented, as they accounted for one-third of trial participants but represented two-thirds of patients with the cancers that were studied (i.e., breast, lung, colorectal and prostate). Another study noted that the consent process itself is a major barrier to recruitment. Assessing the level of information required by patients, discomfort over causing patients to worry about the nature of the trial, and mistrust among patients of the investigators’ motives are only some of the more representative problems of securing consent.³

One might respond to the scenario above with a “principled” approach or a more pragmatic one. A prominent tenet of a principled approach on research recruitment requires that investigators insure that the benefits and burdens of research participation are fairly distributed, such that the populations (or subgroups) of research participants mirror the population of end-users of the research.^{2,4} There are always burdens in participating in a research project, even if they only involve taking a few minutes out of one’s schedule, signing some papers, and answering some questions. On this view, excluding minorities might be seen as a moral failure among the investigators. Similar to more elaborate randomized studies where minorities are under-represented,² this pilot has failed to insure that Hispanics shoulder their fair share of the research participation burden.

A second principle-based argument would focus on depriving minorities of a *benefit* per the team member’s objection as above. While other team members believed that research participation “would not benefit the research participants in any way,” how does one define “benefit” in this scenario? We know that some persons believe that an obligation or duty to

participate in research exists as everyone, sooner or later, benefits from it. Others are pleased to have the opportunity to exercise their altruism in helping their fellow human beings. In her systematic review of barriers to participation in randomized controlled trials, Ross noted that “in contrast to the barriers to participation, the most commonly mentioned motivation for participation was altruism.”^{3, p. 1152} Consequently, the investigators’ eliminating the opportunity among Hispanics to dispatch a duty or to gain satisfaction from exercising their altruism might be interpreted as morally problematic.²

A third principle-based argument might well complain that the decision to exclude “Hispanics” relies on the social construct of ethnicity/race rather than directly identifying the practical constraint that motivated the exclusion, namely, problems in translating the consent form to non-English speaking persons. Thus, when the researchers decided to exclude “Hispanics,” did they mean (1) persons biologically descended from people who once resided in Spain, or (2) persons for whom Spanish is their first language, including those whose parents moved from England to Venezuela before they were born, or (3) people who showed up “light brown, dark haired, and Spanish speaking”? Clearly, a more thoughtful and sensitive exclusion criterion would have been “persons who do not have 8th grade level literacy in English” rather than an omnibus ethnic category like “Hispanic,” even though the latter term happens to map roughly onto illiteracy in the geographical region of the study.

The principled approach, then, would lament the decision to exclude Hispanics, and would probably urge that the sponsoring department find a few more dollars to hire an additional, Spanish-speaking investigator who could dissolve this problem. Nevertheless, those dollars might be hard to find, which invites a more pragmatic treatment of exclusion. Setting aside the question of whether minorities have a right or a duty to participate in research, a more practical problem is: Will the exclusion of Hispanics so contaminate the pilot’s findings that they will be worthless, especially by way of being nongeneralizable? And might that nongeneralizability imperil future persons who hail from populations that were initially excluded from enrollment?

This latter possibility recalls the exclusion of women from cardiovascular pharmacologic studies for most of the 20th century. Although the drugs that succeeded in these trials and eventually came to market would be used by women, the fact that they were excluded from trial participation meant that investigators had no statistical confidence about the effectiveness and safety of these new medications among women.⁴ Indeed, there was speculation that women with heart disease were less likely to receive diagnostic and therapeutic procedures than men, presumably because of the failure among researchers to study and become familiar with the phenomenon of heart disease in women. As a result, the 1993 NIH Revitalization Act was passed such that, today, all NIH funded clinical research as well as phase III randomized controlled trials must include women and racial and ethnic minority groups in order to test the efficacy of a new treatment.^{2,4}

At the cost of belaboring the point, we might also note that there is an overwhelming bias in American medical literature to understand white, Anglo males as the “norm” when, in fact, various internet sites note that northern European Caucasians probably account for less than 30 percent of the world’s population (with some sites speculating less than 10 percent). One might say, then, that the very group about which we have the most research data represents an inbred sub-clone. Arguing that African Americans or Hispanics are “different” misses the fact that “northern Europeans” represent an overstudied, inbred population that is hardly a representative sampling of human beings. (One might also relate this to the many psychological studies done solely on mostly white college undergraduates.)

But if our concern is with representativeness, the pilot study described above is a long way from the kind of representativeness required in an NIH randomized trial. Let's therefore consider some conditions under which exclusion might be pragmatically as well as ethically valid. What would one say, for example, about an fMRI study that purposely excluded *left-handed* persons? Suppose the goal of the project was to discern the existence of a particular neural activation pattern, whose discovery would provide no immediate or foreseeable therapeutic benefit to anyone. However, its findings would be totally irrelevant to left-handed persons. Not only that, the inclusion of lefties would skew the data. Thus, it would be a waste of research monies and effort to enroll them. So, one could not seriously maintain a claim of "discrimination" in this project: Discrimination prevents a group from receiving a benefit to which they have a right. Here, there is no practical benefit that is being withheld from lefties; to include them would be a waste of time and money and sabotage the experiment.

What about research that studies a socially important phenomenon occurring in certain populations but not in others, such as doing clinical research on diseases that particularly affect persons who are homeless or imprisoned? Here, the exclusionary methodology is morally justified on the basis of a widely-recognized need to understand the nature of health problems that only affect a particular group. The justification of exclusion rests on moral common sense: There is no need to include other populations in the study because they are not afflicted by the phenomenon being investigated.

Consequently, it is crucial to know what this pilot study is about. Presumably, the essence of a pilot project is:

to ensure that proposed methods and procedures will work in practice before being applied in a large, expensive investigation. Pilot studies provide an opportunity to make adjustments and revisions before investing in, and incurring, the heavy costs associated with a large study.⁵

So, we'll assume that the point of the pilot project in the scenario above is to discern whether or not evidence exists that would support proceeding on to a more elaborate, pilot grant. On that basis, if there is utterly no physiological reason to think that excluding Hispanics would taint or corrupt its preliminary findings, and if those findings constitute only the very first, *primitive* step in what will be a more elaborate investigation later on—one that will certainly enroll representative subgroups of research participants—then the current exclusion of a particular population of potential enrollees might be marginally justifiable.

We say "marginally" because a pragmatic approach would also note that a pilot project should provide knowledge or experience that enables that more serious, elaborate, and formal investigation later on to better anticipate, manage, and execute its performative challenges. Obviously, one finding from the pilot project above is that recruiting Hispanic participants will require a more elaborate informed consent protocol. But it is also quite possible that because Hispanics were excluded from the enacted pilot, investigators will face additional, *unanticipated* challenges in a later project. For example, the researchers don't know how Hispanics will react to the informed consent materials and content of a later grant. Will they find the methodology incomprehensible or frightening? What kinds of questions will they ask? Will there be any culturally embedded resistance that Hispanics might have to the research objectives or methodology that will take the investigators by surprise?⁶ What barriers to the research participation of Hispanics might appear when a later grant begins that could have been uncovered by an earlier research experience that included them?

In conclusion, if this pilot project is simply to determine the feasibility of a project idea that will be elaborated and refined further on, the exclusion of Hispanics seems mildly objectionable at most. (We anticipate that the investigators informed their IRB of the protocol

change involving exclusion of Hispanics.) But if its data are going to be included and mentioned in a more formal pilot application seeking external funding later on, that application should at least describe the participant population studied, i.e., make clear that Hispanics were not included. Ironically, that future application might consider explicitly mentioning the challenges in securing consent from Hispanics, either to justify funding for a Spanish-speaking investigator and/or to point out that such a one will be in place so that minorities will be duly represented in the new project. In an odd way, noting the uncomfortable experience of failing to secure consent from an adequate sample of minority participants, and the subsequent measures being taken to insure that the problem does not reoccur might impress the reviewers of the future application and improve its chances of being funded.

References:

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Suggested reading:

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