

## *We're Not Recruiting Enough Participants!*

I recall a cancer study I participated in where our patient recruitment numbers were dismal. One day, though, a research associate received a call from a potential participant who said she received a letter inviting her to participate in a clinical trial. She said she would like to be enrolled. However, this potential participant was sent an invitation letter by mistake because she lived outside the geographical recruitment area that we stipulated in our proposal. Also, she said she was only interested in being in the experimental group, not in the control group.

The research associate knew that the randomization table indicated that the next several people to be enrolled were going to the control group, but he manipulated the randomization schedule so that he could enroll the patient in the intervention group. His rationalization was that the study enrollment was down, and if the potential subject was enrolled and then told she was going to be in the control group, she would drop out.

Was the associate's recruitment manipulation unethical? What are the ethical factors that need to be considered?

### *Expert Opinion*

First of all, the research associate should have respected the recruitment protocol that had been stated in the proposal and not enrolled patients from outside the stipulated geographical area. Such geographical determinations are usually based on local knowledge that a significant percentage of persons living beyond a certain radius from the research site are likely to drop out as the study proceeds because they tire from the travel.

But failing that, the research associate should have explained to the caller that the experimental intervention was not adequately proven to help people. That's the reason the study was being conducted. Hence, the caller's insistence on being in the experimental group was likely based on the unsubstantiated and probably erroneous belief that she would almost certainly benefit from participation.

Further, the patient's insistence on being in the experimental group would defeat randomization's purpose of enrolling nonbiased participants (or evenly enrolling biased participants in the two groups). A participant's passionate interest in enrolling in the experimental group can bias the data, especially if such persons represent a distinct socioeconomic, educational, or racial background. It is easy to see how accommodating such persons' enrollment preferences could skew the membership of the control and experimental groups and, most importantly, compromise the generalizability of the data.

Perhaps so as to not have a conflicted research associate be tempted to do what this one did, one might have the randomization be known and controlled only by a superior, or have the randomization completely automated when a new enrollee is entered.

Finally, it might be a good idea to have the research team reminded of the contents of the research protocol and why randomization is necessary. If a research team's data are to be valid and

meaningful, adherence to protocol is not only required, it constitutes the ethical fulfillment of the team's promises as originally stated in their research proposal.

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