

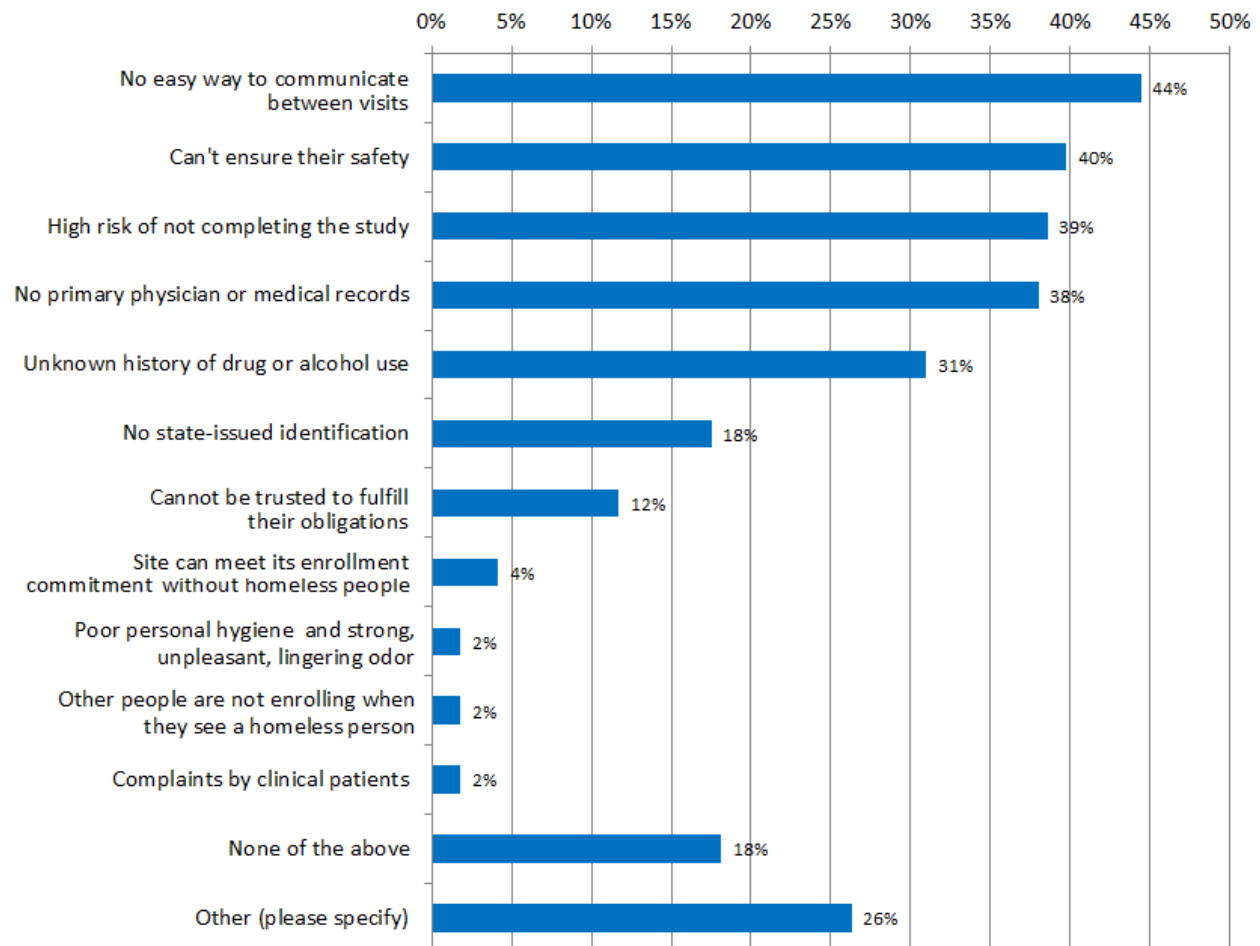
Clinical Research Ethics Question of the Month: Homeless Participation

By Norman M. Goldfarb

You are the chairperson of a central IRB overseeing a large phase 3 study. Based on an anonymous call, you determine that one of the investigators is not accepting homeless people who want to enroll in the study. What should your policy be for participation by homeless people in clinical studies?

Results

Question 1. On what basis, if any, can an investigator exclude homeless people from a study?



Of the 171 respondents, no more than 44% agreed on any one reason to exclude homeless people from the study. The most common reasons were: “No easy way to communicate between visits” (44%), “Can’t ensure their safety” (40%), “High risk of not completing the

study" (39%), "No primary physician or medical records" (38%), and "Unknown history of drug use" (31%). The least common reasons were: "Complaints by clinical patients" (2%), "Other people are not enrolling when they see a homeless person" (2%), "Poor personal hygiene and strong, unpleasant, lingering odor" (2%), "Site can meet its enrollment obligations without homeless people" (4%), "Cannot be trusted to fulfill their obligations" (12%), and "No state-issued identification" (18%).

Eighteen percent of respondents stated that none of the above reasons for exclusion are valid. A number of respondents stated that they would rely on the study's eligibility criteria. One respondent noted that many homeless people are just ordinary people who happen to be homeless at the time. One respondent noted that the above criteria can also apply to people who have homes. Several respondents expressed concern about discrimination against the homeless or economically disadvantaged. Several respondents commented that enrollment decisions should be on a case-by-case basis.

Respondents stated the following other reasons to exclude homeless people from the study: vulnerable population (especially with respect to compensation), no proper storage conditions for study medicine, transportation issues for study visits, and they might be "professional" research subjects. One respondent noted that Phase 3 studies often have long durations and look for relatively rare adverse events, so reliable communications are essential.

Question 2. What reasonable steps, if any, should the investigator make to accommodate homeless people?

Respondents suggested issuing limited-service mobile phones, requiring an emergency contact number and frequent check-ins, issuing bus passes, conducting visits at a convenient location, getting a relative, homeless shelter, church, YMCA or social worker involved, and conducting study visits during off hours, as appropriate.

Question 3. What reasonable requirements, if any, can the investigator place on homeless people who want to enroll in the study?

In addition to compliance with the protocol, respondents said there would have to be a serious discussion about study participant responsibilities and how the above issues would be addressed.

Several respondents suggested there should be an exclusion criterion that gives the investigator some discretion based on the many factors that, typically, are not listed in a protocol.

Question 4. How would the characteristics of the study affect your answers?

Respondents cited safety/risk, the necessity/ability of participants to comply with the protocol (depending, in part, on study complexity), and issues related to vulnerable populations. One respondent commented that the investigator should not ask people to enroll in a study if the treatment, which, if it is eventually approved, will not be available to that person or population.

Discussion

Homelessness, *per se*, is not a reason to exclude anyone from a clinical study. However, homelessness is often associated with valid reasons for exclusion. Every study is different, as is every potential study participant, so exclusion criteria should be established for each

study, and then reviewed individually for each potential study participant. In theory, many of the issues can be addressed. For example, it might be possible for a shelter to store the study drug for a person who is living on the streets.

Investigators should make *reasonable* accommodations for any potential study participant, including someone who is homeless. However, they should not be obligated to enroll people who are not able to fulfill their responsibility to help investigators fulfill their responsibilities to the participants, the study sponsor, the public, their families, and themselves. For example, we cannot reasonably require physicians to significantly disrupt their clinical practices or personal lives to accommodate an unruly or offensive study participant. Study coordinators should also have a say in the matter. However, it is reasonable to ask investigators, study coordinators, and study sponsors to make a reasonable additional effort or incur a reasonable additional cost to accommodate study participants with special needs, regardless of legal obligations. For example, sponsors might have to accept higher screen-failure rates or pay for mobile phones but not jeopardize the scientific validity of the study.

Protocols should give investigators enrollment discretion based on considerations that are not listed in a protocol. For example, few protocols list "Poses a physical danger to study personnel" as an exclusion criterion. Investigators, like restaurants, should have the right to "refuse service to any customer" within the limits of the law and within the ethical requirements set forth by their institution and in their IRB's approval letter.

This discussion begs the question of what is "reasonable," under which circumstances, and in the local community. The IRB in the survey question above should establish a policy based on the issues addressed above, consistent with the principles of justice, autonomy and respect for persons, and not just apply it to homeless people.

Next Month's Question

You are a member of an IRB that is reviewing a diagnostic study for a new viral disease, PVD, that, in exactly 50% of those infected, causes Polaiter dementia. The PVD virus has infected the entire population. Dementia does not evidence itself until age 70. If detected before age 30, it can be treated successfully. The experimental test is believed to be 100% accurate in identifying who will get dementia. However, it has the unique "quantum" effect of flipping the medical condition of the person tested... Will you vote to approve the study? Read the full question and give us *your* answer at:
<https://www.surveymonkey.com/r/X3S7K33>.

Please send your ethical conundrums to ngoldfarb@firstclinical.com.

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