

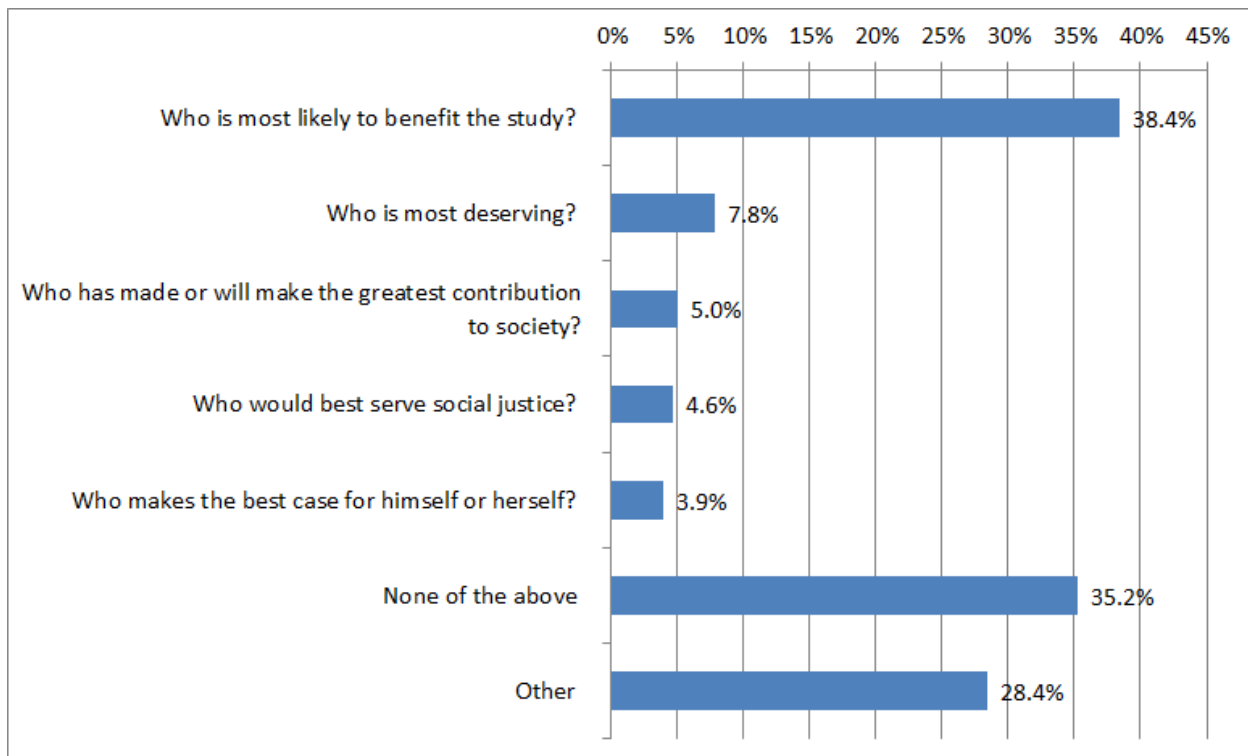
## Clinical Research Ethics Question of the Month: Who Do You Enroll?

By Norman M. Goldfarb

You are a principal investigator in a very promising Phase 3 pancreatic cancer study. The sponsor has just informed you that you can enroll only one more patient before enrollment closes. Enrolling in this study might save your patient’s life. Ten of your patients are eligible for the study. One is a young child; one is a well-respected physician; one is your mother-in-law; one has a large family to support; one is a convicted felon; one has been the victim of racial discrimination; one is a recovering drug addict; one is the brother of someone already enrolled in the study; one is a famous composer close to completing a symphony; one is an illegal immigrant; and one has donated \$1 million to support research on pancreatic cancer. Who do you invite to participate in the study, and how do you decide? You have no other information to make your decision and no clever way to dodge it.

### Results

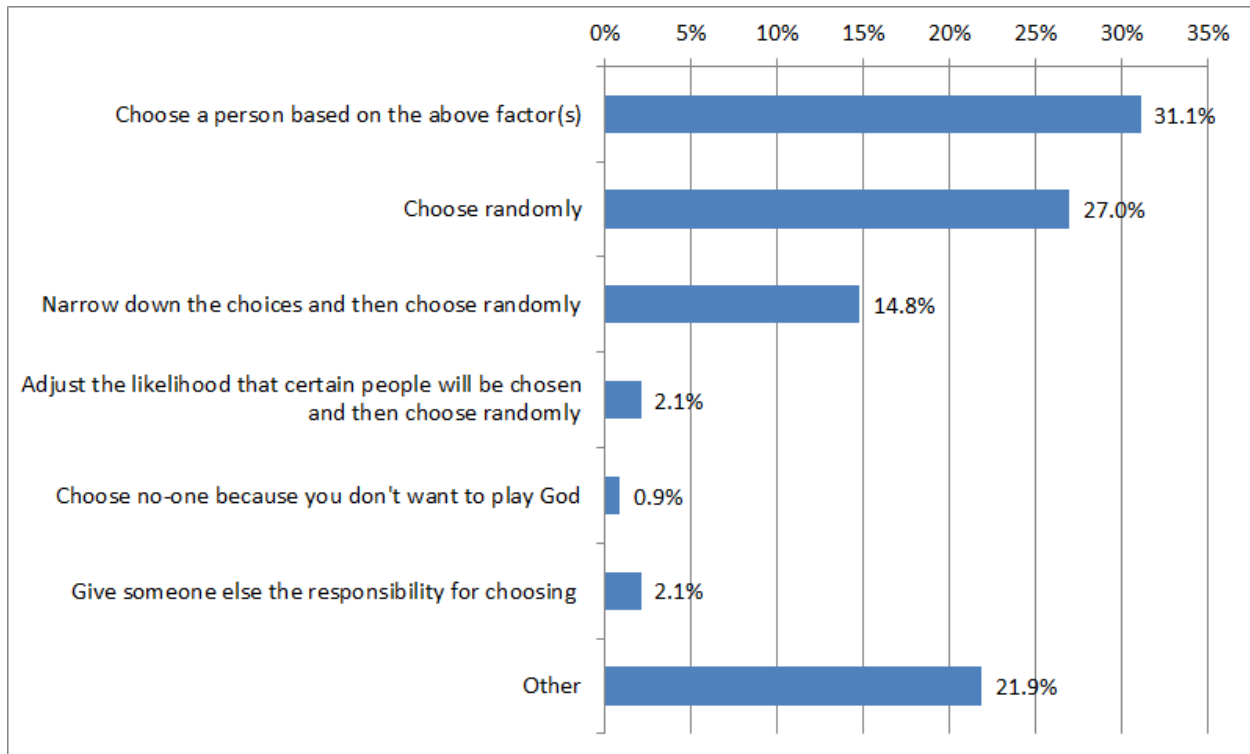
**Chart 1. Which of these factors would you consider?**



Of the 443 respondents who participated in the survey, 38% would take into account the person who is most likely to benefit the study. Only small numbers of respondents would take into account any of the other factors. About two-thirds of respondents would not use any of the factors listed in Chart 1 or would also consider other factors. The most popular other factors were (a) who would most benefit from the study and (b) who had been

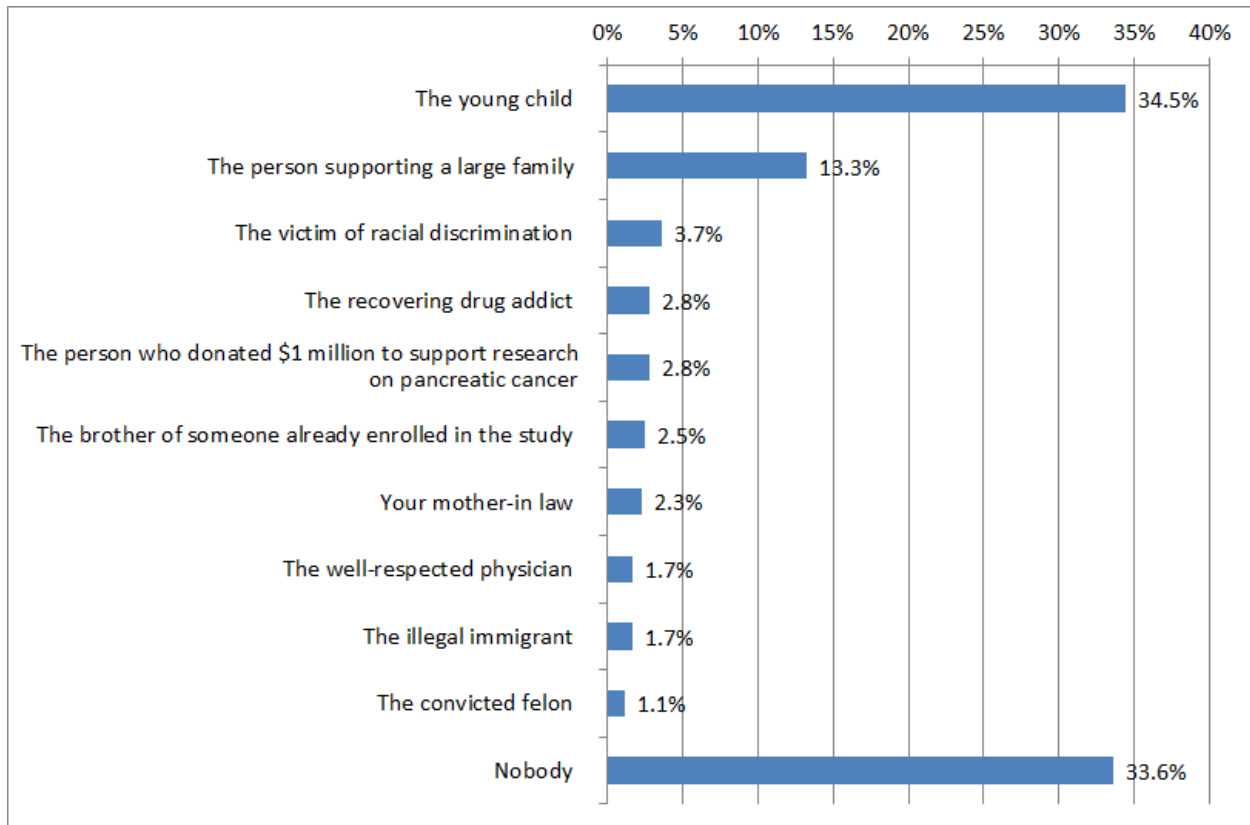
screened, identified or contacted first. One respondent would focus on the risk/benefit ratio for each person. Some respondents would exclude their mother-in-law because of the familial relationship, and then proceed.

**Chart 2. What would your process be?**



Thirty-one percent of respondents would choose a person based on the factors in Chart 1, 28% would choose randomly, 15% would use a hybrid method, and 22% would use none of the methods listed. Of the 22% who would use unlisted method, there was a clear preference for the person who was screened, identified or contacted first. Some respondents would call them all at the same time and enroll the first one who called back.

**Chart 3. Whom did you choose?**



Regardless of the method used, 35% of respondents would choose the young child and 13% would choose the person supporting a large family. The recovering drug addict and the person who donated \$1 million to support research on pancreatic cancer both came in at 2.8%. The convicted felon would have been the least likely to be chosen, at 1.1%.

**Were you satisfied with your choice? And, if you were dissatisfied with your choice, did you change it?**

Only 71% of respondents were satisfied with their initial choice. Of the 39% who were dissatisfied with their initial choice, 11% changed it.

**Discussion**

Forty-six percent of respondents would consider the factors in Chart 1 in making their choice. Forty-two percent of respondents would use randomization in making their choice. A significant but unknown percentage would choose based on first-come-first-served.

Thirty-eight percent of respondents would choose based on who is most likely to benefit from the study, while roughly half that number would choose based the merit of the person.

Only 10-20% of respondents said they would consider factors related to merit, such as who is most deserving. In addition, a significant, but unknown, percentage would consider which person would most benefit from the study. Respondents were much more comfortable using a mechanistic method, such as randomization or first-come-first-served, or making an objective medical/scientific judgment as to who would most benefit the study. Nevertheless,

47% chose the young child or the person supporting a large family, and 34% of respondents could not choose anyone.

**Next Month's Question:**

You are a member of a local IRB reviewing an influenza vaccine study. The investigator wants to ask enrolled study participants to help recruit additional study participants. The investigator wants to express her gratitude for this assistance. She has asked the IRB whether tangible expressions of gratitude, e.g., cash, would be acceptable. What expressions of gratitude would be acceptable to you?

Read the full question and give us *your* answer at:  
<https://www.surveymonkey.com/r/D683HJQ>

***Please send your ethical conundrums to [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).***

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