

Subject Recruitment Mailers

By Terry Stubbs

The first place to look for study subjects is in your database(s). Many sites now have databases of patient electronic health records. Most clinical sites have databases with at least diagnosis and billing codes. Ideally, your site also has a database of people who have participated in, or expressed interest in participating in, a study.

The easiest way to contact these patients about a study is with a paper mailing. (Email messages can have confidentiality issues, e.g., if people share email addresses). Make the text short, easy to understand, and to the point. (See Figure 1.) The more words, especially medical terminology, the lower the response rate will be. The document should be pleasing to the eye, but it does not have to be fancy. It is more important to reinforce the personal connection, so use mail merge to put their names on the mailing. The text should be large enough to be read by an older person. Mailings can include just a letter, just a flyer, or both. Remember to ask the recipient to call if he or she is interested.

Figure 1. Sample Letter

RE: Alzheimer's Clinical Study Right Here in Haverhill

Dear [Patient Name]:

I am writing to inform you of a new clinical study that might interest you. The study will test an experimental medication for cognitive function in patients with mild Alzheimer's disease. The study is 18 months long and there are 15 visits.

I am not sure if you qualify at this point. Study participants must be 50-89 years of age and have mild symptoms of Alzheimer's disease. You will receive an MRI scan at no charge. A travel stipend is available for participants, as well as a separate stipend for your caregiver.

If you or someone you know would like more information about this study, please call my study coordinator, Richard, at (978) 372-7252. He will be happy to answer any questions you have. All study inquiries are kept confidential. You do not have to be a patient in our practice to qualify for this trial.

Sincerely,

Sally McCarthy, MD

This message, letter or flyer is a form of advertising, so it needs IRB approval. By including advertisements in the initial regulatory package, you can start recruiting subjects sooner. (Ask your IRB for a quick turnaround.) As a bonus, there is no additional cost to the sponsor if you submit your advertisements in the initial submission to the IRB. Most IRBs allow up to five different advertisements. Each advertisement sent separately to the IRB costs the sponsor \$100 to \$150. It's not your money, but why waste it? And, don't forget to tell your sponsor you saved them money.

Many sites identify potential subjects by reviewing charts and then contacting the people who appear to qualify. However, given that chart reviews can take 20 to 30 minutes each, it can be much faster and cheaper to do a rough selection from electronic medical records and billing systems, based on criteria like the study's medical condition, gender and age, and then send mail to everyone who appears to qualify after a quick visual scan to eliminate names that obviously are not a fit. Charts can then be reviewed for the people who express interest in the study. If it takes a study coordinator earning \$25/hour 20 minutes each to review 50 charts to find 10 people who qualify, of which two enroll, the cost is over \$200 per subject just for the chart review. Instead, if it costs \$1.00 each to mail to those 50 subjects, the cost is \$25/subject. As a bonus, recipients of the mailers can share them with friends and relatives who might qualify.

Send out enough mailers, say 500-1,000 per week, to generate a good flow of calls, but not so many so as to overload site personnel. It might be worthwhile to send a second mailing to some or all of the people six to eight weeks after the first mailers went out.

Author

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