Six years ago, our department of a large academic research center was having difficulty enrolling enough subjects in osteoporosis studies. We wanted to expand into a variety of trials and increase the number of participants. Despite our experience and expertise, our enrollments were down. We wondered if the pool of eligible participants was shrinking, if our competition was doing a better job than we were, or if we needed to modify our project management style.

Eight million women in the United States have osteoporosis, 1 so we were confident that our target population existed. Other local investigators were conducting osteoporosis trials, and although we knew very little about how they were doing their studies, they did not appear to be immune to the same challenges we were experiencing. So, after a critical look at how our projects were managed during recruitment, we decided to modify our project management style.

First, instead of one clinical research coordinator (CRC) handling all the tasks of a clinical trial from beginning to end, we adopted a team approach, beginning with how we conducted the telephone and study visit screenings. Over time, we evolved a recruitment team consisting of a CRC project manager, a dedicated recruiter, a CRC specialist in database management, the technical staff, and research assistants.

With our staff reorganized in this way, we turned our attention to the problem of effective communication with our target audience. Were potential subjects aware we existed? What was their opinion of our research, and of research in general? How could we make them aware of study participation opportunities?

What could be done to make the telephone ring? This article presents some of the lessons we learned in our efforts to improve our recruitment results.

Know your organization
To effectively recruit subjects, you must understand your organization and identify its resources. This includes the mission, institutional regulations, available study personnel, collaborators, physical facilities, and budget.

An effective recruitment plan will be based on the organization’s identity and will project an image consistently reflecting this to the population. Make use of the image and relationship your organization has already built with the community by always using your logo, for example. When developing a recruitment plan for a particular study, consider how it will affect future recruitments, just as past recruitments are foundations for the current recruitment.

Know your target audience
In addition to understanding your own organization’s identity, you’ll need a thorough understanding of the intended study population. The questions will be similar for each recruitment. The answers, however, will vary, because every recruitment has a specific study population. What are the priorities of potential subjects? Where do they get information? How do they feel about research?

In addition to the prospective study population, you need to understand the makeup of the whole community. What are their norms and mores? What do they already know about you? Community members such as physicians, nurse practitioners, physician assistants, and past participants are also potential participants and potential referral sources.

Understanding your community members’ perspectives is as simple as asking and then listening. Advertising vendors and businesses spend a tremendous amount of effort and financial resources on surveys and focus groups in an attempt to understand
consumers. For researchers, however, it is more realistic to communicate with current participants and network within the community to understand the intended study population. Speak to neighbors or to persons you meet at community or church activities or at local shopping centers. Any place people gather provides you with an opportunity to communicate and learn.

Don’t assume that your community understands your work. Although clinical research professionals are very familiar with the normal conduct of research studies, the public may have a misconception about, or mistrust of, the motives and goals of researchers. Remember that the relationship between the clinical research team and the participant is built on trust. Every member of the team, from the receptionist to the investigator, is responsible for maintaining the highest ethical standards and complying fully with regulatory standards. Additionally, everyone is, in effect, a goodwill ambassador.

Understand and remove barriers to recruitment
When you know your organization, you may come to understand some of the barriers to recruitment experienced by your site. Barriers can include limited appointment times or a shortage of staff members to field telephone inquiries, leading to a critical lag in response time. Your site may be inaccessible, suffer from limited parking, or be in a department that is difficult to find once the participant has entered the building. Certain times of year, such as holidays, can make recruitment more difficult, and severe weather may affect appointments in some areas of the country. Talk to current participants and look at this from their perspective. Understanding what the barriers are is the first step to removing them.

Know your project
Short- and long-term goals will be based on the enrollment target and timeline established by the sponsor and investigator. Establish weekly and monthly goals for the number of incoming telephone calls, screen visits, qualifiers, and enrolled participants. Evaluate each category weekly and provide regular reports to the investigator. The sponsor or monitor will want a daily or weekly report on the screen visits and qualifiers.

Develop your tools
Your team will need a few tools to do their work.

Progress charts. Visual affirmation of study progress keeps the entire team informed and focused, and promotes teamwork. Keep available a dry-erase board or wall chart for each study. For one of our osteoporosis studies, we had a progress chart in the shape of a bone that was colored in and dated weekly. Another chart had three columns for each of the “hurdles” the participants had to move through toward final qualification and enrollment. Use your imagination; just make sure that confidentiality is maintained and there is no identifying information about the participants.

Forms. The sponsor will be providing case report forms (CRFs), but sometimes we’ve had to develop worksheets such as the telephone contact sheet for source documentation. We record each telephone contact on our telephone work-sheet, which has space for noting the demographic information, appointment times, and outcome notes. The study-specific screening questions are listed on the back. We make these pages on colored copy paper so they’re easy to find on the desk; the color ties into the study theme.

Our screen visit folders usually contain a copy of the study consent, our registry form, the sponsor’s screen visit worksheets, laboratory and procedure requisitions, and our internal billing sheet. The telephone call sheet for each person who passes the telephone screen is placed inside a preassembled screen folder for use when a study visit is scheduled. Call sheets for people who are not eligible are filed together and entered weekly into the recruitment database.

Develop your team
Communication among your recruitment team members is facilitated by regular meetings, brainstorming sessions to work out problems, and email to keep everyone abreast of small changes that need to be implemented as soon as possible.

Early in the process, have each team member read the consent form; it’s an excellent way for everyone to have a general understanding of the study. Draft a telephone script and the screening visit procedures and review all steps with your team for everyone’s input. Work with the team members who will be helping with calls. Encourage them to stick closely with the script. You are aiming for conversational calls, but it is important to remember your mission. Five to seven minutes is typical for our screening telephone calls.

Have some fun. Choose a nickname and theme for the study. We’ve used colors and simulated political campaigns. For one study, finding persons to fill the “B” stratum was challenging, so the buzzword became “Find the Bs.” Pictures of bumblebees began to pop up everywhere. When we used the bone-shaped progress chart colored with blue marker, the buzzword became “Think blue.” (This was problematic, because we like to bring in “theme” food, and there are few blue food items.)

When recruitment is completed, our investigator gathers the project team members and hosts a luncheon. Then the team enjoys the afternoon off. I like to make award certificates or signs for the workspaces of team members as morale boosters.

Develop a database
The development of a recruitment database may initially seem to require an excessive time investment, but the benefits in the areas of organization, reporting, and control are enormous. Your database will let you track not just the qualifiers, but also the screen failures and those deemed ineligible based on the telephone screening—vital information to have when you’re analyzing recruitment problems.

You can start with the same database for every study and modify it as necessary. The working recruitment database will
12 Tips for Community Presentations and Health Fairs

1. Confirm the date and time of the event with the organizers, and get their approval to distribute research study flyers and educational information. Touch base with the organizer a few days before the scheduled date to make sure there are no changes in the location, time, and expected number of attendees.

2. Some events may charge a fee for displaying at their health fair or seminar. I explain that we are a nonprofit organization, emphasize what educational services we can provide, and decline opportunities that still insist on receiving a fee.

3. Consider a modest investment in a small, easel-mounted sign with your organization’s name, number, and logo on it. Most of the signage provided at a health fair is visible only at the table. An easel-mounted sign is portable and can be seen from across the room.

4. Unless you have made other arrangements with the organizers in advance, arrive on time and stay for the whole event. Try to do a drive-by in advance to find the location of an event so you are sure of where you are going and where to park. If the location is too far away to allow this, ask directions ahead of time and have a map handy. Web sites that generate maps with driving directions are very helpful. Allow yourself plenty of time. Take along a project to pass the time if you are too early.

5. Dress for success: jacket and slacks or skirt, name badge, and comfortable, professional-looking shoes.

6. Bring a box of standard supplies: wide tape, scissors, two hand towels, note pads, pens, bottled water, and plenty of business cards. I keep this box in the trunk of my car at all times. A small, fold-up, two-wheeled hand cart will help you transport your supplies, handouts, and sign.

7. Avoid sitting behind the booth. Be at your audience’s eye level.

8. Never eat at your booth.

9. Avoid overloading the table with paper. Use display racks to raise the flyers and educational brochures above the flat surface of the table. Do not make the same flyer in several colors; the audience members will think they need to take one of each color.

10. Offer food to get people to stop at your booth. I use Hershey's Kisses as a conversation starter. One kiss has 2 mg of calcium, and I joke that people need to eat only 500 kisses per day to get their RDA of calcium!

11. Bring enough handouts for the expected number of attendees, then pack at least 100 more. Nothing is worse than having people walk away without something that has your name on it.

12. During lulls in the traffic passing by your booth, network with the staff of other booths. Not only can they pass on your name to other event planners, but they also may be potential study subjects.

help you identify where someone is in the recruitment loop, flag those who have requested no future contact, and create suppression lists when doing mass mailings. You do not want to recontact enrolled subjects, annoy people who have already asked not to be contacted, or rescreen people you’ve already found to be ineligible. The database from one study can be used to recruit subjects for a subsequent one, although many sponsors and institutions require subjects’ permission before their demographic information can be entered into a permanent registry to be used for future studies.

Document every contact. After the first 50 telephone calls, you will not be able to remember anyone’s status in the recruitment loop. A telephone screen sheet can be easily completed at the time of the telephone call and data entered on a weekly basis. Interested individuals receive a follow-up letter and a registry form they can use to give permission to enter their names into the permanent registry. Sponsor- and IRB-approved informational postcards are an inexpensive and easy way to inform selected database members of a new research study.

At a minimum, be sure you capture information about the referral source, demographics, and the reason for ineligibility. A typical referral source may be a newspaper ad, friend, or health fair. Key demographic information includes first and last name, address, and daytime telephone number. The reason for telephone failure could be, for example, that the participant declined due to study length, had no desire to take medication, or was excluded because of protocol criteria. Again, be sure to specify which exclusion criteria, because this will help in assessing whether or not the target audience is hearing the message.

You can learn public relations and marketing skills just as you learned phlebotomy and computer skills.

Other things to consider capturing include number of contact attempts, special needs, or red flags. If it takes more than five attempts to reach an individual, or if a person leaves messages such as, “Please call me after 9 p.m.,” it is unlikely he or she will be available for study visits. People who comment that they never take pills, or that they are perfect for the study because they have such an unusual medical history, need an explanation of what a research study consists of and its goals. Although these individuals are unlikely to qualify for the study, you still need to clarify and teach, treating them with the same respect and courtesy that would be shown to a qualifying participant. They may spread the word to friends or relatives who will qualify.

In addition to your recruitment database, a project management database is useful for tracking appointment dates, adver-
Every organization practices public relations when interacting with the public. After all, the “public” includes people, other organizations, the media, and the organization’s own employees. The public relations practitioner represents his or her organization to the public and conveys the attitudes of the public back to the organization. Thus, the CRC is a natural public relations practitioner.

Marketing is the exchange between a person or organization with a product or service to offer and a person or organization that desires this product or service. In the case of a clinical trial, you are offering potential subjects the opportunity to enroll, which they may desire for any of a variety of reasons—to learn more about their own health, to fulfill an altruistic desire to help others, or because they enjoy the experience.

Learning some fundamental marketing principles will help you communicate with your audience of potential subjects, even though many marketing methods are not appropriate for research recruiting.

You can learn public relations and marketing skills just as you learned phlebotomy and computer skills. You can take public relations and marketing courses at the local university. Reading textbooks or networking with professors is a more immediate but short-term solution. Your local bookstore sells many advertising books. You can also learn about public relations and marketing from your daily life. As consumers, we are constantly bombarded with advertising messages. Start critically evaluating what captures your attention, what you like, and what you do not like. Then start thinking in terms of what will capture the attention of your target audience. An ongoing, proactive search for new advertising information is a fact of life for the recruiter. Once you’ve learned something about public relations and marketing, you can apply those principles to clinical trial recruiting.

Your institution’s resources. Consider the options available to you at no cost. Perhaps your institution has a public relations department. See if the staff will help by providing study recruitment advice, preparing a press release to inform the media, or finding networking avenues in the community.

Tap into newsletters or electronic computer communications used in your institution. Inform the editors that regulatory guidelines prohibit editing the written material you submit to them.

Sponsor- and IRB-approved flyers describing the study can be placed in your institution’s clinics and in high-traffic areas such as waiting rooms and kiosks near the cafeteria. Be sure to check first with the appropriate administrators for these areas. In the community, permission may be granted for you to place your flyers on bulletin boards, at local physicians’ and dentists’ offices, or at small businesses.

Speaking engagements and health fairs. You can use health education to structure community presentations and health fairs. Spread the word that you are available by contacting the employee health departments of local businesses and community organizations such as women’s auxiliaries and church groups. These organizations are usually looking for speakers, which provides you with an opportunity for health promotion and explanations of how your investigator’s research is finding answers for medical problems. The accompanying box, “12
Tips for Community Presentations and Health Fairs,” explains how to get the most out of these events.

Paid advertising. Medical marketing options include, but are not limited to, print advertising, radio and television spots, and direct mail marketing. If you decide, based on your understanding of the target audience for the study and the local media options, that you are ready to pay for some advertising, here are some general definitions and tips.

Newspapers. You can buy space in large cities’ daily newspapers as well as small towns’ weekly newspapers. First, make sure your audience reads the paper. Several times a year, city newspapers conduct surveys to understand their readership. They will provide you with extensive information about their readers’ ages, income ranges, and the sections of the paper they read. Because we want to connect with mature women, I place our ads in our city paper’s “Living” section, which typically has social news, features about food and entertainment, and puzzles and crosswords, or in the “Midlands” section, where the obituaries are listed.

Each day’s advertising costs are different. The mature population in our area of the country reads the paper almost every day, so we can easily run the ad on the least expensive days and not worry that we are missing our target audience. If we were recruiting young adults, I would advertise in the Sunday paper, which according to the newspaper’s research, more young adults tend to read.

Develop copy for the ad, sketch the desired layout, or produce the ad using a desktop publishing program. Obtain approvals from the sponsor and IRB. Then contact the newspaper’s advertising representative. The ad rep has the experience and talent to produce an attractive ad, usually at no extra cost. Remember that he or she does not understand the regulatory and GCP guidelines we are working under, so consider that person’s advice, but maintain control. Figure 1 shows the development of a newspaper ad.

Radio. Radio is an excellent medium for connecting with many potential participants. I contact the advertising sales person and ask about the demographics of the station’s listeners. The station has ratings reports that document who is listening and when. Taking this information into consideration is important, but you must remember to talk to your audience. During a recruitment several years ago, I set up six radio spots on the number one talk radio station in our city at a cost of $100 per spot. We received no directly measurable response from our $600 investment. During a subsequent recruitment, I decided to try radio again, this time purchasing “remnant space,” the off-peak time from 6 p.m. to 6 a.m., at a cost of $10 per spot. I had spoken with mature women, our intended audience, and found that although they did listen during the day, many of them listened to the radio at night until they fell asleep. Also, since we need less sleep as we mature, many women woke very early in the morning and chose to stay in bed, again listening to the radio. This time our $600 bought us 60 spots run over three weeks. After the first week, we began to get calls on our dedicated telephone line at 4:15 a.m.!

Television. Television is certainly an advertising option; however, its expense in most cases is prohibitive for our budgets. Television stations charge for production as well as for the 15-, 30-, and 60-second spots. Consider producing a spot and sending it to the station as a public service announcement (PSA), which would be run at no charge to you, most likely late at night.

Direct mail. In a direct mail campaign, printed postcards or letters are sent bulk mail rate to a large number of addresses. The bulk mail rate is lower than first-class postage (about half, in the case of postcards) because you, or your mailing company, are

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**Figure 2.** You can create appealing flyers like the ones at top left and middle using a page wizard in a basic desktop publishing program. Vary the look of the materials from study to study so that your audience is not confused. Devices such as the memorable telephone number in a bone-shaped font help catch readers’ attention. Reminder postcards like the one at top right are useful. Tailor your materials to the audience’s needs, like the flyer at left. Is your flyer appealing and culturally sensitive? Will you need materials in more than one language?
doing the job of presorting mail. The recipients may be people from your database who have expressed interest in previous studies. Or you can rent a list from a mailing list company. These companies collect people’s addresses and demographic information. A person’s name gets on the list if he or she enters a contest, buys a subscription to a magazine, or purchases a product from a company that sells names to the list company.

When you buy a list, you can choose names of people with a certain age, race, income level, or gender in order to target the desired audience. The more specific a list is, the more expensive it is. For example, a list of 25,000 females age 50 and over within a 100-mile radius of Omaha costs us $1200. Keep in mind that with direct mail, a 1% to 2% response rate is considered good.

You can purchase a list directly from the company or hire an advertising agency or direct mail company to obtain the list and perform all or part of the other necessary mailing services. The tasks involved with a direct mail job include obtaining the list, producing the postcard or letter, printing, production (addressing, sorting by zip code, traying, and tying the pieces), and applying postage. If you wish, you can do some of these tasks in-house and outsource others to the direct mail company. In our department, we run a cost comparison on this every year, and outsourcing wins every time.

Typically, the direct mail provider will need two days to get a count of the number of names within a desired zip code (you do not have to pay for this), three days to get the list ordered for use, three to five days for printing, and five days for production. In general, obtaining the lowest price usually requires some flexibility in the timeline. For example, if your postcard ink color is blue and Tuesday is the printer’s designated day to print blue jobs, you will get the best price by waiting until Tuesday. If you ask for a rush job, the printer must clean another color off the press, put on your color, run your job, and then clean your color off the press. Of course, the cost of the printer’s time and trouble is passed on to you. The total cost for a list, production mailing tasks, and postage for 25,000 postcards runs us about $4500.

People we contact usually wonder how we got their name. We explain that we are working with a local advertising agency and their name was part of a 25,000-piece mailing. With each 25,000-piece direct mail job, we are usually contacted by an average of 10 people who ask for no further contact or inform us that the person who received the card is deceased. We extend our sincere apology for the inconvenience or distress this may have caused and offer an explanation of how we got their name. We record this information and generate suppression lists before all future mailings so that we never contact these individuals again. If they ask how to get their name off the master list, I refer them to the direct mail company.

I have heard many coordinators say direct mail is too costly and has too low a response rate. Direct mail is not appropriate for every recruitment. Although the fundamentals have been presented here, many more details specific to a job exist, as do many

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reasons why a direct mailing might not bring the desired results. I suggest starting small, working with a direct mail company that will provide much information and support, and measuring your response critically. Visit the company’s facilities. Not only can you evaluate the company’s ability to deliver the goods, you can also get ideas for your mailing pieces by looking at other clients’ jobs in progress. A visit also lets you network with employees. Maybe they have relatives who would qualify for the study.

Word of mouth. Personal contact is a powerful recruiting tool. Always carry business cards and flyers for your studies in your handbag or briefcase. You will meet potential subjects on the elevator, in the parking lot, and at the gym.

Not only you, but also your subjects and even people ineligible for the study can provide word-of-mouth recruiting. Do not underestimate the value of every person you speak with about a study. Taking the time to introduce the fundamental concepts of research, describe a research study, and explain the results of a screening visit to the participant is never wasted time or effort. Perhaps the next research study will be a better fit. I am always amazed by the numerous and complex connections between people. I often receive telephone calls from a friend or family member of a person I rejected. One person rejected from a study left our department so satisfied with her experience that she spoke about it in the elevator to a complete stranger, who then contacted us and ultimately qualified for the study.

Invite everyone who calls or visits your office to complete a registry form. Remember, you are building a master database for future contacts. But also remember to keep your registry form short enough that people won’t mind completing it. Determine what information is important, and do not suppose that you can eliminate future rescreening.

We mail our newsletter to members of our database twice a year. This is an excellent way to remind them of us and keep addresses current.

Creating materials. Printed advertising materials can be developed on a desktop publishing computer program and submitted to the sponsor and IRB for approval. They are easily modified, as needed. Page wizards can help even the novice get started with page designs and are an inexpensive and convenient method for generating small numbers of flyers. Desktop publishing programs can be very useful. We generated holiday postcards to send to a large number of participants in a study with a very small budget.

Take advantage of advertising space where you find it. We are experimenting with short study ads placed at the bottom of our fax cover sheets. This formerly wasted space costs us nothing.

Keeping track of costs. Develop a database for tracking the advertising budget. Obtain at least three bids for outsourced work whenever possible. File the written bids, your faxes authorizing the job, and billing invoice copies in a binder for each study. Make regular reports of the advertising budget balance to the investigator. In our experience, the sponsor may authorize additional funds when progress is being made.

Evaluation
The final phase of the recruitment process is evaluation. The sponsor and investigator often focus solely on the enrollment number, but the recruiting team needs more information. The database will help you assess what is working, what is not, where you are going, and where you need to be going. A database query can give you the volume of calls and the ratio of telephone rejects to acceptances, which tells you how many calls must be generated. Another query will tell you why the callers are being rejected. The number of screening appointments can be tracked. The number of no-shows and reschedules will point to whether appointment reminder calls or cards need to be made. The screen pass-to-fail ratio will tell you what your target number of screen visits per week will need to be. The referral source for qualifiers and rejects will tell you what medium is reaching your target audience and, therefore, where to continue to spend money.

The questions that an evaluation may answer include:
• Are you reaching your target audience?
• Does your audience understand the message?
• Do you understand the barriers to reaching your audience?

By keeping abreast of these evaluations, you can keep the investigator and sponsor fully informed of recruitment progress. This information will help now and can provide a start for the next similar recruitment.

Recruitment for clinical trials is challenging. The inclusion and exclusion criteria are strict by nature, and you have no control over them. You are working with people who, even if they qualify, will make their own decisions as to whether or not to participate. Their choices are another factor over which you have no control. What you can do is accurately explain the research study, represent the investigator, and educate the public about the importance and value of medical research.

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