CHAPTER 6

RECRUITMENT AND SCREENING OF STUDY PARTICIPANTS

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Experienced investigators have long recognized the importance of well-planned recruitment and screening activities for a successful clinical study. It is surprising, therefore, that the literature in this area is so recent. Studies formally began in the 1980s with the recruitment and screening activities and procedures of the Lipid Research Clinics Coronary Primary Prevention Trial (LRC-CPPT). Prior to this time, many new investigators learned about recruiting and screening subjects either by word-of-mouth from experienced investigators or by conducting their own studies. Many actually assumed that recruitment and screening would be effortless and free of problems (1).

The LRC-CPPT study has provided a wealth of information about how to recruit and screen participants successfully for large clinical trials. Many of these approaches are applicable to smaller studies as well. An important legacy of the LRC-CPPT is that it demonstrated the importance of developing recruitment plans and screening strategies and allocating adequate resources for them. Standardized recruitment and screening procedures are now part of the protocol for many different types of clinical studies (2), including well-controlled feeding studies. This chapter discusses issues and strategies needed to meet recruitment goals.

RECRUITMENT

The major goal of recruitment is to enroll the required number of eligible participants necessary for the study within a projected time line with the resources available (3). Careful planning, a well-trained staff, good communication among the staff as well as with potential study participants, flexibility, and contingency plans are critically important. Close attention to all aspects of recruitment will help launch the research project successfully. This will help keep staff and participant morale high from the start, which is key for sustaining interest and participation throughout the study.

A detailed recruitment plan includes realistic short- and long-term goals; carefully defined recruitment strategies with consideration given to the effort required for the number of participants needed for the study; and adequate resources including funding, staff, space, and time. The eligibility criteria for participation in the study must be defined and screening procedures must be in place before the study begins. Eligibility criteria, recruitment, and screening are all linked. The success of the study depends on how effectively eligibility criteria are defined and how well recruitment and screening activities are planned and carried out.

Eligibility Criteria and Screening

The eligibility criteria are guided by the research questions and objectives and essentially define the study population. A study population can be broadly or narrowly defined based on eligibility criteria. For example, a study may be designed to examine the effects of diet on a selected outcome variable in women. Specific eligibility criteria would identify a subgroup of women on the basis of factors such as age, body weight, menopausal status, smoking status, alcohol consumption, or vitamin and mineral supplement usage. Eligibility criteria help to control for factors that may confound the interpretation of the results.

However, a general caution for investigators is that, although there is decreased variability in the study population when a larger number of eligibility criteria are used, the results are less generalizable to the general population. For example, in Protocol 1 of the Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA) study, the effects of diet on lipoprotein and hemostatic endpoints of interest were studied in healthy, adult, Caucasian and African-American men and women. In Protocol 2, subjects were dyslipidemic and/or insulin resistant. Thus, the results of the first study are generalizable to essentially the entire healthy, adult US population, whereas the results of the second study are applicable to a much smaller group, approximately 25% of adults. Both, however, address significant clinical issues that are relevant to different population groups. (See Chapter 25, ''The Multicenter Approach to Human Feeding Studies,'' for more information on the DELTA program.)

Eligibility criteria affect the resources required to screen participants adequately. Broadly defined eligibility criteria generally require fewer resources for screening than eligibility criteria that are narrowly defined. It is relatively simple to recruit potential participants for a study if the eligibility criteria are just for women of all ages. In contrast, considerably more resources (time, staff, space, and specialized equipment) are required to recruit participants for a study designed to examine the effects of an experimental diet on selected outcome variables of, for example, Native American men from one tribe, between the ages of 20 and 30 years, with body mass indexes (BMIs) of 27 to 32, a sedentary activity level, and an abnormal glucose tolerance test. More resources are needed principally because there is a smaller pool of potential participants and because many volunteers would have to be screened, measurements of BMI and physical activity would have to be obtained, and results of a laboratory test would be required. Thus, when planning a study, investigators must consider fully the resources needed to recruit and screen an adequate number of individuals to answer the research question of interest.

Sometimes eligibility is determined in a certain order during a series of screening visits. For cost-effectiveness, easily ascertained information is obtained first, like age or past history of disease, to screen out early in the process individuals who are obviously ineligible. Also, because of measurement error and regression to the mean (see Chapter 2, ''Statistical Aspects of Controlled Diet Studies''), eligibility criteria for primary outcome measures may be broader at the earlier stages of screening and narrower at the later stages to minimize excluding potential participants who are indeed eligible.

In some instances, it may become necessary to revise eligibility criteria and, in so doing, the research question may become modified. In the example of Native American men just cited, the age range and BMI of the study participants could be less restrictive; however, this may affect the research objectives. Eliminating the glucose tolerance criteria would simplify screening considerably but would also markedly change the research question.

Sometimes eligibility criteria may be redefined during the study based on the recruitment experience. For example, if recruitment difficulties are encountered (eg, an inadequate number of participants is recruited within the expected time line), it may become necessary to relax or reduce some of the exclusion criteria. Should recruitment proceed more easily than expected, then the exclusion criteria actually can become more restrictive. Both of these situations occur sometimes. In the Multiple Risk Factor Intervention Trial (MRFIT), the age criteria were more broadly defined, whereas the blood pressure criteria initially defined to classify men as hypertensive were made more exclusive simply because a greater than expected number of potential participants were found to be eligible (4).

If recruitment difficulties occur, the alternatives to redefining the eligibility criteria are to delay the starting date of the study and allocate more time and resources to recruit the required number of participants. This option, however, is not without potentially serious ramifications, such as

- Losing the interest of participants recruited early on.
- Possibly not meeting the proposed objectives of the funded research because of less funds and less time available for the implementation of the study.
- Loss of staff morale.

Commonly used eligibility criteria for many feeding studies and comments about their use are listed in Table 6–1. There are many eligibility criteria to consider. Although these may seem easy to apply in most studies, in practice considerable thought and discussion must be given to the

TABLE 6-1

Common Eligibility Criteria for Well-Controlled Feeding Studies

Inclusion/Exclusion Criteria	Comment
Demographic Criteria	
Gender	Including only one gender controls for the effects of sex; including both genders enables comparisons to be made between sexes.
Age	Narrow age criteria reduce variability but also increase recruitment efforts and reduce generalizability. Including different age groups permits determination of age effects. Chronological age may differ from biological age. For example, some women are postmenopausal at age 45; others at 55.
Race and ethnicity	Race and ethnic groups usually are heterogeneous and difficult to define. Usually obtained by self-report.
Anthropometric Criteria	
Height, weight, body mass index, adiposity, % of ideal weight	Ideal body weight is difficult to define. Strict upper-limit criteria can eliminate many potential participants especially in older age or some ethnic groups. May be appropriate to also establish lower weight limit and exclude for underweight.
Length of time stable weight has been maintained	Recent (must be defined) weight gain or loss (amount gained or lost also must be defined) may be a confounding variable.
Biochemical Criteria	
Various indexes of health status such as albumin, creatinine, liver enzymes, thyroid-stimulating hormone	Helps identify individuals with coexisting diseases and conditions who should not participate in this study.
Indexes of nutritional status such as protein, iron, calcium, zinc levels	The research question will determine the use of biochemical indexes. For example, to study the effect of iron status on heme iron absorption, hemoglobin, hematocrit, and transferrin measurements would be important for stratifying participants according to iron status or adjusting for iron status.
Plasma Lipid Concentrations	
Total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides	Cut points for dyslipidemia are used to define the study population or are based on ethical considerations to exclude dyslipidemic individuals who need treatment and should not be subjected to a control condition. Cut points can be established on the basis of percentiles (using NHANES or LRC data) or national recommendations. Using absolute value cut points will influence the age of participants who are eligible because total cholesterol and low-density lipoprotein cholesterol increase with age. A narrow range will increase recruitment efforts. A wide range permits evaluation of the effects of baseline lipids on outcome variables. Most individuals with a total cholesterol level between the 10th and 90th percentile are responsive to diet.
Dietary Criteria	
Habitual diet and eating practices	Investigators should assess whether prospective participants will adhere to the experimental diet. Food allergies and food avoidances including vegetarianism not compatible with the experimental diet are the basis for exclusion, as are other atypical eating practices. Potential participants following a prescribed therapeutic diet or other special diet (eg, for weight loss) usually are ineligible.
Nutritional supplement use	Usually an excessive nutrient supplement intake and even intake of a multivitamin supplement that meets the RDA is contraindicated if the potential participant is unwilling to discontinue use during the study.

Continued

TABLE 6-1

Inclusion/Exclusion Criteria	Comment
Dietary Criteria (continued)	
Alcohol consumption	In addition to assessing average weekly consumption, it is important to examine binge drinking habits and history of alcoholism. During the study, for participants who meet the alcohol eligibility criteria, consumption practices should not change.
Caffeine consumption	It often is necessary to permit consumption of caffeinated beverages in moderation especially for long-term feeding studies to facilitate recruitment.
Smoking Criteria	
Use of tobacco	Eligibility criteria related to tobacco products must be defined. If a potential participant is a former smoker, criteria for smoking cessation period must be defined.
Physical Activity Criteria	
Physical activity Occupational and leisure time activity	Considerations include type, intensity, frequency, and duration of physical activity. Long-term and seasonal exercise practices should be assessed to ensure that they are compatible with the study protocol.
Medical History Criteria	
History of diseases and conditions	Diseases and conditions that will adversely affect the outcome variables or adherence to the study protocol should be identified. Examples to consider include cancer, diabetes, hypertension, renal disease, major gastrointestinal diseases, and mental illness.
Medication Criteria	
Use of prescription and nonprescription drugs	Potential participants who take any medications or substances that will affect the outcome variables of the study should be excluded. Examples of commonly used medications to consider include antihypertensive and lipid-lowering drugs, oral hypoglycemic agents, antidepressive drugs, oral contraceptive agents, hormone replacement agents, antibiotics, steroidal compounds, and allergy medications. Nonprescription drugs such as aspirin antihistamines, laxatives, and antacids should be considered.
Attitude Criteria	
Willingness to adhere to the experimental diet(s) and protocol	A means of assessing willingness to participate is important. Even one participant with a poor attitude is a risk to the study. Many can become dropouts, adversely influence staff morale, or cause other participants to leave the study.
Other Criteria	
Expectation of not being away	Investigators should determine whether potential participants have plans to relocate or be away (eg, for vacation or a business trip).
Pregnancy	Because of the effects of pregnancy and lactation on the metabolism of various nutrients, it is advisable to control for these conditions. Conversely, there may be concerns related to safety of experimental regimens during pregnancy or lactation. Knowledge of exact stage of pregnancy and lactation is needed when these are specific areas of interest.

cutoff points appropriate for each criterion for every study. Sometimes the population distributions for variables of interest are not current or available, which necessitates making some decisions arbitrarily.

Despite careful attention to defining eligibility criteria, investigators should understand that study participants who meet these eligibility criteria may be different from individuals who do not volunteer for a research study (5). This is a philosophical issue of some interest, but it is not amenable to being tested, and the scientific importance of this observation is not known. Nonetheless, researchers should be aware of a possible limitation in the generalizability of their findings to groups that are similar to the study participants.

Planning and Monitoring Recruitment

Successful recruitment of a sufficient number of participants requires considerable planning. A well-defined and organized recruitment effort must include a realistic time line, including time allowed for institutional review board (IRB) approval of recruitment materials and consent form, consideration of staffing needs, an itemized budget, advertising strategies and approaches, and a monitoring system. Important considerations for each of these components of the research plan are described in this discussion.

Institutional Review Board's Role in Recruitment

Investigators must avoid any recruitment tactic that might be perceived as coercing individuals to participate in the study. The IRB must be assured no coercion is involved in recruiting study subjects. IRBs may also have oversight of the recruitment effort. Consequently, the IRB is mandated to approve all recruitment activities and advertisements that investigators propose to use in their study. At institutions where IRBs do not have this authority, the IRBs nonetheless play an important role in reviewing the planned recruitment effort to ensure that it is appropriate, highly professional, and has the utmost regard for the rights of the participants. (Also see Chapter 5, ''Ethical Considerations in Dietary Studies.'')

Time Needed for Recruitment

The time frame for achieving the recruitment goals must be clearly defined. Recruitment must be initiated far enough in advance of the study start date to elicit a response to advertising and to complete the screening activities. Estimating a realistic time frame depends on understanding factors that influence recruitment. In general, the difficulty of recruiting for a study depends on its complexity. A demanding study for which the selection criteria are restrictive requires more time and effort than less intensive studies with broadly defined eligibility criteria. Factors that affect the recruitment process include the number of participants needed, the study's inclusion and exclusion criteria, and the density of the target population in the community:

Recruitment plan considerations
Time allotment
Staff
Budget
Recruitment strategies
Recruitment monitoring

Factors that affect the rate of recruitment
Study-related issues:
- Number of participants
- Inclusion and exclusion criteria
- Density of target population in community

Participant-related issues:
- Study design and requirements
- Length of participation and time commitments
- Perceived benefits
  - Remuneration
  - Health benefits
  - Good of society and altruism

Factors that directly influence the potential participant—such as study requirements, time commitment, and compensation—also affect the ease of participant recruitment. A prudent philosophy is to overestimate the time needed for recruitment and to have a variety of strategies in place to ensure recruitment goals. Usually the amount of time estimated for meeting recruitment goals is overly optimistic. For a long-term study of dietary fat and blood cholesterol concentrations (6), 4 months were required to recruit 30 male students. One month was spent planning the recruitment strategies, making contacts, and designing the advertising campaign, and 3 months were spent recruiting participants.

Recruitment efforts for another study with a similar design did not require a long planning phase, and only 2 months were needed to recruit 30 participants. For a less complex study, 2 weeks were ample to recruit 6 participants for a small, 1-month pilot study. Personal experience will also help define the amount of time needed for recruitment.

An overly long recruitment effort can not only increase the cost of the study but also cause individuals recruited early to lose interest before the study begins. Maintaining close contact with potential participants throughout recruitment as well as staggering screening efforts are recommended so that individuals recruited early on will not have a long wait from initial contact to acceptance into or exclusion from the study.

Depending on the effectiveness of the recruitment strategies, a large initial response can be expected during the 2 to 3 days after the advertising campaign begins. The response rate should be monitored weekly, and alternative methods should be available and easily implemented if necessary to meet recruitment goals within the prescribed amount of time. Suggestions for alternative strategies are discussed later in Recruitment Strategies.

Staffing Needs

Recruitment can require a large and specialized staff. The staff must be well trained and able to maintain a professional,

friendly, and composed attitude when they interact with the potential participants. For larger studies, a recruitment coordinator is needed to organize recruitment strategies and manage staff and paperwork. Support staff may be full-time staff members of the research team whose duties are shifted during the different phases of the study. Likewise, newly hired staff can assume other responsibilities during the study after recruitment is over. Temporary personnel (eg, people to answer telephone calls) are also important.

Approximately one to one-and-a-half full-time personnel are needed to carry out a recruitment effort for a controlled feeding study with about 30 participants. For a smaller study with fewer participants or simpler eligibility requirements, one half-time position may be sufficient for recruitment activities. In addition to actual recruitment (ie, advertising and telephone or in-person contacts designed to attract potential participants), screening activities that require further gathering of information through measurements and questionnaires require additional staff time.

Budget Considerations

The costs of recruitment can be large depending on the number of people to be screened, the advertising methods used, and the number of staff needed to carry out recruitment. Estimates of costs for various recruitment methods and the associated staff hours are listed in Table 6–2 (6, 7). These estimates are based on recruitment costs in rural central Pennsylvania; however, costs vary by geographic location.

Other factors that contribute to the costs of recruitment include extra telephone lines for telephone interviews, printing costs for screening questionnaires, and laboratory analyses for biomedical screening tests. These costs can be considerable, depending on the complexity of the screening criteria. For smaller studies and studies recruiting college students, simple placement of fliers in mailboxes or small ads in the local or campus newspaper may be sufficient and are considerably less costly than recruitment activities required for larger studies or for studies requiring a diverse population.

Monitoring Recruitment

Careful record keeping is extremely important during recruitment to keep track of recruitment progress, and perhaps even more importantly, to document that the eligibility criteria are met. For small studies involving fewer than 10 subjects in which 1 person manages the entire recruitment and screening process, monitoring and record keeping can be fairly simple and performed either manually or with the use of a simple computer database or spreadsheet program. However, this task can become overwhelming when investigators are recruiting for a large study or when several categories of participants must be managed through a series of screening visits. In addition, enlisting new recruits, scheduling of telephone interviews, face-to-face appointments, laboratory tests and other measurements, and evaluating eligibility data must be effectively coordinated to efficiently use resources and meet the recruitment deadline.

During the first DELTA study, each of the four field centers had recruitment goals for African-American and Caucasian subjects in the following categories: males younger than 40 years; males older than 40 years; premenopausal females; postmenopausal females. The field centers, which often had several staff members involved in recruitment and screening, had to quickly identify and differentiate between new contacts and the participants who were going through each phase of screening. A computerized system was developed in which each new contact was assigned an identification number that was entered into a database. This database subsequently provided staff members with current information about the status of each participant. The system also facilitated monitoring the recruitment progress to identify when each category was filled (and thus recruitment for that group could end) and which category needed more intensive recruitment efforts. With recruitment monitoring and analysis of the yields for each screening step, investigators can plan how many people need to be screened and estimate when recruitment activities may be halted.

Another use of the monitoring database is in enabling the research center to maintain essential information from interested volunteers, who perhaps are ineligible for the cur-

TABLE 6-2

Recruitment Costs for Feeding Studies Conducted by the Authors (6, 7)

Strategies	Cost/Item	Total Staff Hours
Mailing (1,000 letters)	$0.60	20
Fliers (100)	$0.05	5
Telephone calls (100)	(local)	20
Recruitment meetings (10)	Staff salary	40
Ads		
Newspaper (per ad)	$25–$150	1–2
Television (15 seconds)	$50	1–2
Radio (15 seconds)	$0 (public service)	1–2

rent study but who may be eligible for future studies. The system can be adapted so that mailing and telephone lists can be generated from a list of potential participants, thus aiding recruitment for future studies.

Recruitment Strategies

The goal of recruitment is to attract potential participants into the study. Using different methods to advertise the study will facilitate recruitment. Common recruitment advertising venues include newspaper, television and radio, work sites, fliers and posters, letters, mass mailings, health fairs and community screenings, telephone solicitation, word-of-mouth, and physician referrals. The choice of recruitment methods varies with the number of participants needed, budget considerations, and participant needs. Using multiple methods to advertise the study will facilitate recruiting enough participants into the study.

In addition to having a wide-reaching distribution and high visibility, advertising enhances the study's credibility and acceptability within the target population, factors that are important determinants of volunteerism (5). The advantages and disadvantages of various recruitment methods are summarized in Table 6–3. Table 6–4 rates the effectiveness of common recruitment methods experienced by several research centers (see references 7–20 for descriptions of these studies).

Newspaper Advertising

An ad in a local newspaper is a common and effective form of recruiting participants (21). Content and location are important considerations in placing newspaper advertisements.

Advertising Content

Consider the target population and requirements of the study during advertisement design. An effective advertisement provides enough information to generate interest as well as to discourage ineligible individuals. A brief, concise description of the study should be included, as well as several key inclusion and exclusion criteria.

Exhibit 6–1 illustrates how newspaper advertisements can be used as a screening tool. The first advertisement (A) does not provide sufficient information and many ineligible individuals may call for more information, flooding the phone lines and wasting time and money. The second advertisement (B) provides some important selection criteria (ie, those for nonsmoking males, requirements for blood samples) that will screen out many ineligible individuals and those not willing to give blood. In addition, individuals interested in losing weight will not be eligible. Including in the advertising the requirement to maintain weight during the study is important in screening out a large number of persons who want to lose weight. Ad B also lists some incentives (ie, all food provided plus some financial compensation) that could encourage interested individuals to call for more information. The affiliation of the study with the local university enhances its legitimacy and may encourage potential participants to respond.

Advertising Placement

Most newspapers allow the designation of a particular section in which the ad should appear. For example, in a study targeting male college students conducted at Pennsylvania State University, ads drawing the greatest response were

TABLE 6-3

Advantages and Disadvantages of the Various Recruitment Methods

Method	Example	Advantage(s)	Disadvantage(s)
Newspaper	Large ads in specific sections. Smaller ads in classifieds	Reaches a wide audience Inexpensive (small ads)	Can be costly (large ads)
Radio and television	Public service announcements	Reaches a wide audience	Can be costly
Mass mailings	Letter describing study sent to target population. Addresses from registrar, directories, other organizational memberships	Letters can be personalized	Labor-intensive Can be costly
Flyers, posters	Posted in high visibility areas	Inexpensive	Usually insufficient when used alone
Physician referrals	Physician describes study to patient	Targeted population	Slow rate of referrals
Word-of-mouth and networking	Presentations to clubs or individuals	Inexpensive Targeted population	Yield small
Recruitment meetings	Potential participants attend informational meeting	Personal contact Large audience	Requires participant effort
Telephone solicitation	Individuals are called, study is described	Personal contact	Labor intensive

TABLE 6-4

Effectiveness of Common Recruitment Methods for Feeding Studies[1]

	Pennsylvania State University[2]	Tufts University[3]	Columbia University[4]	University of Minnesota[5]
Newspaper	1	1	—	1
Mailings	2[6]	—	1[7]	2
Word of Mouth	3	3	3	3
Flyers/Posters	4	—	2[8]	—
Radio	—	4	—	—
Other: (television, physician referrals, articles, unknown)	5	2	—	—

[1]Not all methods used by each group. Rated on a scale from 1 to 5 (Most Effective = 1; Least Effective = 5).
[2]Information provided by Vikkie Mustad, PhD; see reference 7.
[3]Information provided by Alice Lichtenstein, ScD; see references 8–14.
[4]Information provided by Maliha Siddiqui, MS, MPH, and Wahida Karmally, MS, RD, CDE; see references 15, 16.
[5]Information provided by Peggy Martini, PhD, and Joanne Slavin, PhD; see references 17–20.
[6]Letters sent to all age-eligible students.
[7]Letters to incoming medical school students were included with admission materials with letters of recommendation from the College Dean.
[8]Flyers placed in student post mailboxes and posted in communal locations.

large (5″ × 7″) copy ads located in the highly visible sports sections of the university publication. Smaller, less expensive ads placed in the classified, personal, and help wanted sections were less successful. Designating a specific section for the ad is more expensive, but an ad with low visibility can slow recruitment efforts. It may be worthwhile to discuss placement of the ad with an advertising editor.

Radio and Television Advertising

Advertising on radio and television may be the best way to target a large number of participants in a short period of time; however, it is not commonly used because of its expense. A low-cost alternative to more formal advertising is to use public service announcements on local radio or cable television stations. A major drawback to these advertisements is the limited time (less than 15-second spots) as well as lack of control over when the message is aired (ie, possibly at a time when the audience is small). Thus, radio and television may be best used in conjunction with other media promotions (ie, newspaper ads).

News Stories

An alternative and free method of advertising results from a news story, featured by the local newspaper, television station, or radio news. Nutrition and health science news topics are regular features in most local papers and some radio and television news programs. News stories that describe human research are excellent advertisements for any upcoming studies. For example, a short press release about the DELTA study evoked such interest that it led to local and national television, radio, and newspaper stories.

EXHIBIT 6-1

Sample Advertisements Used to Recruit Subjects into a Well-controlled Feeding Study

A

Healthy men needed for diet study.
Call J. Smith, 555-1212 for more information.

B

NUTRITION STUDY
– Healthy, nonsmoking men (25–50 years) needed for study of diet and blood cholesterol.

- All food provided by University's Nutrition Department.
- Must maintain weight.
- Must be able to provide blood samples.
- Some financial compensation.

For more information, call J. Smith, PhD, at 555-1212.

Newsletters

Many workplaces routinely publish an in-house newsletter or newspaper that can be an effective means of advertising the study. Professional, civic, and special-interest groups and clubs publish newsletters regularly that are distributed locally. This is a particularly good way of targeting special groups of interest for the study. Employers may also have a space on employees' pay stubs for comments or news and may allow the study to be advertised this way.

Physician Referrals

Recruitment of participants with metabolic disorders or medical conditions (eg, diabetes or hyperlipidemia) can be carried out through physicians' offices, hospitals, or clinics. Access to a patient population that can be contacted quickly can facilitate meeting recruitment goals within the projected time line. Alternatively, patients are given information about the study during a regular visit, in which case the recruitment effort will require more time. The major advantage of recruiting through referrals is the reliable identification of the target population. Another advantage is the perceived credibility of the study by potential participants because of their physicians' support of it.

To maintain the confidentiality of the medical information, investigators do not ask physicians directly to supply the names of patients. Rather the physician's office is provided, at the study's expense, with materials to send to the patients. Labor costs are also covered by the study.

Fliers and Posters

In general, fliers and posted advertisements work best to supplement other recruitment efforts. Location is an important determinant of the effectiveness of posted advertisements, and those that are seen by individuals many times per day work best to reinforce continually the need for study participants. Posters in a medical clinic or physician's waiting room generally are more effective than those posted in a storefront window. Posters hung in the workplace can reinforce the employer's support of the study. Posters should include tear-off slips with the name and phone number of the contact person.

Mass Mailings and Electronic Communications

Although the yield—that is, the number of participants randomized per hundred mailings sent—from mass mailings is low, the number of mailings is large, usually many tens of thousands. Thus, mass mailings have been found to be an effective method of recruitment, particularly in some large-scale studies (22). An advantage of advertising by mass mailings is that most of the pertinent information about the study can be included in a single letter. Mailing lists can be generated randomly, by zip code region, from employers' club registries, from state motor vehicle bureaus, and from university registrars. These lists can be used to target segments of the population. Using official letterhead for the return address also can ensure that the envelope will be opened and not considered junk mail.

A major drawback is that mailings can be fairly expensive in terms of postage and staff time. However, mailing services can be contracted to stuff envelopes and address envelopes.

Electronic mail (e-mail) and bulletin boards (Web sites) are relatively new forms of communication with promising potential for recruiting certain population groups efficiently and inexpensively. For example, all incoming students at some universities are required to have a personal computer. E-mail frequently is used by the faculty and administrators to communicate with students. Likewise, researchers can advertise a study widely using e-mail and the Internet. However, at this time individuals must have a computer to use e-mail or to access the Internet.

Future technologies, such as interactive television, will also make electronic information more accessible. Thus far, recruitment experience through electronic mail has not been widely reported.

Personal Contacts

Word-of-mouth and networking for recruitment are often adequate for acquiring participants in small studies, but larger recruitment efforts require other strategies or a combination of methods. Such strategies may also include word-of-mouth and networking. Word-of-mouth recruitment can be effective, especially if done by former participants or by those who are considering participating in an ongoing study (eg, to create a buddy system). Personal contacts with directors of local organizations tap into a pool of potential volunteers. Enlisting the aid of instructors or group leaders to make announcements prior to college or adult education classes or local meetings is another way to advertise the study. Networking with other experienced researchers also provides access to another pool of volunteers.

Recruitment Meetings

An efficient method of recruiting and simultaneously screening a large number of individuals is to hold recruitment meetings. Interested individuals are invited in the advertisement to attend one of several meetings, held at different dates and times, at which they can learn more about the study (ie, its purpose, general design, time commitments, attendance requirements, and key criteria for participation). Individuals are invited to leave at any time throughout the meeting if they are no longer interested.

At the conclusion of the meeting the attendees are given an opportunity to ask any questions in private. Interested individuals also can be given an opportunity to schedule a formal screening visit or instructed to call back if they need time to consider their participation.

The location of this meeting may be an important consideration. A neighborhood community center, church, or school auditorium may be a convenient location for studies

seeking participants within the community. For studies conducted on the Pennsylvania State University campus, holding recruitment meetings in the dining room and giving interested individuals an opportunity to tour the facility was found to be ideal. Not only did this approach allow potential participants to visualize their involvement in the study but it also eased some of their apprehensions.

Recruiting Special Populations

The National Institutes of Health (NIH) has established guidelines for the inclusion of women and minorities and their subpopulations in its funded research with human subjects (23). Updates to these guidelines are released periodically and should be reviewed before submission of any grant application. Federal funding agencies now require that all proposals and applications with human subjects must include women and minority groups to improve gender and race representation in clinical trials. Such requirements target understudied groups that are disproportionately affected by certain diseases or disorders. To comply with these guidelines, special recruitment efforts are necessary.

The initial step in recruiting special populations is to identify rich pools of potential participants. A valuable resource for identifying potential target groups is census data. Information on population census data, cross-classified by age, race, and gender, can be obtained for any county or township from the Bureau of the Census. Summary books of ''General Population and Housing Characteristics'' are prepared for each state for each decennial census by the Bureau of the Census, US Department of Commerce. This documentation is generally available in the reference section of a university library and can be requested by contacting Customer Services, Bureau of the Census, Washington DC 20233, telephone (301) 763–4100. Some states also have regional census offices.

Once target groups of interest have been identified, the most appropriate recruitment strategies can be implemented. Strategies for recruiting minorities, women, older adults, and other groups are discussed next. (Recruitment of children is discussed in Chapter 9, ''Children as Participants in Feeding Studies.'')

Minorities

One way to establish and promote multiethnic contacts is to develop and maintain ongoing relationships with minority organizations and professional associations at the worksite and within the community. Enlisting the aid of churches and networking through church programs are effective ways in which to recruit minorities in the community. Effective presentation programs concentrated within these organizations also can initiate positive word-of-mouth publicity.

A key factor in recruiting minority populations is having a liaison or recruiters of similar ethnicity and socioeconomic background to allay concerns about cultural or ethnic bias. If necessary, special bicultural and bilingual liaisons and recruiters should be hired. In special cases, it may be necessary for the liaison or recruiter to make personal contact in the families' homes for successful recruitment. Such an approach may be especially helpful in Hispanic communities, in which the support of the male head of household may be the major determinant for participation of family members in research studies.

Women

Women within the community can be targeted through service organizations, religious institutions, parent-teacher associations, women's organizations and volunteer clubs, and health clubs. College women can be targeted through sororities, women's dormitories, or through other programs (eg, nursing, dietetics) that enroll a large proportion of women. Pregnant and lactating women can be targeted through obstetricians' offices; Lamaze classes; La Leche groups; or government-sponsored Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) programs. Women with children living at home are more difficult to recruit because of family and household responsibilities. Similar difficulties are also encountered with older women whose husbands are retired and at home.

Women with career responsibilities can be difficult to recruit because of time constraints. Programs that minimize the time imposed on these potential participants are most effective. For example, women may be more interested in studies that provide incentives designed to save time (eg, precooked meals that are delivered and research sites providing child care services). In the DELTA study, some women did not want to participate in the study if their significant other was not also eligible. In some instances, meals have been provided for spouses and children when difficulties were encountered in recruiting women.

Older Adults

Recruitment of older individuals for research can be a difficult task. Poor health, mental confusion, fatigue, sensory impairment, and lack of transportation are problems commonly encountered (24). Although these obstacles can be overcome to some extent if a rich pool of healthy older individuals has been identified, a substantially larger number of interested potential participants may be required to yield one participant who meets the eligibility criteria and is enrolled in the study.

Individuals who do not perceive a direct health benefit from participation are less motivated to participate in the study (Mustad and Kris-Etherton, unpublished observation). Additionally, attrition due to illness means that more older individuals must be recruited into longer-term studies in order to ensure adequate sample size (25).

A personalized approach to recruitment has been shown to be effective with older individuals (25). Personal letters sent to retired individuals (eg, mailing lists obtained from university or employer's records or from the American As-

sociation for Retired Persons) also have been used effectively to recruit older individuals for studies. Letters and newsletter articles that describe the study and its staff in particular, with pictures if possible, also are ideal for this population (26).

A personal presentation conducted by a staff member to groups of older individuals is a popular recruitment strategy at senior centers, community meal sites, churches, and retirement residence communities (27). The recruiter should have experience dealing with older adults because personal contact and extensive interviews will be helpful in alleviating fears and concerns about any adverse health effects of the study. Older individuals need time to think about participating in the study without feeling pressured. Close contact between the staff and participant during the recruitment and screening is essential to successful recruitment of older individuals.

Patients

Research with individuals who have medical conditions or metabolic abnormalities (eg, diabetes, hypercholesterolemia, or arthritis) can present special recruitment problems. Identification of these groups can be simplified by recruiting through physicians' offices or medical clinics (see the earlier discussion under Physician Referrals) or patient support groups. National registries (eg, cancer registries) also can be used to identify individuals with a specific or rare condition. A recruitment effort that is combined with free medical screening (eg, cholesterol assessment at the local mall) is also a way to identify these individuals, but must be done in ways that avoid coercion. (See Chapter 5, ''Ethical Considerations in Dietary Studies.'')

Other Considerations

Factors that Motivate Individuals to Participate in Feeding Studies

Understanding the factors that motivate individuals to participate in feeding studies will facilitate choosing appropriate recruitment strategies. Sounder (25) provides a detailed report of motivators of older individuals gathered during several years of recruiting subjects for aging and dementia studies. Sounder found that motivators were: altruism (opportunity to help others), need for personal contact, curiosity of a novel experience, hope for a personal health benefit, and interest in scientific involvement. Our experience in conducting studies of diet and heart disease risk factors suggests that most younger (<40 years) participants are motivated by financial reasons (free food, reduced grocery bills, financial compensation) and the convenience of having food prepared and served. Middle-aged and older people appear to be less motivated by the financial benefits of study participation but have a greater interest in personal health benefits and their own results. Participation in studies that have no obvious or immediate health benefit in this group may require more intensive approaches to recruitment.

Modifying Recruitment Efforts

Recruitment progress should be monitored in a timely fashion (eg, weekly), and when recruitment goals are not met, alternative recruitment strategies must be implemented. Different advertising strategies or multiple strategies should be used. Modification of the exclusion criteria (eg, age restrictions) may be considered to expand the participant pool; however, this should be done so as not to compromise the study's research question. Another strategy is to offer incentives to encourage individuals to participate in recruitment (see the discussion under Incentives). A final option is to extend the recruitment period; however, this should be considered last because it could increase study costs, inconvenience participants already recruited, and compromise staff morale.

In multicenter studies, one center that has been more successful with recruitment can make up for a recruitment shortage at another center. However, it is important for the final distribution of all study populations to be evenly divided among the field centers to eliminate possible geographical bias.

Incentives

Incentives are used to stimulate interest in the study and to encourage potential participants to participate in the screening activities. Examples of appropriate incentives include blood test results, diet assessments, medical exams, coffee mugs, T-shirts, calendars, movie tickets, and gift certificates. Incentives should not be so attractive that they give the impression of coercion; they are only offered to encourage individuals to participate in screening. Moreover, they should not be inappropriately generous prior to study enrollment such that individuals go through screening but have no intention of becoming a participant in the study. Also, IRBs often assess the appropriateness of incentives as part of their human subjects review of research protocols.

Incentives can be useful to encourage individuals to participate in recruitment and screening activities during the initial phases of the study. The most cost-effective incentives are those that are combined with the screening process. Incentives also can be offered to encourage enrolled participants to recruit other potential participants. These incentives can include small monetary incentives in addition to those already mentioned. Any incentives that are provided for participant screening should be appropriate and offered to promote genuine interest in the study.

''Professional'' or Repeat Volunteers

Some individuals keep volunteering for many studies because of financial incentives, social reasons, concern about their health, a strong sense of altruism, or other reasons. Investigators should consider whether potential participants' prior enrollment in other studies would compromise the results of the proposed investigation. As a matter of routine, investigators should ask recruits about prior participation in research studies.

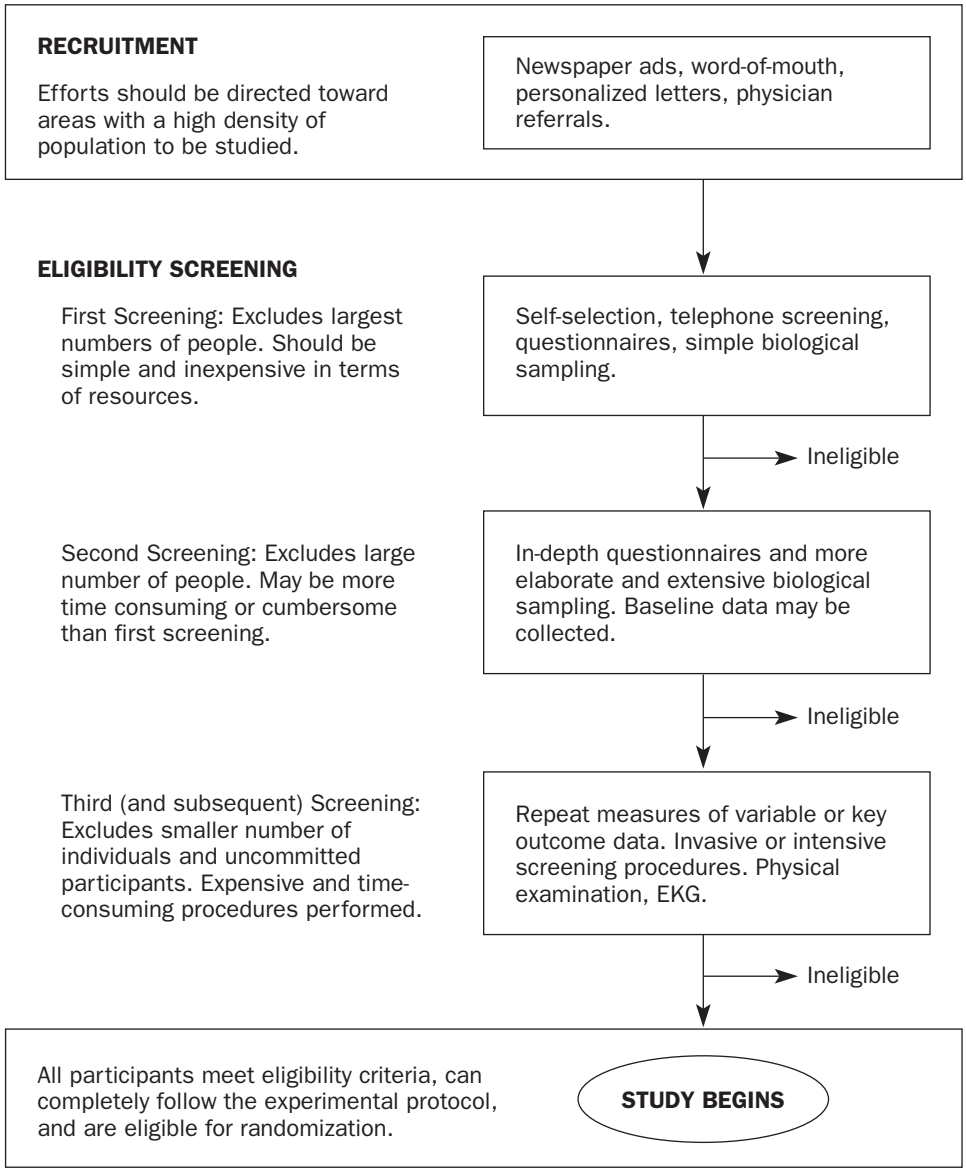

FIGURE 6-1. Recruitment and screening flowchart.

SCREENING

The goal of screening is to recruit the best possible participants into the study. Although this activity can require considerable time and effort, it is well worth the investment because participant retention is enhanced. Experienced staff frequently can identify individuals who likely will not complete the study or adhere to the study protocol. This will reduce the participant dropout rate, enhance compliance, and improve the research environment for participants and staff.

The screening process must be carefully planned. Information is collected during screening not only to establish the eligibility of potential participants and assess (often subjectively) their ability to adhere to all aspects of the study protocol, but also to collect baseline data as well as other data of interest. Enthusiastic and inexperienced investigators may attempt to collect too much data at this time. This can be a disincentive for potential participants to participate in the study, can unnecessarily increase the workload of the staff, and can waste time and resources.

A general rule is to collect only data that will be analyzed or used. Experienced investigators appreciate that some data may be important for interpreting the results of the study or planning future research directions. Therefore, data should be collected prudently.

Screening Visits

Most typically, screening proceeds in a step-wise fashion (Figure 6–1). The eligibility criteria will, in practice, be used to screen potential participants. Many interested individuals will be screened out simply because they do not meet the eligibility criteria listed in the recruitment materials and advertisements. For potential participants who meet the initial

screening criteria, further screening then can be scheduled. Initial screening may involve a telephone interview or rapid collection of various simple laboratory measurements, such as a blood total cholesterol level, hemoglobin level, blood pressure, or a brief dietary assessment about dietary intake and food practices.

Some of these measurements can be made at a health fair, in a shopping mall, or supermarket. Another initial screening approach can be carried out in a primary health care provider's office followed by the referral of a potential participant to the study staff. This referral is based on the eligibility criteria and information from the patient's chart.

In some instances initial screening can be done without directly contacting the potential participant. If the first screening contact is a telephone interview, an interested potential participant could subsequently receive various forms in the mail to complete and return. Forms that might be given to a potential participant in this manner are a food record, physical activity record, family history questionnaire, and body weight log. This information then could be mailed to the investigator or hand-delivered at the next screening visit or other scheduled visit. Thus, this early stage of screening actually often requires little contact between screenee and staff.

The next screening visit involves more intensive or invasive data collection. A potential participant may have height, weight, skinfold thickness, and blood pressure measurements taken, and blood may be collected. Some measurements made earlier may be repeated and verified. Information about a potential participant's diet is often collected during screening. In addition to the 24-hour dietary recall—which can be obtained by a telephone interview—or a food record, information should be collected about food patterns and behaviors (eg, whether they are atypical or inappropriate for participation in the study, and whether they are highly variable), and food avoidances. Potential participants can be shown menus of the experimental diet to assess whether they think they can follow it.

Whenever possible, more than one screening visit should be required so that major variables that determine eligibility—especially if those variables are also primary endpoints of the study—can be thoroughly assessed. For example, a second visit for repeat blood cholesterol or blood pressure measurement would be used to establish the accuracy of the first measurement, especially if eligibility criteria define the limits for blood cholesterol or blood pressure levels of the study participants. Because of regression to the mean (see Chapter 2, ''Statistical Aspects of Controlled Diet Studies'') the extra effort to obtain at least a second measurement will result in a higher likelihood that the study participants are truly within the range of eligibility limits when the study begins. Sometimes biological samples that are collected at this second visit (eg, blood and urine) are analyzed at a later time for certain parameters should the potential participant meet all other eligibility criteria. This reduces assay costs and simplifies screening efforts.

A third screening is frequently required. For many parameters, it is necessary to collect more than 2 repeated measurements. For example, at least 3 blood pressure measurements are required to diagnose hypertension and 3 triglyceride measurements are recommended to diagnose hypertriglyceridemia. If there is considerable variation in these 3 measurements, another might be warranted. Another reason for a third screening visit is to carry out more sophisticated measurements. Examples include hormone measurements, lipoprotein analyses, and body composition determinations from hydrostatic weighing.

Finally, more extensive screening procedures, if needed, can be done. These might include a complete medical exam, a treadmill test, various invasive procedures such as a cardiac catheterization, a sigmoidoscopy, or a tissue biopsy. During this visit, potential participants may be interviewed by a behavioral scientist or asked to complete a personality assessment questionnaire to determine their suitability for participating in the study. Because of the time required and cost of these more extensive procedures, they are only done if necessary and only during the latter stages of screening after the majority of ineligible individuals have been already screened out—usually just before the study begins.

Eligibility Criteria Issues During Screening

To avoid confusion and minimize wasted effort during the screening process, clear cut criteria regarding medical issues should be detailed prior to the initiation of the screening process. These criteria are usually formalized in the consent form and reviewed and approved by the institutional review board (IRB). (Also see Chapter 5, ''Ethical Considerations in Dietary Studies.'')

Every effort should be made to be as specific as possible in order to anticipate as many permutations or individual scenarios as possible. However, it is inevitable that gray areas will arise. Whereas use of medications may be the basis for exclusion, questions always arise about allergy medications, aspirin, and antacids. If a volunteer is identified as having an elevated thyroid-stimulating hormone level during screening and thyroid hormone replacement is initiated, investigators must decide whether the volunteer is still eligible to participate in the study. The medical officer for the study can review individual situations and make decisions about the suitability of a potential participant for a particular study.

Frequently during screening some persons are identified with high levels of blood pressure, blood glucose, or plasma cholesterol. These individuals should be referred to their physician. In addition to ensuring that a referral procedure is in place and followed, investigators must assume responsibility for the safety of potential subjects during screening. Those who require immediate medical attention must be informed immediately of their condition. A listing of medical clinics in the surrounding area could be made available to individuals who do not have a personal physician, medical insurance, or adequate resources for medical care.

Common strategies for collecting screening information are described in Table 6–5. Although not inclusive, the table provides a representative listing of frequently collected screening data. Methods used to collect this information also are presented. Several screening instruments used for different feeding studies conducted by the authors are included in Exhibits 6–2 through 6–4.

It is critical during the screening process to assess the ability of the potential volunteer to understand and follow directions. This is particularly important for outpatient studies that require specimen collections, reporting to the study center in the fasted state at certain intervals, or the use of some type of self-administered supplements. An individual's response to the screening process is a valuable way to assess important qualities for compliance with the experimental protocol. These include adherence to all aspects of the screening protocol, for example, attending all scheduled sessions, being prepared as required, completing all assessments, and having a positive attitude.

Usually, if potential participants do not carry out their responsibilities related to the screening process, it is unlikely they will comply with all aspects of the study protocol. Therefore, noncompliance during the screening process can be the basis for excluding an individual from the study.

Estimating Screening Pool Size

As discussed throughout this chapter, the major determinant of the difficulty or ease of recruiting subjects depends on the number of participants needed, the restrictiveness of the eligibility criteria, and the participant burden based on the complexity of the study. Table 6–6 shows response, screening, and recruitment yields for well-controlled diet studies having different participant characteristics and study designs.

For example, the studies conducted at Pennsylvania State University (7), Tufts University (8–14), and Columbia University (15, 16) focused primarily on effects of dietary fatty acids and cholesterol on plasma lipids and lipoproteins and required that free-living participants consume prepared diets in a metabolic study setting. The examples from University of Minnesota are from studies in which participants repeatedly self-selected experimental diets and were instructed to incorporate daily fiber and flax seed supplements (17–20).

The number of respondents that is encountered during the recruitment period is greatly influenced by the overall participant burden based on the study requirements as well as by the methods used to advertise the study. The data included in Table 6–6 give a general overview of the effort involved in recruiting participants for different studies. As Table 6–6 illustrates, younger men and medical students of both sexes appear to be relatively easier to recruit into feeding studies (~2–3 respondents screened for each participant randomized into the study) than either younger women (9 screened: 1 randomized) or healthy middle-aged and older men and women (~6–22 screened: 1 randomized). The latter groups often require a larger number of initial respondents in order to meet the recruitment goals, usually as a result of

TABLE 6-5

Strategies for Collecting Screening Information

Criteria	Methods
Demographics	• Questionnaire, self-administered, or interviewer-administered
Anthropometrics	• Direct measurement • Obtained from participant's medical record • Self-reported with or without interviewer assistance
Biochemical data	• Direct measurement • Obtained from participant's medical records
Diet	• Multiple 24-hour recalls • Food records • Food frequency questionnaire (self- or interviewer-administered) to query about supplement use, food allergies and avoidances, special dietary practices and needs, and alcohol and caffeine consumption practices • Ask prospective participant to review test diet menus to assess willingness to adhere to the controlled diet
Smoking habits	• Questionnaire including information about active and passive exposure • Saliva or blood for cotinine or breath CO_2 to verify questionnaire
Physical activity	• Questionnaire • Activity monitoring device
Medical history	• Questionnaire • Participant's medical record
Attitude	• Interview • Follow-through on screening protocol

EXHIBIT 6-2

Medical Questionnaire[1]

Name: _____

Address: _____

_____

_____

Phone number (Daytime): _____ (Evening): _____

Date of Birth: _____ Age: _____

Smoking:

Do you smoke cigarettes at present? Yes ( ) No ( )

Did you quit in the last year? Yes ( ) No ( )

If yes, how many cigarettes did you smoke per day? _____

Alcohol:

Do you drink alcoholic beverages? Yes ( ) No ( )

If ''yes,'' which of the following do you drink?

Beer _____ Wine _____ Mixed drinks _____

How much do you drink in one week?

Beer _____ Wine _____ Mixed drinks _____

Medications:

Are you currently taking any medications or treatments? Yes ( ) No ( )

If ''yes,'' list all below:

_____

_____

_____

Medical Problems:

Do you have, or have you had, any of the following? Please indicate the dates, frequency, and seriousness of the condition.

	Yes	No	Dates/Frequency/Seriousness
Nausea	_____	_____	_____
Vomiting	_____	_____	_____
Diarrhea	_____	_____	_____
Constipation	_____	_____	_____
Ulcer-peptic	_____	_____	_____
Irritable Bowel Syndrome	_____	_____	_____
Colitis	_____	_____	_____

Other medical conditions (such as high blood pressure or diabetes):

_____

_____

_____

Continued

EXHIBIT 6-2 *(continued)*

Family History:

Please indicate if any of the following family members has or had a history of heart disease, high blood pressure, hyperlipidemia, overweight, stroke, diabetes, liver disease, etc:

	Living		Deceased	
Relationship	**Age**	**Ailments**	**Age**	**Ailments**
Paternal Grandfather				
Paternal Grandmother				
Maternal Grandfather				
Maternal Grandmother				
Father				
Mother				
Brothers				
Sisters				

[1]This form can be used as a screening form and set up to exclude potential subjects if they do not meet the established medical history criteria. In addition, it can be set up to collect screening data.

a greater number of exclusions because of confounding comorbidities.

In general, the greatest number of potential participants is excluded during the initial screening phase. Exclusion during this phase is often through the participant not meeting the major eligibility criteria or through participant self-exclusion, either because of the study's restrictions and other conflicts, or aversion to the study's protocol (eg, blood draws, fecal collections). Of those who pass through the initial screening visits, subsequent exclusion of potential participants is usually the result of failure to pass the eligibility criteria measured at the last screening visit, which tend to be more invasive or have time-consuming measurements.

Specific Issues in Selecting Participants for Feeding Studies

Study Disclosure

For the protection of human subjects, IRBs require that informed consent be obtained prior to participation in any aspect of screening. As discussed in Chapter 5, ''Ethical Considerations in Dietary Studies,'' it is essential for the potential participant to understand fully what is expected during screening, as well as during the study. Adequate time and resources must be allocated to this aspect of the study. Screening activities can be useful in helping potential participants understand their responsibilities during the study. Full disclosure of the benefits of the study revealed during screening include incentives to participate as well as the realities of participation (eg, inconveniences, boredom with the diet, potential risks).

Psychosocial Factors

Habitual Lifestyle

Involvement in a feeding study will necessarily interfere with participants' habitual lifestyle relative to food preparation and eating behavior. In addition to collecting information about a potential participant's habitual diet, investigators also should collect information about food practices and behavior. This can be done during an interview with a screenee or by a questionnaire that is either interviewer- or self-administered. Examples of questions that are typically asked are as follows:

- Do potential participants usually eat at home or out?
- If they dine at home, do they eat with other members of the household?
- Are potential participants the main food preparers at home? If so, how will study participation influence the rest of the household unit?
- Has participation in the study been addressed with other members of the household?
- If the potential participants usually eat out, does this involve other people? Would the pattern of social interaction and support system be altered by the lack of this activity? Is there a substitute activity for social interaction?

EXHIBIT 6-3

Nutrition History[1]

Name: _____ Today's Date: _____

Measured Height: _____ Measured Weight: _____

Have you recently gained or lost weight: Yes ( ) No ( )
If yes, how much? _____ gained ( ) lost ( )

How long have you been at your present weight? _____

Do you follow any strict restriction in your diet? Yes ( ) No ( )
If yes, list what they are: _____

Do you have any food dislikes? Yes ( ) No ( ) (Examples: fish, vegetables, beans, etc)

_____

Do you have any food intolerances? Yes ( ) No ( ) (Examples: milk, spices, etc)

_____

Do you have any food allergies? Yes ( ) No ( ) (Examples: wheat, shellfish, milk, berries, nuts, etc)

_____

Do you take any vitamins or nutritional supplements? Yes ( ) No ( )

If yes, what kind, and how often? _____

Do you have any problems chewing or swallowing? Yes ( ) No ( )

Are your bowels (check one): Normal ( ) Constipated ( ) Diarrhetic ( )

Do you eat regularly? Yes ( ) No ( )

How many meals a day do you eat? _____

Where are most of your meals prepared? _____

How often do you eat in restaurants? _____

Do you think your diet is nutritionally well-balanced? _____

[1]This form can be used as a screening form and set up to exclude potential subjects if they do not meet the established nutrition history criteria. In addition, it can be set up to collect screening data.

A similar, but more intensive evaluation needs to be made if the protocol involves an inpatient feeding protocol.

Interaction Patterns with Staff and Other Participants

Protocols that involve extensive staff interaction are, for example, studies that involve inpatient protocols, frequent study-related visits, or overnight stays. Important points on which to evaluate the subject include the ability to adapt to small changes in the routine or in personnel, any tendency to be manipulative of rules, or evidence of attempts to manipulate or be divisive of staff.

Protocols that involve extensive participant interaction would be, for example, those that involve sharing one or more common meals. A participant who has a tendency to complain about the screening process, especially to other potential participants, may continue to complain and create problems during the study.

Food- and Diet-Related Issues

Food Preferences

In most well-controlled feeding studies there are essentially no food choices. When potential participants review the test diet menus and express concern about the inclusion of specific foods categories or food allergies, subsequent problems are likely. Thus, it is important to identify these problems early in the screening phase. The degree to which the study protocol can allow substitutions must be predetermined and the potential participant must understand these boundaries. Numerous requests for minor changes may be an important predictor of future problems.

Habitual Dietary Practices and Patterns

A comprehensive screening process should include a discussion of various dietary practices and patterns that involve restriction of foods and food combinations entirely or during

EXHIBIT 6-4

Physical Activity Questionnaire[1]

1. Do you train for a competitive sport(s)?

   _____Yes
   _____No

2. If you live greater than ½ mile from campus, do you regularly bike or walk?

   _____Yes
   _____No

3. List physical activities you regularly engage in.

   Type of Activity: _____

   Frequency: Number of times per week or month you engage in the activity: _____
   Duration: How long do you engage in the activity (in minutes or hours)? _____
   Intensity:

   _____Low (slow movement with occasional breaks)
   _____Moderate (brisk, steady movement)
   _____High (rapid, continuous movement)

   How long has this physical exercise been a part of your normal routine (ie, weeks, months, years)? _____

   Type of Activity: _____

   Frequency: Number of times per week or month you engage in the activity: _____
   Duration: How long do you engage in the activity (in minutes or hours)? _____
   Intensity:

   _____Low (slow movement with occasional breaks)
   _____Moderate (brisk, steady movement)
   _____High (rapid, continuous movement)

   How long has this physical exercise been a part of your normal routine (ie, weeks, months, years)? _____

   COMMENTS:

[1]This form can be used as a screening form and set up to exclude potential subjects if they do not meet the established physical activity history criteria. In addition, it can be set up to collect screening data.

certain periods. This includes religious practices. The ability to participate in a study depends on the specific issues raised.

Facilities at Home for Storing and Heating Food

Requirements for safe storage and warming of the participant's packed meals at home should be discussed. The ability to understand food storage safety should be one of the selection criteria for participants, and adequate refrigeration space at their home is fundamental to this issue.

Accommodating Special Needs

Long-term feeding studies that require subjects to commit to the protocol for extended periods of time must address the reality that subjects will have conflicts that may interfere with the study's protocol. Occasional work-related travel, schedule conflicts, transportation problems, and family responsibilities are common situations that may interfere with the complete adherence of an otherwise outstanding participant.

If the conflict does not interfere with the study protocol, important questions to ask are: How much effort is required? and, How much can be spent accommodating special needs? Data from subjects who have participated in the study for a long period of time are especially valuable, as are those in a group with a small number of participants. In some studies, meals for an ineligible spouse have been provided in order to collect data from a participant who would not participate

TABLE 6-6

Screening and Enrollment Rates for Well-Controlled Feeding Studies with Different Designs and Populations[1]

	Pennsylvania State University[2]	Tufts University[3]			Columbia University[4]	University of Minnesota[5]	
	Healthy Men (21–35 yr)	Healthy Men (≥40 yr) and Postmenopausal Women[6]			Male & Female Medical Students (~25–30 yr)	Healthy Young Women	Healthy Young Men
Length of entire study	14 wk	30 wk	30 wk	55 wk	27 wk	7 mo	9 wk
Number of individuals:							
Initial response	350	666	578	220	150	NA[7]	NA
Screened	125	203	315	114	90	200	40
Randomized into study	51	17	14	19	39	23	20
Screened: Randomized ratio	3:1	12:1	22:1	6:1	3:1	9:1	2:1
Time for recruitment and screening	8 wk	4–6 wk			4–6 wk	4–6 wk	

[1]For methods of recruitment, see Table 6–5.
[2]Information provided by Vikkie Mustad, PhD; see reference 7.
[3]Information provided by Alice Lichtenstein, ScD; see references 8–14.
[4]Information provided by Maliha Siddiqui, MS, MPH, and Wahida Karmally, MS, RD; see references 15, 16.
[5]Information provided by Peggy Martini, PhD, and Joanne Slavin, PhD; see references 17–20.
[6]Data reported for 3 different studies using a similar participant population for 30 or 55 weeks.
[7]NA = not available.

alone. Studies also have provided reimbursement for parking and transportation for participants who could or would not participate otherwise.

The ramifications of each special request must be considered carefully in terms of how it affects other participants' expectations and additional requests to accommodate special needs. Sometimes it is not possible to accommodate the special needs of participants. The expense, time, and inconvenience incurred to accommodate any special need must be balanced by extra time needed for recruitment and screening of additional participants.

Pilot Studies

Once the recruitment and screening procedures have been developed, they then can be pilot-tested and ''debugged.'' Even for small studies, a pilot study to test recruitment and screening procedures can help to identify and resolve potentially significant problems before the actual study begins. A pilot study also is an efficient and effective staff training activity that helps prepare competent and experienced members of the research team. A pilot study, therefore, enables investigators to assess the adequacy of the recruitment plan, revise it as indicated, and train staff to conduct recruitment and screening activities. It is well worth the time and effort, even if conducted on a small scale, to ensure that the study can begin on schedule.

Pilot studies sometimes are conducted to demonstrate to a funding agency that the investigative team can recruit the study population described in a grant application. These pilot data provide convincing evidence that the research question and protocol will be carried out as planned and not modified because of an inability to recruit the proposed populations.

Conclusion

This chapter describes important components of recruitment strategies and screening procedures for well-controlled feeding studies. The scope of the recruitment and screening effort depends principally on the sample size and complexity of the study, which in turn depend on the research question.

It is important that eligibility criteria be defined carefully. Screening is essential for determining potential participants' suitability for a study. This process includes establishing whether they meet the eligibility criteria and also whether they are likely to comply with the experimental protocol. Screening usually is conducted in a series of visits, and increasingly more comprehensive procedures are conducted in the later stages.

It is important for investigators to advertise the study effectively so that the recruitment goals are met. Using different methods to advertise the study will facilitate recruiting enough subjects into the study. The choice of advertising strategies depends on many factors, including number of subjects needed, size of the eligible participant pool, requirements of the study, budget, and other factors. Researchers should also develop a contingency plan in case initial strategies do not yield enough recruits.

A well-thought-out plan is essential to avoid recruitment shortfalls, reduce recruitment costs, and prevent cost and time overruns. A realistic time line, an adequate and well-managed staff, and an appropriate budget that can accom-

modate unexpected events and problems are necessary to plan a good recruitment effort that can be implemented successfully.

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