

An efficient recruitment effort occurs when one of the investigators has ready access to a clinical population by virtue of his position, e.g., staff member in an inpatient or an outpatient setting. When subjects are recruited from a site where an investigator has a clinical role, an additional advantage is that patients and staff are all ready familiar with the investigator. Patients may feel more comfortable volunteering for the study, and staff in the clinical area will assist with successful recruitment efforts.

A similar recruitment strategy is to negotiate for subjects with a private practice or managed care organization which has a large volume of patients eligible for study inclusion. This strategy was extremely useful in the stroke study described above. One of the investigators enlisted the interest of the medical director of a large health maintenance organization (HMO). He required that the investigator present details of the study to the HMO's research committee. Upon approval of the research committee, a letter was generated and co-signed by the investigator and the medical director, and sent to all patients with a diagnosis of stroke from the HMO database. This letter briefly explained the study and invited the patients to contact the study recruiter for additional information. Several subjects were recruited in this fashion, however recruitment efforts and the overall working relationship with this organization would have been stronger if a collaborator from the HMO was sought at the time of inception of the study.

Other low cost recruitment strategies include: placing posters and brochures in key locations, such as bulletin boards, cafeteria table tops, and physician offices; sending informational letters, along with patient brochures, to physicians who may serve as a referral source; screening activities and giving presentations to patient groups, such as senior centers, senior housing facilities, clubs, and public businesses.¹⁰ It is the experience of this author that direct mail to physicians does not yield many patient referrals for the study unless a physician is involved in the study as a co-investigator or consultant. Furthermore, when requesting permission to give a presentation to a patient group, it is appropriate to provide an educational session for patients/families, while also providing information about

the study for the purpose of recruitment.

Costly recruitment strategies include the use of the media, specifically newspaper and radio advertisements. These are typically successful methods of recruitment, however they must be planned in advance so that funds are allocated. Specialty newspapers, such as newspapers for senior citizens, often contain advertisement space at a lower cost. These newspapers may also allow the investigator to write an educational article about the specific health care issue, and will print the article next to the recruitment ad.

Subject Retention

Since clinical trials evaluate the efficacy of an intervention, they are characterized by a prospective design in which subjects are followed over time. Depending on the length of the intervention and any follow-up period, subject attrition may be an issue. As described by Given et al.,¹¹ attrition occurs when subjects fail to complete the study following enrollment. Since the internal validity of an experimental design may be jeopardized, efforts must be made to minimize attrition.

First and foremost, the character of the staff in a clinical trial will influence the retention of subjects. Subjects may interact with multiple staff members in clinical trials, such as the investigators, recruiters, individuals responsible for implementing the intervention, and individuals responsible for measuring the outcome variables. Therefore, it is critical that all staff members represent the study with enthusiasm and honesty, reflect knowledge and the importance of the study, have a warm demeanor with a genuine concern for others, and demonstrate excellent communication skills.¹¹

Ongoing communication with subjects is key to retention. Depending on the length of the intervention and follow-up period, along with the length of the interval between subject visits, it may be wise to incorporate periodic phone calls, e-mail, letters, or newsletters. These strategies will help to maintain subject interest; phone calls will potentially alert the staff to compliance-related or other problems. Reminder phone calls should be made prior to scheduled appointments. In general, subjects should always feel "connected" to the study, and know that they have access to staff members when necessary. Phone calls from subjects must be re-