Recruitment and Retention in Clinical Research

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• Nursing • Recruitment • Retention
• Clinical research • Databases

Recruitment and retention of participants in clinical research is a process, not an event. Recruitment and retention can either ''make or break'' the success of a research study. Recruitment and retention strategies go ''hand in glove'' with one another and should be considered one of the most vital aspects of the day-to-day conduct of clinical research. Successful recruitment and retention strategies guide the enrollment of the very first research participant and ultimately lead to the final number of total research participants secured. Successful strategies result in adequate statistical power leading to firm study conclusions. Unsuccessful strategies can increase day-to-day costs of clinical research, limit study efficiency, and ultimately threaten the internal and external validity of study results.

Recruitment is defined as the process of identifying and enrolling volunteers for participation in a research study. Retention is the ability to maintain individual participation throughout the duration of the research study. Recruitment and retention are enormously vital aspects of clinical research. This article reviews the process of identifying and enrolling participants for recruitment; describes regulatory requirements influencing subject recruitment; discusses special considerations in the recruitment of children, minorities, and at risk individuals; describes the process of participant retention; describes the utility of tracking databases; and explores clinical nursing roles and responsibilities in recruitment and retention in clinical research.

PROCESS FOR IDENTIFYING AND ENROLLING PARTICIPANTS FOR RECRUITMENT

As stated earlier, recruitment is defined as the process of identifying and enrolling volunteers for participation in a research study. The emphasis in the definition of recruitment is on ''process.''

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Identifying Volunteers

The process of identifying volunteers for participation in research starts with thinking out loud in constructing the research proposal. Investigators must have basic information about the target population. Details such as the type of participant needed for the study must be specified. These details include, but are not limited to, the age, gender, type of characteristic or condition (eg, preoperative, postoperative, post hospitalization), disease (eg, cancer, heart disease, diabetes, stroke, hypertension, osteoporosis), health problem (eg, pain, sleep disturbance, nutritional deficit), and relationship (eg, patient, caregiver, parent, sibling) of participants. The greater the specificity an investigator has in delineating the characteristics of the target population, the better the process of identifying potential participants for the study.

Once the details of the target population are specified, the next step in identifying the target population is adding details about study eligibility, including inclusion and exclusion criteria and racial and ethnic diversity. For example, let us take the variable of age as an inclusion or exclusion criteria. Age must be specified with explicit rationale for such a decision. If the target population is older women with diabetes and heart disease, the age of the older women must be defined. Is older age defined as 55 years and older with an upper limit or age 55 years and older with no upper limit? Is older age defined based on Medicare criteria of 65 years and older? Defining the variable of age makes a huge difference in identifying participants.

Enrolling Volunteers

The second part of recruitment is the process of enrolling volunteers. This process is highly detailed and includes the following steps: (1) determining how many participants are available for recruitment, (2) determining a viable recruitment plan, (3) using levels of screening for participation, (4) exploring barriers to participant enrollment, (5) examining factors that contribute to likely enrollment, and (6) finding potential participants through various advertising methods. Unfortunately, investigators have traditionally been cavalier in overprojecting the number of participants available for enrollment. An overly zealous and mistaken assumption that the majority of eligible participants will likely enroll is a huge and costly error once enrollment begins.

Determining the number of participants available

Determining the number of participants available for recruitment may be easy or very difficult. If a sampling frame is available, the process is facilitated. A sampling frame is the actual list of potential participants. For example, in the measurement article in this issue, Froman refers to a researcher surveying level II and level III neonatal intensive care units (NICU) as to practice. Enrolling these participants was made easier through use of a sample frame or list of all registered level II and III NICUs in the United States. Referring to that sample frame defined the target population from which to draw. Unfortunately, sample frames are often unavailable. If one were to consider enrolling homeless people or the caregivers of Alzheimer's patients in a study, there is no sample frame or list of such individuals to draw from.

Calculating the accessible sample often begins with reviewing existing data. For example, identifying the magnitude of a particular condition such as breast cancer within the United States can begin with consideration of publicly available Surveillance Epidemiology and End Results (SEER) federal data from the National Cancer Institute.[1] Drilling down to the total number of newly diagnosed individuals with breast cancer within a specified county or within a particular health care setting takes additional fact finding. If an investigator wishes to enroll a population-based cancer sample from a state, either SEER data must be identified or the state in question must collect