

Veterans, Researchers, and IRB Members Experiences with Recruitment Restrictions

OMB 2900-0819

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Recruitment of study participants:

Conceptual framework. Brown and colleagues (2000), proposed three mutable factors that are relevant to the recruitment of diverse populations into research studies—awareness, acceptance and access. The model was developed from a literature review, two focus groups with study recruiters, surveys conducted with study participants to gather their attitudes toward research, and one-to-one interviews with community leaders. In addition, the authors convened a focus group to discuss a complicated study design for the purposes of identifying study components that were seen as a threat to the stability of subject recruitment and retention. Although this conceptual model was developed to address recruitment for clinical trials and recruitment of women, it is comprehensive regarding a variety of considerations around participating in research. It focuses on potential mutable aspects of study design and recruitment, as opposed to immutable variables that may impact recruitment (e.g., race and education). Awareness is at the level of the individual Veteran and includes understanding the importance of research in general, understanding the procedures that comprise the research process, the value of each individual's participation, and beliefs about the positive outcomes from participation for one's self—or Veterans in general. Awareness includes trust or distrust in the VA and government researchers and personal experience with disease. Acceptability is at the level of the collective community and includes social support for participation reflected in the message disseminated by community leaders. Social marketing efforts by leaders can be used to modify individuals' beliefs about issues and educate individuals about alternative options for their actions. Access includes the degree to which the subject can obtain information about the study, and the researcher can obtain information about the potential subject. (It also includes barriers to participation such as finances, transportation, etc., that are not the focus of this study.)

Population and Procedure. Two focus groups of approximately 8-10 Veterans will be conducted at each site—Ann Arbor, Portland, Denver, and the Bronx VAs. These VAs were chosen because they are geographically diverse, have active research programs, and have site investigators who agreed to participate. Inclusion criteria are Veterans Health Administration enrolled Veterans who have attended at least one health care appointment in the previous year, can speak and understand English, are willing to participate in a group and willing to have comments recorded. Subjects with substantial cognitive impairment, severe dysarthria, or severe hearing impairment will be excluded. One focus group will include Veterans who have participated in research previously. The second group will only include Veterans who have never participated in a research study.

Veterans will be recruited using methods that have been found to be effective based on the culture of each VA and what is acceptable to the local and VA Central IRBs. The goal of the study is to recruit Veterans who are already potentially interested in participating in research. We are more interested in determining among Veterans who are potentially interested in research participation, how different recruitment methods are perceived. Having two groups reflects the concern that quality of discussion may differ among these two groups, and that in a mixed group, individuals with substantial research experience may be more vocal than those without and not allow full voicing of concerns of those with no experience.

All sites will advertise with approved flyers/posters posted at the medical centers. Should interest in participation lag, IRB approved methods will augment recruitment. At Portland and the Bronx, the research coordinator can staff a research information table in the hospital entrance area and can talk with Veterans who express interest in the study. In Denver research tables are intermittently set up in the lobby and certain clinics in the hospital. At Ann Arbor a poster board with flyers is prominently displayed in the clinics, and if Veterans take information, a research assistant can approach them asking if more information is wanted. In addition, in Denver the focus group for Veterans with previous research experience will be enriched with subjects from an established research repository—Veterans who have indicated their interest in being contacted to participate in research studies.

Veterans who are interested will contact the local study coordinator regarding their interest. Once approximately 16-18 Veterans in each group express an interest, the focus group will be set up at a time at which the most can attend. Site principal investigators (PIs) will help focus group participants solve transportation barriers so that disability is not a barrier to participate. We anticipate of 16-18 potential participants, approximately 12 will be able to attend a focus group at a particular date and time. We anticipate that 2-4 persons will not attend despite agreeing to do so. Consequently, we will conduct groups of 8-10 persons and obtain a sample of approximately 64-80 Veterans. This size sample should be more than large enough to provide saturation of themes for analysis.

Subjects will be screened at the time they respond to the study flyer. During the phone screening, potential subjects will be required to provide basic information and to set up an appointment. Through this process, the screener will be able to determine that potential subjects can speak and understand English and do not have severe hearing impairment or dysarthria. If Veterans are able to complete the telephone screening (as judged by the screener), we believe they will be able to adequately participate in the focus group. Formal cognitive testing will not be necessary. During phone screening, eligibility criteria will be reviewed with potential subjects and they will be asked if they meet the criteria, but no health information will be recorded. Patients will only be marked as eligible or ineligible; specific reasons for ineligibility will not be documented. The informed consent process will also occur by phone. We have received a waiver of documentation of informed consent from the VA Central IRB

In order to maximize participation and minimize attrition, we also plan to have the site staff send a reminder 10 days before participation and call subjects 1-2 days before the on-site session to remind them of the date, time, and place. The reminder will include a copy of the VA Central IRB approved information sheet. Each group will be conducted in a private room arranged by the hosting site PI. We have chosen to conduct the groups on-site at the local VA medical centers to leverage existing transportation options and to provide a familiar environment for participants (and hence, increase participation).

Subjects will be greeted by site group leaders and will be asked to complete the HIPAA authorization and the consent to be audiotaped. Site investigators will then facilitate the discussion beginning with a few simple ground rules (e.g., all answers must be kept in strict confidence and treated with respect) and answering any questions. The leaders will direct the discussion using the questions listed below. The total time invested by each Veteran will be 1.5-2.0 hours. Subjects will receive a \$40 gift card to a national chain such as Target or Walmart the end of the session.

The deliberative focus groups will explore Veterans' views about research in general and recruitment for research in particular. In the group for which there is previous research experience, we will start by exploring their reasons for participating in research. Specific issues to be explored in both groups include whether they would like to hear about potential studies by phone, in person, by letter or in clinic; views on the role of their treating clinicians in the recruitment process; what is the most important information for

them to receive in recruitment letters; what type of recruitment information might make them more interested in participating or less interested; role of confidence and trust in VA researchers in general and their VA in particular; confidentiality concerns associated with recruitment practices; how confidentiality concerns could change in some types of disease situations; specific views on opt in/opt out methods; and impact of methods of reimbursement for participation. As each method is discussed we will ask them to project the risks and burdens, and clarify in terms of magnitude and probability of the bad outcome occurring. We will ask them to clarify how these perceived risks and burdens influence their decision. We will present the group with brief recruitment scenarios for discussion to make sure that a variety of themes are adequately covered including privacy, intrusiveness, and burden to self and family.

Focus group responses will be digitally audiotaped and transcribed; any identifying information will be omitted from the transcript. Study data, including audio recording files and identifying information will be maintained at the local site where it was collected, and will be kept indefinitely as required by current VA policy.

Data analysis. We will conduct a rigorous, systematic analysis of the data so that a detailed description of the deliberations can be mapped, through qualitative content analysis. The first 10 transcripts will be verified to assure accuracy and 20% of the remaining transcripts will also be verified. The transcripts will then be analyzed using standard qualitative coding procedures. Subjects will raise considerations, arguments, and concerns that we did not anticipate, and we will develop codes for these considerations as well. From this coding, themes will be identified and evidence assembled to document the themes. Data will be organized in Atlas TI. Dr. Ganzini and Ms. Risa Cromer, the qualitative analyst, will meet frequently to determine a coding scheme that best fits and organizes the data to answer our research questions.

Rationale for overall approach to study design. Because this is a qualitative study, it contributes to the literature by exploring how Veterans who might participate in research think about recruitment practices. Focus groups are a widely-used, efficient and cost effective method for obtaining the opinions, values and beliefs from an identifiable group in collective context through facilitated interview techniques. After reviewing the literature we decided that too little was known about Veterans views on research recruitment precluding the ability to design a comprehensive and valid survey. Unlike quantitative surveys, information from focus groups is limited in the degree to which it is scientifically generalizable. Other factors that limit generalizability include that enrolled Veterans who are potentially interested in participating in research may differ from non Veterans or Veterans who have chosen not to enroll in VA care in how they view these issues. The information obtained in this study does, however, lay the basis for improved conceptual models and hypotheses. This type of work may form the basis for future larger surveys of the views of Veterans based on the catalog of the types of recruitment restrictions found in our study.

Reference.

Brown BA, Long HL, Gould H, Weitz T, Milliken N. A conceptual model for the recruitment of diverse women into research studies. *Journal of women's health & gender-based medicine* 2000;9:625- 32