Comprehensive approach to recruitment and retention of minority and medically underserved persons to PSHCI studies

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This document arose from the April 10, 2012 workshop on recruitment and retention sponsored by the Community Sciences and Health Outcomes (CSHO) Core of the Penn State Hershey Cancer Institute (PSHCI). The approach and guidelines in this document are intended to improve recruitment and retention of diverse populations to cancer-related studies at the PSHCI. The guidelines were developed by reviewing the evidence-based and best practice literature related to recruitment and retention. For the purposes of this report, a cancer-related study is a study that addresses any part of the cancer continuum – prevention, early detection, diagnosis, treatment, or survivorship.

The low-level and non-representative recruitment and retention of persons to cancer-related studies is a national problem. The Institute of Medicine (IOM) has reported that low rates of recruitment and retention of people to clinical trials and the lackluster recruitment effort of physicians and other providers of care are reasons many planned trials are not completed. This disappointing fact led the IOM to recommend a comprehensive five-tier approach to recruitment and retention. Interestingly, the approach starts with the public and community practitioners, not the cancer institute.[1,2] High-levels of recruitment and retention of diverse populations do not merely help studies to be more efficient and less costly, but are necessary to avoid study bias and incorrect conclusions.[3] In a review of 253 randomized clinical trials, Gan et al (2012) found that investigators consistently made overly optimistic assumptions concerning the treatment benefits of phase III randomized cancer trials, in part from overly ambitious expectations about recruitment and retention of participants.[4] On the positive side, a representative and high-level of recruitment and retention to as study increases its external validity and the impact to the scientific profession. A history of a high-level of recruitment and retention may be seen as a strength during the review of future funding applications.

Investigators and cancer centers often consider a study's recruitment effort successful when a potential study participant provides informed consent. However, recruitment and retention should be viewed as a process, which includes enhancing a potential participant's receptivity to study participation, positive engagement with potential participants and community organizations, enrollment of participants in discussion and information sessions about a specific study, acquisition of informed consent from a study participant, and retention in the study until the study ends for the participant. Successful recruitment is not a singular event. Similarly, successful recruitment cannot be attributed to a specific action. While important and possibly necessary, it is not sufficient to assume that recruitment and retention will be successful if the

study coordinator/recruiter is similar to the sociodemographic of the population from which recruitment is sought. In addition, this approach is unrealistic for most studies that seek to recruit diverse populations.

The measurement of successful recruitment needs to include successful retention also. Longitudinal studies need participants to remain engaged over months or years because the study hypothesis may include a longitudinal reduction in biomarkers or other cancer risk. Thus, it becomes necessary to not only to recruit, but also to retain study participants. Consequently, we refer in this paper to recruitment and retention.

Investigators and institutions are largely left on their own knowledge and experience during the development of effective recruitment and retention strategies because the reports on studies to test various cancer recruitment and retention strategies are sparse. However, authors of reports in the scientific literature have proposed recruitment and retention guidance that is systematic and based in health behavior theory.[5-13] These report in the literature are helpful, but they often have focused upon the role of specific links in the chain of successful recruitment and retention. For example, Paskett et al focused upon the role of the community in recruitment[6] while other authors have focused upon the role of informed consent[14-17]. In addition, there have been reports that summarize the recruitment and retention experience of specific studies.[18] Also, reports have focused upon the recruitment of specific populations, such as African American[5,8,11,18] , Native American[11], and the elderly[7]. We have not found reports that sought to bring the various components of recruitment and retention into one model.

Much of the literature draws from the perspective of randomized therapeutic trials that involve cancer patients and the evaluation cancer therapies. However, many current studies in comprehensive cancer centers seek outcomes in the areas of prevention, early detection, and survivorship; these outcomes rely upon the enrollment of persons who are not in the midst of cancer treatment. Consequently, their methods, particularly their sources of potential participants are different from the methods for recruitment to therapeutic trials.

The literature and our experiences suggest that the institute, investigator, and community each have an important and unique role in successful recruitment and retention. Within the PSHCI, the Community Sciences and Health Outcomes (CSHO) Core may assist with issues surrounding community engagement, cultural sensitivity, and community and care networks. In addition, the Clinical Trials Office tracks much of the data that is necessary for reports to federal funders on recruitment and retention. Of course, the investigator has the primary and coordinating role in creating a protocol and allocating funding that will lead to successful recruitment and retention.

Traditionally, the investigator, especially those leading cancer control studies, have the primarily responsibility for the success of study recruitment and retention. However, this perspective is not efficient because it does not capitalize upon the expertise of other investigators and groups in the cancer institute. Without the perspective of community members, the study may lack cultural sensitivity and therefore not be well-received, resulting in low recruitment and retention. Rather, a shared responsibility between investigator, institute, and community may be more productive and efficient. In addition, a shared approach will help to assure that successes, either in individual studies or as an institute, will be sustainable.

In its 27-county catchment area, the PSHCI has identified three primary populations: rural, African American, and Latino. The CSHO Core supports community advisory committees for each population. These advisory committees may help with many of the community

engagement and cultural sensitivity issues. In addition, the CSHO Core maintains sociodemographic and cancer statistics on these three populations in the catchment area; investigators may use these statistics to help determine priorities areas as well as strategies for successful recruitment and retention.

The PSHCI catchment area does not appear diverse by many traditional measures, typically defined by race and ethnicity. However, the catchment area is unique in that its population is largely rural. This population often has lower education levels than other white populations. In addition, the catchment area has a sizeable population of Amish. These population characteristics could be emphasized in recruitment and retention strategies, which would highlight the uniqueness of its study population.

We developed the following guidelines with the expectation that recruitment and retention can be greater than it currently is in the cancer institute and have grouped these guidelines according to the primary responsibilities of the institute, investigator, and community.

PSHCI

1. Regularly and systematically monitor and review reasons for non-enrollment (including reasons for being ineligible) of approached and consented participants
2. Regularly and systematically monitor reasons that people drop-out of cancer-related studies
3. Systematically promote studies throughout the affiliate hospital and community networks
4. Develop tailored media campaigns (e.g., radio, TV, internet) to strategically promote studies to primary study audiences
5. Rather than using standard study promotional materials (e.g., flyers), develop study materials that vary in layout, design, and format
6. In its review of study protocols, the Scientific Review Committee should comment on and offer suggestions on the effectiveness of a study protocol's proposed strategies for recruitment and retention
7. Seek hospitals and other health care providers to the affiliate network so as to increase recruitment and retention from the PSHCI catchment area.
8. Participate in ResearchMatch or similar program to pre-match study participants to new studies[13]
9. Create new registries of potential study participants or link to existing registries (e.g., the Penn State Diabetes Registry). These registries will serve in part as a "pool" that investigators can draw from for study recruitment.
10. Develop and implement front-door consent program for Penn State Hershey and the affiliates of the PSHCI.
11. In addition to the typical characterizations of study populations (e.g., race and ethnicity) characterize enrolled study population by rurality, education level, and religious affiliation.

Study Protocol and Budget

1. Choose study sites that are more likely to recruit minorities and medically underserved persons [9,18,19]. Provide incentives to the sites for their participation. [18]
2. When appropriate, tailor the eligibility criteria to the specific populations (i.e., SELECT establish a lower age cutoff for prostate cancer screening among African Americans, compared to whites, because the age-specific incidence of prostate cancer is higher among African Americans than it is among Caucasians)[18]
3. Develop and use a regional infrastructure of recruitment sites so that diverse persons might be recruited and retained to the study[18]

4. Dedicate resources to tailoring media opportunities that will promote the study[18]
5. Assure that the informed consent is acceptable to and understandable by the target population[14-17]
6. Choose strategic services and marketing strategies that are more likely to reach the minority and medically underserved populations.

Community and Individual Engagement

1. Adequately characterize the sociodemographics, behavioral risks and health care access of the target population[6]
2. Involve members of the target population in planning the methods for the study[6]
3. Take the prevention and health improvement message to the target population[6]
4. Give something from the study back to the community[6]
5. Enhance the credibility of a study by using a community spokesperson[6]
6. Identify and remove barriers to participation[6]
7. Improve cultural sensitivity of investigators and staff[6]
8. Educate the target population about the importance of the study and how it could improve the health of the larger population[6]
9. Consider recruitment sites that are convenient and acceptable to the minority and medically underserved populations[9,19]
10. Provide reasonable and attractive, but not coercive, incentives for participant enrollment and continued participation. Provide incentives to all participants, even those that participate in enrollment but may not be eligibility criteria.

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