### Title

Barriers and Strategies for Recruitment of Racial and Ethnic Minorities: Perspectives from Neurological Clinical Research Coordinators.




### Journal

Journal of Racial and Ethnic Health Disparities, 4(6)



### Authors

Haley, Sean
Southwick, Lauren
Parikh, Nina
et al.



### Publication Date

2017-12-01

### DOI

10.1007/s40615-016-0332-y

Peer reviewed

HHS Public Access

Author manuscript

*J Racial Ethn Health Disparities*. Author manuscript; available in PMC 2018 December 01.

Published in final edited form as:

*J Racial Ethn Health Disparities*. 2017 December ; 4(6): 1225–1236. doi:10.1007/s40615-016-0332-y.

# Barriers and Strategies for Recruitment of Racial and Ethnic Minorities: Perspectives from Neurological Clinical Research Coordinators

**Sean J. Haley, PhD, MPH**[a,*], **Lauren E. Southwick, BA**[b], **Nina S. Parikh, PhD, MPH**[b], **Jazmin Rivera, MPH**[b], **Dorothy Farrar-Edwards, PhD**[c], and **Bernadette Boden-Albala, DrPH, MPH**[b]

[a]City University of New York, School of Public Health and Health Policy, 55 West 125th St, New York, NY United States

[b]Division of Social Epidemiology, College of Global Public Health, New York University, 41 East 11th St, 7th Floor, New York, NY United States

[c]Department of Kinesiology, University of Wisconsin-Madison, 2176 Medical Sciences Center, 1300 University Avenue, Madison, WI United States

## Abstract

**Introduction—**Randomized Controlled Trials (RCTs) are the gold standard within evidence-based research. Low participant accrual rates, especially of underrepresented groups (e.g., racial-ethnic minorities) may jeopardize clinical studies' viability and strength of findings. Research has begun to unweave clinical trial mechanics including the roles of clinical research coordinators, to improve trial participation rates.

**Methods—**Two semi-structured focus groups were conducted with a purposive sample of 29 clinical research coordinators (CRCs) at consecutive international stroke conferences in 2013 and 2014 to gain in-depth understanding of coordinator-level barriers to racial-ethnic minority recruitment and retention into neurological trials. Coded transcripts were used to create themes to define concepts, identify associations, summarize findings, and posit explanations.

**Results—**Barriers related to translation, literacy, family composition and severity of medical diagnosis were identified. Potential strategies included a focus on developing personal relationships with patients, community and patient education, centralized clinical trial administrative systems, and competency focused training and education for CRCs.

[*]Corresponding author. Sean.Haley@sph.cuny.edu (S.J. Haley)., *Phone:* 646.364.9544, Sean J. Haley, PhD, MPH, CUNY School of Public Health and Health Policy, 55 West 125th Street, New York, NY 10027.

Conflicts of Interest: Sean J. Haley, Lauren Southwick, Nina S. Parikh, Jazmin Rivera, Dorothy Farrar-Edwards and Bernadette Boden-Albala declare that they have no conflicts of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

MSC Primary 91C99; Secondary 92C50;

**Conclusion—**Patient level barriers to clinical trial recruitment are well documented. Less is known about barriers facing CRCs. Further identification of how and when barriers manifest, and the effectiveness of strategies to improve CRCs recruitment efforts is warranted.

### Keywords

clinical trials; underrepresented populations; clinical research coordinators; barriers; strategies

## 1. Introduction

Randomized clinical trials advance medical practice by testing the safety and effectiveness of new and established procedures, equipment and pharmaceuticals.[1, 2] For example, findings from stroke clinical trials have improved patients' quality of life by reducing symptoms and improving functional status.[3] Yet, despite medical advances, low rates of participant accrual can reduce clinical studies' viability and strength of findings.[4, 5]

Historically low participation rates among racial-ethnic minorities have limited the scientific application of clinical trial findings, and in some instances, have contributed to the failure to detect potential harm when population representation was insufficient to detect negative effects.[6, 7] Furthermore, as medical technology advances to cure complicated diseases, low rates of clinical trial participation by historically underrepresented groups may amplify health disparities.[8] The National Institutes of Health (NIH) sought to ensure the recruitment of women, racial and ethnic minorities into clinical trials with the adoption of the NIH Revitalization Act of 1993.[9] Despite the legislation, poor recruitment and retention continue to contribute to the failure and early termination of many clinical trials.[6]

A deep literature describes racial and ethnic minorities' reluctance to participate in clinical research trials.[5, 10] Research findings suggest that patients' mistrust of physicians[11] and research,[12, 13] religiosity,[14, 15] lack of understanding of clinical trials,[12, 13, 16] fear of harm, [12, 13] as well as time, costs, and logistics were the leading barriers that discouraged participation among racial and ethnic minorities.[12, 13, 15] Factors corresponding to study design have also been identified as supporting racial and ethnic minorities' participation including patients' relationship with their doctor, the doctor's reputation, how well the research study is explained, and the extent to which the knowledge gained will benefit others.[17] Although evidence based strategies to improve recruitment exist (including telephone call reminders, use of culturally sensitive materials),[18] they are not always deployed.[19] The longstanding recruitment lag among racial and ethnic minorities suggests that the problem has proven complex and somewhat intractable.

Principal investigators (PIs) are ultimately responsible for study recruitment and management. Yet, given limited PI time to participate in lengthy informed consent processes, clinical research coordinators (CRCs) often serve on the front lines of site level recruitment, randomization, retention, data collection, and reporting adverse events.[20] Although the ability of CRCs to influence the patient composition of clinical trials and the potential for selection bias has long been recognized,[20–22] most research on barriers to clinical trial recruitment has focused on organizational, medical provider and patient-level barriers.[23, 24] Despite the considerable influence of CRCs on the composition of clinical

trials, relatively little research has been conducted to understand factors that may influence their engagement with patients.[20, 25, 26]

Furthermore, emerging research suggests that interpersonal interactions are perceived to take longer when one participant experiences racial discordance and potential discomfort.[27] Such research, in addition to documented unconscious racial bias in the delivery of medical care services,[28, 29] may have implications for how often and how long study recruiters engage patients from under-represented groups. The current study sought to identify barriers experienced by CRCs when recruiting under-represented populations and to identify potential opportunities to improve representation.

## 2. Methods

The National Institute on Minority Health and Health Disparities (NIMHD), and National Institute of Neurological Disorders and Stroke (NINDS) provided funding for the National Initiative for Minority Involvement in Neurological Clinical Trials' (NIMICT), which aims to assist researchers to increase female and racial-ethnic minority participation in neurological clinical trials. NIMICT investigators conducted sequential semi-structured focus groups with a purposive sample of CRCs at the International Stroke Conference in 2013 and 2014 to identify coordinator-level barriers to recruitment, CRCs' training needs, and to inform the content of a toolkit for research staff. The research questions were:

1. What barriers do CRCs face in recruiting underrepresented participants to clinical trials?
2. What strategies would be most helpful for improving the recruitment of underrepresented populations?

In preparation for the focus groups, the research team reviewed the literature to identify recruitment challenges and best practices for neurological studies. Researchers opted to emphasize recruitment barriers for the 2013 group, and strategies to improve recruitment in 2014. In 2013, two NIMICT researchers (BBA and DFE) facilitated a 90 minute focus group. Topics included: 1) challenges to integrating NIH Inclusion Policy into trial design and recruitment strategies; 2) distinctive barriers to minority recruitment in stroke/neurological trials; and 3) identification of best practices to enhance minority involvement through improved communication. In 2014, two NIMICT researchers facilitated a 120 minute focus group and topics included: 1) information seeking behaviors among CRCs including barriers identified in the previous year; 2) use of available tools and resources; and 3) requested tools, resources, and services to recruit and retain clinical trial participants with particular attention to resources needed for racial-ethnic minority and underserved populations. Prior to beginning each focus group, participants were informed that the discussions would be recorded for academic research purposes and that the results may be published. Anonymity was guaranteed and participants had the option to withdraw from the discussion at any time. The [Institution redacted] Committee on Activities Involving Human Subjects (UCAIHS) approved the study.

### 2.1 Analysis

All focus group sessions were audio-taped and transcribed verbatim by trained professional staff. In addition to audio-recordings, NIMICT staff used field notes to document the characteristics of the groups' conversation, including participants' tone and non-verbal responses. The study used a deductive framework analysis.[30, 31] The five stages of framework analysis (familiarization, identifying a thematic framework, indexing, charting, mapping, and interpretation) are well suited for applied analysis as they allow researchers to use existing conceptual models and theories to describe and interpret processes within a given setting.[31] After repeated readings, transcripts were coded by two authors (SJH and JR). Coded passages across all transcripts were then placed into separate charts according to identified themes. Coded charts were independently reviewed by two authors (LES, NSP) for consistency and agreement. Continuous chart and transcript reviews were used to further define concepts, identify associations, summarize findings, and posit explanations in the mapping stage.

The study used the leadership framework developed by Heifitz and Laurie to identify technical and adaptive strategies that can address barriers to enrollment.[32] Heifitz and Laurie describe adaptive problems as systemic with no ready answers. Adaptive strategies are those that engage the collective intelligence of employees at all levels and cause some discomfort. In contrast, technical problems are those that may be solved by reengineering with little input or participation from those who do the work.

## Results

A total of 17 CRCs participated in the 2013 focus group and 12 participated in 2014. Participants in 2013 were mostly female (88%) and 47% had nursing backgrounds, including BSN, CRNP, CNRN, and RN credentials. Nearly a quarter (24%) held specialized clinical research credentials (e.g., CCRA, CCRC, and CCRP). Participants in 2014 were similar (85% were female; 50% had backgrounds in nursing and 23% held specialized clinical research credentials). All CRC participants recruited patients for clinical trials from hospital settings. Most participants had significant experience working on clinical research studies, with an average of 12 and 11 years of experience in the 2013 and 2014 groups respectively. Four individuals participated in both years.

### Research Question 1: What barriers do CRCs face in recruiting underrepresented participants to clinical trials?

CRCs identified both administrative and patient impediments to recruitment of underrepresented participants to clinical trials. Administrative barriers included limited translation services and job training that was not titrated to employee's needs. Patient-level barriers included poverty, literacy, family composition, and perceived seriousness of the medical condition. In addition, participants identified the historical legacy of racialized clinical trials as a consistent barrier to patients' participation.

### Barrier: Role of Translation

Several CRCs reported narrow eligibility time constraints imposed by study protocols. CRCs stated that time constraints sometimes influenced which patients were approached and how rigorously patients were engaged. Acute trials that enrolled patients within hours of an index event were particularly susceptible to such sorting. For example, having a first language other than English was seen as a barrier by some CRCs where the need for translation was an impediment to meet time thresholds:

> …you won't be able to spend days with a patient, and I have found that in those situations, because it is a very long process, it takes twice as long because it is being spoken twice….(2013 Participant)

Whereas the prior statement reflected adequate translation capacity but insufficient time, another CRC identified concerns about the barriers that translation created for recruitment, but focused on the resources needed to offer such services, especially when the demand was relatively rare:

> I have 17 different African dialects and a number of Asian dialects….. I can't always translate something into 25 different languages that I don't speak, and have to call someone to have them come and translate things. (2014 Participant)

The need for translation also raised fidelity concerns about the appropriateness of translating scales into many languages, even when translation services were readily available.

> I also don't know if the scales that I'm using are even translatable. If I'm doing a cognitive scale, can I just translate that literally, and does that still work? I don't know the answers to those questions. That's what makes it very difficult when you are looking at minority populations, trying to put them into those areas. I could translate anything. We have translators to do that. (2014 Participant)

In this instance the participant raises a central concern related to whether instruments retain their validity when translated as recruitment extends to diverse participant pools.

### Barrier: Patient literacy

Translation concerns were not the only language-related barrier. CRCs discussed ways in which patients' low literacy levels served as a deterrent to recruitment, especially as informed consent processes have grown more complicated. CRCs highlighted concerns about participants' ability to meet IRBs' comprehension standards.

> We don't have this problem with minorities per se, but we have a lot of issues with education. We have a population of Caucasians with low education. (2013 Participant)

For some, the need to repeat explanations for a participant to attain necessary comprehension thresholds for informed consent imposed considerable recruitment barriers.

### Barrier: Family composition

Time constraints were also identified as a potential barrier for enrollment of participants with different family size compositions. One CRC offered:

> I would say I have a lot of interactions with Hispanics because they want to get their entire family together. You tell it to one daughter who is the primary decision maker, but that daughter also wants the other daughters to know. (2013 Participant)

And another participant offered the following:

> When it's [informed consent] English, I have had very large white families that had 10 siblings, but I had to do multiple meetings because they wanted the whole family to be involved. (2013 Participant)

CRCs suggested that the size composition of a family can add time to the recruitment process, which was especially concerning during acute trials. In addition, the identification of the family as a "very large white family" may be intended to reinforce a sense, even an expectation, of colorblindness among CRC participants.

### Barriers: Patients' Race and Ethnicity

Several CRCs stated that race was not a barrier to participant recruitment.

> "It's not a black thing, it's their [patient] education." (2013 participant) It has nothing to do with race. (2013 participant)

> … I don't think about their race or ethnicity, I just think that they are eligible, so I kinda go that way. We have pretty good success because we are looking at eligibility and we want our numbers to be high. I don't care what color they are, honestly. (2013 participant).

Participants did not perceive race and ethnicity as a barrier. In fact, the participants above insisted that neither played a role in trial recruitment, despite extensive evidence of a historically racialized medical delivery system.[33, 34] Even as racial and ethnic differences were downplayed, CRCs' perception of the influence of other patient characteristics was complex and varied. Although most CRCs denied that race played a role in their approach to recruitment, members of the 2014 focus group relied on other (poverty, literacy, and language) factors when deciding to engage a potential participant. For example, CRCs readily identified barriers related to socio-economic status. A 2014 participant offered the following scenario,

> I have this address for him, he lives under a bridge, by the hospital. Yeah, probably not the best person to enroll- who's going to be coming back, when I look at his history he never shows up for any of his appointments. … [T]hese are people who are not going to stay in your study.…(2014 participant)

Similarly, another 2014 respondent suggested that: "there is an entire population of people that are too poor to have a place to live and they are not getting into clinical trials because of their poverty" (2014 participant).

Even as CRCs' perceptions of a patient's ability to consent and comply with study requirements appeared to influence their motivation to actively recruit patients, some attempted to transcend initial impressions to offer participation to anyone who was eligible. For example, a 2014 participant suggested that: "Even though I have a feeling that you are

not going to do well, I still need to at least try to put you in the study." Another participant reflected on the experience of "otherness," and CRCs' role.

> If you're going to enroll a population that feels in any way 'other' to you personally, it takes a little more effort and if you're not proactive in being prepared to do that and really working toward that before it occurs, you are more likely to either inadvertently or deliberately miss that deadline and timeline. And that will result in a lower enrollment than you should have reflecting the population that you have the opportunity to work with. (2013 participant)

This passage was one of two in the transcripts that raised the specter of implicit bias,[28] although the speaker was careful not to identify race or ethnicity explicitly, or to suggest that such biases could be in any way intentional or structural. The participant's use of "other" appears to imply a myriad of diverse patient characteristics, even as it avoids making those differences explicit.

### Barriers: Historical Legacy

Although several CRCs moderated the role that race and ethnicity played in their recruitment, CRCs' repeatedly described under-represented patients' distrust of research, specifically clinical trials. In the shadow of the Tuskegee Syphilis study,[35] concerns often took the form of patients' lack of trust in medical research. A participant offered a personal experience,

> One is about 4 years ago, [I] had a [research study acronym] patient's wife say 'I know all about Tuskegee, we are not going into the study.' (2013 Participant)

The legacy of the Tuskegee Syphilis study,[35] in combination with other racialized epidemiological and medical events, may contribute to a sense of research skepticism among potential study recruits. One CRC discussed the ramifications of underrepresented groups' medical marginalization and connected those historical reverberations with patients' hospitalization experiences during a serious medical event.

> I don't think it's a Hispanic or a Black problem. I think it's a problem of how they have developed in their family, church, and community, and what type of medical care they have had in normal circumstances before they end up in the ICU, incapacitated with a family that is scared to death that their loved one is going to die within the next four hours. (2013 participant)

More than one participant suggested that CRCs may anticipate this lack of trust and either avoid or engage racial and ethnic minority patients differently.

> Sometimes, I think we are afraid, especially white people, are afraid to approach minorities. I really do. I wonder if we are afraid and so if you are afraid, then you go into the situation, do you think that patient does not know that you are just funky? (2013 participant)

### Barrier: Serious Medical Condition and Grief

Several CRCs raised recruitment concerns related to patients' grief. Approaching a patient with a serious medical condition or a patient whose family was grieving was identified as a barrier.

> I work in the ICU with ICH patients, many of which are very, very ill. And it is a challenge. Sometimes I get those patients when, 24 hours, these patients are not going to make it. It is weird because you are pursuing someone who you know is not going to make it. (2013 Participant)

As such, some of the CRCs expressed hesitation to engage when they perceived patients to have little time remaining.

### Barrier: Hiring and Training

Participants identified workforce issues, including the young age at which CRCs are often hired, their short tenures, relative independence, lack of on-going support as well as their inexperience with serious illness and loss. Identification of these constraints led to a discussion of the need for better, standardized CRC training, especially among newly hired CRCs. Given less than robust training, a CRC wondered if the culmination of repeated recruitment denials manifested such that a CRC's anticipation of an impending denial become a self-fulfilling prophecy.

> I wasn't smart enough about my protocols and consenting process to be able to convey the security that that person needed. So you get denied. Then subconsciously, you think you will just not go there because you are tired of getting denied. And so then, my PI would say to me, what's your deal? Why are you not enrolling these patients? Because at the end of the day, it's if this patient meets criteria, why aren't they involved? (2014 participant)

Even as CRCs identified multiple barriers (e.g., insufficient training, translation and literacy requirements, patient severity, etc.), they also offered recommendations to improve recruitment efforts.

## *Research Question 2:* What strategies would be most helpful for improving the recruitment of underrepresented populations?

CRCs' recommendations to improve recruitment of under-represented groups focused on study preparation, patient education, community outreach, site education and the need for enhanced recruitment and training of study staff.

### Strategy: Advanced preparation

CRCs underscored the need to conduct rigorous advanced planning to improve recruitment efforts among the underserved, including: beta testing of recruitment scripts and consent forms to anticipate cultural pitfalls, simplifying complicated medical concepts, and streamlining the informed consent process. One 2014 respondent recommended developing a short multi-language overview of the study to gauge non-English speakers' interest in participation before summoning translators. The respondent suggested that a brief written

introduction could conserve translators' time and help to assure appropriate resource deployment.

### Strategy: Leveraging translation

Although several CRCs were concerned about the time required for translation during acute trials and whether the translation preserved validity, one CRC framed translation as an opportunity to more strongly engage. When time was not such a factor and where a facility served large numbers of people whose first language was not English, the institution tended to have the necessary infrastructure, including written resources and interpreter services to recruit under-represented populations. In these instances, when a facility was accustomed to servicing a particular linguistic need, the interpretation services appeared seamlessly integrated into the workflow and the additional time in translation was considered an opportunity to build stronger relationships with potential participants to improve recruitment rates.

> I feel like these patients benefit from enrolling in a trial because they have someone who sits down with them and spends, over the course of a day or two, hours with a translator explaining consent and then answering other medical questions they have about what's going on. (2013 Participant)

### Strategy: Patient education

CRCs frequently mentioned the need to develop recruitment language that carefully and authentically explained the study and reassured prospective participants. For example, one 2013 participant explained that their institution's investigators explored the use of recruitment language used at their site. They discovered that their patients tended to perceive the term "randomization" as binary-where the available options meant that a patient could either receive the "good" (successful) treatment or something that was not effective. Instead, the CRC suggested replacing "randomization" with the use of metaphoric language that compared study assignment to "having a baby, it's [either] a boy or a girl, 50/50" to convey that both options are equally "good." (2013 participant)

Another recommendation was to identify the federal funding source during the introduction of the study to underscore the importance of the study's scientific merit. However, the respondent added that privacy assurances must follow such funding attributions. In keeping, some participants asserted the need to reassure under-represented patients that they were not being recruited because of their race, ethnicity, or gender, but because they fit the study's specific enrollment criteria. Similarly, a participant described the importance of sharing detailed study protocols procedures with patients and family members, including assurances that patients will receive high quality care (not an alternative, sub-standard version), regardless of whether or not they enroll or terminate early, as well as information about how the study aligns with their providers' care plan. The participant suggested that such detail often reduced patients' concerns about being used as a "guinea pig." (2013 participant)

One participant described the process of patient education as a vehicle to enhance trust to ultimately improve recruitment: "patient education is key because then you are gaining trust immediately." (2013 participant) The participant described the need to educate potential

participants about both the study and the disease, observing that many patients are not able to fully absorb all relevant information about their condition during their initial physician consultation: "…before I even talk to the patient or a family about the study, I talk to them about the disease." (2013 participant) Participants also discussed the types of materials that advanced patients' education. Participants suggested that using a well-organized informational packet, a dedicated website, and on-line videos to meet patients' different learning styles were helpful to address patients' and family members' questions once they left the hospital. (2014 participant) Pamphlets that defined "placebo," "clinical trial," and "informed consent" also seemed to aide recruitment efforts, especially when they included customized information for various populations.

### Strategy: Community outreach

As an extension of the need to educate individual patients, one CRC discussed a macro approach to improve study participation whereby team members conducted information sessions at community centers about clinical trials generally and about their particular study. Another participant emphasized the importance of having strong community relationships and focused on the need for PI's to have sufficient community connections, networks and willingness to deliver a diverse clinical trial population if that was the expectation of the funding source.

> If you want to look at including a larger range or different populations in trials as a whole, you need to develop PIs that are really aggressively going to work at building this also….. (2014 participant)

### Strategy: Personal relationships with patients

Most participants agreed that personal communication was a core patient engagement strategy: "I still feel like a personal connection is the strongest way" (2014 participant). As a specific relationship building strategy, one participant suggested that language akin to "we want to partner with you and be partners in this research so that we can really find an answer" was helpful to establish the sense of trust that is often missing in such encounters (2013 participant). Others suggested that asking whether a patient liked to "help others" could prove successful to recruitment efforts. Some coordinators suggested that allowing patients to use "FaceTime" (Apple i-phone technology) to access PIs when patients had questions could be beneficial to extend interpersonal connections.

Participants emphasized different strategies to enhance the patient-CRC connection. Some emphasized the value of creating authentic communication to establish that "… you care about them and you are conveying that, and you are honest with them…." (2013 participant) while other CRCs focused on their ability to assure quality treatment: "I hope that they get whatever group that they want to be in. But my job as a coordinator is to keep an extra set of eyes on them……" (2013 participant) Several participants expanded the conversation about the importance of fostering relationships to include hospital staff.

### Strategy: Relationships with hospital staff

Akin to the recommendations to build relationships with patients, participants called on study staff to develop strong relationships with hospital staff, especially nurses, to improve patient recruitment.

> What the patient or what the family is going to do after you leave is that they are going to say to the nurse, "What do you think about that?" And unless you build that relationship, the nurses are not going to be able to support. (2014 participant)

Some participants identified specific strategies to enhance recruitment such as the need to introduce oneself often, describe study content, to remind hospital staff about the various studies regularly, and to provide monthly recruitment feedback (number patients screened, enrolled, etc.). Some described using posters and white boards where nursing staff congregated to highlight on-going studies and study contact information-including pager numbers. Given that one institution can host multiple studies at any given time, CRCs are often in competition for staff members' attention. Participants underscored the need to remind staff often about study opportunities: "You have to go all the time. Talk to them, remind them about studies." (2014 participant) Some participants were able to use monthly meetings with hospital staff to follow up on recruitment progress and to reconcile the number of eligible patients, contacts made and patients enrolled. Others made consent forms available throughout the hospital to facilitate recruitment.

### Strategy: Staff Training

Participants offered several suggestions to improve CRCs' training, especially for new employees. Participants talked about the time required to learn what patients need in order to feel safe to participate. Several described the value of having more seasoned CRCs available to answer questions from newer CRCs.

> There should be something that you can always look at or talk to somebody who has done this for a long time and say, 'Look, here are a few things you may want to know.'(2014 participant)

One suggestion that did not gain much traction was to establish a telephone "hotline" for staff; participants thought that as health service professionals they should know the content of their studies. Alternatively, the suggestion that senior coordinators "shadow" more junior coordinators during early patient interactions elicited positive feedback. It was also recommended that new CRCs receive training on research study implementation protocols so that they are clear about study functions and where to turn for questions. (2014 participant) "Best practice" guides, were recommended for all CRCs, but especially during the "on-boarding" process of new hires. However, training related conference calls and webinars were perceived as less helpful for seasoned staff. (2014 participant) Lastly, CRCs identified the need to offer all CRCs support related to the emotional pitfalls of the job.

> To have something to give coordinators to say 'Yeah, you must keep your feelings outside the door'…would be helpful. I still struggle with that. (2014 participant)

Even as participants identified a number of helpful organizational and personnel strategies to improve recruitment efforts, neither the need for cultural sensitivity training,[36, 37] nor

improved competencies related to engaging patients of different backgrounds were identified.

### Strategy: Staff Hiring

The training discussion quickly segued into a conversation about hiring requirements and the importance of identifying CRC competencies that include those for novice, intermediate and expert CRCs.

> I think it's a great idea…how to hire a coordinator who will be effective at recruitment. How many times has everyone heard a PM or PI say 'I really dropped the ball on that person'? (2014 participant)

## Discussion

CRC focus group participants identified a myriad of challenges when they attempt to recruit patients for neurological trials. Much of the focus groups' conversations about recruitment barriers and strategies centered on securing informed consent. Barriers included translation, literacy, family composition, patients' demographics, symptom severity and the social legacy related to disparate racial treatment in medical research studies. CRCs also identified numerous recommendations to improve study recruitment including the need for: advanced preparation, patient education, community education, relationship building with patients and hospital staff, as well as improved CRC hiring using recommended competency assessments, and training. Potential adaptive and technical solutions that align with identified barriers and strategies are offered below (also see Table 2).

Study participants emphasized the importance of informing hospital staff about clinical studies and used a variety of education strategies. Some of the approaches were personality dependent (tenacity and charisma were valued character traits), but many were pragmatic, including the use of white boards where nursing staff gathered to list studies and contact information, regular reminders about study eligibility, and recruitment updates. An adaptive approach would systemize all clinical trial eligibility standards across institutions and make operational units (and their staff) partially responsible for patient recruitment rather than place the full responsibility on individual CRCs. An institution-wide clinical trial recruitment process could reduce the vagaries of personality required to develop individual relationships for each clinical trial, staff member by staff member.

CRCs repeatedly identified the emotional challenges associated with having to request participation from seriously ill patients. The difficulty of such recruitment has been documented by prior literature.[38] CRCs requested additional support to help them cope with the daily emotional demands of their engagement with seriously ill patients. Participants also recommended enhanced training for new CRCs to help them engage patients, including the need for training materials to be available in multiple formats, shadowing of recently hired CRCs by senior staff, ongoing technical assistance, and competency measures aligned with novice, intermediate and expert CRC roles. These focus group recommendations are consistent with a growing call for the consolidation of clinical trial functions, and the adoption of standardized, competency focused training for all clinical

trial recruiters.[39, 40] A technical strategy to improve recruitment might require individual PIs to certify CRCs' competencies, including cultural competence.[36]

Although frequently identified as a barrier, translation did not seem to manifest universally as a challenge. Sites that lacked racial and ethnic diversity or whose translation infrastructure was insufficient to support on demand service requests experienced the most challenges. One recommendation was to create a brief, multi-language study introduction to assess patients' initial interest before translators are summoned. However, where translation capacity appeared sufficient, participants were cautious about widespread adoption as some participants relied on the help of in-person translators to build trust with patients who may already be alienated from U.S. health care services and suspicious of medical care research. Using an adaptive approach to problem solving, those hiring CRCs would prioritize bilingual staff in diverse catchment areas to maximize opportunities for relationship building during the introduction phase. Such an adaptive approach to translation would take time to assure a sufficiently trained bilingual workforce. Technical approaches might rely on translation call centers and the use of hand-held technology.

Literacy concerns transcended nativity, racial, and ethnic categories as did concerns related to family composition. Literacy challenges were an especially serious concern when consent processes required participants to respond in a short period of time or reach predetermined comprehension thresholds. Concerns about patients' literacy and their ability to manage their health conditions have been longstanding.[41] Adaptive approaches to literacy concerns include having hospital staff assess all patients' comprehension about their health issue immediately after diagnosis to improve treatment adherence, educating patients and families about clinical research studies a-priori, including commonly used research language, and expanding the unit of recruitment from the individual to the family. Technical approaches would require that all materials be brief and meet national literacy recommendations.[42]

Although CRCs generally downplayed the role that race and ethnicity played in their recruitment efforts, it is worth noting that they readily described the challenges presented by patients' other demographic features including literacy, the need for translation, and poverty. When specifically queried about whether race affected their recruiting, several participants were strident that it did not. However, when asked what got in the way of participation by under-represented groups, CRCs quickly identified distrust of medical studies and referenced Tuskegee. In part, the reluctance to discuss race may have to do with the sensitivity of the topic. CRCs were more willing to talk about the impact of poverty, translation, family size, and patients' medical severity on their recruitment efforts than about race. The reluctance of medical staff to discuss the influence of race and ethnicity has been documented in other studies.[43, 33]

In addition, participants' general reluctance to discuss race and ethnicity does not attenuate their recognition of differences. In fact, participants remained keenly aware of patients' differences. Whether to indicate economic standing ("too poor to participate"), or even differences related to severity of illness ("*these patients are not going to make it")*, language invoking participants' "otherness" appeared sporadically throughout the transcripts.

Participants invoked such differences to indicate extremes, as in the example above with very sick patients, or to insinuate sameness, as when participants suggested that literacy concerns were not a “black thing” (suggesting that they were also a “white thing”).[44] While an in depth analysis of the theoretical underpinnings of difference is beyond the scope of this study, it is worth noting that such binaries are often imbued with a power differential.[44] Given the institutional legacy of racialized health care services and medical research, more investigation into CRC’s perception of difference is warranted.[36, 37]

Participants suggested that patients often do not fully retain the intricacies of their providers’ communication at the time of their diagnosis.[45] Participants further described the need for simplified (non-technical) study language to encourage authenticity as a prerequisite to recruiting participants. Widespread documentation concerning a lack of health literacy across populations supports simplification of clinical trial language.[46, 47] For example, assignment language that avoids the win/lose juxtaposition of ‘randomization,’ such as the use of metaphor to convey diagnosis information and treatment options simply and directly can also enhance trust between CRCs and potential participants. [48]

Most of the strategies recommended by CRCs focused on the accessibility of study language to potential participants, enhancing the training of CRCs, the importance of building relationships across hospital staff, and other strategies consistent with the role of CRCs and study implementation. Fewer strategies focused on study purpose and design, including the role that patients’ physicians play in transferring information and trust to the study team, the P.I’s reputation, or how likely results from the study will benefit others.[17]

An adaptive problem focused framework would have the host institution assure that the research is important to the community and understandable, not just scientifically novel. It will also necessitate a deeper connection between study priorities and underrepresented communities to more closely align with the patients they serve, increased transparency of study procedures and goals, including visible, consistent, and meaningful community outreach by the host institution that transcends clinical trial or study recruitment. For example, given the description of barriers related to patients’ identification of a legacy of racialized medical research studies, a few participants recommended that study staff, especially physicians, provide education in under-represented settings to explain clinical trials generally and then particular study aims. Similarly, one suggestion was to explicitly assess the ability of the PI to engage under-represented communities during the review process before funding decisions were made.

Internal Revenue Service requirements now mandate that hospitals conduct community needs assessments and plans to maintain their nonprofit 501(c)(3) tax exempt status.[49] These requirements might be leveraged by State health departments to support deeper community engagement from hospitals. For example, state and local health departments from Rhode Island to California have created and staffed health equity units to improve residents’ health status within and across communities.[50, 51] Many of these units already conduct or support community based health assessments, and a pairing of efforts between academic medical settings and government public health offices might advance both public health and clinical research priorities within communities. On the technical side, institutional

review boards might require intensive training of the clinical trial workforce to examine and challenge CRCs' potential discomfort or biases.[52, 53]

Although it is reasonable to expect that an additive effect may operate whereby the presence of more than one barrier (e.g., need for translation, large family involvement, literacy concerns) might compound CRCs' reluctance to engage a patient, it is unclear from this study what, if any, those interactions might be. Although four CRCs participated in both focus groups, 2014 participants heard a summary of barriers identified by the 2013 group, they did not develop their own set. As such, there may have been some variation in the identified barriers between years. In addition, CRC participants were not asked to identify their race, ethnicity, or language capacities. CRCs were also not sorted by their years of experience or assessed for their ability to recruit participants from underrepresented groups. Furthermore, this preliminary study can only identify themes as participants were not asked to rank barriers by either intensity or frequency. Future research may be warranted to identify CRCs who are highly effective in recruiting underrepresented populations to identify strategies that are most effective. In addition, recruitment strategies might be compared to determine relative effectiveness.

Other limitations in this study are consistent with standard qualitative methodological practice. Although the authors maintained sensitivity during data analysis to ways in which power relationships informed participants' responses, the authors were not themselves CRCs. In addition, participants were recruited from neurological conferences, and as such may not be representative of all CRCs. In turn, any conclusions may not apply to research recruiting for other health conditions and diseases.

## Conclusion

Future research to improve the recruitment of underrepresented populations should focus on the role of the medical center within the community, the PI, including her/his ability to enroll underrepresented groups,[54] the process of developing scripts that are short, simple, clear and authentic, the availability of on-demand translation services and delivery mechanisms (in person, in writing, or video format), as well as enhanced CRC training to support patient initiation and study engagement. Several other authors have begun to call for adaptive changes in study design,[1] training and recruitment of CRCs, and the use of competency based hiring and training.[40, 54] In addition, research that focuses on what situations CRCs avoid, (in addition to what they do and how they do it), and strategies to help them better engage, is needed to better understand recruitment deficits among racial and ethnic minorities, especially where disease prevalence is compelling.

## Acknowledgments

Heather Carman Kuczynski, MPH, CHES for focus group facilitation; Noa Appleton, MPH for review of manuscript and technical assistance, and the participants of the 2013 and 2014 ISC focus groups.

Funding: This work was supported by National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Minority Health and Health Disparities (NIMHD) (U24#MD006961, PI: Bernadette Boden-Albala).

## References


1. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. Jama. 2003; 290(12):1624–32. [PubMed: 14506122]
2. Lamas GA, Pfeffer MA, Hamm P, Wertheimer J, Rouleau J-L, Braunwald E. Do the results of randomized clinical trials of cardiovascular drugs influence medical practice? New England Journal of Medicine. 1992; 327(4):241–7. [PubMed: 1535419]
3. Emberson J, Lees KR, Lyden P, Blackwell L, Albers G, Bluhmki E, et al. Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomised trials. The Lancet. 2014; 384(9958):1929–35.
4. Haidich A-B, Ioannidis JP. Patterns of patient enrollment in randomized controlled trials. Journal of clinical epidemiology. 2001; 54(9):877–83. [PubMed: 11520646]
5. Hussain- Gambles M, Atkin K, Leese B. Why ethnic minority groups are under- represented in clinical trials: A review of the literature. Health & social care in the community. 2004; 12(5):382–8. [PubMed: 15373816]
6. Roberts J, Waddy S, Kaufmann P. Recruitment and retention monitoring: facilitating the mission of the National Institute of Neurological Disorders and Stroke (NINDS). JVIN. 2012; 5(1.5)
7. Sanoff HK, Sargent DJ, Green EM, McLeod HL, Goldberg RM. Racial differences in advanced colorectal cancer outcomes and pharmacogenetics: a subgroup analysis of a large randomized clinical trial. Journal of Clinical Oncology. 2009; 27(25):4109–15. [PubMed: 19636001]
8. Chen MS, Lara PN, Dang JH, Paterniti DA, Kelly K. Twenty years post- NIH Revitalization Act: Enhancing minority participation in clinical trials (EMPaCT): Laying the groundwork for improving minority clinical trial accrual. Cancer. 2014; 120(S7):1091–6. [PubMed: 24643646]
9. NIH Revitalization Act of 1993. Pub L No PL 103-43. 1993
10. Lai GY, Gary TL, Tilburt J, Bolen S, Baffi C, Wilson RF, et al. Effectiveness of strategies to recruit underrepresented populations into cancer clinical trials. Clinical trials (London, England). 2006; 3(2):133–41.
11. Branson RD, Davis K, Butler KL. African Americans' participation in clinical research: importance, barriers, and solutions. The American journal of surgery. 2007; 193(1):32–9. [PubMed: 17188084]
12. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. American journal of public health. 2014; 104(2):e16–e31.
13. Ford JG, Howerton MW, Lai GY, Gary TL, Bolen S, Gibbons MC, et al. Barriers to recruiting underrepresented populations to cancer clinical trials: a systematic review. Cancer. 2008; 112(2): 228–42. [PubMed: 18008363]
14. Daverio-Zanetti S, Schultz K, del Campo MAM, Malcarne V, Riley N, Sadler GR. Is religiosity related to attitudes toward clinical trials participation? Journal of Cancer Education. 2015; 30(2): 220–4. [PubMed: 24953236]
15. Rivers D, August EM, Sehovic I, Green BL, Quinn GP. A systematic review of the factors influencing African Americans' participation in cancer clinical trials. Contemporary clinical trials. 2013; 35(2):13–32. [PubMed: 23557729]
16. Giuliano AR, Mokuau N, Hughes C, Tortolero-Luna G, Risendal B, Ho RC, et al. Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. Annals of epidemiology. 2000; 10(8):S22–S34. [PubMed: 11189089]
17. Kurt A, Semler L, Jacoby JL, Johnson MB, Careyva BA, Stello B, et al. Racial Differences Among Factors Associated with Participation in Clinical Research Trials. Journal of Racial and Ethnic Health Disparities. 2016:1–10. [PubMed: 26896100]
18. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: a review of randomised controlled trials. BMC medical research methodology. 2006; 6(1):1. [PubMed: 16412232]

19. Foy R, Parry J, Duggan A, Delaney B, Wilson S, Lewin-van den Broek N, et al. How evidence based are recruitment strategies to randomized controlled trials in primary care? Experience from seven studies. Family Practice. 2003; 20(1):83–92. [PubMed: 12509377]
20. Pelke S, Easa D. The role of the clinical research coordinator in multicenter clinical trials. Journal of Obstetric, Gynecologic, & Neonatal Nursing. 1997; 26(3):279–85.
21. Davis AM, Hull SC, Grady C, Wilfond BS, Henderson GE. The invisible hand in clinical research: The study coordinator's critical role in human subjects protection. The Journal of Law, Medicine & Ethics. 2002; 30(3):411–9.
22. Poston RD, Buescher CR. The essential role of the clinical research nurse (CRN). Urologic Nursing. 2010; 30(1):55. [PubMed: 20359145]
23. Ross S, Grant A, Counsell C, Gillespie W, Russell I, Prescott R. Barriers to participation in randomised controlled trials: a systematic review. Journal of clinical epidemiology. 1999; 52(12): 1143–56. [PubMed: 10580777]
24. Mills EJ, Seely D, Rachlis B, Griffith L, Wu P, Wilson K, et al. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. The Lancet Oncology. 2006; 7(2):141–8. doi:http://dx.doi.org/10.1016/S1470-2045(06)70576-9. [PubMed: 16455478]
25. Speicher LA, Fromell G, Avery S, Brassil D, Carlson L, Stevens E, et al. The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: Recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. Clinical and translational science. 2012; 5(6):470–5. [PubMed: 23253669]
26. Morgan SE, Mouton A, Occa A, Potter J. Clinical Trial and Research Study Recruiters' Verbal Communication Behaviors. Journal of health communication. 2016:1–8.
27. Moskowitz GB, Okten IO, Gooch CM. On Race and Time. Psychological science. 2015; 26(11): 1783–94. [PubMed: 26423460]
28. Moskowitz GB, Stone J, Childs A. Implicit stereotyping and medical decisions: unconscious stereotype activation in practitioners' thoughts about African Americans. American journal of public health. 2012; 102(5):996–1001. [PubMed: 22420815]
29. Bean MG, Stone J, Badger TA, Focella ES, Moskowitz GB. Evidence of nonconscious stereotyping of Hispanic patients by nursing and medical students. Nursing research. 2013; 62(5): 362. [PubMed: 23995470]
30. Pope C, Ziebland S, Mays N. Qualitative Research in Health Care: Analysing Qualitative Data. BMJ: British Medical Journal. 2000; 320(7227):114–6. DOI: 10.2307/25186804 [PubMed: 10625273]
31. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. The qualitative researcher's companion. 2002:305–29.
32. Heifetz RA, Laurie DL. The work of leadership. Harvard business review. 1997; 75:124–34. [PubMed: 10174450]
33. Feagin J, Bennefield Z. Systemic racism and US health care. Social Science & Medicine. 2014; 103:7–14. [PubMed: 24507906]
34. Boulware LE, Cooper LA, Ratner LE, LaVeist TA, Powe NR. Race and trust in the health care system. Public health reports. 2003; 118(4):358. [PubMed: 12815085]
35. Jones JH. Bad blood. Simon and Schuster. 1993
36. Beach MC, Price EG, Gary TL, Robinson KA, Gozu A, Palacio A, et al. Cultural competency: A systematic review of health care provider educational interventions. Medical care. 2005; 43(4): 356. [PubMed: 15778639]
37. Anderson LM, Scrimshaw SC, Fullilove MT, Fielding JE, Normand J, Services TFoCP. Culturally competent healthcare systems: a systematic review. American journal of preventive medicine. 2003; 24(3):68–79. [PubMed: 12668199]
38. Steinhauser KE, Clipp EC, Hays JC, Olsen M, Arnold R, Christakis NA, et al. Identifying, recruiting, and retaining seriously-ill patients and their caregivers in longitudinal research. Palliative Medicine. 2006; 20(8):745–54. DOI: 10.1177/0269216306073112 [PubMed: 17148529]

39. Sonstein SA, Seltzer J, Li R, Silva H, Jones CT, Daemen E. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. Clin Res. 2014; 28(3):17–23.
40. Snyder DC, Brouwer RN, Ennis CL, Spangler LL, Ainsworth TL, Budinger S, et al. Retooling institutional support infrastructure for clinical research. Contemporary clinical trials. 2016; 48:139–45. [PubMed: 27125563]
41. Williams MV, Baker DW, Parker RM, Nurss JR. Relationship of functional health literacy to patients' knowledge of their chronic disease: a study of patients with hypertension and diabetes. Archives of internal medicine. 1998; 158(2):166–72. [PubMed: 9448555]
42. National Institutes of Health. Clear communication: An NIH health literacy initiative. 2012. Disponibile da: http://www.nih.gov/clearcommunication/healtHealthLiteracyiteracy.htm [consultato il 13 Settembre 2014]
43. Malat J, Clark-Hitt R, Burgess DJ, Friedemann-Sanchez G, Van Ryn M. White doctors and nurses on racial inequality in health care in the USA: whiteness and colour-blind racial ideology. Ethnic and racial studies. 2010; 33(8):1431–50.
44. Hall S. The spectacle of the other. Discourse theory and practice: A reader. 2001:324–44.
45. Olson DP, Windish DM. Communication discrepancies between physicians and hospitalized patients. Archives of Internal Medicine. 2010; 170(15):1302–7. [PubMed: 20696951]
46. Paasche‐ Orlow MK, Parker RM, Gazmararian JA, Nielsen‐ Bohlman LT, Rudd RR. The prevalence of limited health literacy. Journal of general internal medicine. 2005; 20(2):175–84. [PubMed: 15836552]
47. Safeer RS, Keenan J. Health literacy: the gap between physicians and patients. Am Fam Physician. 2005; 72(3):463–8. [PubMed: 16100861]
48. Krieger JL, Parrott RL, Nussbaum JF. Metaphor use and health literacy: A pilot study of strategies to explain randomization in cancer clinical trials. Journal of Health Communication. 2010; 16(1): 3–16.
49. Internal Revenue Service. Internal Revenue Bulletin: 2011–30. 2012. http://www.irs.gov/irb/2011-30_IRB/ar08.html. Accessed February 20 2015
50. State of Rhode Island. Health Equity. 2016. http://www.health.ri.gov/equity/. Accessed December 12 2016
51. Bay Areas Regional Health Inequities Initiative. Health Equity and Community Engagement Report: Best Practices, Challenges and Recommendations for Local Health Departments. 2013. http://barhii.org/download/publications/hecer_regionalsummary.pdf. Accessed December 12, 2016
52. Featherstone K, Donovan JL. "Why don't they just tell me straight, why allocate it?" The struggle to make sense of participating in a randomised controlled trial. Social science & medicine. 2002; 55(5):709–19. [PubMed: 12190265]
53. Ford ME, Siminoff LA, Pickelsimer E, Mainous AG, Smith DW, Diaz VA, et al. Unequal burden of disease, unequal participation in clinical trials: solutions from African American and Latino community members. Health & social work. 2013:hlt001.
54. Swanson GM, Ward AJ. Recruiting minorities into clinical trials toward a participant-friendly system. Journal of the National Cancer Institute. 1995; 87(23):1747–59. [PubMed: 7473831]

**Table 1**

Focus Group Demographics and Background

| | **2013 Focus Group (*n*=17)** | **2014 Focus Group (*n*=12)** |
|---|---|---|
| Female | 88% | 85% |
| Specialized Clinical Research Credentials | 24% | 23% |
| Nursing Background | 47% | 50% |
| Years working in clinical research (mean, range) | 12 (2–26) * | 11(5–24) ** |

* Data from 12 participants (n=12)

** Data from 8 participants (n=8)

## Table 2

Adaptive and Technical Strategies to Improve Recruitment of Underrepresented Clinical Trial Participants

| Organization | Recruitment Barrier | Adaptive Strategy | Technical Strategy |
|---|---|---|---|
| | Patients' health literacy | Hospital staff ensure patients' understand diagnosis and treatment options before discharged<br>Hospital staff educate patients and families about clinical trials in general | Ensure all materials brief and meet national literacy recommendations<br>Use of metaphor rather than the term "randomization" |
| | Patients' symptom severity | See: "Patient: CRC hiring and training" below | See: "Patient: CRC hiring and training" below |
| | Medical research legacy (Tuskegee) | Strong background checks of PIs and connection to communities before finding award<br>Strong and long term institutional commitment to underrepresented communities<br>Hospitals partner with state and local health agencies and communities to identify research priorities<br>Leverage IRS community benefits requirements for hospitals to conduct community needs assessment and planning to identify research priorities with communities | Provider delivered community based sessions to inform residents about specific diseases and clinical trials |
| **Patient** | **Recruitment Barrier** | **Adaptive Strategy** | **Technical Strategy** |
| | Translation capacity | Expand CRC role to prioritize bilingual capacity for institutions serving diverse populations<br>Offer CRC training programs for bilingual workforce. | Use hand help devices to offer on demand translation of introductory script and consent process<br>Access translation call centers |
| | Complexity of recruitment language | Institution assures that all proposed studies are important to the community and easily explained, not just scientifically interesting | Use of simplified language that meets national standards. |
| | Multiple studies competing for hospitals' staff members' time | Create a centralized unit that operates all clinical trials across the institution<br>Link unit and individual nursing staffs' performance to recruitment efforts and outcomes | CRCs develop relationships with staff at each recruitment site |
| | CRC hiring and training | All CRCS hired, trained and promoted according to competency guidelines (administered by central administrative unit) | PI responsible to assure all CRCs achieve prescribed competencies, including cultural competency |