

Research Professionals' Perspectives, Barriers, and Recommendations Regarding Minority Participation in Clinical Trials

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Research Professionals' Perspectives, Barriers and Recommendations Regarding Minority

Participation in Clinical Trials

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ABSTRACT

Objective: To investigate research professionals' perspectives regarding minority participation in clinical trials.

Methods: A web-based survey of research professionals at US institutions receiving NIH and/or AHRQ funding to conduct clinical research in 2013. Descriptive statistics, mean, standard deviation (SD) and the Wilcoxon rank sum test were utilized for analysis.

Results: Distributed were 13,041 surveys with 967 (7.4%) responses. Overall and race-stratified analyses included 633 and 521 surveys, respectively. A majority agreed that patients' race (*mean* 3.4, *SD*=1.0) and primary language (*mean* 4.0, *SD*=0.9) have an effect on enrollment. They had more success in enrolling those whose primary language was the same as their own (*mean* 3.8, *SD*=1.0), and that a language barrier and time spent arranging for interpreters had prevented them from offering a study to potential candidates (*mean* 3.2, *SD*=1.2).

Non-Caucasian respondents were more likely to agree that "fear of unknown side-effects" was a deterrent for minorities ($p<0.01$), "minorities are more likely to be unavailable for follow-up phone calls" ($p=0.07$), and "the unavailability of translated material discourages non-English speakers from participation" ($p=0.08$). They also were more likely to be neutral or agree with being discouraged from enrolling minorities because of the possibility of their withdrawal, or being less likely to be available for phone follow-ups and follow-up visits (all $p<0.01$).

Conclusion: Despite a few subtle racial differences in research professionals' perspectives, a majority expressed no hesitation in enrolling minorities. Patients' race and primary language appeared to influence enrollment. A language barrier appeared to be the strongest barrier for research professionals.

Key words: researchers' perspective; influencing factors; motivators for clinical trial enrollment; barriers to clinical trial enrollment; research professionals; racial disparities in research.

INTRODUCTION

Diversity and equity in clinical trial participation are essential to ensure the safety and efficacy of investigational drugs and devices. Although scientific evidence demonstrates physiological and metabolic differences among many racial and ethnic sub-populations [1-3], demographics in the United States (US) are not replicated in clinical trial participation and minorities remain under-represented in research [4-6].

The existing literature primarily discusses barriers to participation from minority patients' perspectives [7-11], and also suggests racial disparities in clinical trials are partly due to minorities' own unwillingness to participate [9, 10]. However, it has been reported that unequal treatment of minorities may be due to the fact health care providers harbor prejudicial attitudes, which may influence their decision about treatment [12-16]. In addition to Wendler, et al., demonstrating that when invited to volunteer for research, minority patients were significantly more likely to consent than for non-minority patients [17], a recent study reported racial differences in oncologist-patient communication about clinical trials. Visits with African-American patients compared to visits with White patients included fewer mentions of and less discussion of clinical trials [18]. Therefore, racial disparities in clinical trials seen today should not be viewed solely as an aftermath of previous negative experiences with racially-tinged research such as the Tuskegee trial [19], or the result of minorities' personal unwillingness to participate, as long as other problematic issues have been addressed.

Enrollment is primarily done by study investigators, research nurses and research coordinators.

Unfortunately, there is a lack of information about barriers to minority participation from the perspective of enrolling research professionals [20-23] and whether or not disparities seen in clinical trials may also be a result of unconscious bias among these researchers [18, 23].

As the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH) mandate an enrollment plan from their grantees for inclusion of diverse research populations [24, 25], research professionals from NIH- and/or AHRQ-funded institutions should be a robust cohort from which to learn their perceptions, barriers and recommendations regarding minority participation in clinical trials. The current study examines results from a survey of research professionals who actively enrolled patients and belonged to US institutions that received clinical research grants in 2013 from the NIH and/or AHRQ.

We hypothesized that 1) research professionals would be generally hesitant to approach minorities for participation; and 2) there would be differences between Caucasian and non-Caucasian research professionals' perspectives and barriers to enrolling minority patients.

METHODS

Compliance with Ethical Standards

This study was approved by our network's Institutional Review Board (IRB) as exempt research.

Study Design and Population

Based on an extensive review of the literature, a survey was developed by the Principal Investigator and distributed to a group of statisticians and local clinical investigators. Based on their feedback, the survey was revised and IRB approval was obtained for this study. Next, it was randomly piloted among 15 local research professionals. We did not disclose the purpose of the study during the validation process to prevent any bias from these pilot participants. This was simply to test how specific our survey instrument was, especially being the first of its kind in this field. A brief questionnaire was given to these pilot subjects asking whether they could identify what the purpose of our survey was and to also provide general feedback. All respondents accurately concluded that the survey was meant to investigate the

underlying reasons for disparities in research. Revisions were made to incorporate their suggestions and feedback before distributing the survey to the target population.

We identified those hospitals, schools of public health and medical schools that received NIH and/or AHRQ funding in 2013 to conduct clinical trials, and collected the contact information (email and postal mailing addresses) of research professionals listed on their respective institutions' websites. The survey was emailed (via Qualtrics, Provo, UT) to this population in June, 2015 and was designed for completion in approximately seven to eight minutes. Two successive email reminders that contained a link to the survey were sent at two-week intervals. As an incentive for research staff to complete the survey, we randomly picked 100 respondents to each receive a \$50 gift card. This information and the purpose of the study, along with the voluntary and anonymous nature of the survey, were mentioned on the introductory page of the survey. Gift cards were issued to those randomly chosen in September of 2015.

Variables

Participant and workplace characteristics used in this study included: Professional role, gender, race, workplace description, whether respondent enrolls subjects in clinical trials, and whether the respondent works on federally-funded research. Based on their research experience, respondents were asked questions about their perceptions of what discourages minorities from participating in clinical trials versus what discourages research professionals themselves from enrolling minorities. Participants were also asked to identify any secular trends they have witnessed in research, what resources would be helpful to them, and what recommendations they have to promote diversity and equity in research. Questions were formatted on a five-point Likert-type scale ranging from "strongly disagree" to "strongly agree."

Data Analysis

Summary statistics were used to describe study participants and survey responses. Descriptive statistics and relative frequencies were used to summarize categorical variables. Chi-square tests were used to evaluate the distribution of participant and workplace characteristics by participant's race. The Wilcoxon rank sum test was used to assess differences in sample distributions between participants' reported race. Participants who responded "prefer not to answer" for the race/ethnicity question were excluded from the race-stratified analysis. All data management and analyses were performed by Stata V.12.1, Stata Corporation, College Station, TX [26].

RESULTS

Of the 13,041 research professionals who were emailed surveys, 967 (7.4%) responded (Figure 1). After excluding those 334 (34.5%) who did not actively enroll subjects in clinical trials, 633 respondents' data were analyzed for the survey items that focused on general trends, helpful tools and their recommendations. For race-stratified analysis, we further excluded those 113 (17.8%) who either did not mention their race, or "preferred not to answer." The resulting dataset for analysis included 520 survey responses, of which 433 (83.3%) categorized themselves as "Caucasian" and 87 (16.7%) belonged to minority races such as Asian ($n=45$), African American ($n=19$), multi-racial ($n=9$), Hispanic ($n=6$), Native American ($n=2$) and other ($n=6$). Because of this low participation rate from minority respondents, data for each individual minority race could not be stratified separately and were merged into one category, "non-Caucasians."

We compared those participants who preferred not to identify their race and who skipped this question with the remainder of the cohort for the other self-classifying categories. Respondents with missing race information were slightly more likely to be study investigators (71.4%, $n=80$), than those with non-missing information on the employment category question (63.1%, $n=329$, $p=0.09$). No differences were

observed for these individuals when comparing whether their studies were federally funded (72.3% versus 75.2%, $p=0.52$), whether they worked at academic institutions (67.9% versus 70.8%, $p=0.53$), or the total number of research studies enrolling participants categorized as “3 or more” (36.6% versus 40.9, $p=0.40$) (data not presented in table form).

Table 1 presents the distribution of respondents’ professional and demographic characteristics by race. Although no differences were observed in the distributions of professional title, type of institution, total number of enrolling studies, or whether their research was professionally funded, non-Caucasian respondents were more likely to be female (72.4% versus 62.4%, $p=0.07$), less likely to report English as their primary language (84.1% versus 97.4%, $p<0.01$), and less likely to report fluency in only one language (62.1% versus 78.8%, $p<0.01$) compared to Caucasian respondents.

Table 2 shows trends witnessed by research professionals in clinical trials. A majority agreed that patients’ race (*mean* 3.4, *SD*=1.0) and primary language (*mean* 4, *SD*=0.9) have an effect on enrollment success. The majority also indicated they had more success with enrolling subjects whose primary language was the same as theirs (*mean* 3.8, *SD*=1.0). Further, they agreed that a language barrier, as well as time spent on arranging for interpreters, had prevented them from offering a study to potential candidates (*mean* 3.2, *SD*=1.2).

The distributions of participant responses about their perception of barriers to minority participation and their own barriers to enroll minorities were race stratified (Tables 3a and 3b, respectively). Respondents agreed that all barriers listed in the survey tend to discourage minority participation in clinical trials (Table 3a). However, non-Caucasian respondents were more likely to agree that “fear of unknown side effects” was a significant deterrent for minority participation ($p<0.01$). Non-Caucasian research professionals were also marginally more likely to agree or strongly agree with the statements that

“minorities are more likely to be unavailable for follow-up phone calls” ($p=0.07$) and that the unavailability of translated material discourages non-English speakers from participation ($p=0.08$).

Factors that may discourage research professionals from enrolling minorities in clinical trials are presented in Table 3b. The respondents did not agree with any of the deterring factors listed in the survey that might make them hesitate to enroll minorities, with median responses all falling in the “strongly disagree” to “disagree” range. However, subtle differences in some factors were observed between Caucasian and non-Caucasian respondents. Non-Caucasian research professionals were more likely to be neutral or agree that they are discouraged from enrolling minorities because of the possibility of their withdrawal from participation ($p<0.01$), and decreased availability for phone follow-ups ($p<0.01$) and multiple follow-up visits ($p<0.01$).

Regarding the potential tools/resources helpful in training researchers to enroll diverse populations, a majority of research professionals preferred mentoring from experienced investigators (*mean* 3.6, *SD*=1.1) (Table 4). Recommendations from research professionals on how federal agencies should hold grant recipients accountable for enrollment plans are categorized in Table 5. A majority recommended checking with grantees annually to determine whether actual enrollment matched the proposed enrollment plan and to ask for effective strategies for improvement, as needed (*mean* 3.5, *SD*=0.9).

DISCUSSION

While birth and immigration trends predict that non-Caucasians will encompass up to 50% of the US population by 2044 [27], they continue to be underrepresented in clinical trials [4-6]. While a plethora of studies have focused solely on minority patients’ perspectives regarding their participation in clinical trials [7-11], researchers’ perspectives and barriers in enrolling minorities remain understudied and

ignored. We agree that empowering both potential enrollees and enrollers is equally important in resolving racial disparities in clinical trials [23].

Existing literature suggests that the investigator being the same race as a potential study subject appears to be more motivating to minorities' participation and recommends encouraging more minority investigators [9, 11, 28-30]. Also suggested is educating investigators about their own cultural awareness and sensitivity, so they can interact more successfully with minority patients [10, 31, 32]. Our data show even though the majority of respondents agree that race and ethnicity of potential candidates have an effect on enrollment success, they did not indicate they were more successful in enrolling subjects of their own race. In the current study, the language spoken by patients and research professionals appeared more of an important factor in enrollment than race. A majority of respondents agreed not only that a patient's primary language had an effect on enrollment success, but research professionals had more success enrolling subjects who shared their primary language. Further, a majority indicated that the language barrier and time spent arranging for interpreters had, in fact, prevented them from offering a study to potential candidates. It is noteworthy that over 95% of our respondents listed English as their primary language. Several reports have indicated that language is a barrier to the non-English speaking population's participation in research [7, 8, 11]. One possible response to this common issue is to require the costs of translating study materials and hiring interpreters be included in a study's budget at the time of submission.

In contrast to Caucasians, non-Caucasian research professionals were more likely to report that in their experience, the fear of unknown side effects, availability for follow-up telephone calls and unavailability of translated material discourages minority patients from participation. Although these barriers are widely reported in the literature from minority patients' perspectives [11, 29, 33] and are in agreement with our non-Caucasian research professionals' experience, the reasons for Caucasian research professionals not

experiencing or ranking these barriers at the same level as non-Caucasian research professionals are not clear.

Furthermore, data show that compared to Caucasians, non-Caucasian research professionals were more likely to report having been discouraged from enrolling minorities due to the possibility of their withdrawal, as well as their unavailability for telephone follow-ups and multiple follow-up visits. This finding is critical considering that a potential subject should be excluded from research only if he/she was clinically ineligible. No research subject should be excluded from study participation because they might withdraw or did not have a telephone or transportation for follow-up purposes. Options to address these concerns include funding for subjects to make a collect call or providing a phone card, and arranging transportation for subjects or have research nurses drive to participants' place of residence for follow-ups, an approach widely used by home care nurses.

The current study demonstrates that the majority of research professionals think mentoring by investigators experienced in enrolling diverse populations would increase their own success in enrolling diverse populations. Although it is important to train minority physicians as investigators in order to promote diversity in research [34, 35], it is equally important that research professionals of all ethnicities are mentored and receive training to enhance their cultural competence and ability to enroll diverse populations [10, 32]. Of note, when compared to Caucasians, more non-Caucasian research professionals reported having been discouraged from enrolling minority patients.

The current results indicate that asking institutions to provide a plan for enrolling diverse populations when applying for federal funding may not be enough. Study participants recommended that in order to hold grant recipients accountable for their enrollment plan, granting agencies should check annually whether recipients' enrollment matches their proposed plan; if not, the agencies need to request effective

strategies for improvement. This would motivate and enable grant recipients to enroll the number of minority participants projected in their enrollment plans.

Interestingly, a majority of our respondents did not agree that further/successive funding should be contingent upon having complied with prior enrollment plans for diverse populations. Nor did they agree with the suggestion that a drug or device should be approved only for those populations that were proportionally included in a clinical trial representing US demographics. Because multiple reports have shown race and sex differences exist in drug metabolism [1-3], we anticipated research professionals would favor approval of drugs and devices only for those populations that were adequately represented in a trial. The majority of our respondents were Caucasian investigators enrolling patients in federally-funded studies; the number of minority respondents was low, indicating there is a racial disparity at the level of research professionals themselves [36]. A large-scale study including an equal representation of genders, races and research roles may shed more light on barriers to enrolling minorities in clinical trials.

Strengths and Limitations

Our strategy of surveying only research professionals whose institutions received either AHRQ and/or NIH funding in 2013 was based on the fact that these organizations specifically encourage enrollment of women and minorities in clinical research [24, 25]. Since these individuals are expected to more rigorously reach out to diverse populations for participation, learning from their experiences made this investigation a strong one.

In contrast to a previously published study focused only on those investigators who had received funding from the National Heart, Lung, and Blood Institute [37], ours was the first nationwide study of research professionals who were actively enrolling patients and whose institution had received NIH and/or AHRQ funding. Therefore, this study covers a wide range of medical specialties. Ours took a novel approach in

comparing research professionals' perceptions about what prevents minorities from enrolling in clinical trials versus what prevents researchers from enrolling minorities. This is also the first study asking researchers about their suggestions for helpful resources and recommendations to resolve disparities in clinical trials.

Despite a \$50 gift card incentive and two email reminders, our response rate was only 7.4% for this anonymous survey, which required seven to eight minutes to complete. This disappointing response may be due to the somewhat sensitive nature of the questions and hesitancy to admit biases. Further, this low response from a target population of researchers, who might be expected to exhibit high levels of interest in this topic, may be due to the email survey method we utilized. Although we targeted researchers affiliated with institutions receiving NIH and/or AHRQ funding, it is likely that our email list also included some bench or qualitative researchers at these institutions and would have lowered the overall response rate. Further, those who participated due to their personal interest in this topic may have introduced some bias in this self-selected sample.

We were interested in exploring variations in perceptions of research professionals from different racial backgrounds. However, in addition to a low response rate, 17.7% of respondents (primarily investigators) did not respond to the question of race which further decreased our ability to quantify these differences. While investigating researchers' perspectives regarding barriers to each individual minority race should be explored, we did not pursue this approach as we were concerned about the length of the survey further lowering its response rate.

CONCLUSION

Despite a few subtle racial differences in research professionals' perspectives regarding minority patients' barriers, as well as in their own barriers to enrolling minorities, a majority reported no hesitation in

enrolling minorities. Patients' race and primary language appeared to influence enrollment. The language barrier appeared to be the strongest for research professionals when considering enrolling minorities. To promote diversity in clinical trials, a majority recommended mentoring from investigators experienced in successfully enrolling diverse populations and an annual check by federal agencies to hold grant recipients accountable for their enrollment plan.

ETHICAL APPROVAL

All procedures performed in this study involving human subjects were in accordance with the ethical standards of the IRB and with the 1964 Helsinki declaration and its later amendments.

INFORMED CONSENT

This anonymous and voluntary survey study was IRB-approved as "exempt;" therefore, an alteration of informed consent was granted.

FUNDING

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CONFLICT OF INTEREST

The authors have no outside support, conflicts or financial interests to disclose.

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FIGURE 1: CONSORT Flow Diagram

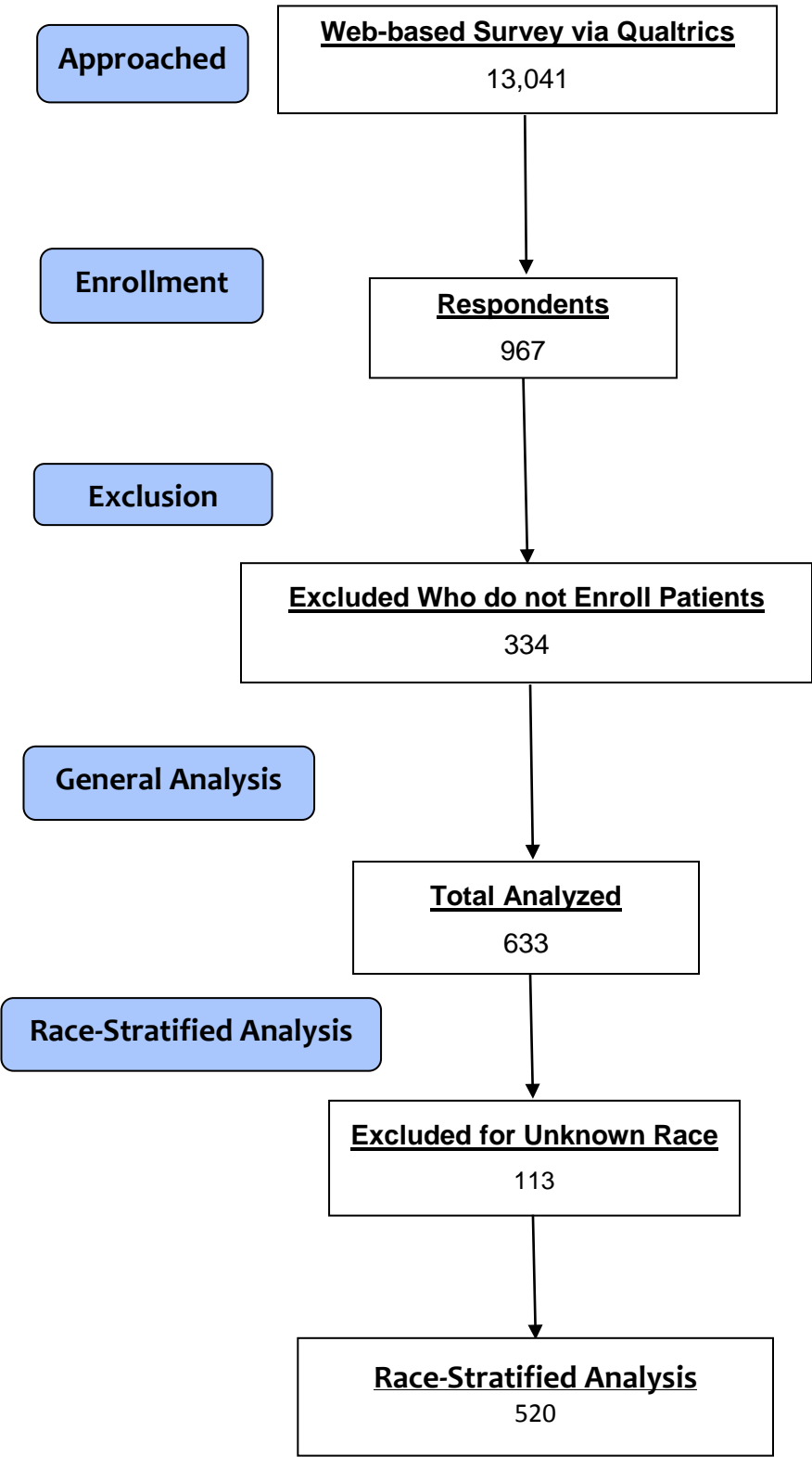


Table 1: Respondents' characteristics stratified by race ($N=520$).

Variable	Coding	Overall <i>N</i> (%)	Caucasians <i>N</i> (%)	Non-Caucasians <i>N</i> (%)	<i>p</i> -value*
What is your role in clinical research?	Investigator	329 (63.3)	277 (64.0)	52 (59.8)	0.20
	Clinical Research Coordinator	81 (15.6)	65 (15.0)	16 (18.4)	
	Research Nurse	17 (3.3)	15 (3.5)	2 (2.3)	
	Research Associate	15 (2.9)	9 (2.1)	6 (6.9)	
	Research Assistant	5 (1)	4 (0.9)	1 (1.2)	
	Other	18 (3.5)	14 (3.2)	4 (4.6)	
	Combination	55 (10.6)	49 (11.3)	6 (6.9)	
What type of institution do you currently work at?	Academic hospital	369 (71)	303 (69.8)	66 (76.7)	0.32
	Community hospital	29 (5.6)	26 (6.0)	3 (3.5)	
	Academic Community hospital	70 (13.5)	58 (13.4)	12 (14)	
	Government/VA Facility	6 (1.2)	5 (1.2)	1 (1.2)	
	Other	23 (4.4)	19 (4.4)	4 (4.7)	
	Multiple	23 (4.4)	23 (5.3)	0 (0)	
How many clinical research studies have you been enrolling for within the last five years?	None	7 (1.3)	4 (0.9)	3 (3.5)	0.14
	1-5	301 (57.8)	249 (57.4)	52 (59.8)	
	6 or more	213 (40.9)	181 (41.7)	32 (36.8)	
Were any of the studies federally funded?	Yes	392 (75.4)	328 (75.8)	64 (73.6)	0.86
	No	119 (22.9)	98 (22.6)	21 (24.1)	
	Don't know	9 (1.7)	7 (1.6)	2 (2.3)	
What is your gender?	Female	333 (64.0)	270 (62.4)	63 (72.4)	0.07
	Male	187 (36.0)	163 (37.6)	24 (27.6)	
What is your primary language?	English	480 (95.2)	411 (97.4)	69 (84.1)	<0.01
	Other	24 (4.8)	11 (2.6)	13 (15.9)	
Total languages spoken?	1	396 (76.0)	342 (78.8)	54 (62.1)	<0.01
	2	116 (22.3)	85 (19.6)	31 (35.6)	
	3+	9 (1.7)	7 (1.6)	2 (2.3)	

**p*-values are based on Chi-square tests.

Table 2: Responses for, “Based on your past experience, what trends have you witnessed in clinical research?”

Trends	<i>N</i>	<i>Mean</i>	<i>SD*</i>	Strongly Disagree <i>N</i>	Disagree <i>N</i>	Neutral <i>N</i>	Agree <i>N</i>	Strongly Agree <i>N</i>
Patients with higher education are more likely to participate.	583	3.3	1.0	14	137	141	236	55
Patients with higher income are more likely to participate.	580	2.9	0.9	25	182	213	134	26
Patients with private insurance are more likely to participate.	580	2.9	0.8	23	160	291	89	17
Race and ethnicity of the potential candidate have an effect on enrollment success.	581	3.4	1.0	17	111	150	240	63
The primary language spoken by the potential candidate has an effect on enrollment success.	580	4.0	0.9	9	33	84	275	179
I have more success enrolling those who are the same race/ethnicity as me.	580	2.7	0.9	58	198	213	100	11
I have more success enrolling those whose primary language is the same as mine.	580	3.8	1.0	18	57	120	239	146
A language barrier and time spent arranging for interpreters have prevented me from offering a study to potential candidates.	578	3.2	1.2	55	127	124	175	97

**SD*=Standard Deviation

Table 3a: Summary statistics and distribution of responses for, “Based on your past experience, what discourages minorities from participating in clinical research?”

Barriers for minority patients	Race	<i>N</i>	<i>Mean</i>	<i>SD*</i>	Strongly Disagree <i>N</i>	Disagree <i>N</i>	Neutral <i>N</i>	Agree <i>N</i>	Strongly Agree <i>N</i>	<i>p</i> -value#
Distrust in doctors	Caucasian	425	3.4	1.0	10	78	92	204	41	0.34
	Non-Caucasian	87	3.5	1.0	1	18	13	43	12	
Fear of unknown side effects	Caucasian	425	3.5	0.9	10	52	119	210	34	<0.01
	Non-Caucasian	85	3.8	0.9	2	6	14	45	18	
Unavailability for multiple follow-up visits	Caucasian	427	3.6	0.9	4	55	95	212	61	0.16
	Non-Caucasian	87	3.8	1.0	2	9	14	45	17	
Unavailability for phone follow-ups	Caucasian	428	3.1	0.9	14	103	152	137	22	0.07
	Non-Caucasian	87	3.3	1.0	1	21	23	32	10	
Unavailability of translated material for non-English speakers	Caucasian	429	3.5	1.0	14	69	107	169	70	0.08
	Non-Caucasian	87	3.7	1.0	1	14	13	41	18	
Unavailability of medical interpreters	Caucasian	429	3.3	1.0	16	81	122	156	53	0.16
	Non-Caucasian	87	3.5	1.0	1	17	21	31	17	

**SD*=Standard Deviation

#*p*-value based on the two-sample Wilcoxon rank-sum test.

Table 3b: Summary statistics and distribution of responses for “Based on your past experience, what discourages you from enrolling minorities?”

Barriers for research professionals	Race	<i>N</i>	<i>Mean</i>	<i>SD*</i>	Strongly Disagree <i>N</i>	Disagree <i>N</i>	Neutral <i>N</i>	Agree <i>N</i>	Strongly Agree <i>N</i>	<i>p</i> -value#
I hesitate to enroll minorities.	Caucasian	430	1.3	0.6	330	76	18	5	1	0.01
	Non-Caucasian	86	1.5	0.8	55	19	8	4	0	
My fear that I won’t be trusted discourages me from enrolling minorities.	Caucasian	429	1.4	0.8	307	86	21	14	1	0.09
	Non-Caucasian	84	1.6	0.9	53	19	8	4	0	
The possibility of their withdrawal discourages me from enrolling minorities.	Caucasian	429	1.4	0.8	298	88	25	17	1	<0.01
	Non-Caucasian	86	1.8	1.0	45	19	14	8	0	
The possibility of their unavailability for multiple follow-up visits discourages me from enrolling minorities.	Caucasian	431	1.6	1.0	278	81	35	36	1	<0.01
	Non-Caucasian	85	2.0	0.1	41	19	13	11	1	
The possibility of their unavailability for phone follow-ups discourages me from enrolling minorities.	Caucasian	429	1.5	0.9	286	82	38	22	1	<0.01
	Non-Caucasian	85	1.9	1.0	41	22	15	6	1	

**SD*=Standard Deviation

#*p*-value based on the two-sample Wilcoxon rank-sum test.

Table 4: Responses for, “Which of the below tools would be helpful in training you regarding how to enroll diverse populations?”

Helpful Tools	<i>N</i>	<i>Mean</i>	<i>SD*</i>	Strongly Disagree <i>N</i>	Disagree <i>N</i>	Neutral <i>N</i>	Agree <i>N</i>	Strongly Agree <i>N</i>
DVDs demonstrating how to approach each specific racial/ethnic group	528	3.1	1.1	66	78	154	201	29
Mentoring from investigators experienced in enrolling diverse populations	528	3.6	1.1	36	41	100	266	85
Mock enrollment sessions targeting specific populations	526	3.2	1.1	55	69	171	190	41

**SD*=Standard Deviation

Table 5: Summary statistics and distribution for, “What would you recommend federal agencies do to hold grant recipients accountable for their enrollment plan?”

Recommendations	<i>N</i>	<i>Mean</i>	<i>SD*</i>	Strongly Disagree <i>N</i>	Disagree <i>N</i>	Neutral <i>N</i>	Agree <i>N</i>	Strongly Agree <i>N</i>
Check annually if actual enrollment matches with the proposed plan and ask for effective strategies, as needed.	526	3.5	0.9	24	54	108	299	41
Award further/successive funding only if the enrollment plan for diverse populations was met.	526	2.7	1.1	85	151	133	141	16
Approve a drug/device only for those populations that were proportionally included in a trial representing demographics of the United States.	524	2.7	1.1	87	155	144	118	20

**SD*=Standard Deviation