Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys

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ABSTRACT: Strengthening the informed consent process is one avenue for improving recruitment of minorities into research. This study examines that process from two different perspectives, that of researchers and that of African American and Latino community members. Through the use of two separate surveys, we compared strategies used by researchers with the preferences and attitudes of community members during the informed consent process. Our data suggest that researchers can improve the informed consent process by incorporating methods preferred by the community members along with methods shown in the literature for increasing comprehension. With this approach, the informed consent process may increase both participants' comprehension of the material and overall satisfaction, fostering greater trust in research and openness to future research opportunities.

KEY WORDS: informed consent, minorities, improving informed consent

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Informed consent is the process by which potential participants are given the opportunity to make informed decisions about their participation in research. In the United States, federal guidelines govern the interaction with human subjects, including the informed consent process and document (U.S. Department of Health and Human Services, 2009). In many cases, the focus of the informed consent process is on the signing of the consent document rather than on the interaction between researcher and participant (Thorne, 1980). Yet a growing body of evidence indicates that many participants are misinformed about research and have incomplete comprehension of information specific to research studies in which they are involved (Corbie-Smith, Thomas, & St. George, 2002; Freimuth et al., 2001; Penman et al., 1984). This is particularly true for racial and ethnic minority participants (Sudore et al., 2006), suggesting that it is necessary for researchers to improve their informed consent process, especially in the context of recruiting minorities who have been underrepresented in biomedical and clinical research (Corbie-Smith et al., 1999; Farmer et al., 2007; Freimuth et al., 2001; Lakes et al., 2012).

Strengthening the informed consent process requires investigators to consider several interrelated factors: the cultural and contextual issues that influence minorities' reactions to informed consent; the ability of researchers to effectively address these issues and engage in the informed consent process; and potential participants' comprehension of information delivered during the informed consent process.

Certain cultural and contextual factors magnify the challenge of informed decision-making for individuals from racial and ethnic minority populations, including both lack of trust arising from past legacy of mistreatment, or misinformation about the informed consent process and inadequate comprehension of the information after the informed consent document is signed.

The issue of minority trust in research is an important factor to consider when evaluating ways to improve the informed consent process. Focus group and survey data with African Americans have revealed a sense of distrust arising from a legacy of mistreatment in the health care system and research abuses (Corbie-Smith et al., 2002; Freimuth et al., 2001). African Americans are less likely to trust that research will be fully explained to them and "more likely to believe that someone like them would be used as a guinea pig without his or her consent" (Corbie-Smith et al., 2002, p. 2459). Overemphasis

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on the initial consent document can compound distrust of research and medical care by contributing to the perception that informed consent serves as a legal waiver of liability for adverse outcomes (Ard et al., 2005; Freimuth et al., 2001). In focus groups, African Americans have stated that providing informed consent amounts to "signing away your rights" and that the intent of informed consent is to protect researchers from lawsuits (Freimuth et al., 2001, p. 802). Too often, informed consent protocols emphasize the signing of the initial consent document—which becomes a sort of "opening ritual" (Thorne, 1980, p. 289)—rather than a process that lays the foundation for ongoing communication and building a longer-term relationship between the researcher or research team and the participant.

Additionally, cultural factors unique to some specific minority communities include the desire for translated materials and trained interpreters (Eder et al., 2007), concerns about being detected as undocumented immigrants, and a desire to meet with researchers multiple times prior to deciding whether or not to participate (Lakes et al., 2012). Investigators who wish to recruit minorities may need to question the assumption implicit in informed consent documents that participation is an *individual* decision (ibid.). In some communities, where the family or community is an integral part of the decision-making process, and risks and benefits of research participation are considered in terms of how the larger group will be affected, investigators should allow enough time for participants to engage in the relevant group decision-making process. Finally, recent research suggests that providing information outside of the formal consent document can enhance minority participation. For example, Dunlop et al. (2011) found that compared to a traditional consent process, a DVD-enhanced consent process resulted in a greater number of study participants expressing a willingness to participate in a hypothetical clinical study and that those who viewed the DVD were significantly less likely to cite mistrust, privacy, fear of side effects, and lack of perceived benefits as reasons for nonparticipation. In another study, minority focus group participants expressed a desire for more detailed information in various formats (such as brochures, FAQs, and DVDs) to increase the "legitimacy" of the research (Lakes et al., 2012, p. 225).

Aside from enhancing minority satisfaction and participation through improved informed consent, an important ethical consideration for investigators is ensuring that participants understand the disclosed information. Studies show that participants frequently have poor recall of the information provided during consent (Penman et al., 1984), do not understand key terms such as "randomization" and "placebo" (Criscione et al., 2003), believe study drugs do not involve additional risk (Barrett, 2005; Criscione et al., 2003), and expect to receive the best available treatment despite having been "informed" of the randomized trial design (Joffe et al., 2001).

Efforts to improve comprehension of informed consent have generally focused on enhanced consent forms and multimedia interventions. Although modifications to consent forms have included condensing the form's length, using plain language and larger font to improve readability, and adding graphics, such efforts have had only limited success, with a majority of studies showing no significant gains to understanding from such techniques (Flory & Emanuel, 2004). One key issue may be lack of familiarity with research concepts. In focus groups conducted with low-literacy Spanish speakers regarding a hypothetical study, Cortés et al. (2010) found that simplified consent forms written in Spanish and using plain language, shorter sentences and paragraphs, large font, and wide margins did not guarantee comprehension. The focus group participants, especially those with no prior experience with research, sometimes did not understand basic research concepts despite their ability to read the simplified document. Similarly, video and computer multimedia interventions have not shown a consistent positive effect on comprehension of informed consent compared with standard written and oral information. Hence, uncertainty remains about the value of such strategies (Flory & Emanuel, 2004; Ryan et al., 2008).

Two literature reviews (Cohn & Larson, 2007; Flory & Emanuel, 2004) suggest that to be successful, the informed consent process needs to include one-on-one interaction with someone knowledgeable about the study, as well as various communication modes, both written and verbal. Person-to-person interaction appears to be more important than videos or paper forms in improving understanding, and limited evidence suggests that consent procedures incorporating tests and/or feedback to check comprehension result in better understanding (Flory & Emanuel, 2004; Sudore et al., 2006).

This article represents the first study to examine issues related to improving informed consent from two perspectives, that of researchers and that of African American and Latino community members. Further, we use these perspectives to develop recommendations on how to improve the informed consent process through (1) increasing participant satisfaction by addressing the discrepancies between researchers'

practices and community members' preferences and (2) increasing comprehension by incorporating effective methods.

Methods

Researcher Participants

The participants were recruited from May to August 2010 using an e-mail invitation to an online survey. Invitations to participate were sent through the listservs of Public Responsibility in Medicine and Research (PRIM&R), which includes researchers and IRB members who conduct many types of research, Community-Campus Partnerships for Health, numerous clinical and translational science institutes, colleagues in academic health centers, and PRIM&R webinars. Additionally, invitations to participate were included in publications such as the IRB Advisor, and on several Facebook sites, including those for the Centers for Disease Control and Prevention, the American Public Health Association, and the *Journal of Medical Ethics*. Demographic variables gathered from 347 participants included: gender, age, race, ethnicity, place of work or employment, primary role in research, and years involved with research.

Researcher Questions

Researchers were asked three questions regarding their practices during the informed consent process. First, researchers were asked to select from a list the strategies they used during the informed consent process: (a) one-on-one discussion between the investigator and potential participants, (b) reading the informed consent form to potential participants, (c) conducting a group discussion with potential participants, (d) enabling potential participants to talk to a current participant in the study, (e) developing an interactive computer program for potential participants, (f) enabling potential participants to have more than one meeting to discuss the study, (g) enabling potential participants to watch a video and have a one-on-one conversation afterwards, (h) giving potential participants information to take home and read on their own, (i) allowing potential participants to bring a friend or family member with them for the introduction to the study, and (j) other strategies.

A second question asked researchers what strategies they used to increase participants' understanding of the informed consent document: (a) use of simple language, (b) use of pictures and illustrations, (c) use of a question and answer format, (d) use of large print in the document, and (e) inclusion of a brief summary at the end of each section of the document.

Finally, researchers were asked to select which practices they used to determine potential participants' understanding during the informed consent process: (a) teach back (participant explains the study in his/her own words), (b) participant completes a questionnaire/survey on study knowledge at the end of the informed consent process, (c) investigator asks participant open-ended questions at the end of the informed consent process, (d) participant signs/initials every page of the informed consent form, (e) use of an independent monitor (who observes the informed consent process), and (f) other. Participants were invited to provide a verbatim response under the "other" category.

Community Participants

A U.S. national telephone survey was conducted by ICF-MACRO from June to December 2010 with 2,455 African American and Latino participants. Prospective participants were randomly selected based on U.S. telephone exchanges associated with geographic areas of high concentrations of African Americans and Latinos. To identify the appropriate exchanges, directory-listed telephone numbers were mapped and assigned to a specific geographic location (census block group, census tract, or zip code), and those exchanges with an estimated concentration of African Americans and Latinos of at least 40% were used. The overall response rate was 20.3%, which is consistent with response rates from other current random-digit-dial surveys (California Health Interview Survey, 2009; Sellars et al., 2010).

Demographic variables included: race, ethnicity, gender, age, education, marital status, income, health insurance, health status, and perceived socio-economic position (SEP). For the purposes of analysis, education was collapsed into two levels: below college and college or above; marital status was collapsed into two levels: married or living with a partner and other; and income was categorized into three levels: (1) below $36,000, (2) $36,000 to $76,000, and (3) above $76,000. Participants were also asked if they had health insurance (yes/no). The participants rated their health status on a 5-point Likert scale (1 = poor to 5 = excellent). Based on the MacArthur scale of socio-economic status (University of California, San Francisco, 2008), participants were asked about their socio-economic position (SEP): "Think of a ladder with 10 steps as representing where people stand in the U.S.; what step would you place

yourself on the ladder?" and to indicate their SEP on a 10-point Likert scale, from 1 = people who are the worst off to 10 = people who are the best off.

Community Participant Questions

The community participants were asked several questions about research and informed consent. The first question was directly linked to the first question for researchers, asking how helpful each item would be in learning about a study: (a) going over the informed consent for the study in a one-on-one discussion with the researchers, (b) being able to take information home and read it on one's own, (c) being allowed to have a family member or friend present during the introduction to the study, (d) talking to someone who is participating in the study, (e) taking part in a group discussion about the study, (f) watching a video about the study, (g) using an interactive game that provides information about the study on the computer, (h) having someone read the informed consent document to the participant, and (i) being able to have more than one meeting to discuss the study. The items were measured on a 3-point Likert scale (1 = not helpful at all to 3 = very helpful).

A second question linked to a researcher question asked the community members their preferences for learning about a study: (a) using plain language, (b) using pictures and illustrations, (c) using a question and answer format, (d) using large print in the document, and (e) having a brief summary at the end of each section of the document. The items were measured on a 3-point Likert scale (1 = not helpful at all to 3 = very helpful).

Community respondents were also asked about their knowledge of common research terminology with these true/false questions: (a) in a study that is confidential, your personal information is made public, (b) a double-blind study means that both you and the researcher will not know what treatment or drug you are receiving, (c) in a study that is anonymous no one will ask you for personal information such as your name or address, (d) in a study where the participants receive a placebo that means you will be getting a fake treatment, like a sugar pill, (e) when you agree to participate in a randomized research study that means you have a 50% chance of being assigned to the treatment, and (f) research that involves needles or incisions into your body is an example of a non-invasive study.

Finally, the community respondents were asked about their understanding of what it means when they sign the consent form: (a) I understand the study and agree to be a part of it, (b) I no longer have the right to sue if something goes wrong, (c) the researchers or institution are protected from a lawsuit if something goes wrong, and (d) I am protected as a research participant. This item was measured on 4-point Likert scale (1 = strongly disagree to 4 = strongly agree).

Analyses and Approvals

Descriptive statistics (mean, standard deviation), frequencies, and cross-tabulations were performed on the variables using STATA 11.2. Both surveys were approved by the University of Pittsburgh Institutional Review Board.

Results

Socio-demographic Measures

RESEARCHERS

A total of 347 respondents with a primary or secondary role as a researcher participated in the survey—130 PIs/co-Is (37.5%), 149 research staff (42.9%), and 68 IRB members (19.6%). Throughout this article, we refer to this group as researchers. Sixty-one percent (61%) were Caucasian, 18% African American, and 12% Latino. The additional 9% of respondents were grouped as "other", and included Asians, Native Americans, other races, and missing race. These participants were excluded from further analysis because the sample sizes were insufficient to analyze each group separately and yet combining them would ignore the heterogeneity of the groups and would lead to an average effect that was not reflective of any one group. Seventy-nine percent were female and the mean age was 46.8 years (SD = 11.8). Over 76% (265 of 347) completed the survey, which is comparable to completion rates in other online surveys (Fricker et al., 2005; Galesic & Bosnjak, 2009). Most importantly, there was no significant difference between participants who completed and did not complete the survey by investigator type (PI/co-I, research staff, IRB), race, or gender. Of the participants who completed the survey, 42.9% had six or more years of federally funded grants versus only 25.9% of participants who did not complete the survey ($\chi^2(1) = 7.50$, $p = .006$, Cramer's $V = .148$). The participants had been involved with research for an average of 14 years (SD = 9.1). There was a significant association between race and type of investigator ($\chi^2(6) = 13.16$, $p = .041$, Cramer's $V = .139$). PIs/co-Is and IRB members were more likely to be white (62% and 69%, respectively) than research staff (53%).

COMMUNITY RESPONDENTS

Of the 2,455 total respondents, 48.5% were African Americans and 51.5% were Latinos. The majority were female, high school or college educated, with health insurance (Table 1). For descriptive purposes, we report the raw results, though we collapse these categories for further analysis. African Americans and Latinos were similar on the demographic measures, with the exceptions that the African American respondents were significantly older than the Latino participants (53.3 vs. 46.7, $p < .001$) and that a higher proportion of the Latinos were married compared to the African Americans respondents (46.5% vs. 32.3%, $\chi^2(1) = 69.94$, $p < .001$, Cramer's $V = .170$).

Researcher Responses

To teach participants about a study, researchers used the following: going over the consent form one-on-one (78.0%), allowing information to be taken home (77.0%), having someone read the consent form aloud (65.1%), allowing a family member to be present (63.1%), allowing more than one meeting (58.5%), having small group discussions (42.1%), providing the opportunity for participants to talk with a current study participant (27.4%), watching videos (18.3%), and using interactive games (8.7%). Graphical representation of these results can be found in Figure 1.

Researchers' use of different formats in the informed consent document is shown in Figure 2. Nearly all the researchers (97.1%) reported that they used plain language in their informed consent document. Over 51% reported the use of question and answer format, 41.4% used pictures and illustrations, 38.5% used large print, and 19.3% incorporated a brief summary at the end of each section.

To determine potential participants' understanding of the informed consent process, researchers asked participants open-ended questions at the end (52.2%), had participants sign/initial every page of the informed consent form (51.5%), used teach-backs (38.0%), used an independent monitor (11.2%), and had participants complete a questionnaire or survey about the study (10.1%). Fewer than 10% of researchers (7.3%)

TABLE 1. Demographics by Race of the Community Participants.

	African Americans	Latinos	χ^2	p	Cramer's V
Gender			7.55	.006	.056
Male	32.2%	37.5%			
Female	67.8%	62.5%			
Education			56.91	<.001	.153
Elementary school	6.2%	12.4%			
High school	34.7%	38.8%			
College	42.4%	35.7%			
Graduate school	13.2%	9.2%			
Technical school	3.1%	2.2%			
Other	0%	1.8%			
Marital Status			69.94	<.001	.170
Married	32.3%	46.5%			
Divorced	13.9%	9.9%			
Widowed	15.4%	8.0%			
Separated	4.5%	3.7%			
Never married	16.7%	15.2%			
Single living w/ partner	17.3%	16.7%			
Health Insurance			27.34	<.001	.106
Yes	82.4%	73.5%			
No	17.7%	26.5%			
			t	p	Cohen's d
Age	53.2 (18.1)	46.7 (18.2)	8.93	<.001	.361
Perceived SES	5.5 (2.1)	5.3 (2.0)	2.30	.011	.095
Health Status	3.1 (1.1)	3.1 (1.1)	−.62	.733	.025

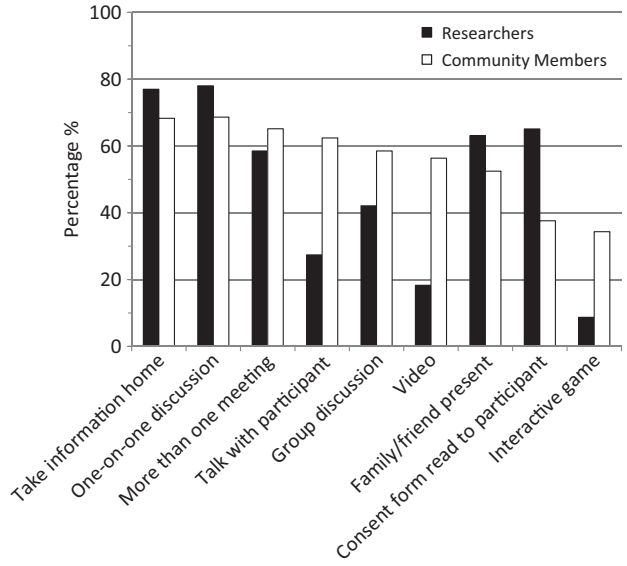

FIGURE 1. Comparison of researchers' use of different practices during the informed consent process with community members' views on the helpfulness of each practice. Black bars show the percentage of researchers who use each item, and the white bars show the percentage of the community respondents who felt each item was "very helpful" in learning about a study. African American and Latino responses were combined into a single percentage as there were no significant differences between the two groups.

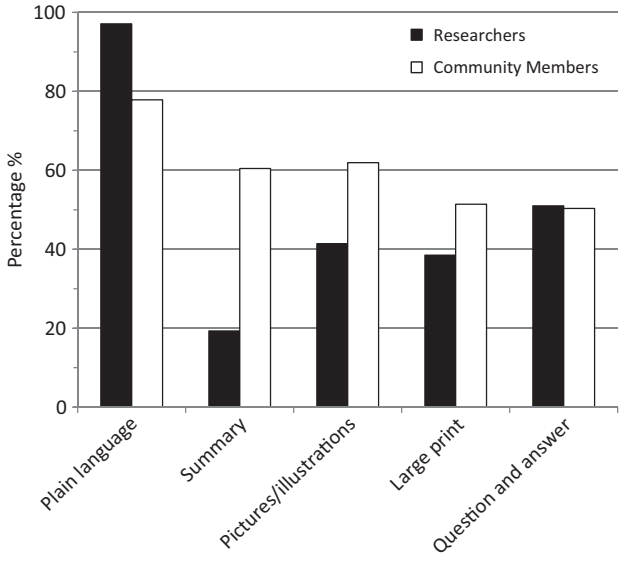

FIGURE 2. Comparison of researchers' use of different formats in the consent document with community members' views on usefulness of each format. Black bars show the percentage of researchers who used each item, and the white bars show the percentage of the community respondents who indicated each item was "very helpful". African American and Latino responses were combined into a single percentage as there were no significant differences between the two groups.

indicated they used another method to assess understanding by checking the "other" category. Researchers who checked "other" were given the opportunity to specify what methods they used through a write-in response. Themes identified from these verbatim responses included: use of open-ended questions, asking participants to complete a questionnaire or survey, and allowing participants to ask questions. Additionally, 32% of researchers did not use any methods to assess understanding, and 25% used only one of the methods. Overall, researchers used an average of 1.4 methods (out of six) to assess participant comprehension.

Community Participant Responses

Community participants indicated that their top four preferred ways to learn about a study were: having a one-on-one discussion with the researcher, being able to take information home, being able to have more than one meeting, and talking to a study participant (Table 2). Community members' top three preferences for formats in the informed consent document were: plain language, pictures and illustrations, and brief summaries (Table 2). There were no significant differences between African Americans and Latinos. These results are also represented in Figures 1 and 2, alongside the researchers' use of the methods for teaching about a study and formats used in the consent document.

Results from the knowledge questions posed to the community participants about common terms used in informed consent documents are shown in Table 3. Again, there were no significant differences between African Americans and Latinos.

When asked what a signature on the consent form means, the majority of both the African American (84%) and Latino (85%) respondents agreed or strongly agreed that it meant they understood and agreed to participate. Sixty-two percent (62%) of African Americans and 56% of Latinos believed their signature meant that they could not sue the research institution, and 50% of African Americans and 56% of Latinos believed that the form protected the researcher and institution. Sixty-eight percent (68%) of African Americans and only 52% of Latinos thought that signing the consent form meant they were protected as research participants.

Discussion

Asking both researchers and community participants similar questions about their practices and preferences

TABLE 2. Rating by the Community Members of Different Methods and Formats Used to Facilitate Understanding of the Research Study during the Informed Consent Process.

	African Americans	Latinos	
	Very helpful	Very helpful	Cramer's V
Strategies for Learning			
Take-home information	70.9%	65.7%	0.055
One-on-one discussion	67.5%	69.8%	0.025
More than one meeting	64.7%	65.6%	0.009
Talking to someone who is participating	60.5%	64.3%	0.039
Group discussion	57.7%	59.3%	0.017
Video	57.0%	55.7%	0.014
Family member or friend in the discussion	53.3%	51.6%	0.016
Have someone read the informed consent form to the participant	34.7%	40.5%	0.059
Interactive game	33.8%	34.9%	0.011
Format			
Plain language	78.8%	76.9%	0.023
Summary at the end of each section	60.7%	60.2%	0.005
Pictures and illustrations	60.3%	63.6%	0.035
Large print in the document	53.0%	49.8%	0.032
Question and answer format	50.3%	50.4%	0.000

TABLE 3. Percent Correct on the Community Participants' Knowledge of Terms Used in Medical Research Studies.

	African Americans	Latinos	
	Correct	Correct	Cramer's V
Confidential	74.1%	75.5%	.016
Anonymous	63.6%	65.3%	.018
Placebo	59.4%	54.1%	.053
Non-invasive study	57.9%	55.2%	.027
Randomized research study	56.2%	54.1%	.021
Double-blind study	47.1%	42.3%	.049

during the informed consent process allowed us to identify three key areas of discordance that can be targeted to improve the informed consent process: (1) ways to learn about a study that are preferred by community members but are not frequently used by researchers, (2) strategies used by researchers to help potential participants understand a study that are not viewed as helpful by the community members, and (3) formats for the informed consent document that are preferred by the community members but are not frequently used by researchers. We utilize our results, along with the published literature, to offer guidance to researchers to improve the informed consent process in two distinct ways: (1) increasing participants' satisfaction by incorporating those practices identified by the community respondents as useful and preferred, and (2) increasing comprehension by incorporating more effective methods. In some cases, these practices will be the same, while in others, a combination of methods may be used to accomplish both goals.

The first important discrepancy is in methods preferred by community respondents for learning about a study. Although the top two methods preferred by community members were also the two most often used by researchers (going over the consent form one-on-one and taking the information home), the next two most preferred methods of the community respondents (being able to have more than one meeting and talking to someone who is currently participating in the study) are less commonly used by researchers. Although incorporating these methods may not always be practical due to confidentiality, time, or logistical constraints, researchers should consider designing multiple meetings into the informed consent process or providing access to current participants when possible. Additionally, incorporating these preferences may increase

comprehension by allowing more one-on-one discussion, either with the researcher or with study participants and may increase participants' understanding and satisfaction with the process.

Researchers might also take note of some of their commonly used practices that are ranked as less helpful by the community members. These practices include allowing a family member to be present and having someone read the informed consent document to the participant (used by 63.1 and 65.1% of researchers, respectively), yet were ranked in the bottom three in terms of helpfulness by community members responses, and were considered less helpful than group discussion and watching a video. Though videos have not shown a clear impact on comprehension, face-to face interaction may be one of the more effective ways to deliver information, and therefore, group discussion is likely to be effective in increasing comprehension. Thus researchers might consider integrating group discussions as a way to increase both participant comprehension and satisfaction.

In the consent document itself, the top method (use of plain language) preferred by community respondents was also the most frequently used by researchers (97.1%). However, the community respondents' preferences for a brief summary at the end of each section, the use of pictures and illustrations, and the use of large font were less frequently used by researchers. Although Flory and Emanuel (2004) did not find incorporating these formats into the consent document to be effective in increasing comprehension, additional studies show that patients are more satisfied with simpler consent forms (Coyne et al., 2003; Davis et al., 1998) and the use of video (Philippe et al., 2006). Therefore, we suggest researchers consider incorporating formats the community respondents preferred, such as large font, summaries, and illustrations to increase participant satisfaction.

Our results also indicate areas where there is a good match between community members' preferences, researchers' practices, and effective methods for increasing comprehension. The two methods of learning about a research study most preferred by the community respondents (ability to take information home and one-on-one discussion with the researcher) were also the two methods most often used by researchers. These methods are also likely to be among the most effective in ensuring comprehension. One-on-one discussions and extended or multiple conversations about a study have been shown to increase understanding in several studies (Flory & Emanuel, 2004), and the ability to take information home can allow participants ample time to read, process, absorb the material, and potentially discuss the study with family members. This could be useful for those participants for whom the decision to participate in a research study is a collective decision within the family.

Additionally, there is concordance between researchers' practices and preferences of the community respondents on the use of plain language within the consent document. The issue of comprehension during the informed consent process is complex, however, and we raise the question of whether the use of plain language is as widespread as it is reported by researchers. Our doubt about researchers' use of plain language is also founded in Paasche-Orlow, Taylor, and Brancati's study (2003), which found that sample informed consent text from 114 medical school websites was written at a mean grade level of 10.6, though nearly half of all Americans read at or below the eighth grade level. Other relevant studies have found that study participants, and minority participants in particular, continue to show incomplete comprehension of the study information and are misinformed about the purpose of the informed consent process (Corbie-Smith et al., 2002; Flory & Emanuel, 2004; Freimuth et al., 2001; Penman et al., 1984).

In fact, the results from our study support previous reports of low comprehension or misunderstanding of information provided during the informed consent process and limited knowledge of general research terms. Our results showed that the community participants were unfamiliar with several key terms used in clinical trials and were often misinformed about the purpose of their signature on the consent document as well as with the overall informed consent process.

Clearly, researchers' assessment of participants' understanding is critical to ensure that a participant is capable of making an informed, voluntary decision to participate. In our survey, some of the methods (open-ended questions and teach-back) may be particularly useful to assess participant's consent capacity and comprehension of the information given, and to increase understanding as the assessment continues. Discussion and teach-back methods are recognized by many adult learning programs as the most effective ways of increasing retention of new information and are consistent with the one-on-one methods of interaction identified by Flory and Emanuel (2004) and Cohn and Larson (2007) for enhancing understanding. Additionally, the U.S. Department of Health and Human Services suggests the use of independent monitors to ensure that the consent process is adequate and effective (U.S. Department of Health and Human Services, 2012).

Most startling, however, was that 32% of researchers reported that they used no methods to assess comprehension, and 25% used only one of the methods. For those researchers using open-ended questions and teach-back to assess understanding, using only one method may be sufficient. For the 50% of researchers who asked participants to sign or initial every page, there is a greater need to incorporate some other measure of comprehension, as signing does not give the investigator any indication of whether or not the participant understood the consent document. Use of effective methods to assess comprehension can assure the researcher that a potential study participant is adequately informed about the study.

Limitations of This Study

A limitation of this study is that the community member responses may not be generalizable to all African Americans and Latinos, as we focused our recruitment efforts on those living in predominantly minority communities. However, with a strong national sample, we are confident in our overarching recommendation that the informed consent process incorporate thoughtful and respectful consideration of a participant's current knowledge and cultural context, and an extended and ongoing dialogue to ensure that the participant is informed about the study. The researcher survey is limited in that it is a convenient, nonrepresentative sample for which we cannot calculate a response rate.

Overall, this study offers a unique look at the informed consent process from the viewpoints of both researchers and African American and Latino community members, identifying areas of discordance between researchers' practices and community members' preferences. The community respondents' results on the knowledge portion of the survey and their interpretation of the consent document speaks to the need for improving the informed consent process so that study participants fully understand the nature of the study and their rights as participants.

Best Practices

Improving the informed consent process should include a combination of incorporating methods to increase community members' satisfaction with effective methods for increasing comprehension of the material. These methods include: taking study information home, one-on-one discussion, more than one meeting, talking to another study participant, and to a lesser degree, group discussions and videos.

Within the consent document, we recommend the use of plain language, inclusion of summaries, and use of pictures and illustrations. The U.S. government describes plain language as communication that is understood the first time it is seen or heard, describing it as "easy to read, understand, and use" (Federal Plain Language Guidelines, March 2011). By revisiting the plain language guidelines (http://www.plainlanguage.gov/howto/quickreference/checklist.cfm) and utilizing readability assessments, researchers can ensure that both their written and verbal communication is delivered at a level and in a manner that is appropriate to their audience. One respondent in our survey commented that his IRB did not allow many modifications to the consent document that might make it easier to read. This may not be an uncommon challenge. We recommend working with the IRB to allow more tailoring of consent documents to enhance their appropriateness, and if these changes are not allowed, then expanding the verbal portion of the consent process to allow for extra time to discuss the study, remembering that the document itself is just one part of the overall process.

We also emphasize encouraging one-on-one interactions through the use of multiple meetings or, when appropriate, with current study participants. We also suggest that researchers consider cultural factors when designing the informed consent process for the study, such as allowing material to be brought home, or involving family members. Finally, we suggest that within the research team, they may consider utilizing evaluation tools to determine the effectiveness of different methods or conducting qualitative interviews with participants to ascertain their assessment of the informed consent process.

Of critical importance is that, ultimately, the research team should conduct its own formative research prior to beginning the informed consent process to fully understand the participants they are seeking to recruit and to tailor the strategies and language used in the informed process to their local needs. Along with formative research, a grasp of best practices from the current literature, and evaluation of the informed consent process throughout the recruitment phase of the study, will enable research teams to create the strongest and most effective process for their study.

Research Agenda

Future studies are necessary to continue to evaluate the informed consent process, and specifically what methods can be used to improved comprehension of study

information. Further investigation into what factors contribute to higher levels of comprehension and what methods of assessing comprehension are being used could help to determine the most effective means of conveying information to potential study participants.

There is an important need for additional studies that focus on whether there are differences in the quality of the information delivery during the informed consent process between minority and nonminority participants. Simon and Kodish (2005) found that minority women received less information than their white counterparts during the informed consent process. Furthermore, there is no substantial body of published research to date that examines the extent to which the interaction between the race, ethnicity, or gender of the researcher and that of the potential participant shapes the informed consent process.

Educational Implications

Our results suggest several educational needs for researchers, research staff, and IRB staff. First, educational programs can focus specifically on guidance about how consent processes may be improved, including the implications of the results from this study on effective strategies to increase comprehension of study materials, and preferred methods deemed helpful by minority participants. Secondly, educational efforts can focus on the use of readability assessments and plain language guidelines to strengthen informed consent documents. Some resources for investigators on informed consent are provided by the U.S. Department of Health and Human Services, and can be found at: http://www.hhs.gov/ohrp/policy/consentckls.html, http://www.hhs.gov/ohrp/policy/ic-non-e.html, and http://aspe.hhs.gov/sp/nbac/appendixc.shtml.

Finally, it may be particularly important to create educational initiatives that enable researchers to become more **culturally confident** and committed to self-reflect and critique over one's lifespan. Thomas et al. (2011, p. 411) describe the importance of cultural confidence in researchers, defining it as "a lifelong process based on the individual's self-reflection about their personal biases and prejudices. We define a **culturally confident** person as someone who is flexible and humble enough to admit ignorance and is willing to be uncomfortable addressing complex racialized issues." In our Building Trust between Minorities and Researchers: A Bioethics Research Infrastructure Initiative, we have developed a curriculum for researchers, *Becoming a Self-Reflective Researcher: Successfully Engaging Minority Communities*, which includes video vignettes for enhancing the informed consent conversation and process with minority participants (see www.healthequity.umd.edu for further details). Participation in such an educational program can increase researchers' understanding of how the impact of their own conscious and unconscious biases may shape their interaction with minorities during the informed consent process, and they can learn new strategies for strengthening communication with participants from whom they may differ by race, ethnicity, or class.

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