

Voluntary Participation and Informed Consent to International Genetic Research

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Informed consent represents a key ethical concern in clinical and community-based epidemiological genetic research.^{1–9} Voluntary informed consent is universally accepted as a precondition for scientific research involving human beings. National and international guidelines for ethical conduct in research outline specific requirements for obtaining informed consent.^{10–13} Despite the promulgation of ethical guidelines for obtaining informed consent, the application of national and international guidelines can be difficult in practice.^{14–17}

Research participants may have difficulty understanding consent documents that include information about complex biomedical and genetic concepts.^{18–28} Language barriers may hinder effective communication between researchers and participants invited to join a study.²⁹ Requirements for written consent can further exacerbate challenges to effective communication, particularly in areas with high illiteracy rates or low levels of trust in medical institutions, or where signatures are seldom used for conducting business.³⁰ In many non-Western settings, family members or community leaders may have an important role in determining participation in medical and genetic research.^{31–37} In resource-poor settings, individuals and communities may be vulnerable to coercion because of their social status or poverty, and political conditions may complicate the ethical principle of voluntary participation in research.^{38–40}

There is a small but growing literature on informed consent to medical research conducted in low- or middle-income countries.^{41–49} However, little is known about informed consent to genetic epidemiological research in culturally or socioeconomically diverse communities in resource-poor or industrialized nations.^{50–52} The increasing global effort to use genetic epidemiological tools to understand the etiology of complex diseases such as HIV infection, malaria, diabetes, and

Objectives. We compared voluntary participation and comprehension of informed consent among individuals of African ancestry enrolled in similarly designed genetic studies of hypertension in the United States and Nigeria.

Methods. Survey questionnaires were used to evaluate factors associated with voluntariness (the number of people volunteering) and understanding of the study's genetic purpose. A total of 655 individuals (United States: 348; Nigeria: 307) were interviewed after participation in the genetic studies.

Results. Most US respondents (99%), compared with 72% of Nigerian respondents, reported being told the study purpose. Fewer than half of the respondents at both sites reported that the study purpose was to learn about genetic inheritance of hypertension. Most respondents indicated that their participation was voluntary. In the United States, 97% reported that they could withdraw, compared with 67% in Nigeria. In Nigeria, nearly half the married women reported asking permission from husbands to enroll in the hypertension study; no respondents sought permission from local elders to participate in the study.

Conclusions. Our findings highlight the need for more effective approaches and interventions to improve comprehension of consent for genetic research among ethnically and linguistically diverse populations in all settings. (*Am J Public Health*. 2006;96:1989–1995. doi:10.2105/AJPH.2005.076232)

hypertension requires more direct and intense collaborations between many disciplines and between wealthy and poor nations.¹⁹ The rapid growth of genetic research initiatives worldwide heightens the urgency to understand more about informed consent practices for genetic studies with diverse populations.

Participants may respond differently to informed consent for genetic research because the research may have serious implications for family relationships, personal and ethnic identity, and the emotionally charged notions of “race.”⁵³ Genetic research differs from other types of medical research because of culturally embedded beliefs about heredity. Inherited genetic traits cannot be changed. Moreover, results of genetic research may reinforce racist stereotypes or result in discriminatory practices against individuals or populations.

These issues are relevant for populations everywhere. However, individuals involved in genetic research in industrialized settings with high rates of literacy might be expected to have greater understanding of the genetic

purpose of such studies than their counterparts in low-income countries, particularly in areas of low literacy.⁵² Differences in understanding the voluntary nature of participation might also be expected between participants in genetic research in these diverse environments.

In order to examine these assumptions, we compared factors associated with voluntary participation and comprehension of the purpose of studies among individuals participating in genetic epidemiological research on hypertension in an urban setting in the United States and in a rural town in Nigeria. Although commentary (editorials and opinion pieces) is abundant, this study is unique because it is the first large-scale cross-cultural empirical investigation of voluntary participation and informed consent among individuals enrolled in similarly designed and implemented genetic studies conducted in an industrialized and a resource-poor country. Moreover, all participants were African American or Nigerian.

METHODS

Research Design

We surveyed patients and control participants enrolled in 2 genetic epidemiological studies of hypertension, 1 in the United States and 1 in Nigeria, from 2001 to 2003. These investigations were designed to use the migrational history of the African Diaspora to examine gene–environment interaction on complex diseases, including hypertension. Reflecting the natural course of enrollment and accrual, participants in the genetics of hypertension studies in Nigeria and the United States joined these investigations at various times in the past.

Our informed consent study was designed and implemented after the genetics of hypertension studies were initiated. Therefore, the time interval between consent to the genetic study and our interview date was long and variable for both patients and control participants in Nigeria and patients in the United States. The time interval was shorter for participants in the control group in the United States. In Nigeria, both patients and control participants were enrolled in the genetic study over the course of several years. In the United States, patients were enrolled during an earlier phase of this investigation. By contrast, control participants for the consent study in the United States were enrolled while investigators were actively recruiting control participants for the genetics of hypertension study.

Individuals from Maywood, Ill, were interviewed for this study after participating in ongoing studies of the genetics of hypertension among African Americans.^{54,55} Maywood is a stable, historically African American, primarily working class community adjacent to Chicago. According to the 2000 census, 83% of the 26 987 Maywood residents were African Americans; median household income was nearly \$42 000. Participants in the Igbo-Ora, Nigeria, hypertension study were interviewed during follow-up clinic visits for an ongoing family study of the genetics of hypertension.⁵⁶ Igbo-Ora, a farming community of approximately 45 000 people, has a long and stable history. The predominantly Yoruba population are involved in subsistence agriculture, trade, and craft work.

At both sites, patients were individuals who had been diagnosed with hypertension (i.e., systolic blood pressure \geq 140 mm Hg or diastolic blood pressure \geq 90 mm Hg or already taking prescribed medication for high blood pressure); control subjects were individuals who had been tested and not diagnosed with hypertension. All participants were aged 18 years or older. Participants signed or placed thumbprints on written consent forms for both genetic studies.

In Nigeria, consent forms for the genetic study were translated into Yoruba and back-translated into English, which is the official language of Nigeria. Consent forms were read to and discussed with all participants by research assistants fluent in English and Yoruba. The studies in the United States and Nigeria were similar, but not identical. Therefore, the consent forms differed slightly, but all consent forms described the genetic purpose of the study and included information on voluntary participation and study withdrawal.

The research protocol for the study on informed consent was reviewed and approved by institutional review boards of all participating institutions in the United States and Nigeria. Verbal informed consent was obtained from all individuals. Participants were given an information sheet, translated into Yoruba and back-translated into English for Nigeria, explaining the study. Research assistants at both sites received training on obtaining informed consent in a culturally and linguistically appropriate manner. Research assistants in Nigeria were fluent in both English and Yoruba. Consent was obtained in English or Yoruba at the Nigerian site, depending on the participant's comfort level with the languages.

Our study design included quantitative and qualitative methodological approaches. In-depth audiotaped interviews were conducted with 10% of the survey respondents in order to explore topics in greater detail. The design of the survey instrument was based on previous research on cultural issues surrounding consent to genetic research in Nigeria.⁴² The survey instrument was pretested in the United States and Nigeria to confirm its accuracy in measuring participants' understanding of informed consent and decisionmaking regarding participation in genetic epidemiological studies.

The survey addressed a range of topics including comprehension of informed consent, motivation to participate in the genetic studies, involvement of others in decisions to participate, concerns about blood drawings, knowledge that blood samples might be used in future investigations, and past experience with medical research. We present the results of our analysis of a limited number of survey variables relevant to comprehension of the study purpose and voluntary participation.

The survey was translated into Yoruba and back-translated into English for the Nigerian site. Interviews were administered in English in the United States and Yoruba or English in Nigeria, depending on the participant's comfort level with the language. Interviews were conducted in health clinics at each site. In the United States, after completing the survey, individuals were paid \$20 for their participation in the study. In Igbo-Ora, individuals were reimbursed for transportation and lost daily wages and provided with a small gift such as vitamins.

Data Analysis

Voluntary participation was measured through respondents' answers to 3 questions: (1) Were they told that participation was voluntary? (2) Did they feel pressure to participate? (3) Did they understand that they could withdraw from the study? We also determined if married respondents sought permission to participate in the study from their husband and, in Nigeria, if respondents sought permission from community elders. Two measures are reported for comprehension of the study purpose. First, respondents were asked if they were told the purpose of the study. Second, those who indicated that they were told the study purpose were asked to describe the goal of the study. We analyzed whether or not respondents reported that the study purpose was to learn about the genetic inheritance of hypertension. Covariates included respondents' gender, age, education, marital status, ability to read the consent form, past participation in research, and the time interval between consent to the genetic study and the interview date for our study.

Data reliability was ensured using double-entry verification. Survey data were entered into Microsoft Access version 11 (Microsoft

TABLE 1—Distribution of Participant Characteristics by Site and Hypertension Status: Maywood, Ill, and Igbo-Ora, Nigeria, 2001 to 2003

	Chicago, Ill (n = 348)		P	Igbo-Ora, Nigeria (n = 307)		P
	Control Participants (n = 245), No. (%)	Patients (n = 103), No. (%)		Control Participants (n = 192), No. (%)	Patients (n = 115), No. (%)	
Gender			.006			.006
Men	135 (55.1)	40 (38.8)		116 (60.4)	51 (44.4)	
Women	110 (44.9)	63 (61.2)		76 (39.6)	64 (55.7)	
Education			.383			.001
None	7 (2.9)	0 (0.0)		69 (35.9)	65 (56.5)	
< High school	38 (15.5)	17 (16.5)		43 (22.4)	15 (13.0)	
High school	114 (46.5)	48 (46.6)		35 (18.2)	9 (7.8)	
> High school	86 (35.1)	38 (36.9)		45 (23.5)	26 (22.6)	
Able to read consent form			<.001			.021
Yes	243 (99.2)	95 (92.2)		91 (47.4)	39 (33.9)	
No	2 (0.8)	8 (7.8)		101 (52.6)	76 (66.1)	
Past research participation			.733			.35
Yes	81 (33.1)	36 (35.0)		17 (8.9)	14 (12.2)	
No	164 (66.9)	67 (65.0)		175 (91.2)	101 (87.8)	
Marital status			.269			.256
Not married	183 (74.7)	71 (68.9)		13 (6.8)	12 (10.4)	
Married	62 (25.3)	32 (31.1)		179 (93.2)	103 (89.8)	
Religion			.53			.386
Christian	203 (82.86)	90 (87.38)		112 (58.33)	58 (50.43)	
Muslim	5 (2.04)	1 (0.97)		78 (40.63)	56 (48.7)	
Other	37 (15.1)	12 (11.65)		2 (1.04)	1 (0.87)	
Age, y, mean \pm SD	40.7 \pm 7.4	47.9 \pm 10.4	<.001	51.8 \pm 10.2	58.2 \pm 10.2	<.001

Corp, Redmond, Wash). Data management and analysis were done using univariate and multivariable techniques (SAS version 8.1, SAS Institute, Cary, NC). We compared responses using Wilcoxon rank-sum tests for continuous variables and χ^2 tests for categorical variables. Age-adjusted logistic regression was used to identify significant variables at $P < .10$. These were then used in multivariate logistic regression models to identify significant predictors of outcomes at $P < .05$ or those that changed the effect estimate by more than 10%. We report P values, odds ratios, and 95% confidence intervals.

RESULTS

There were 655 participants in the study; 348 from the United States and 307 from Nigeria (Table 1). More than 95% of the individuals approached at the Nigerian site and more than 90% of those approached at the

US site agreed to participate. In the United States, there were almost the same number of men and women; in Nigeria, there were more men than women. Patients were aged, on average, 7 years older than control participants across sites, and the participants in Nigeria were older than were those in the United States. In Nigeria, most people reported being married (92%; 282/307) compared with only 27% (94/348) of US respondents. The majority of respondents in the United States identified themselves as Christians (84%; 293/348). In Nigeria, 55% (170/307) reported being Christian and 44% (134/307) indicated that they were Muslim.

Overall, the interval between the time of consent to the genetic studies and the interview date for our study was longer for participants in Nigeria than for those in the United States ($P < .001$). In the United States, the time interval between consent to the genetic study and our interview was longer for

patients (424 \pm 590 days) than for control participants (48 \pm 103 days). In Nigeria, the time interval between consent to the genetic study and our interview was comparable for patients (623 \pm 400 days) and for control participants (568 \pm 391 days). In the United States, 34% (117/348) of respondents reported previous participation in medical research, compared with 10% (31/307) in Nigeria ($P < .001$). Significant differences were not observed on past participation in medical research between patients and control participants at either site.

In the United States, most respondents reported a high-school education or higher; in Nigeria, nearly half reported no education ($P < .001$). Most participants in the United States reported being able to read the consent forms; in Nigeria, more than half said they were unable to read the consent form ($P < .001$). In Nigeria, educational level and gender were significant predictors of the ability to read the consent form. After adjustment for age and gender, there were significant differences in the ability to read consent forms between those who had more than a high-school education and those who had less ($P < .001$). There were no differences in the ability to read the consent form between patients and control participants in the United States. Patients in Nigeria were less likely than control participants to be able to read the forms (odds ratio [OR], adjusted for age, gender, and educational level = 0.16; 95% confidence interval [CI] = 0.05, 0.49; $P < .001$).

Voluntary Participation

The majority (94%; 617/655) of respondents at both the US and Nigerian sites reported being told that participation was voluntary. Most (99%; 650/655) reported that they did not feel pressured to participate. In the United States, 97% (336/348) of the respondents said they were told they could withdraw compared with 67% (206/307) in Nigeria ($P < .0001$). Adjustment for the time interval between consent to participate in the genetic study and our interview did not change the results of these analyses. In the multivariate analyses, the regression coefficient for the site remained significant ($\beta = -2.602$; SE [β] = .405, $P < .0001$) whereas

that for the time interval was not ($\beta = -.043$, SE [β] = .069, $P = .536$).

Overall, 86% (121/140) of the women in Nigeria and 32% (56/173) in the United States were married. None of the married women in the United States asked for permission, compared with 47% (57/121) of those in Nigeria ($P < .001$). There were no differences between patients and control participants at the Nigerian site in response to the question on getting permission from a spouse to participate in the research. None of the men or women participating in the Nigerian hypertension study reported seeking permission from community elders to join the study.

Comprehension of Study Purpose

Respondents were asked if they had been told the study purpose during the consent discussion. Most (99%, 344/348) US respondents reported being told the study purpose, compared with 72% (220/307) of the Nigerian respondents ($P < .001$). In Nigeria, 15% could not recall whether they were told the study purpose, and 13% said they were not told. A separate analysis was done for Nigerian respondents combining reports of “cannot recall the purpose” and “not told the purpose,” and comparing these responses with those who said they were told the study purpose.

Results showed that at the Nigerian site, education was a significant predictor of whether or not someone reported being told the purpose of the study or if they could not recall or were not told (OR = 1.74; 95% CI = 1.37, 2.22; $P < .001$). We adjusted for the potential confounding influence of the time interval between consent to participate in the genetic study and our interview in our logistic models. The coefficient for the time interval was statistically significant ($\beta = -.226$; SE [β] = .090; $P = .012$).

Respondents who reported being told the study purpose were asked to describe the goal of the research. In Nigeria, 39% (86/220) and in the United States, 41% (142/344) said the purpose was to learn about the genetic basis of hypertension.

Results of multivariate analysis, after adjustment for the time interval between consent to the genetic study and our interview, indicated no significant differences between patients and control subjects at the US and Nigerian sites (Table 2).

TABLE 2—Multiple Logistic Model for Relation Between Hypertension Status and Knowledge That Study Purpose Is to Learn About Genetic Inheritance of Hypertension, With Adjustment for Age, Gender, Education, and Interval as Covariates

	Chicago, Ill		Igbo-Ora, Nigeria	
	Coefficient (SE)	P	Coefficient (SE)	P
Understanding of genetic inheritance as study goal	0.676 (0.356)	.058	0.281 (0.012)	.379
Age	0.092 (0.022)	<.0001	0.062 (0.016)	.0001
Gender	1.017 (0.361)	.005	0.838 (0.327)	.010
Education	-0.040 (0.222)	.859	-0.105 (0.135)	.438
Interval ^b	0.359 (0.088)	<.0001	0.087 (0.093)	.348

Note. Specified statistical model is hypertension status (yes/no) = genetic inheritance + age + gender + education + interval.

^aCoded yes = 1, no = 0.

^bTime interval between genetic and consent studies.

DISCUSSION

Informed consent depends upon an individual's accurate understanding of the nature and purpose of the study. In this cross-cultural study of consent to genetic epidemiological research on hypertension in the United States and Nigeria, fewer than half of the respondents at both sites reported that the study purpose was to learn about the genetic inheritance of hypertension. This is an important finding because individuals from industrialized rather than low-income countries might be expected to have greater comprehension of the genetic nature of these studies. The longer time interval between the consent to the genetic studies and our interview for patients and control participants in Nigeria and patients in the United States may have affected their recall of information about the study purpose described during the informed consent for the genetics of hypertension studies.

However, after adjustment for the time interval, analysis suggests that the shorter time interval for the US control participants did not bias the study unduly. If bias had occurred, we would expect this subgroup to have much better recall of the study purpose than the other subgroups. Because we did not find this to be the case, it is unlikely that the effect of the time interval between consent to participate in the genetic study and our interview on the outcome was substantial.

Our finding highlights the need for genetic epidemiological researchers working in either industrialized or resource-poor settings to pay

greater attention to participants' understanding that they are involved in genetic research. Critics such as Screenivasan⁵⁷ have argued that less importance should be given to the comprehension of consent. However, other investigators are proponents of ensuring participants' understanding of study goals and risks before enrollment and instituting methods to assess comprehension.¹⁴ Because consent forms for genetic research may be difficult to understand, forms could be modified, substituting words where appropriate (e.g., the phrase “in your genes” might be replaced with “in your blood” in areas where the term “blood” is used to signify “genes.”) Unfamiliar words should be defined, and forms should include basic information rather than lengthy descriptions of topics. Researchers should aim for brevity and clarity.

Moreover, challenges associated with comprehension are diminished when adequate time is provided and creative efforts made to facilitate understanding of the study goals and risks during the consent discussion.^{14,22,24,27,44,49,58} Although some investigators have employed techniques such as brief “tests” to assess comprehension, follow-up conversations in which individuals are asked a series of questions to evaluate their level of understanding after the consent discussion may also be effective for improving participants' understanding.⁴⁴ When potential risks associated with a study are high, investigators might consider not enrolling participants until adequate levels of comprehension are determined.

Most respondents in our study recalled being told that participation was voluntary

and reported that they did not feel pressured to participate. Fewer Nigerian respondents reported that they could withdraw from the study at any time. This finding could indicate that some Nigerian participants were not given information about withdrawal from the study during consent or that they simply could not recall, perhaps because they did not remember being told or because they did not consider it to be important.

On the other hand, our finding may corroborate results of other research indicating participants' misunderstandings or concerns about refusing to join or withdrawing after enrollment.^{45,47,49,59} Pace et al.,⁴⁵ in their report on the quality of consent for a research trial in Thailand, found that 71% of the respondents reported that they could withdraw from the study; 29% did not know that they were able to withdraw. Karim et al.,⁴⁹ in their examination of informed consent to HIV testing for a perinatal HIV transmission study in South Africa, found that the majority of participants believed that the hospital would not allow them to withdraw, and approximately one third believed that withdrawing from the study would affect their medical care.

Similarly, Molyneux et al.,⁴⁷ in their study of comprehension of parental consent to inpatient clinical research in a coastal Kenya hospital found that nearly half of the parents interviewed reported that their children would not have received optimal treatment had they not agreed to participate, and some parents interviewed in a community discussion expressed concerns about withdrawal because they believed their children would not be treated. Pace et al.⁵⁹ found that many Ugandan parents of children enrolled in a malaria treatment trial felt that they could not refuse because their children were sick and they did not know or understand that they could obtain treatment apart from the study; one third of the parents did not remember being told they could withdraw.

Individual Consent and Voluntary Participation

Informed consent for participation in scientific research relies heavily on the concept of individual autonomy and personal decisionmaking. Nevertheless, in Western and

non-Western settings, people often talk with others about medical decisions, including involvement in scientific research. Our results indicate that in settings such as Nigeria, particularly rural communities, some women may seek permission from their husbands before giving consent. However, it is important to note that only about half of the Nigerian married women said they needed spousal permission, suggesting that this is not the general standard of behavior for married women, even in more rural areas such as Igbo-Ora. Moreover, the need for spousal permission does not necessarily diminish the potential for voluntary participation in research. Married women—and men—in both Nigeria and the United States may talk with their spouses to seek guidance about participating in research.

In our study, no one in Nigeria asked community elders for permission to participate in the hypertension research. Although international guidelines for biomedical research emphasize that in some settings community leaders and elders may have an important role in deciding whether or not community members should be involved in a study,^{10,13} there is little empirical evidence to suggest that individuals personally seek permission from local authority figures.^{48,50}

Our findings indicate that in Igbo-Ora, the views of community elders are not considered essential in personal decisions about research participation in the genetics of hypertension study. Researchers usually consult with designated elders or tribal leaders in settings where community members recognize these individuals as local authorities.^{1,60,61} The opinions of elders regarding a study might be communicated to local populations through accepted social venues such as council meetings or public events. It is in this public context that the views of community leaders are likely to influence decisions about study participation.

Conclusions

Our study represents the first cross-cultural empirical investigation of consent to similar genetic epidemiological research on hypertension conducted in 2 very different settings with individuals of African heritage. From this perspective, our study increases knowledge

about informed consent in an area previously unexamined and among populations who have been underrepresented in studies of consent to genetic research. Nevertheless, an important limitation of this study concerns the time interval between consent to participate in the genetic studies and our interview and the interval's potential influence on respondents' recall. Another potential limitation concerns the translation of the survey from English to Yoruba for Nigerians. However, a careful process of back-translation was implemented, and all field staff were fluent in English and Yoruba and were trained to administer the survey.

Our findings indicating that fewer than half of all respondents reported the genetic purpose of the study emphasize the need for more effective approaches and educational interventions to improve comprehension of informed consent for genetic research among ethnically and linguistically diverse populations in all settings. Investigators conducting genetic research should adopt models for enhancing comprehension of consent through community consultation, educational sessions, or preconsent evaluations that have been shown to be successful in other research settings.^{1,2,14,22,24} Simplified consent forms that use clear and linguistically relevant terms should be developed and tested with individuals participating in genetic research in culturally diverse settings globally. Creative educational interventions might include developing and testing innovative videotapes used in conjunction with informed consent to reinforce comprehension. Developing community-based participatory research or implementing community consultation before and after initiating a genetic study provide other opportunities for augmenting consent to genetic research. ■

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Contributors

P.A. Marshall originated the study and supervised all aspects of its implementation. C.N. Rotimi assisted in developing the research design, leading and supervising data analysis, interpreting findings, and writing the article. C.A. Adebamowo assisted in the development of the research design, supervised 1 site in Nigeria, participated in data analysis and interpretation of findings, and helped write the article. A.A. Adeyemo assisted in the study, supervised 1 site in Nigeria, participated in data analysis and interpretation of findings, and helped with article preparation. T.O. OgunDIRAN supervised data collection at 1 Nigerian site and helped with article preparation. M. Vekich assisted with data analysis. T. Strenski supervised data collection at the Chicago site and assisted with data analysis. J. Zhou assisted with data analysis. T.E. Prewitt assisted with the study supervision at the Chicago site. R.S. Cooper was helped with research design.

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Human Participant Protection

This study was approved by the institutional review boards at Loyola University of Chicago, Maywood, Ill; University Hospital, Case Western Reserve University School of Medicine, Cleveland, Ohio; Howard University College of Medicine, Washington, DC; and the University of Ibadan, Ibadan, Nigeria.

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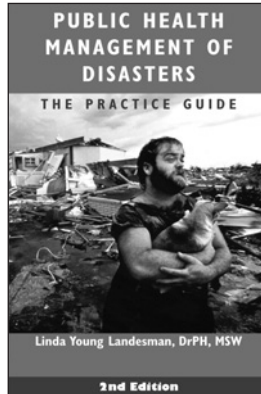
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