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DECISION-MAKING AND MOTIVATION TO PARTICIPATE IN BIOMEDICAL RESEARCH IN SOUTHWEST NIGERIA

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Abstract

Motivations and decision-making styles that influence participation in biomedical research vary across study types, cultures, and countries. While there is a small amount of literature on informed consent in non-western cultures, few studies have examined how participants make the decision to join research. This study was designed to identify the factors motivating people to participate in biomedical research in a traditional Nigerian community, assess the degree to which participants involve others in the decision-making process, and examine issues of autonomy in decision-making for research. A descriptive cross-sectional study was conducted with 100 adults (50 men, 50 women) in an urban Nigerian community who had participated in a biomedical research study. Subjects were interviewed using a survey instrument.

Two-thirds of the respondents reported participating in the biomedical study to learn more about their illness, while 30% hoped to get some medical care. Over three-quarters (78%) of participants discussed the enrolment decision with someone else and 39% reported obtaining permission from a spouse or family member to participate in the study. Women were more than twice as likely as men to report obtaining permission from someone else before participating. More specifically, half of the female participants reported seeking permission from a spouse before enrolling. The findings suggest that informed consent in this community is understood and practised as a relational activity that involves others in the decision making process. Further studies are needed in non-Western countries concerning autonomy, decision-making, and motivation to participate in research studies.

Keywords

informed consent; decision-making; motivation to participate; developing world

BACKGROUND

Informed consent is intended to help protect participants in research studies from harm or exploitation ¹. Grounded in the ethical principle of respect for persons, informed consent is a key requirement for ethical research with human subjects ². Informed consent requires disclosure of information, understanding of that information, and voluntary, autonomous decision making about enrolment. While a small but growing literature examines what participants in different settings understand about research, little literature to date has examined *how* participants make their decisions, including factors related to voluntariness.

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Authors' contributions

Both authors designed the study. PEO supervised the field work, managed the data and conducted data analysis. Both authors interpreted the data, and drafted and approved the manuscript.

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Related to decision making, there is increasing literature on why participants decide to enrol, both in wealthier and lower income countries. For example, studies have shown that participants may join because they believe research participation will be beneficial for their health. (Mfutso-Bengo et al 2008, Leach et al 1999, Preziosi et al 1997). Alternatively, individuals may participate with more altruistic intentions, (Bevan et al 1994) for instance to provide information about their cultural group³, or because they or their family members have a disease and they want to help find a cure. Other individuals decide to participate because they want to access one or more of the perceived benefits of participation, including access to experimental therapies or medications, lower cost medical treatment, or, for healthy volunteers, to earn extra money³

While most of these studies have been performed in industrialized countries, there is a growing literature concerning decisions to enrol in medical research conducted in developing countries⁴. Molyneux and colleagues⁵ suggest, for example, that many parents of children involved in studies in a coastal town of Kenya expected their children to benefit medically from their participation. They argued that this misunderstanding is an important factor in deciding to allow a child to join a study. Kass and colleagues⁶ found that all but one of the 18 individuals interviewed about their participation in international health studies reported they expected help or treatment for their medical problem; two of the individuals noted that they thought their medical care would be improved. Findings from Marshall et al⁷ revealed that more than 80% of 400 participants in a genetic epidemiological research study on hypertension and breast cancer in Nigeria reported the primary reason for joining the study was to obtain medical treatment.

Similarly, Tindana et al⁸ reported that some respondents thought their participation would give them access to medical care, with some also believing the research was treatment. Thus, reasons for participation in biomedical research are being increasingly studied in various settings and contexts.

While some studies have looked at *why* people decide to join research studies, however, very few have examined *how* they make their decisions, including the degree to which they involve others in the decision making process. Examining how decisions are made may provide context through which to interpret existing ethical guidelines, which tend to emphasize individual decision making and rarely address the role of others who may be importantly related to the individual participant.

Indeed, guidelines for informed consent for research studies are based on Western views of autonomy and, as such, tend to focus on individual decision making and self-determination⁹. Voluntary entry into research is viewed as a fundamental global standard for scientific research, and this standard is said to be implemented through an informed consent discussion with a single individual, who generally would be engaged alone. It is expected that autonomous people who consent to research should not be coerced into participation; neither should they be subject to another person's veto or prohibition.

In non-Western societies, however, community leaders or family members may play important roles in determining participation in biomedical research¹⁰. While the issue of community consent in many developing world contexts is now widely acknowledged (for example, see the WHO Ethics Review Committee guidelines), the issue of other people (such as spouses or other family members) being involved in or influencing research participation by responsible adults remains largely under-studied. The existing studies show that this may be crucial to understanding the decision making process. For example, a study in Chile found that women in a contraceptive study joined after consulting partners or relatives.¹¹ In a study on voluntary participation and informed consent in Nigeria and The

United States of America, Marshall et al found that married women and men in both sites often sought guidance from their spouses about participating in a research project¹². Indeed, in many parts of Africa it may be close to impossible for some people, especially women, to feel they can make important decisions without consulting their spouses. Beyond discussing or consulting with a spouse is the issue of having to ask permission, i.e. some other person having the power to veto participation by the potential participant. Notably, in the comparative study cited above¹³, it was only at the Nigerian site that some women sought *permission* from their husbands before giving consent.

Since most ethical guidelines define valid informed consent in the context of an individual encounter with a sole decision maker, it is important to know how participants in various regions make enrolment decisions in order to consider, if necessary, what valid consent demands in the context of a more inclusive model.

A study site in Nigeria presented an opportunity to examine not only why people participated in a biomedical research project, but also how they made their decisions about participation. Idikan, an urban community in Ibadan, southwest Nigeria, offers an opportunity to study the ways in which people in a traditional African community make decisions, including the degree to which they involve others in their decisions about research and whether this differs by the gender of the potential participant.

The primary goals of our research were to study the factors motivating people to participate in a biomedical research study in a traditional Nigerian community, to assess the degree to which others were involved in the decision-making process, to examine issues of autonomy in decision-making, and to identify any male-female differences in these outcomes.

METHODS

Study Site

This study was conducted in the Idikan community, within Ibadan, a city in the southwest part of Nigeria. Metropolitan Ibadan has five Local Government Areas (LGAs) namely Ibadan South-West, Ibadan South-East, Ibadan North, Ibadan NorthEast, and Ibadan North-West. The site of this study is the Idikan community, an urban, low-socio-economic community, situated in Ibadan North–East LGA. Idikan is located in the indigenous part of the city of Ibadan, and is a densely populated urban community, with a population of 15,042 (National population commission, 2009). It is bounded in the East by Ibikunle Road, West by Ifeeye Road, North by Ladapo Road and South by Agbaje Road. The Yoruba form the bulk of the residents of Idikan. People from other ethnic groups (Igbos, Hausa and the Edos) comprise a minority of residents. The early settlers were predominantly farmers, but with urbanization, their occupation changed to traders, blacksmiths, drivers, carpenters, welders, auto-mechanics and Islamic teachers. There are more traders than housewives among the women. Housewives depend on their husbands for financial assistance and to maintain the home. The poverty rate in the Idikan community is high. The major languages spoken are Yoruba, English and “Pidgin English”. The Idikan community is a mixed religious community, comprising of Christians, Moslems and indigenous religion worshippers. The dominant religion in the area is Islam.

The Idikan community is organized in a “compound” system, where a compound (identified by a family name) houses members of an extended family (and sometimes, an outsider). The community comprises of 65 compounds, 586 houses and 1,962 families. The community is made up of more polygamous families than monogamous ones. Not many homes have private indoor toilets. There are public toilets, which are usually under lock and key for the purpose of maintenance. Community members use pit toilets and streams and rivers are used

for waste disposal. Water supply is mainly from wells dug in the compounds and neighbourhoods, and individuals draw water from the well with a bucket-like rubber container attached to a rope to fetch the water. There are taps in some houses and some people have boreholes where people buy water from and there is usually tap water if the government supplies water. The community has seven primary schools and one Arabic primary school. There are also public, private and mission secondary schools located in the community.

The health facilities in the community include an outreach clinic run by the Department of Preventive Medicine and Primary Care of the University of Ibadan, four private clinics and a small dental clinic run by the Dental Centre of University College Hospital (UCH). There are 150 registered patent medicine stores in the area. There are three traditional healing homes, and they are all accessible to members of the community. The outreach clinic run by the Department of Preventive Medicine and Primary Care was started in 1957 after a successful research project was conducted in the area. Thereafter, many projects have been successfully conducted in the community using the Idikan clinic as the research base. The clinic also provides community aid to assist in rendering health services to members of the community.

Study Participants and Recruitment

The study was approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (IRB) and the Joint University of Ibadan-University College Hospital Ibadan IRB. Study participants were adult residents from the Idikan community. Participants were eligible for this study if they were already enrolled in a then-ongoing biomedical research study being conducted in the community examining the relationship of serum lipids to genetic variants. Participation in the lipid study required the completion of a questionnaire, measurement of weight, height and blood pressure, and a blood draw. These participants were paid a small, nominal amount of compensation for their time and transportation. While the lipid study enrolled approximately 25 participants per week, this decision-making study identifying the factors motivating people to participate in biomedical research enrolled as many of the lipid study participants per week as were willing and logistically possible until the target of 100 participants was reached. An effort was made during enrollment to ensure equal representation of men and women. In other words, enrollment was cumulative until 50 men and 50 women had been enrolled into the study. Inclusion criteria included: age 25 years and above, participation in the lipid study, and willingness to participate in the present research study. Exclusion criteria included age over 65 years, and unwillingness to participate in an interview lasting about an hour.

The researcher from the lipid study introduced our decision-making study to lipid study participants before referring them to our research assistant. Our research assistant then explained the purpose of this decision-making study to participants. Verbal consent was obtained from those willing to participate in the decision-making study before completing the questionnaire. A trained interviewer who was not associated with the lipid study administered the questionnaires.

The Interview instrument

The survey instrument included both close-ended and open-ended questions. Both the consent form and questionnaire were translated into the local language and back-translated into English. The instrument was pilot tested and adjustments made where needed before the main data collection. The questions covered the following themes: motivation to participate in the lipid study, perceived harms and benefits of participation, the decision-making process related to study enrolment, and persons consulted prior to making the decision or

from whom permission to participate was obtained. Motivation to participate was determined by responses to a series of open ended questions including, “Tell me the reason(s) why you decided to participate in the study”. The decision-making process was measured by questions such as: “How did you decide to participate in the study?” Involvement of others in the decision-making process was determined by asking, “Did you talk with anyone before you decided to join the study?”, “Did you ask for permission from anyone to join the study?” and “If the person you asked permission from had said no, would you still have participated?” Subjective experiences about participation were assessed by asking participants what they thought the risks or unfavourable aspects of their participation were, and how satisfied they were with their participation overall.

Data Analysis

Completed survey questionnaires were checked for accuracy. Any errors such as unanswered questions were corrected before data entry. Open-ended responses were coded for analysis. Data entry and management were conducted using the *Statistical Package for Social Sciences (SPSS)* version 11.0 (SPSS Inc. Chicago, ILL). Exploratory data analysis examined the extent of missing data and identified outliers. Frequency distributions were used to summarize categorical variables. Associations between categorical variables were explored using chi-square tests or Fisher’s exact tests when the assumptions for the chi-square test were not met.

RESULTS

Demographic Characteristics of Respondents

A total of 100 individuals (50 men and 50 women) participated in this survey. The ages of the respondents ranged from 27–60 years, with a median age of 47 years. Approximately 32% of respondents had no formal education, 25% had only primary education, 16% had secondary education, and 23% had tertiary education. Four percent (4%) of the respondents had some other form of education such as adult literacy school, Bible school, or Arabic school. Almost all of the respondents (98%) were of Yoruba ethnicity. Eighty-two percent (82%) of respondents were married, 9% were single, and 9% were widowed. Half of the respondents (50%) were traders and business people, while 21% were teachers (formal school teachers or Arabic teachers). Twelve percent (12%) of the respondents were farmers. The remaining 17% were civil servants, clergy men, and students.

Motivating Factors

Respondents were asked about their reasons for participating in the lipid study. The majority of respondents (67%) reported that they decided to participate in the research study because they wanted to know more about their illness; 30% said they decided to participate in order to get medical care, 22% said they participated because they were invited, and 2% said they participated for the monetary compensation offered. None of the respondents said they participated to please the research team or doctor. There was no significant difference between men and women in the reasons indicated for participating, except that a higher percentage of men (76%) than women (56%) participated to learn more about their illness (Fisher exact test $p=0.03$).

Benefit and Harm from Participating in Research

Sixty percent (60%) of respondents believed that there were benefits from taking part in research, while 40% said there were no benefits. Respondents were then asked if they believed that they benefited from the research in which they were currently participating; 56% said they benefitted by learning their blood pressure readings, and 18% said they

benefitted by learning their cholesterol levels. Only 10% mentioned money as a benefit from the study.

Respondents were asked what negative outcomes they thought could occur as a result of participating in the research study. The majority of respondents (96%) said there were no bad outcomes from participating in the study. However, 4% of the respondents said they had pain at the site of blood draw.

Involvement of Others in Decision-Making to Participate in Research

Over three-quarters of the respondents (78%) said they talked with someone else before deciding to participate in the research study, while the remaining 23% did not. There were multiple responses among those who said they talked with someone else. Fifty-eight percent (58%) talked with their spouses, 23% talked with a family member, 29% talked with friends, 12% talked with a health care provider, and 7% talked with other people such as their pastors, teachers, and neighbours before joining the research study.

Respondents were also asked if they obtained permission from anyone before they enrolled in the research study. Thirty-nine percent (39%) said they obtained permission from someone else, while 61% said they did not. Of those who said they obtained permission from someone else, 28% had obtained permission from their partner, and 18% from other family members. One participant reported receiving permission “from God”. The majority of respondents (73%) said they would have participated in the research study even if their partner, family members, or friends had objected to their participation. Seventy-five percent (75%) of respondents said it took them as long as a week to decide to participate in the study, while 10% said they made the decision immediately.

Respondents were also asked how satisfied they were with their decision to participate in research. Almost every participant (98%) said they were either very satisfied (70%) or satisfied (28%). Two respondents reported that they did not know if they were satisfied or not. Reasons given by study participants who said they were satisfied included: receiving free physical check-ups and treatment (40%), having the opportunity to know more about their health condition (20%), having their blood pressure measured (30%), and having the opportunity to know their blood sugar and cholesterol levels (10%). When asked if they would make the decision to participate in other research studies, 95% said yes. The reasons they gave were that they had benefited from past participation, received free medical care, and enjoyed good health.

Male-female differences in decision-making regarding participation in biomedical research

Nearly 4 out of 5 participants (78%) talked with someone else before deciding to participate in the research study; this proportion was similar for men and women (76% of men versus 80% of women, $p=0.591$, see Table 1). Slightly more men than women (62% vs. 54%) talked with their spouse before deciding to participate, while more women than men talked with a friend (38% vs. 20%) or with another family member (26% vs. 20%) before deciding to participate.

There was a marked gender difference in obtaining *permission* to participate, however. Women were more than twice as likely as men (54% versus 24%, $p=0.002$) to report that they obtained permission from someone else before participating. Nearly one-half of women (42%) obtained permission from their husbands, while only 14% of men obtained permission from their wives ($p=0.002$). Furthermore, all of the men who reported that they obtained permission from their spouses stated they would have participated even if the spouse had not given permission. Two-thirds of the women stated they would have done the same. In other words, one-third of the women who obtained permission said they would not

have participated if their spouses had refused to give permission. Similarly low proportions of men and women reported obtaining permission from another family member (12% vs. 16%), a friend (6% vs. 4%) or a health care provider (4% vs. 6%) (See Table1).

DISCUSSION

This descriptive study sought to determine factors motivating individuals to participate in biomedical research in Western Nigeria and to document how potential participants for community based research make the decision about enrolment. Issues of autonomy are important when people make the decision to participate in biomedical research, and it is expected that those who agree to participate in research studies do so autonomously¹⁴. Indeed, the concept of informed consent originated with the recognition of individuals' rights to freedom and human dignity. The typical informed consent process takes place in a one-on-one interaction between the participant and the enrolling investigator or designated research associate. Western notions of autonomy often guide ethical guidelines for biomedical research. In this regard, it is expected that a responsible adult (in contrast to a minor or vulnerable adult) will make the decision to participate on their own, without someone else forcing them or prohibiting them from participating. This process does not imply that people would not discuss with anyone else or discuss their options with others. However, while some people discuss their options with spouses, family members, and/or others, some studies¹⁵⁵ have shown that some people feel they must obtain *permission* before participating in research. Exploring how these issues are reflected in non-Western cultures, especially those that differ in concepts of individualism, is essential to understanding the decision making process in research participation..

Concerns have been raised that financial or medical incentives may create undue influence to participate in research¹⁶, although the degree to which such inducements are problematic remains a matter of debate¹⁷

In this study, more than half of the respondents reported that they decided to participate in the research because they wanted to know more about their illness. This is similar to studies from developed countries that have shown that participants often join a study in the hopes of obtaining medical care, drugs, or better care¹⁸. Other studies concerning motivations to participate in research reported that participants joined primarily to obtain medical treatment, with the expectation of help or treatment for their medical problems from the researchers¹⁹. In their study, DeCosta et al²⁰ reported that altruism was the most common motivating factor for participating in a community based research study; other reasons for participation included an implicit faith in doctors and the opportunity to learn about the illness in question. To the extent that participants join research studies hoping for medical care, it is important to determine whether the study actually provides such benefits or not.

With regard to decision making, most of the respondents in this study said they talked with someone before they decided to participate in the lipid study. In a similar study in rural India, about two-thirds of respondents reported that they would need to consult other people (family, friends, or neighbours) before joining a research study²¹.

Beliefs about personhood, individual autonomy, and the capacity to make decisions are embedded within social and cultural practices²². In the developing world, it can be typical, particularly in some regions, for an individual to make personal decisions only after involvement of others in the community. In our study, some proportion of participants sought permission from their spouses before giving consent to participate in research. However, there was a marked gender difference, where essentially twice as many women said they obtained permission than did men. Nearly one-half of married women received

permission from their husbands, while only 14% of men obtained permission from their wives. A similar scenario has been described in Uganda²³, where Ugandan women refused to make a decision regarding their own participation without their partner's consent. In another study, Marshall et al²⁴ reported that approximately half of the Nigerian women in the study who were married said they needed spousal permission.

Significantly, the results of our study found that the majority of the respondents said they would have participated in the research study even if their partner, family members, or friends objected to their participation. Therefore, the need for spousal permission may not necessarily diminish the potential for voluntary participation in research in this setting. A key finding in the present study was the male-female differences in obtaining permission from significant others before participating in the research study.

While similar proportions of men and women talked with someone else before participating, women were more than twice as likely to obtain permission from someone else before participating. Nearly one-half of women received permission from their husbands in contrast to only 14% of men receiving permission from their wives. However, obtaining permission was not the only factor that determined participation since all of the men who reported receiving permission from their spouses said they would have participated even if their spouse had withheld permission. In contrast, only two-thirds of the women would have participated in the study if their husbands had not given permission.

There are few empirical studies that have been conducted in the area of health research decision making and gender in non-Western contexts, particularly those in sub-Saharan Africa. Understanding motivation to participate and how decisions to participate are made is crucial to conducting successful cross-cultural and/or international studies. This study sheds light on some of the issues within a single community in West Africa. Given the variation in decision making styles in different communities and cultures, the present study contributes data to how research decision making occurred related to one biomedical research study in West Africa. Western concepts of autonomy dominate the discourse in ethical guidelines for research and, often, clinical care. However, these concepts are by no means universal. Tan notes that the Western principle of autonomy maintains that the patient is the final authority to make medical decisions and that the major value that the Western principle of autonomy is individual independence^{25, 10}

In contrast, in East Asia there is a sense of "harmonious dependence," in which the family has the final authority to make clinical decisions²⁶. In many West African communities (as in many developing world countries), the community defines the individual and many aspects of the person's life, including decision-making. This concept of community-individuality is in strong contrast to Western concepts of individuality. There are implications for decision making because, for many people, the individual usually makes decisions only after consultation with others (family, friends, community elders) and only after consideration of the potential benefits, risks and other effects on the community (not just on the individual)²⁷. For this reason, community based research studies in West Africa usually seek community consent before starting the process of approaching individuals and seeking their individual consent to participate.¹¹

Some work has been conducted on the concept of autonomy and personhood within Africa and how these should influence the formulation of ethical guidelines²⁸, and some international guidelines do indeed address the issue of gender and consent. However far more attention is needed in this area, especially in contexts such as Nigeria, where there may be hundreds of different ethnic groups and traditions within a single country or region. Furthermore, there exists the need for formal analyses of the general concept of autonomy

for most parts of Africa and how these relate to various aspects of life, including health care seeking, medical decision-making, reproductive health, child care and participation in research. Such formal analyses are needed, possibly starting with specific issues such as: what is (are) the over-riding principle(s) underlying the concept of autonomy in that culture?; who has the final authority to decide in accordance with the principle?; what is the basis on which to decide?; and what is the major value that the principle upholds? Such studies are important to conduct in Africa, where there is such a great cultural and linguistic diversity that limits the generalization of the findings of most studies. Descriptive studies such as the present one can serve as data points for such analyses.¹²

The findings of this and similar studies suggest ways that may be appropriate to strengthen ethics committees (EC) or institutional review boards (IRB) in West Africa. First, in reviewing applications for community based research, ECs should look for an acceptable approach towards community engagement and obtaining community consent²⁹. Second, given that many potential participants desire to consult with other people (family, friends, elders) before providing individual consent, investigators should allow a suitable interval (days, if necessary) between the initial approach to the individual and obtaining informed consent. This should include allowing individuals to take home consent documents to discuss with others. These and other issues need to be addressed to strengthen the role of ECs in research ethics in developing world contexts and to ensure that consent fulfills its obligation to be respectful of the participants targeted for the research³⁰.

The issues of a feasible and realistic compensation system for research participants that minimizes the issue of undue inducement will continue to be context dependent. Many ECs concentrate on financial compensation issues, trying to limit the absolute amount to avoid what they believe will be undue inducement.

While these are valid concerns in resource poor countries, these populations also often have limited access to health care and medicines, exhibiting the profound “disparities in wealth and health” between developing countries and industrialized ones³¹.

Therefore, provision of health care and/or medicines as part of research is often important compensation or benefit that may have far more impact than in industrialized countries. However, there is the larger issue of what is appropriate compensation for a given study. Important issues to consider include: the location of the study (rural or urban), the type of study (community based or hospital based), the study participants (healthy participants or patients with a disease), the wealth of the community and the proper balance of financial versus non-financial compensation. These decisions need to be made against the background of the resources available to research projects. As more studies are done in different developing world societies, it would be necessary to start developing a framework for realistic, context-sensitive and appropriate compensation for individuals that participate in research; in the short term, discussions with a few different local residents and experienced local researchers may be useful in identifying appropriate norms and levels of compensation.

This study has several limitations. First, in survey type interviews, it is always possible that the interview format precludes participants from providing longer responses which provide more detail and context. In-depth qualitative methods (such as focus group discussions and in-depth interviews) may have provided extended narratives and more opportunities for discussion and clarification, resulting in a richer dataset. Second, the issues have been studied within the context of a single biomedical study in a single community. The situation may not be generalizable to other communities or studies.

This study examined issues of autonomy and the motivation to participate in biomedical research studies in a Nigerian community. Findings suggest that decision making about

research is practiced in this community, often, as a relational activity involving others. This may have implications for how researchers frame the information they provide as well as whether they offer to delay decision making about enrolment until others can be consulted. Further research is needed to expand our understanding of why people decide to participate in research studies and the process they go through in order to make that decision.

CONCLUSIONS

The primary motivations for participating in research studies in this community were to learn more about the illness and to obtain medical care. While most said they were autonomous in deciding to participate, participants usually talked with someone else and, in many cases, sought permission from a spouse. This is an important finding because current notions recognize the need for individual autonomy in making the decision to participate and having to seek permission from a spouse seems contrary to this expectation. It is now common for research studies to give consent forms to potential participants and allow them to discuss with family members before making a final decision (for example, see Creed-Kanashiro et al 2005). Further research is needed to uncover the nature of these interactions with other family members.

A key finding in the present study were the male-female differences in obtaining permission from significant others before participating in the research study. While similar proportions of men and women talked with someone else before participating, women were more than twice as likely to reporting obtaining permission from someone else before participating. However, obtaining permission was not the only factor that determined participation since all of the men and two-thirds of the women who reported receiving permission from their spouses said they would have participated even if their spouse had not given permission. These findings reflect differences in gender dynamics within relationships in this community as well as some of the nuances of these relationships. Further studies are needed in poorly-studied regions of the world concerning autonomy, decision-making, and motivation to participate in research studies, especially as patterns may vary by gender.

The findings of the present study suggest some practical implications. First, it is important to understand the unique local factors and cultural context of *how* the decision to participate in research studies is made. This may lead to a culturally-adapted informed consent process. For example, in this community, it would be appropriate to make the process at least two stages, the first of which would comprise the initial discussion and leaving the consent form to allow discussion within the family, and the subsequent stage (providing consent) occurring after the participant has addressed these spousal interactions. Second, researchers working in non Western societies need to investigate how such decision making processes that involve spouses and others impact on issues of autonomy, privacy and confidentiality in research studies. In this context, it is important to delineate the boundary between *consultation/discussion* and *permission*. By virtue of the potential participant involving others in the decision making, issues that are usually discussed between researcher and participant become more widely known. While these issues will vary depending on the context and the actual disease being studied, such data would provide a way to optimize the informed consent process for different communities.

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References

1. Marshall PA, Adebamowo CA, Adeyemo AA, et al. Voluntary Participation and Informed Consent to International Genetic Research. *Am J Public Health*. 2006; 96:11. [PubMed: 16317195]
2. Dickens BM. Issues in preparing ethical guidelines for epidemiological studies. *Law Med Health Care*. 1991; 19:175–183. [PubMed: 1779685]
3. Elks ML. Ethics: the right to participate in research studies. *J Lab Clin Med*. 1993; 122:130–136. [PubMed: 8340698]
4. Leach A, Hilton S, Greenwood B, et al. An evaluation of the informed consent procedure used during a trial of a *Haemophilus influenzae* type B conjugate vaccine undertaken in The Gambia, West Africa. *Sol Sci Med*. 1999; 48(2):139–48. Karim Q, Karim S, Coovadia H, et al. Informed consent for HIV testing in a South African hospital: is it truly informed and truly voluntary. *A J Public Health*. 1998; 88:637–40.
5. Molyneux CS, Peshu N, Marsh K. Understanding of informed consent in a low-income setting: Three case studies from the Kenyan coast. *Soc Sci Med*. 2004; 59(12):25–47.
6. Kass NE, Maman S, Atkinson J. Motivation, Understanding, Voluntariness in International Randomized Trials. *IRB: Ethics & Human Research*. 2005; 27(6):1–8. [PubMed: 16425478]
7. Ibid; 7 (Marshall, Adebamowo, Adeyemo et al (author), op.cit. note 1
8. Tindana PO, Kass N, Akweongo P. The Informed Consent Process in a Rural African Setting: A case study of the Kassena-Nankana District of Northern Ghana. *IRB: Ethics & Human Research*. 2006; 28(3):3–6.
9. Ibid; 9 Dickens (author), op. cit. note 2
10. Ibid; 10 (Marshall, Adebamowo, Adeyemo et al (author), op.cit. note 1
11. Sanchez et al
12. Ibid; 12 (Marshall, Adebamowo, Adeyemo et al (author), op.cit. note 1
13. Ibid
14. Beauchamp and Childress. 1994
15. Ibid; 15 (Marshall, Adebamowo, Adeyemo et al (author), op.cit. note 1
16. Macklin, R. *Against Relativism: Cultural Diversity and the Search for Ethical Universal in Medicine*. New York: Oxford University Press Inc; 1999.
17. Emanuel E, Wendler D, Killen J, et al. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis*. 2004; 189:932.
18. Ibid; Kass, Maman and Atkinson (author); op.cited note 6
19. Ibid
20. DeCosta A, D'Souza N, Krishnan S. Community based trials and informed consent in rural north India. *J Med Ethics*. 2004; 30:318–323. [PubMed: 15173372]
21. Marshall PA. Anthropology and bioethics. *Med Anthropol Q*. 1992; 6:49–73. [PubMed: 11659464]
22. Loue S, Okello D, Kawum AM. Research bioethics in the Ugandan context: A program summary. *J Law Med Ethics*. 1996; 24:47–53. Ibid. [PubMed: 8925012]
23. Marshall, Adebamowo, Adeyemo et al (author), op.cit. note 1
24. Tangwa GB. The traditional African Perception of a Person: Some Implications for Bioethics. *The Hastings Center Report*. 2000; 30:39–43. [PubMed: 11057387]
25. Ibid; 25 Tangwa (author), op.cit. note 24
26. Tan R. Self-determination vs. family-determination: two incommensurable principles of autonomy: a report from East Asia. *Bioethics*. 1997; 11(3–4):309–22. [PubMed: 11654785]
27. Marsh VM, Kamuya DK, Parker MJ, Molyneux CS. Working with concepts: the role of community in international collaborative biomedical research. *Public Health Ethics*. 2011; 4.1. Doumbo OK. Global voices of science. It takes a village: Medical research & ethics in Mali. *Science*. 2005:679–81. [PubMed: 15692036] Emanuel et al, op.cit. note 9, p.15

28. Joint United Nations Program on HIV/AIDS (UNAIDS). Ethical considerations in HIV preventive vaccine research. GenevaUNAIDS2000Dickens, op. cit. note 2.
29. Ibid; 29 Marsh et al (author), op. cit. note 27
30. Benatar SR. Reflections & recommendation on research ethics in developing countries. Soc Sci & Med. 2002;54.
31. Ibid; 31 Benatar (author), op. cit. note 30

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Table 1

Male-female differences in approach to decision-making regarding participation in biomedical research

Action taken before decision making	Men	Women	* P
	n=50	n=50	
Talked with Spouse	31 (62%)	27 (54%)	0.544
Talked with friends	10 (20%)	19 (38%)	0.077
Talked with family members	10 (20%)	13 (26%)	0.635
Talked with health care provider	5 (10%)	7 (14%)	0.760
Permission from spouse	7 (14%)	21 (42%)	0.003
Permission from family members	6 (12%)	8 (16%)	0.774
Permission from friends	3 (6%)	2 (4%)	1.000
Permission from health care provider	2 (4%)	3 (6%)	1.000

*
p value for Fisher exact test