COMMUNITY ENGAGEMENT IN INFORMED CONSENT PROCESS IN RESEARCH IN TWO LOCAL GOVERNMENT AREAS OF OSUN STATE, NIGERIA

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CERTIFICATION

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DEDICATION

This work is dedicated to the Almighty God who gave the opportunity, my late husband and wonderful children for their unflinching support and prayers.

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ABSTRACT

The increased numbers of researches in developing countries and requirement for informed consent for its implementation poses challenges for researchers. Knowledge is still limited about how community engagement can improve informed consent administration. This study examined the role of community engagement in informed consent process.

The study was a comparative cross sectional survey of people aged 18 and above years in Ife North and Ife Central LGAs of Osun State which are designated rural and urban respectively. A total of 490 respondents (240 Ife North and 250 Ife Central) were recruited at the household level in the LGAs using multistage sampling technique. The study employed the use of qualitative and quantitative data collection methods. Data were analysed using STATA version 11, Univariate, bivariate and multivariate analyses were performed for the quantitative data while Nvivo 6 and narrative analytical approach was used to analyse the qualitative data.

Forty six percent (46$^{0}/_{0}$) of the rural dwellers compared to 32.9% urban dwellers had heard of community engagement. Forty three percent of the urban dwellers had good knowledge of community engagement compared to 31.3% of rural dwellers. The proportion of urban dwellers (59.1%) that had good knowledge of informed consent was significantly higher than the proportion of rural dwellers (28.9%) ($p<0.05$). The level of education might be responsible for an observed difference in knowledge about informed consent when rural and urban dwellers were compared. Over 70% of the urban and rural dwellers indicated that permission of community leaders is crucial to research participation,, community

leaders' need to be consulted before research, researchers provide adequate information about risk/ benefits of the research and community leaders' be involved in planning and carrying out research. However, 26.1% of urban dwellers as compared to 17.1% rural dwellers did not agree with the need for permission of community leaders before commencement of research. Incentive giving is statistically significant in trust building (OR= 0.64, p=0.03). Similarly, researcher being from the community is statistically significant in trust building in research (OR=1.45, p=0.002). A significant proportion of urban dwellers (18.1%) as compared to 8.8% of the rural dwellers did not agree with the provision of information as a factor that would influence willingness to participate in research (OR=2.49, p= 0.002). Also, a significant proportion of urban dwellers (32.5%) as compared to 10.9% of rural dwellers did not agree with the attitude of researchers as a factor that would influence willingness to participate in research (OR =5.29, p<0.001). The FGD participants reported consultation with community leaders as a step in community engagement in informed consent. Few of the participants reported provision of information and community involvement in planning and carrying out research. The participants were of the opinion that attitude of researcher would influence trust building while the rural participants reported giving of incentives in addition. The factors reported by participants (urban and rural dwellers) that would encourage or discourage willingness to participate in research include feedback on previous researches and relevance of the research to the community. The participants (rural dwellers) included fear of the research and reputation of researcher as a factor.

The community and religious leaders reported "researcher meeting them before meeting with other members of the community" as a step in community engagement. The leaders

were of the opinion that truthfulness of the researcher was a factor that could build trust and provision of information and making use of the information collected could encourage or discourage willingness to participate in research.

The study observed low level of awareness of community engagement among the urban dwellers however, the researcher reported good knowledge of informed consent amongst the urban dwellers. There were significant differences on their views on the importance of permission of community leaders in individual participation in research. They also disagreed on the attitude of researchers as a factor that might influence willingness to participate in research.

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CHAPTER ONE

INTRODUCTION

1.1 Background Information

Community engagement has become a common ethical requirement in researches involving human subjects, in particular cross cultural researches and international collaborative researches (Andanda, 2005). This is illustrated by one of the core themes of Bamako 2008 (the Global Ministerial Forum on Research for Health) which is 'engagement of all relevant constituencies in research and innovation for health' (Horton & Pang, 2008). The engagement of community members and organizations in the development and implementation of research is an important aspect of biomedical, public health and intervention research (Parkin, 2004).

The recruitment and retention of participants as well as the possibility of valid and meaningful result in research can be enhanced by respecting the interests and values of community members (O'Fallon & Dearry, 2002). Recent reports on researches conducted in developing countries have shown that inadequate community engagement can undermine research even where ethical issues have been addressed (Singh & Mills, 2005). Successful completion of these researches or adoption of the resulting technologies will depend on successful engagement with the intended beneficiaries.

It is important to define a community because different types of community may require different types of engagement. Community is defined in different ways depending on the context. It may be a group of people who live in close proximity, or a group of people who are linked by social ties, or share common perspectives, or are engaged in joint action in a geographical location or settings. It has also been previously argued that different levels of community cohesiveness or specific features may warrant different research protections. Such protections might include consultation in protocol development, information disclosure about proposed research and informed consent, involvement in research conduct, access to data and collected samples, and involvement in the dissemination and publication of the research results (Weijer & Emanuel, 2000).

Community engagement (CE) refers to the process of collaborative work with relevant partners who share common goals and interests. This involves "building authentic partnerships, including mutual respect and active inclusive participation; power sharing and equity; mutual benefit or finding the 'win-win' possibility" (Zakus & Lysack, 1998) in the collaborative initiative. CE activities represent efforts to ensure authentic, appropriate authorization and permission for research undertaken within specific communities with appropriate levels of community involvement in and ownership of these activities (Dickert & Sugarman, 2005). The four ethical goals that have been identified are enhancing protection, enhancing benefits, creating legitimacy, and sharing responsibility. These are facilitated through the incorporation of a community's views and its participation in research (Dickert & Sugarman, 2005).

The increasing recognition of the need to consider the ethical implications of biomedical research participants as members of a wider community and not just as individuals, has led to active international debate on the value, goals and practicalities of involving communities in many aspects of the planning and conduct of research (Dickert & Sugarman, 2005; Emmanuel et al 2004; Newman, 2006; Quinn, 2004; Strauss et al 2001).

Informed consent is a process that enables persons to voluntarily decide whether or not to participate in research study. The process ensures respect for individual autonomy to take part in a study and indicate consent that can be available for reference in future (CIOMS, 2002). Previous studies in Africa suggest that trust and social norms rather than information disclosed through the consent process may be what influence participation in research (Adongo et al 1997; Tindana, 2006). This is because in many rural communities, trust engendered by long term relationship between the research team and the community may be more important than signing an informed consent document. The challenge then is how to balance the requirements of the modern research ethics principles with local norms and expectations. In addition to addressing community interests, there is a need to strengthen individual protection in research by supporting informed consent processes through dissemination of information on research goals, risks and benefits and incorporating local views into the development of informational aspects of research (Strauss et al, 2001). On this basis, it was recently proposed that research review boards that evaluate public health and population-based researches should move away from the biomedical model that primarily focuses on assessing risks to individuals towards assessing risks to communities and creating methods for community consent (Fleischman, 2007).

Meanwhile, this study examines community engagement in development and administration of informed consent and explores factors that may influence willingness of the community to participate in research in Osun State, Nigeria

1.2 Statement of Problem

There is an increase in the number of research activities in developing countries. At the heart of ethical recruitment of participants in a study is the principle of informed consent. However the informed consent process does not engage the people thereby leading to poor knowledge about informed consent and its content. Hence, the people lack adequate knowledge about their participation.

Concerns have been expressed in a larger debate about individual autonomy and the "universal validity" of the Western conceptualization of autonomy as embodied in informed consent (Levine, 1991). However, the traditional requirements of community representatives to influence decisions regarding a range of activities in which community members should be engaged, including participation in research projects in communal societies may be at odd with the concept of autonomous voluntariness. It is therefore not clear whether or not the Western oriented process of administering informed consent is acceptable to research participants. Previous studies have reported that community engagement is an appropriate strategy to gain insight into this.

In 2007, a study conducted in Nigeria looked into the methodological approaches of engaging communities in different sites in Ibadan. The study therefore recommends future research to look into describing in details the findings in individual sites and additional communities (Rotimi et al 2007). Hence this study sets out to answer the following research questions.

1.3 Research Questions

1. What is the understanding and opinion of community members on community engagement as part of the informed consent process while conducting a research?

2. What are the processes of trust building in research preparation and implementation?

3. What are the factors that influence willingness to participate in research?

1.4 Aim and Objectives

The aim of this study is to examine community engagement in development and administration of informed consent and explores factors that may influence willingness of the community to participate in research with a view to improve participation in research.

Meanwhile, the specific objectives of the study are to:

1. Examine the awareness and knowledge of respondents on community engagement and informed consent process.
2. Examine their opinions on community engagement in informed consent process in research.
3. Assess respondents' perception of the process of establishing trust in research.
4. Determine factors that may encourage or discourage communities' participation in research.

1.5 Justification of Study

This study will provide a framework on the process of community involvement in decision making and participation in research in different settings in developing countries. This framework can be translated to models which can be added to existing models that researchers in countries with significant cultural diversity like Nigeria can make use of to improve the process of informed consent and participation in research. Furthermore, findings from this study will provide resources for policy formulation on international collaborative research in Nigeria. The data generated will provide guidelines for implementation of informed consent and resources required for developing training programs for researchers on community engagement.

CHAPTER TWO

LITERATURE REVIEW

2.1 Brief Historical Perspective of Community Engagement in Health Research

The practice of involving communities in research has developed over recent years both in response to a perceived mistrust between communities and researchers and in an effort to enhance research by improving the quality, relevance, and impact of research in the community (Leung et al, 2004; Corbie-Smith et al, 2004). This mistrust has been generated by valid community concerns that perhaps well-intentioned research investigators have "used" communities as laboratories without engaging the communities in defining priorities, planning studies, or developing implementation strategies (Kmietowicz, 1998). Community members have also voiced concerns that researchers may actually be more interested in personal and professional gain than in benefiting the communities they study or the larger society.

The process of giving a voice to the communities involved in research is advocated along with traditional ethics models based on the application of universal principles. However, it has been argued that community involvement may not be appropriate in all types of settings for research (Weijer & Emanuel, 2000). The relevance of community involvement has been increasingly articulated for international research (Diallo et al, 2005; Doumbo, 2005; Emmanuel et al 2004; Weijer & Miller, 2004).

There is no single definition for community engagement in the literature. The broad concept has been defined as "a process of working collaboratively with and through groups of people affiliated by geographical proximity, special interest, or similar situations to address issues affecting the well-being of those people" (CDC, 1997). Other definitions include "a method to improve communities by identifying and addressing local ideas, concerns and opportunities" (Tamarack, 2007). The terms 'community participation' and 'community involvement' are used synonymously in the literature while community engagement goes further to include the long term involvement of communities in specific activities. Community consultation is often viewed as the first step to community engagement. The process involves consulting with, and engaging relevant stakeholders prior to, and during the course of the research activities. It also involves determining the appropriateness of approaching members of a community to participate in research, designing appropriate consent seeking procedures, identifying areas of particular concern to the community, providing feedback and sharing of research results with the community. Community engagement is more consistent with concepts such as authorization, permission and acceptance, whereby the will and interests of the community are not presumed to be homogeneous and immutable but related to discussions about legitimacy of community leadership, assent, etc (Tindana et al, 2007).

Community engagement may take place at the project level, for example, when a one-off community engagement process is conducted. It can also take place at the program level, when a sequence of community engagement activities contributes to the development or delivery of policies, programs or services.

Strategic approaches to developing appropriate levels and types of community engagement have been described based on the characteristics and structure of research communities, and the type of research (Weijer & Miller, 2004). The important characteristics of the research community include common culture and traditions; knowledge and shared history; comprehensiveness of culture; health-related common culture; legitimate political authority; representative groups or individuals; mechanism for priority setting; geographic localization; common economy and shared resources; communication network and self-identity. The definition of "community" is not as simple as one might think, as the views and perspectives of what constitutes a community and the role community should play in the research process are widely divergent. In reality, communities are not homogeneous and may have competing interests and priorities; they may not always fit a single definition. Key stakeholders, political leaders, and decision makers, who comprise part of the broader community are often included in educational and outreach activities so that they can be informed of research plans, goals and the potential impact. The support of this broader community is essential to the ongoing success of the clinical research process and partnerships within any given region. Brunger and Weijer (2007) have argued, in the context of a study of ethno-botany and indigenous knowledge that the community constitutes the collection of individual people who share research-related risks.

Emmanuel et al 2004 landmark paper on research ethics emphasizes the need for researchers to develop, among other things, partnerships with local stakeholders and involve them in sharing responsibilities for determining the importance of health problem, assessing the value of research, planning, conducting, and overseeing research and integrating research into the health-care system. The purposes or goals of the community engagement effort should be made clear to the populations and/or communities to be engaged. The researchers need to be knowledgeable about the community in terms of its economic conditions, political structures, leaders, norms and values, demographic trends, history (overall and regarding research) and experience with previous engagement efforts. The researchers need to learn about the community's perceptions of those initiating the engagement activities after going into the community, establishing relationships and building trust, seeking commitments from community-based organizations' as well as formal and informal leadership to mobilize the community. The community is allowed to express itself independently during the community engagement process. Partnering with the community is necessary to create change and improve health. Sustainable community engagement can only be achieved by identifying, mobilizing the community and developing the capacities and resources within the community. Community collaboration requires long-term commitment by the research organization and its partners.

Benefits of Community Engagement

Dickert and Sugarman (2005) recommend four (4) ethical goals: enhancing protection, enhancing benefits, creating legitimacy and sharing responsibility to facilitate the incorporation of community's views into research. Engaging communities is a means of avoiding exploitation, improving the benefits to local communities, encouraging recognition of the distinct character and interests of individual communities participating in research, and improving the likelihood that research will result in durable improvements for the host communities. The other benefits of community engagement include ways of ensuring that relevant research is culturally and practically acceptable in the context in CIOMS, ensuring that the community feels some ownership. Also it is able to take appropriate responsibility and authority of the study, minimizing community disruption and avoiding exploitation by ensuring a fair distribution of the risks and benefits of research. A community's attitude toward a proposed research and its willingness to participate has been shown to be a key determinant of the success of the research. Many potentially valuable studies have been either severely compromised, or have failed completely to effect beneficial change, because of challenges at the community engagement level.

Rationale for Community Involvement

The inclusion of and collaboration with community representative in research process help to build trust and increase the likelihood that affected communities are interested in and supportive of the research being done. The people who form a community provide the most direct opportunity for making a difference within that community; public health researcher that aims to be successful cannot afford to overlook this resource when planning the required strategies. Also collaboration between researchers and communities helps to ensure that communities invest themselves in the research, making data and results more significant for the community, thereby "increasing the likelihood for a successful project with mutual benefits" (Leung et al, 2004). Active collaboration between communities and researchers is critical to developing appropriate public health research strategies that address community concerns. It has been suggested that effective community-researcher collaborations require a paradigm shift from traditional practices to an approach that involves acknowledging community contributions, recruiting and training minority people to participate in research teams, improving communication, sharing power, and valuing respect and diversity (Kone et al, 2000).

2.2 Cultural Issues and Community Engagement

Scholars have generally defined the word "culture" in different ways. For example, Kneller defines it as the totality of ways of life that has evolved through history. He goes further that a particular culture is the total shared life of a given people – their modes of thinking, acting and feeling, as expressed in religion, law, language, art, technology, child-rearing, and, of course, education (Kneller, 1971). In his book, *Philosophy and an African Culture*, Kwasi Wiredu tells us that culture goes beyond art, song and dance to include everything that is connected with a people's way of life (Wiredu, 1992). Culture, he says, is seen in the way people work or recreate, in their worship, and courtship, in the ways they investigate nature and utilize its possibilities; and in their ways of viewing themselves and interpreting their place in nature. It is also seen in the manner in which people house and clothe themselves; in their system of statecraft, education, rewards and punishment; in the way they regulate personal relations generally and the ideas underlying these institutions and practices. (Wiredu, 1992).

John Mbiti offers a definition of culture that is similar to that of Wiredu above. Writing specifically about African culture, Mbiti says it covers such areas as the social organizations and political systems of the African people - their ethics and morale; their philosophy and laws; their customs and institutions as well as their pattern of economic activity (Mbiti, 1990).

The point Wiredu makes in his definition is to say that in a certain sense, human beings are really who they are (or almost who they are) by the virtue of their culture. Put differently, culture cannot be separated from human experience since it is that experience that produces and nourishes it. By "human experience," we have in mind the totality of our experiences in life - in politics, in our social relationships, in our use of technology, and even in our encounter with nature. But human experience itself is only possible, or can only be gained within the community. On this last score, it is commonly held that Africans are community conscious. What this means is that community consciousness and solidarity dominates the individual in his thinking and actions. It is in submitting to family or community authority, in being "immersed" in group values and norms that one becomes a true member of the community. Nyasani (1997) illustrates this point in a somewhat different manner when he argues that usually in the African community, the individual is not expected to act outside of his community prescriptions or proscriptions. The will of the individual person is simply dissolved in the collective will of the community.

2.3 Conceptual Models of Community Engagement

A number of research institutions have recognized the importance of local lay knowledge and have developed strategies for ensuring local inputs in their research activities. Some of these approaches are projects which are institution or community driven i.e. community advisory boards, community entry and consultation, participatory research in most social science studies and community outreach programmes.

2.3.1 Community Entry and Community Consultation

The process of community consultation is perhaps the most common concept of engagement in the field of health research. In other settings, research institutions have utilized existing protocols in host communities in their community outreach programmes. The engagement process involves a community entry approach where key informants of the community often lead researchers into the community to hold consultative meetings with chiefs and residents of the community. This approach allows for concerns about proposed research activities to be addressed and for local inputs to guide the actual activities of the research. The key stakeholders are community leaders, known as traditional chiefs, local health authorities, development partners and researchers. This approach utilizes existing local protocols, which are often used by several research projects as well as to engage communities. The process of "Community Entry" in some settings enables researchers to meet with all relevant stakeholders to solicit their views on the proposed research and to agree on the level of community involvement in the research. Stakeholders' meeting also provides a forum for allaying the fears and concerns of community members and an opportunity for consensus building with all partners. Relevant stakeholders could include community leaders, religious leaders, local health authorities, the media, local NGOs and researchers working in the community. Identifying a respected opinion leader to lead the research team into the community is also vital to the process. Community Consultation -In some culturally diverse settings throughout the world, investigators must seek approval from community leaders or tribal elders before implementing a study. Ideally, community consultation and active engagement in research represent a reciprocal and dynamic process that serves to educate both the researchers and the individuals and the communities involved in a study. Molyneux et al (2005) found that discussions with village chiefs and elders were considered necessary to gain permission to implement research in the area, but local leaders could not consent for individuals or family households.

2.3.2 Community Advisory Board (CAB)

CABs are established for specific studies or specific communities and serve as a liaison between the research team and the community. CABs have evolved to play very important roles in research. Community advisory boards often have members drawn from the community who are expected to make inputs into a proposed research and then feedback to the wider community. They represent a diverse array of community members and are often selected in consultation with relevant local authorities i.e. community leaders, and chiefs. At the front end of a study, they support the formulation of research questions and approach to the community. In the middle, they serve as a check point for how things are going and at the back end interpreting and applying the findings. The community advisory boards are also expected to facilitate research by providing advice about informed consent process and the design and implementation of research protocols (Quinn, 2004).

2.3.3 Participatory Action Research

It is also known as community-based participatory research. It is another approach used mostly by social scientists to engage communities in research. It involves a cyclical process of identifying a problem, action planning, action taking, evaluating and identifying findings with members of the community. A number of non-governmental organizations (NGOs) often utilize this approach in their research activities. This model ensures collaborative and participatory efforts by both researchers and members of the community to directly address the local needs of the community. Principles have been developed to aid researchers to consider Community-based Participatory Research as a potential solution to these problems (Israel et al, 2005). Flicker et al (2007) describe the principles of Community-based Participatory Research and argue that "this approach has evolved as an effective new research paradigm that attempts to make research a more inclusive and democratic process by fostering the development of partnerships between communities and academics to address community-relevant research priorities".

2.3.4 Community Research Advocacy Groups

Community research advocacy groups (CRAGs) should be encouraged by Research Ethical Committees (RECs) to monitor research activities in their domain and report doubtful practices to the nearest REC. The membership of such CRAGs should include opinion leaders, religious leaders, male and female leaders and youth leaders. The advocacy group in each community should register with their respective local governments and RECs. They should function as community based organizations, with funding from the local government and research institutions working in the community as well as interested funding agencies (Jegede, 2009). CRAGs is an approach which involves a community liaison officer or a public relations officer, knowledgeable about the community who serves as the link between the community and the research team. Quite similar to community-based participatory action research, this approach also involves key stakeholders within the community to identify local needs and to set research priorities. The difference between this approach and the Community Advisory Board (CABs) approach is that the liaison office or officer is a staff-member of the research project while members of CABs are independent of the research project.

The existing ethics guidelines have been criticised as having arisen partly or wholly in response to research ethics crises. For example, the Nuremberg Code was a result of the trial of doctors and scientists that conducted unethical research during the Second World War. It is also believed that excessive weight has been accorded the principle of autonomy and failed to meet current challenges in research ethics such as community concerns, use of placebos, conflicts about standard of care, resource availability when research is over, and quality of an adequate informed consent process (Emmanuel et al, 2004; Emmanuel et al 2000). The Nigerian Code reflects these new paradigms in ethics guidelines and includes explicit information about protecting communities and their interests as well as the application of the ICH-GCP guidelines in clinical trials (Emmanuel et al, 2000; Marshall, 2006).

2.4 The Informed Consent Process in Research

The CIOMS guidelines give the concise definition of informed consent as a decision to participate in research made by competent individual who has received the necessary information; has adequately understood the information; and after considering the information, has arrived at a decision without having been subjected to coercion, inducement or intimidation. Informed consent is a key ethical requirement in clinical practice involving patients and in health care or biomedical research involving human participants.

Marshall *et al* (2001) reported that not only is voluntary informed consent universally accepted as a precondition for scientific research involving human beings, it is specified in national and international guidelines for ethical conduct of research with laid out conditions for obtaining it. The purpose of these guidelines include among other things, to minimize unethical practice in the conduct of research, to protect research subjects from undue harm and to ensure that the desire for knowledge does not lead to "inhumane, unethical or inconsiderate treatment in experiments on human beings" (McNeill, 1998). In the first context, consent is said to be informed when an adequately informed participant comprehends information about a research or clinical intervention and approves/authorizes a healthcare professional or researcher to undertake an intervention on her body or person. In the second place, consent refers to a process by which a prospective research participant indicates his or her willingness to be part of a research involving human subjects. The crucial concepts in these characterizations are "approve," "authorize," and "willingness."

The ethical basis of informed consent is woven around the moral principle of respect for the research participants' autonomy, the competence and capacity to make appropriate decisions (Andanda, 2005). In obtaining consent for research, the fundamental principle of research ethics is that a participant agreeing to take part in research should do so voluntarily and with sufficient knowledge and understanding of the procedures, risks and benefits involved. This is usually ensured through oral consultation and written consent. Determining what constitutes free and informed consent and the best method of obtaining it can be difficult in some circumstances (Parliamentary Office of Science and Technology, 2008).

2.5 Informed Consent and Community Engagement

Ethical conduct in research involving human participants has become one of the principal challenges faced by researchers. In recent times, increasing attention has been paid to ethical implications of carrying out research in settings with low socio-economic status. This trend has become particularly central in Africa owing to an increasing number of multinational research institutions operating in sub-Saharan African countries. It is at times erroneously assumed that collectivist cultures in parts of Africa and Asia place little value on personal autonomy such that proxy consent of local authorities, leaders and government officials replaces first person consent of individual community members. This is not the correct position, as anthropological literature on the differences between societies characterized by collectivist and individualist values does not support the conclusion that collectivist societies unconditionally reject individuality. (Ijsselmuiden & Faden ,1992) As there is no guarantee that such proxy authorities have the best interest of all potential participants at heart, first person voluntary consent must be obtained.

For purposes of respecting the local customs and expectations of the communities from where participants are drawn, it is polite to contact local authorities and seek their authorization and co-operation before approaching individual participants. The relevant authorities' authorization in this regard enables the recruiting investigator to approach potential participants who must in turn give personal informed consent, which cannot be substituted by the community leader's approval of recruitment. Individual participants should similarly feel free to discuss the issue of participation with their family members, spouses and friends due to possible effects of such participation on their personal relationships, but this does not take away their autonomy to give consent personally (Gostin, 1995). However adherence to local customs and expectations is an important aspect of informed consent which should not be overlooked, not only in Africa but in any community. Thus the ethics of human subjects research may be universal but is at the same time deeply particularized, so that what autonomy or informed consent or even benefit and harm mean depends on the circumstances (Marshall & Rotimi, 2001). The recently proposed additional ethical principle of “respect for communities” and guidelines on when and how to establish mechanisms for community engagement moves the debate towards ways of defining goals, identifying characteristics and avoiding pitfalls in understanding a local context for ethical principles (Quinn, 2004).

There is a general consensus amongst researchers, scientists and bioethicists that acquiring effective informed consent from research participants is a prerequisite to the conduct of an ethically sound study (Dickert & Sugarman, 2005). Informed consent may be defined as 'the legal term describing a patient's voluntary agreement to a doctor performing an operation, arranging drug treatment, or carrying out diagnostic tests' (Peters, 2008). Whatever meaning one gives to informed consent, it is a voluntary agreement or acquiescence to what another person proposes or desires, or an agreement as to a course of action (Lawal et, 2011). Consent is considered 'informed' when given by a person who understands the purpose and the nature of research, what is required from the participant and what may be the potential benefits and risks resulting from the study (Council for International Organizations of Medical Sciences (CIOMS), 2002 ; Alderson & Goodey, 1998).The signing of a consent document begins as process of deliberations between the research team and participants, which enables them to decide whether to continue in the research study or not.

The centrality of informed consent in local and international research cannot be overemphasized. Ideally, informed consent describes an interactive process in which an individual or his or her parent or surrogate voluntarily agrees to join a study after the purpose, risks, benefits and alternatives have been thoroughly described and understood (Faden & Beauchamp, 1986; Levine, 1986; Veatch, 1987) Even though there has been consensus among nations to adopt international regulations guiding research, each society has distinctive socio-cultural features which influence the level of adherence among researchers. Knowledge of the peculiar socio-cultural factors in an unfamiliar research setting can influence the process by which informed consent is obtained. This is significant in determining the extent to which the consent for research guarantees understanding, voluntariness, and authorization (Beauchamp & Childress, 2001).

The process of informed consent in social contexts emphasizes comprehension of information, the communication of risks, and the locus of decisional authority. Comprehension of the nature of the study does not necessarily indicate that someone understands other dimensions of informed consent. An individual's comprehension is always enhanced when researchers engage the study community in active discussions of project goals and procedures through meetings with local leaders or public forums, and when information is provided to potential participants before obtaining consent (Fitzgerald et al, 2002; Dickert & Sugarman, 2005). An informed choice concerning research participation depends upon a clear understanding of the potential risks and harms associated with the study. There are cultural and social factors that influence beliefs about what actually constitutes a risk or potential harm. In western industrialized countries where personal autonomy is emphasized, individuals are expected to make decisions about research participation for themselves or through designated surrogates. In contrast, in many non-western settings, family members, or community leaders may play a significant role in decisions concerning medical research (Molyneux et al 2005; Hyder & Wali, 2006).

2.6 Health Research and Community participation

The World Medical Association's Declaration of Helsinki (2004) states that the primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments).

Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. International guidelines and regulations on human subjects' research lay down the conditions to be met before a given research can be said to be ethically sound or justified. Research sometimes helps to develop an appropriate process of community engagement, taking into account community issues and dynamics. For example, if communities have no prior knowledge or history in an issue, it may be necessary to provide a first round of information exchange and then a later round of consultation or active participation to help decide on outcomes. Alternatively, if the community has a negative history with respect to the issue, the first round of engagement may instead focus on building trust and relationships.

2.7 **Trust Building in Research and Related Factors**

Trust building and trust maintaining constitute a never-ending process which can be achieved through the following processes: (1) acknowledging personal and institutional histories, (2) understanding the historical context of the research, (3) continuous presence of academic partners in the community listening to community members, (4) acknowledging the expertise of all partners, and (5) maintaining a stand on expectations and intentions.

Wallerstein and Duran (2006) notes that researchers are influenced by their backgrounds and values when they come into a community to do research; they also carry with them other histories (e.g., history of their institution in that community) that they may or may not know anything about. To work effectively and build trust, researchers need to acknowledge these backgrounds and histories. Researchers need to gain an understanding of the broader histories in the work engaged in , including the history of research between the specific community and institution, the broader history of research and the history of the community with which they are working. The process of building relationships will involve the researchers being present and listening to community members as this will dispel the idea of been considered strangers. There is a need to also build trust relationship between researchers, their institutions, participants and the group they represent in order to ensure adequate protection of the participants. Trust is valuable in determining the willingness of potential subject to participate in research. Without trust, there is no willingness on the part of potential subjects to participate in research (Kahn, 2005). Communities want researchers who are sincere and honest about their intentions. Funding can act as a barrier to building trust because it influences the time and resources available to researchers to build relationships. Researchers have to make considerable effort to be seen in the community and be a part of the community events. By doing so, they will enhance the community's perception of their commitment to the project and the community. Trust building can be enhanced by acknowledging and appreciating the priorities of the community as well as the research priorities. It is necessary to have mutual respect and a partnership that is mutually beneficial to foster trusting relationships.

2.8 Participation in Research and Factors Encouraging or Discouraging Participation

Previous commentaries noted that in some cultural environments, respect for family and elders strongly influenced receptivity to joining a study (Ajayi, 1980; Ekunwe & Kessel, 1984). Marshall (2004) argues that it is important to recognize the variability that exists in both urban and rural sectors of the population. In studies conducted in Africa, Burma, China, the Philippines, South America, and Thailand, researchers reported that they often required the permission of village leaders to talk with individuals, "because they gave them the credibility they needed to begin the informed consent process with individual community members" (Marshall, 2004).

Plowe conducted studies in Mali and Malawi and noted difference between the two settings. In Mali, the study was conducted in a remote rural area in which community leaders were heavily involved. In contrast, the Malawi study took place in a large city with an established health care system and a more educated population. In the Malawi setting, consent by community leaders did not have an undue impact on the decisions of individuals as community consent at national and international level is removed from individuals and the local community. In addition, in an urban context, it is more difficult to identify appropriate spokespersons for the larger community, especially as individuals in urban areas tend to associate themselves with many different kinds of communities (Plowe, 2000).

Researchers have also noted that community leaders in urban areas have less authority than in rural areas because urban populations are more diverse and mobile. Leach *et al* (1999) also found urban–rural differences in beliefs about the importance of community elders in decisions regarding research participation in their study of informed consent with parents whose children participated in a vaccine study conducted in the Gambia. While the parental consent sought among the 189 parents interviewed conformed to western standards, 25% of the rural parents, compared to only 10% of the urban parents, and agreed that the village chief should have some input concerning the decision to participate in the influenza vaccine trial.

Factors influencing the recruitment and retention of subjects into research studies are not well understood. Two urban community-based intervention studies of elderly African-American participants showed different issues and strategies in recruitment and retention. The following six concepts emerged as fundamental to successful recruitment and retention of diverse population groups: (1) historical cognizance; (2) sanctioning; (3) trust-building; (4) mutuality; (5) recognition of heterogeneity; and (6) researcher self-reflection and introspection (Dennis & Neese, 2000).

Trust is fundamentally important to the process of communication during informed consent (Kass et al, 1996 ; Molyneux et al, 2005). An individuals' or community's past experience in research and factors associated with social status and power influence levels of trust. This might also determine the proportion who finally join a study. Socioeconomic background, caste, gender, age, and education reinforce differences in the relative power experienced by individuals during the consent discussion and this has implications for trust and voluntary participation (Kuczewski & Marshall, 2002). In a survey of views of USA researchers on international collaborative studies, researchers concluded that participants joined the research because of compensation or other benefits, and refusals were much fewer (Dawson & Kass, 2005). In line with this, other previous studies have suggested that monetary payment increases respondents' willingness to participate in research regardless of the level of risk; higher levels of payment make respondents more willing to participate, even if the study is relatively risky (Bentley & Thacker, 2004).

Engaging communities in researches is seen as a means of avoiding exploitation, improving the benefits to local communities, encouraging recognition of the distinct character and interests of individual communities participating in research, and improving the likelihood that research will result in durable improvements for the host communities. Moreover, the move towards community engagement also reflects a growing recognition that "community consent" is simply not the same as individual consent, but at an aggregate level. Efforts to ensure that participating communities understand the purpose and procedures of research could help to enhance mutual trust and to create a sense of collective ownership of research.

CHAPTER THREE

METHODOLOGY

3.1 Research Design

The study design is a comparative and cross sectional survey of the people living in two LGAs in Osun State, Nigeria. While one was predominantly urban, the other was rural based on their population and level of infrastructural development. The research was conducted amongst adults aged 18 years and above.

3.2 Study Location

The study was conducted in two Local Government Areas (LGAs) in Osun State, namely Ife Central and Ife North LGAs. In this study, Ife Central LGA represents the urban setting and Ife North LGA represents the rural settings. Both LGAs have been involved in various researches because of their proximity to the tertiary institution’s main campus and the distance learning centre of the same school.

3.2.1 Ife Central Local Government Area

Ife Central local Government, one of the three local governments carved out of the defunct Oranmiyan local Government Area in May, 1989, has its headquarters at Ajebamidele in Ile-Ife. It covers an area of approximately 350 square kilometers, lying between latitudes 25^0N and 30^0N of the equator, and is bounded by the Ife North, Ife South, Ayedaade, Atakumosa West and Ife East Local Government Areas. Yoruba and other ethnic groups like Hausa, Igbo and other foreigners live in the local government. The 1991 census put the population of the local government at 96,580 while the estimated population for the year 2006 is 167,254. The local government area is considered urban because it consists mostly of towns. The local government has 11 wards and most of the streets in the wards are located within Ile-Ife town.

Ile-Ife is an ancient town in Ife Central Local Government Area. It has a special place in Yoruba culture because it embodies the Yoruba concept of *Orirun* - it is held to be the place of the world's creation and the final resting place of soul after death. From this concept of *orirun* flow other important beliefs such as that Ife is the 'father kingdom' of all other Yoruba kingdoms. As a sacred capital, Ife was and still is a religious and ceremonial center. Ife's sacredness lies at the heart of its long survival, and has ensured its continued importance to the Yoruba people.

The town is headed by a king who is supported by chiefs who administratively oversee several sub-communities within the town. Apart from this group of people, there are community leaders like Baale and political leaders who are in charge of the wards. Most families are nuclear, living separately from their extended families in modern houses though there are few old traditional buildings within the heart of the town close to the king's palace. The town is a mix of different cultures and ethnic groups. The people are a mixture of Christians, Muslims and traditional worshippers. A large number of people in this local government are farmers. There is also the pre- pondering majority that work in public institutions while others are traders and artisans.

A tertiary institution, Obafemi Awolowo University is located in the town. Hence several researches have been conducted in the town and its environs.

3.2.2 Ife North Local Government Area

Ife North Local Government Council of Osun State was created in May 1989 from the defunct Oranmiyan Local Government, Ile-Ife, and Oyo State in the South Western part of Nigeria. It is made up of semi-urban communities (Asipa, Akinlalu, Edunabon, Ipetumodu, Moro, Yakooyo) and villages like Oyere, Famia and other smaller settlements. The local government shares boundaries in the north with Ede South with Ife South and some parts of Ife Central Local Government, in the west with Ayedaade Local Government, in the North West with Atakunmosa West Local Government and in the east with Ife Central Local Government Area, respectively. The 2006 census put the estimated population of the local government at 153,694. The council is delineated into 10 wards with a councilor elected from each of the wards into the local government and political leaders are elected to be in charge of the wards. The Ife North Local Government Area is considered rural because it is made up of more villages than towns. The wards are located in the semi –urban communities and villages mentioned above which are headed by crowned chiefs and there are also community leaders like "baale" heading compounds or households. The family type is a mix of nuclear and extended family.

The people are mostly Christians and Moslems while traditional religion worshippers also abound. Aside from this, the people are predominantly Yoruba but other ethnic groups, such as Hausa, Igbo and several other ethnic groups are also resident in the area in large numbers. The communities enjoy adequate rainfall annually with normal dry season periods and normal temperatures. This could be said to be responsible for the reason why the people of the area are predominantly farmers, though others engage in making of clay pots, African black soap lumbering and a host of other commercial activities.

One of the wards in Ife North Local Government Area of the state is located in Moro, a semi –urban community where the Centre for Distance Learning of Obafemi Awolowo University is situated .The centre runs the pre-degree arm of the Obafemi Awolowo University and the

Executive MBA students have their classes in the semi urban community. The presence of the Centre for Distance Learning has opened opportunities for researches in the Ife North Local Government.

3.3 Study Population

The study was conducted amongst males and females in the study locations and opinion leaders such as “Baale”, chairmen of community development committees and religious leaders (Christian and Muslims) in the communities.

Inclusion criteria – This study involved anyone aged 18 years and above, who has been living in the community for 5 years or more and is an indigene of the communities. The participant must also be able to give informed consent.

3.4 Sample Size Determination

The sample size was estimated using the formula for 2 independent samples shown below.

$$n= \frac{[2(Z_{\alpha} + Z\beta]\,^{2}pq]}{d^{2}}$$

Where n is estimated sample size

P_1 = 25 % of rural parents agreed to the village chief having some input concerning the decision to participate in the influenza vaccine trial.

P_2 = 10% of urban parents agreed to the village chief having some input concerning the decision to participate in the influenza vaccine trial (Leach et at 1999)

$$P = \frac{P_1 + P_2}{2} = \frac{0.25 + 0.10}{2} = 0.175$$

$Z\alpha$ = Z score corresponding to the probability with which it is desired to be able to conclude that an observed change of size ($P_2 - P_1$) would not have occurred by chance $\alpha = 0.10$, $Z\alpha = 1.96$. (two tail).

Z_β = Z score corresponding to the degree of confidence with which it is desired to be certain of detecting a change in size ($P_2 - P_1$) if one actually occurred.

$\beta = 0.20$, $Z_{1-\beta} = 0.84$

$$n = \frac{[2(1.96+0.84)]^2 (0.175) (0.825)}{(0.1)^2}$$

$$= \frac{2.2638}{0.01}$$

= 226.38 per group.

Based on the differences in response rate and population in two LGAs, the estimated sample size for rural LGA was increased to 240, while the estimated sample size for urban LGA was increased to 250.

3.5 Sampling Technique

Multi-stage sampling technique was used to select 250 and 240 respondents from Ife Central and Ife North Local Government Areas respectively. Ife Central LGA has 11 wards out which 10 wards were used because one of the wards was located in a disputed area with limited access. Eight of the 10 wards in Ife North LGA were used as the other two wards were located in disputed areas. Maps of the two LGAs showing the wards and streets were retrieved from the National Population Commission. The first stage involved computer generation of a list of the streets to be used in the wards in the two LGAs, which is selection of streets from the total numbers of streets in the wards in the two LGAs. There is an average of 7-12 streets in each ward in urban LGAs and 6-7 streets in the rural LGAs and one or two streets were selected using the random sampling technique. The houses within the streets were selected using the probability proportionate to size method that is houses were selected based on estimated number of houses in the streets and number of respondents sought in the street/ wards (second stage). The sampling units were the households. A total of 25 households were interviewed per wards in the urban LGA while 30 households were interviewed per wards in the rural LGA. In any visited household the eligibility for participation was the presence of youths and adults (males and females) aged 18 years and above. In cases where the households had more than one of such respondent, a ballot system was adopted to select the reference youth / adult (third stage).

Table 3.1: Selected wards and streets used in Ife Central Local Government Area

Id Number	Wards	Streets
1.	Ilare 1	Awoyeku and Akindoyin
2.	llare 2	Ajegunle
3.	llare 3	Obalogun
4.	llare 4	Oduduwa College Road
5.	Iremo 1	Old & New Ede Road and Adesanmi
6.	Iremo 2	Mayowa and Tademikawo
7.	Iremo 3	London street and Onireke.
8.	Iremo 4	Gbelekan and Aiku
9.	Iremo 5	Aderemi and Isale Agbara
10.	Moore	Idoo street and Aladanla

Table 3.2: Selected wards and streets used in Ife North Local Government Area

Id Number	Wards	Streets
1.	Akinlalu/	Oke- Oje
2.	Ashipa	Oke Ola
3.	Edunabon 1	Behind the palace
4.	Edunabon 2	Tonkere road and Olubiyi
5.	Ipetumodu 1	Ayegbaju and Catholic hospital street
6.	Ipetumodu 2	Odo and Surulere
7.	Moro	Ayepe
8.	Yakoyo	Akinrinade and Celestial Road

3.6 Instrumentation

3.6.1 Questionnaire

Quantitative data was collected using an interviewer administered structured questionnaire. A total of 490 questionnaires were applied in the two LGAs (250 urban and 240 rural). The questionnaire included information on the socio-demographic characteristics of respondents, awareness and knowledge on community engagement and informed consent process in research, opinion on community engagement in informed consent process, process of trust building in research participation and factors influencing willingness to participate in research. Most of the questions were close-ended.

Pre-test of Questionnaire: The instrument was developed and pre-tested in Atakumosa West Local Government Area. The people of the town shared common social and cultural characteristics with the proposed study area. Their responses were used for modifying the content of the research instruments. The instrument was pre-tested in two days and the analysis was used to effect corrections on the draft instrument before it was finalized. This took place before the recruitment and training of field workers. Field workers were trained with the final version of the instruments. Investigators were randomly selected to complete questionnaires for spot check for consistency.

Translation of Instruments: The research instruments were translated into Yoruba, the local language of the proposed study population. This was done to enhance adequate comprehension of the content of the instruments by participants and also to assist the fieldworkers to ask questions without distorting their original meanings. The translation of the instruments was to ensure consistency and accuracy.

3.6.2 Focus Group Discussion and In-depth Interview Guide

A guide was developed to collect information on awareness and knowledge on community engagement and informed consent process in research, process of trust building in research and factors influencing willingness to participate in research. Responses were recorded on tapes and in writing with the permission of the participants.

3.6.3 Training of Interviewers on the Instruments

Recruitment and Training of Interviewers: For questionnaire administration, 6 interviewers with experience in conducting surveys were recruited to conduct the study. Their recruitment was gender sensitive by recruiting women and men alike. A one day training workshop was conducted for them. This involved reading through the questionnaires, role-plays and practical sessions to strengthen their capacity.

For qualitative data collection, 2 moderators and 2 recorders were trained to work on the project. The content of the training involved: familiarization with the instruments, determination of their understanding of research instruments, interview techniques, face validity of the instruments as it relates to the study objectives. In addition, those for qualitative study were trained on facilitation techniques, note taking, use of tapes, transcription and observation techniques.

3.7. Data Collection Techniques

Quantitative and Qualitative data collection methods were employed for the study. Quantitative data was collected using the pre-tested semi-structured questionnaire. The qualitative data was collected using the key informant interview and FGD guides. The field work was supervised by a field supervisor and meetings held with the field workers on daily basis to review each day's activity. This helped in correcting perceived anomaly arising from the field. For the FGD data collection, the recorders transcribed the tapes on daily basis when the information was still fresh in their memory. The interviewer wrote up the responses of the informant after the key informant session as this enabled the interviewer capture the observed phenomena of the interview. At the end of the fieldwork, field workers met with me and the field supervisor to review the fieldwork experience.

Field Management: I supervised the fieldwork alongside with the field supervisor. Fieldworkers reported to me and the field supervisor and we were meeting on daily basis to facilitate information flow. The modalities of these meetings were established before commencing fieldwork. At every stage of the study, each fieldworker submitted a written note of observations on a daily basis. The research team discussed this before starting another day’s work.

3.7.1 Quantitative Method

The pretested structured questionnaires were applied on the urban and rural dwellers in Ife Central and Ife North LGAs respectively. At the end of each day during the field work, the questionnaires’ were reviewed by the researcher and the field supervisor to ensure they were completely and correctly filed.

3.7.2 Qualitative Method

Qualitative methods were used to provide more information to complement the findings from the quantitative survey. Respondents interviewed were youths, adults**,** community representatives and community based opinion leaders (Muslims, Christians and Baales) in the two LGAs.

Focus group discussions (FGD): A total of 8 FGD sessions were conducted among selected respondents in the 2 LGAs. Four sessions were conducted in 6 wards in the 2 LGAs and each session consisted of 6 to 8 respondents matched for age and sex. A trained moderator and a recorder conducted the discussion sessions per LGA. The FGD sessions were conducted in Yoruba, the local language of the studied population. At the end of each session, tapes were transcribed and translated from the local language to English and translated back to the local language to ensure consistency and correctness.

Key informant interview: A total of 8 interviews were conducted on the opinion leaders (Baales, Christian and Muslim leaders and community leaders) in the 2 LGAs. The interviews took place at a venue approved by the respondents. The guide used for the FGD was also used to guide data collection.

All interviews were conducted in the local language of the participants. The interviews were recorded on tape and in writing with the permission of the participants. All the tapes were transcribed verbatim in the local language and translated to English language.

Table 3.3: Respondents interviewed per LGA.

Methods	Respondents	Ife Central LGA	Ife North LGAs
Focus Group Discussion	Youths (males)	1	1
	Youths (females)	1	1
	Adult males	1	1
	Adult females	1	1
Key informant Interviews	Baale	1	1
	Christian religious leader	1	1
	Muslim religious leader	1	1
	Chairman/ member of community development committee	1	1

3.8 Data Analysis

3.8.1 Qualitative Data Management

Data was transcribed and translated to the English language from the local language and translated back to the local language for consistency and retention of original meaning. All data collected were stored in notebooks and scrutinized before storage into a computer. To protect the confidentiality of the respondents, codes were used for respondents' names. Only the investigator had access to the complete data set. No information from the study was communicated or discussed with anybody outside the research team. For proper handling of the data received, all tapes were reviewed at the end of each session to ensure that the recordings were done correctly. To check for reliability of transcription, 5% of the tapes were re-transcribed by the researcher, apart from the people who conducted the interviews.

The qualitative data was analysed using Nvivo 6 and narrative analytical approach. Data was analyzed by developing codes and sub-codes after reading and re-reading of the field notes. The codes used for the transcribed data were based on the themes and sub-themes developed following the research objectives. Information received was presented verbatim, preserving language and concepts used. Analysis was done by LGAs for purpose of comparison. The report was accompanied by phrases in quotes, which were the recorded explanations of the respondents.

3.8.2 Quantitative Data Management

The data collection took place for a period of four weeks. In order to ensure quality, data check of entries of questionnaire daily on the field, double entering of data, range and internal consistency tests were done weekly.

The data was analyzed using statistical software STATA version 11.0. Univariate analysis was conducted to examine frequency distributions and multivariate analysis was employed to examine the association between independent and dependent variables. In order to ascertain respondents' knowledge about community engagement, they were asked to respond "yes" or "no" to questions about whether (a) community engagement means consultation of elders, (b) provision of information on proposed research to members of the community, (c) community involvement in planning of proposed research or (d) community participation in research. The total score for knowledge was 5 , a score of 3 or 4 was considered good, that is, respondents indicated 'yes' to 3 or 4 options listed above, fair if respondents have a score of 2, that is respondents indicated 'yes' to 2 options listed above and poor if the respondent indicated 'yes' to one option or don't know. The knowledge of respondents about community engagement was re-categorized as knowledgeable (good/fair knowledge) and not knowledgeable (poor knowledge).

The knowledge of respondents about informed consent process was categorized as good if the respondent picked the options "giving information", "signing of form" and "agreed to participate", fair when the respondent picked either "agreed to participate" or "signing of form" and poor if the respondent picked "don't know".

In order to ascertain the opinion of the respondents on community engagement in informed consent process , they were asked to indicate 'strongly agree',' agree' , 'disagree', 'strongly disagree' or 'indifferent' to the following statements: a) community leaders should be consulted before research, b) researchers should provide community leaders adequate information on risk/ benefits, c) community leaders should be involved in the planning and carrying out of research, and d) permission of the community leaders is crucial in individual's participation in research. This was later collapsed to 'agree', 'disagree' and 'indifferent' for ease of analysis.

3.9 Ethical Consideration

The proposal was sent to the University of Ibadan/University College Hospital, Ibadan Ethical Review Committee for approval. Approval of the ethical clearance is attached in the appendix.

Comprehension: The issue of distortion of meanings of questions and standardization of instruments was handled by translation of instrument to Yoruba and back translated before use. This was also done to enhance adequate comprehension of the content of the instruments by participants.

Confidentiality of data: The data collected was coded and no names recorded on the questionnaire to ensure confidentiality. The data was stored in a folder in the personal computer of the investigator which only the investigator had access to and the complete data set.

Beneficence: They benefitted indirectly through improved knowledge and attitude which ultimately might increase their participation in research.

Non-maleficence: The study carried no known risk or harm as the information provided couldnot be linked with the respondents.

Voluntariness: The respondents were given adequate information about the research: what it entails, the benefits and risk/ harm involved and the use of the data. The respondents were given opportunity to make a decision to participate in the research and sign a written consent form. The respondents could therefore decide not to be part of the study or decide not to continue with the study

CHAPTER FOUR

RESULTS

Some 249 questionnaires were returned completed from Ife Central LGA (urban) and 239 questionnaires were returned completed from Ife North LGA (rural) giving a 99.6% response rate.

Section A: Socio-demographic Data

The respondents were within age 18 - 50 years and mostly Christians and Yoruba's. The mean ± SD age of urban dwellers was 36.3 ±15.7 years compared with 34.3 ±15.1 for rural dwellers. There was no significant difference in age between the rural and urban dwellers in this study (t= 1.43, p=0.15). There was no significant difference in the proportion of males and females interviewed in the urban and rural LGAs.(x^2= 1.63, p=0.20) A significant proportion of the rural dwellers attained primary level of education while a significant proportion of urban dwellers attained tertiary level of education..(x^2= 35.4, p=0.0001)

Table 4.1: Socio-demographic Characteristics of Respondents in Ife Central and Ife North LGAs

Characteristics	Urban (Ife Central) N=249 (100%)	Rural (Ife North) N=239 (100%)
Mean age	36.3± 15.7	34.3± 15.1
Sex		
Male	167(67.1)	173(72.4)
Female	82(32.9)	66(27.6)
Educational status		
None	14(5.6)	21(8.8)
Primary	19(7.6)	37(15.5)
Secondary	103(41.4)	131(54.8)
Post secondary	37(14.9)	20(8.4)
Tertiary	76(30.5)	30(12.5)
Occupational status		
Unskilled	90(36.1)	108(45.2)
Skilled	109(43.8)	90(37.7)
Professional	50(20.1)	41(17.1)
Religion		
Christianity	201(80.7)	204(85.4)
Others (Islamic& Traditional)	48(19.3)	35(14.6)
Ethnicity		
Yoruba	234(94.0)	230(96.2)
Others (Igbo &Hausa)	15(6.0)	9(3.8)

Section B: Awareness of Respondents about Community Engagement

Table 4.2 shows that about half (46.9%) of rural dwellers had heard of community engagement compared to 32.9% of urban dwellers. This difference was statistically significant (x^2=9.27, p=0.002). When age and education status were adjusted for in a logistic regression model, the difference was still statistically significant (p=0.002).

Table 4.2: Awareness of Respondents about Community Engagement

Awareness	**Urban (n/%)**	**Rural (n/%)**	**Total (n/%)**
Yes	82(32.9)	112(46.9)	194(39.8)
No	167(67.1)	127(53.1)	294(60.2)
Total	**249 (100.0)**	**239(100.0)**	**488(100.0)**

Table 4.3 shows that the proportion of urban dwellers (43.9%) with good knowledge of community engagement was slightly higher than the proportion of rural dwellers (31.3%) though this was not significant (x^2 =3.28, p=0.19). Similarly, the proportion of rural dwellers (12.4%) with poor knowledge of community engagement was slightly higher than the proportion of urban dwellers (9.8%) but this was also not statistically significant in difference (x^2 =3.28, p=0.19).

Table 4.3: Respondents' Knowledge of Community Engagement in Ife Central and Ife North LGA

Knowledge	**Urban (n/%)**	**Rural (n/%)**	**Total (n/%)**
Good	36 (43.9)	35 (31.3)	71(36.6)
Fair	38(46.3)	63(56.3)	101(52.1)
Poor	8(9.8)	14(12.4)	22(11.3)
Total	**82(100.0)**	**112(100.0)**	**194(100.0)**

Table 4.4 shows that more than half (59.1%) of urban dwellers had good knowledge of informed consent as compared to 28.9% of rural dwellers whilst 65.7% of rural dwellers had fair knowledge as compared to 33.7% of urban dwellers. In bivariate analysis, these differences in level of knowledge of informed consent were statistically significant ($x^2=50.9$, $p=0.0001$). However, when age and education were adjusted for using logistic regression model, no statistically significant difference in the level of knowledge was demonstrable ($p=0.34$).

Table 4.4: Respondents' knowledge of Informed Consent Process in Ife Central and Ife North LGA

Knowledge	**Urban** **n (%)**	**Rural** **n (%)**	**Total** **n (%)**
Good	147 (59.1)	69 (28.9)	216(44.2)
Fair	84(33.7)	157 (65.7)	241(49.4)
Poor	18(7.2)	13(5.4)	31(6.3)
Total	**249 (100.0)**	**239(100.0)**	**488(100.0)**

As shown in Table 4.5, majority of urban and rural dwellers agreed that the permission of community leaders is crucial before individuals can participate in research. However, 26.1% of urban dwellers compared with 17.1% of rural dwellers disagreed with this opinion. This difference was statistically significant in bivariate analysis (x^2= 5.74, p value = 0.02) and remained so after adjusting for age and education in a multivariate logistic regression model (p value= 0.02).

Table 4.5: Respondents' Opinion on Community Engagement in Informed Consent Process in Ife Central and lfe North LGAs

Opinion	**Urban**		**Rural**			
	n (%)		**n (%)**		**x^2**	**p value**
	Agree	**Disagree**	**Agree**	**Disagree**		
Permission of community leaders is crucial in individual participation in research.	184(73.9)	65(26.1)	198(82.9)	41(17.1)	5.74	0.02*
Community leaders should be consulted before research takes place.	196(78.7)	53(21.3)	192 (80.3)	47(19.7)	0.20	0.66
Researchers should provide community leaders with adequate information on risk/ benefit.	225(90.4)	24(9.6)	213(89.1)	25(10.9)	0.20	0.65
Community leaders need to be involved in planning and carrying out research.	195(75.3)	54(24.7)	192(80.2)	47(19.8)	1.76	0.19

Section C: Respondents' Perception of Process of Trust Building in Research

The proportion of the urban dwellers (16%) that agreed with provision of incentives as motivation for trust building in research was higher than the proportion of rural dwellers (10%). The difference was statistically significant (OR = 0.64, z =2.23, p=0.03). The proportion of the urban dwellers (6.0%) who agreed that having a member of the community in the research team matters for trust building was higher than the proportions of rural dwellers (2.5%) . The difference was also statistically significant (OR= 1.45, z=3.03, p=0.002) (Table 4.6).

Table 4.6: Result of Multivariate Logistic Regression on Types of Motivation that Facilitates Trust Building in Research

Motivation	Urban (who agree) n (%)	Rural (who agree) n (%)	OR	z	P value	95% CI
Incentives	40 (16.1)	24(10.0)	0.64	2.23	0.03	0.08-1.21
Researcher is from community	23(6.0)	6(2.5)	1.45	3.03	0.002	0.51-2.39
No idea	15(6.0)	13(5.4)	0.70	1.43	0.16	-0.26-1.65

Table 4.7 shows that the proportions of urban and rural dwellers that reported community entry, community consultation, information sharing and verbal/written consent as procedures carried out by researchers for informing, asking permission or documenting consent in research were similar. 10.5% of the rural dwellers reported community entry as one of the procedures for informing and seeking permission as compared to 4.5% of the urban dwellers while 45.3% of the urban dwellers reported information sharing as one of the procedures as compared with 43.9% of the rural dwellers. No significant difference was demonstrable ($x^2= 6.86$, $p=0.11$).

Table 4.7: Procedures for Informing/asking Permission/documenting Consent in Ife Central and Ife North LGAs

Steps	Urban (n/%)	Rural (n/%)	Total (n/%)
Community Entry	11(4.5)	25(10.5)	36 (7.4)
Community consultation	75(30.4)	62(25.9)	137 (28.2)
Information sharing	112(45.3)	105(43.9)	217(44.5)
Verbal/ written consent	37(15.0)	35(14.6)	72(14.8)
No idea	12(4.8)	12(5.1)	24(4.9)
Total	**249(100)**	**239(100)**	**488(100)**

Section D: Factors Influencing Willingness in Participation in Research

Majority of the urban and rural dwellers indicated that provision of information about the study; voluntariness and benefits of research were factors influencing willingness to participate in research (Table 4.8).

However, there were significant differences in their negative responses. Some 18.1% of urban dwellers did not agree that provision of information on study would influence willingness to participate as compared with 8.8% of the rural dwellers (x^2=8.99, OR= 2.49, 95%CI =1.41-4.42, p=0.002). The proportion of urban dwellers (32.5%) that did not agree on the value of attitude of researchers as a factor that would influence willingness to participate in research was significantly higher than the proportion of rural dwellers (10.9%) (x^2=33.4, OR=5.29, 95%CI = 3.15-8.23, $p<0.001$).

There were no significant differences in the proportion of urban and rural dwellers that did not agree with spousal approval, (x^2= 1.89, p=0.17) community and religious leaders' approval (x^2= 1.27, p=0.26) and voluntariness in research.(x^2=2.75, p=0.13) (Tables 4.8 and 4.9).

Table 4.8: Factors Influencing Willingness to Participate in Research

	Urban (Ife Central) (n/%)		Rural (Ife North) (n/%)			
	Yes	**No**	**Yes**	**No**	**x^2**	**p value**
Research conducted in the community	96(38.5)	153(61.5)	97(40.6)	142(59.4)	0.21	0.65
Spousal agreement	121(48.6)	128(51.4)	131(54.8)	108(45.2)	1.89	0.17
Community/religious leaders agreement	128(51.4)	121(48.6)	135(56.5)	104(43.5)	1.27	0.26
Provision of information on the study	204 (81.9)	45(18.1)	218(91.2)	21(8.8)	8.99	0.003*
Voluntariness	228(91.6)	21(8.4)	227(95.0)	12(5.0)	2.25	0.13
Researcher well known in the community	93(37.4)	156(62.7)	108(45.2)	131(54.8)	3.09	0.08
Attitude of researchers	168(67.5)	81(32.5)	213(89.1)	26(10.9)	33.4	<0.001**
Benefits of research	219(88.0)	30(12.0)	222(92.9)	17(7.1)	3.41	0.07

Table 4.9: Result of Logistic Regression Analysis on Negative Responses to Factors Influencing Willingness to Participate in Research

Factors	OR	Z	95% CI	p value
Provision of information on the study	2.49	3.13	1.41-4.42	0.002**
Attitude of researcher	5.29	6.22	3.15-8.23	<0.001**
Researcher well known in the community	1.40	1.77	0.96-2.04	0.08
Benefits of research	1.67	1.41	0.82-3.14	0.16

*A total of 488 urban and rural dwellers were included in the logistic model

* Variables excluded- rural and positive responses.

FINDINGS OF QUALITATIVE SURVEY

The findings of the qualitative survey are similar to the findings of the questionnaire survey

"What are the processes involved in community engagement"? (Moderator)

"*Community engagement involves community participation in whatever way*" (Community leaders in the urban and rural communities).

*"Inform the leaders who will get across to the people, who will get more people to get more information" (*Female participant in urban community).

*"Get to the palace , meet with community leaders who will get across to the society. They select representatives to represent each house or family to deliberate together with the king"(*Male participant in rural community).

What are your opinions on community engagement in informed consent process in this community? (Moderator)

Table 4.10: Opinion of Respondents on Community Engagement in Informed Consent Process in Research (participants of FGD in Ife Central and Ife North LGAs)

Process of community engagement	**Urban**	**Rural**
Community leaders consultation.	+++	+++
Provision of information by researcher.	++	+
Community involvement / participation in planning and carrying out research.	++	+

Legend:

++ + - most of the respondents

++ - some of the respondents

+ - few of the respondents' opinions

There are similarities in the reports from the FGD sessions on opinions of participants in community engagement in informed consent process and the findings of the quantitative survey. Most of the urban and rural dwellers reported that community engagement in informed consent process should involve consultation of community leaders. Half of the urban dwellers reported that the information on the research should be provided by the researcher and the community leaders should be involved in the planning and carrying out of research. On the other hand, only few of the rural dwellers reported that the researcher should provide information and community leaders should be involved in planning and carrying out of research in the community.

The head of the community need to be informed of the research work in the community and the chief relate it to the community" (Male religious leader in rural community).

"The researcher do come, will first sensitize us and later come and question the community . They do take permission first before the community answers them" (Chairman, Committee Development).

The reports from the FGD sessions are similar to the findings of the questionnaire surveys except for the steps that should be taken in mobilizing people for research.

What are the steps taken to mobilize dwellers for research in this community? (Moderator)

"*The media is good... that can make recruiting of participants for research activities easy as prior information via media especially radio and television will make the community aware of such and make them available when the researchers are ready*" (Male participant in urban community).

"To give public enlightenment through radio, churches, mosques for people to be part of research so as to help the community and researchers" (Male Religious Leader in urban community).

What factors will influence trust building in research in your community? (Moderator)

"Meeting with the community always enhance their relationship and build trust" (Female Participant in urban community).

"The attitude and way of approach of the researchers can either build trust or distrust among participants. A researcher should be friendly and present issues well to participants"(Female participant in rural community).

Rural and urban participants in the FGD and in-depth interviews reported that attitude of researcher, feedback on previous research, fear of research and benefits of research as factors that influence willingness to participate in research.

What are the factors that encourage and discourage willingness to participate in research in this community? (Moderator)

"*Money and incentives are used to gain trust and willingness; however a truthful and sincere explanation of research benefits that is devoid of monetary gains or incentives even with a friendly attitude can build trust and willingness in community participation"* (Male participant in urban community).

" Feedbacks of previous researches can encourage us to know that our time is not wasted during the research activities" (Female participants in rural community).

On the other hand, some participants emphasized the character of the researcher and relevance of the study to the community:

"*Researchers must be trustworthy and by so doing they have to give feedbacks of previous research work and keep to their words with failing. Relevant and beneficial researches will encourage full participation over and over again*" (Community leader in a rural community).

CHAPTER FIVE

DISCUSSION

This study was carried out to assess and compare awareness and knowledge of urban and rural dwellers in Osun State on community engagement and informed consent. The study also explored their differences in opinions on community engagement in informed consent process and factors that would influence willingness to participate in research.

Awareness and knowledge of dwellers on community engagement

The level of awareness on community engagement among the rural and urban dwellers was low however more rural than urban dwellers were aware of community engagement in research. This might be because rural communities tend to remain tightly knit with household units that are based on family relationships and persistence of traditional governance structures in contrast with urban centers where those bonds are considerably looser and modern governance structures prevail. It is therefore necessary to formally consult community leadership before individuals living in rural areas are approached for research participation (Rotimi et al, 2007). In spite of the low awareness of urban dwellers about community engagement, most of the urban dwellers who knew about community engagement had good knowledge while the rural dwellers' knowledge tended to be fair as evidenced by their ability to describe community engagement as community consultation, community participation, provision of information and community involvement. This finding was supported by previous reports where the terms "community participation" and "community involvement" connotes manifestation of community engagement particularly in social science literature (Tindana et al, 2007). Community consultation has been described as another example of community engagement and community engagement is also viewed as involvement of local stakeholders in assessing local health problems, determining the value of research, planning, conducting and overseeing research, and integrating research into the health care system (Jones & Wells, 2007).

Knowledge of informed consent process

A greater proportion of urban dwellers had good knowledge of the process of informed consent in terms of being able to mention all the processes involved (that is giving information, signing of forms and agreeing to participate) as compared to the rural dwellers whilst a greater proportion of rural dwellers had fair knowledge demonstrable by being able to mention some of the processes involved (agreed to participate and signing of form or agreed to participate and giving information) as compared to urban dwellers. These differences disappeared when age and education were included in the multivariate models suggesting that these factors explained the observed differences.

Lindegger and Bull reported informed consent as a process that enables persons to voluntarily decide whether or not to participate in a research study or procedure. It is more than merely getting a potential participant to sign or thumbprint a written document (Lindegger & Bull, 2003). Genuine informed consent has been described as a process that encompasses researcher providing full and transparent information about the research, a broad understanding of the proposed research, the associated risks and benefits, and agreement to participate (Nuffield Council on Bioethics, 2002). Present result confirms previous observations that this is dependent on education therefore when studies are conducted among people with low levels of education or in rural areas where there may be a high proportion of such individuals, additional attention needs to be paid to ensuring that the participants are adequately informed about the research.

Opinion on community engagement in informed consent process

Majority of the urban and rural dwellers agreed that community leaders should be consulted before research takes place; researchers should provide community leaders with adequate information and permission of community leaders is crucial in individual participation in research. However, more urban than rural dwellers disagreed with the permission of community leaders being crucial in individual participation in research. This is consistent with observations of persistence of traditional values of respect for elders and traditional forms of government in the rural compared to urban centers. Urban populations are more diverse, mobile and less respectful of traditional authorities but instead focus more on modern entities of state authority. The findings of studies conducted in other parts of Africa, Burma, China, the Philippines, South America, and Thailand showed that the consent of village leaders is often required before researchers talk with individuals (Marshall, 2004). Nevertheless, this observation needs to be carefully interpreted because of findings such as that of Leach *et al* (1999) which showed that only 25% of the rural parents, compared to only 10% of the urban parents, agreed that the village chief should have some input concerning the decision to participate in the influenza vaccine trial.

Steps in building trust in research

There were significant differences in the views of the urban and rural dwellers on types of motivation that facilitate trust building in research. A higher proportion of urban dwellers valued the use of incentives and the researcher being from the community as motivational factors for building trust compared to rural dwellers, even though these were in the minority. The process of building relationships involves researchers being present and listening to community members as this will dispel the idea of being considered strangers (Khan, 2005). Urban and rural participants in the FGD and in-depth interviews reported, in addition to giving incentives, feedback on previous research as an important process that facilitates trust building in research. It has been reported that majority of researchers do not usually give feed back to research communities unless the funding organization requests it. Lack of feedback might breed mistrust and suspicion by the communities in which research is being carried out (Ochieng & Bukuluki, 2007).

There were no significant differences in the views of the urban and rural dwellers on procedures for informing/asking permission and documenting consent. The urban and rural dwellers emphasized community entry and consultation alongside information sharing as procedures for informing and seeking permission for participation in research. This was supported by the report of current procedures for obtaining and recording consent in developing countries through community gatekeepers. The multiple levels of consent within communities require community information and discussion, however, this stepwise process of information sharing and consent can be resource intensive, labour intensive and time intensive (Bhutta, 2004).

Urban and rural dwellers reported that written and verbal consent should be used to document consent in research. This is in agreement with WMA 2000, CIOMS 2002, and CoE 2004 and NCOB 2002 recommendations that researchers should obtain written consent when appropriate. When written consent is not feasible, various National Codes (including that of Nigeria and international guidelines including WMA 2000, CIOMS 2002, CoE 2004, EU 2001 and NCOB 2002) state that verbal consent is acceptable, provided that it is formally documented and witnessed.

Respondents' willingness to participate in research

The proportion of urban and rural dwellers that gave positive responses to willingness to participate if community leader or spouse granted approval were similar but far below 91%, and 94% reported in a study on community involvement and ethics in HIV vaccine trial carried out in 32 communities in south west Nigeria (Adeyemi et al, 2009). It is not clear why this is so and willingness to participate in research may be related to individual's and communities' perception of the value of the research and its relevance to their health burden.

Urban dwellers were more than twice as likely as rural dwellers to disagree with provision of information as a factor influencing their willingness to participate in research. The urban dwellers not agreeing with provision of information as factors might be because most of them have access to other sources of information on research projects before they decide on participation.

Urban dwellers were more than four times as likely as rural dwellers to disagree with attitude of researcher as factor influencing willingness to participate in research but these were in the minority. The attitude of researchers can encourage or discourage willingness to participate. The findings of the study are consistent with reports that aspects of researchers' behaviour and attitudes such as openness, truth-telling and respect are important in establishing a trusting relationship which can lead to rejection or acceptance of studies (Marsh et al, 2011).

The result of the qualitative survey reveals that rural dwellers emphasized fear of research and feedback on previous research as factors encouraging or discouraging willingness to participate in research. A study on the role of ethics in HIV trial reported fear (36%), lack of involvement of community head/leader (22%) and previous research without community benefit (18%) as reasons given for refusal to participate in research (Adeyemi et al, 2009). In addition, urban participants emphasized benefits of research as factors influencing willingness to participate in research. The study carried out amongst parents in rural Ghana found trust and beneficial outcomes as factors influencing participation in research (Oduro et al, 2008).

CHAPTER SIX

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

SUMMARY

The study was carried out among urban and rural dwellers of Osun State to assess their awareness and knowledge on community engagement in administration of informed consent process in research. The study also examines differences in their opinion and factors that would influence their participation in research. The qualitative and quantitative method of data collection was employed and data was subjected to univariate, bivariate and multivariate analyses.

The study showed that awareness of community engagement was higher among rural than urban dwellers but among those who were aware, urban dwellers' knowledge of community engagement was slightly better than that of the rural dwellers even though this was not statistically significant. Age and level of education were responsible for an observed difference in knowledge about informed consent when rural and urban dwellers were compared. Slightly more than a quarter of the urban dwellers did not think there was need for permission of community leaders before commencement of research compared to less than a fifth of the rural dwellers. Urbanites, more than rural dwellers, were likely to say that incentives and researcher being from the community were important for trust building, though in both cases, these were minorities. Similarly more urban dwellers compared with rural dwellers did not think that provision of information and attitude of researchers would influence their willingness to participate in research even though, again these were in minority. The findings of the qualitative methods were used to complement the findings of quantitative methods.

Conclusions

This study highlights differences in the attitude of urban and rural dwellers to community engagement and suggests that researchers need to pay attention to this context when planning their research. Factors that are relevant in rural areas may differ from those that are important in urban areas. Education and attitude to traditional institutions of leadership appear to be the major determinants of the difference in attitudes.

Recommendations

1. The level of awareness of potential research participants in community engagement needs to be improved upon through campaigns. There should be continued effort to impress the importance of community engagement on the urban dwellers in spite of preserving the voluntariness of individual for participation in research.

2. There is a need to improve the knowledge of the potential research participants on the informed consent process emphasizing that informed consent involves a process of giving information, agreeing to participate and signing of form.

3. There is a need to develop appropriate types of engagement process for research taking place in the urban centers where there are looser kinship ties.

4. Research ethics committees need to be aware of the need for community engagement and where necessary request that there should be an agreement which includes responsibilities of researchers and community, use and dissemination of information by researchers, and community participation in research.

5. Ethics codes and guidelines need to include information on the requirement for community engagement and ethics committees need to evolve mechanisms for ensuring compliance with this requirement.

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APPENDICES

QUESTIONNAIRE

This study is on community engagement in informed consent process in research. The process of informed consent involves the individual making an informed decision after comprehension but this decision can be influenced by community engagement. Your responses will be kept confidential and held in high esteem. Thanks for agreeing to participate.

LGA ……………………….. Locality…………………….

Building Number……………. Household Number………..

Id number

Section A: Socio-demographic characteristics of the respondents.

Age:

Sex:

Address:

Occupational status:

Educational status:

Ethnicity:

Religion:

Section B: Awareness, definition of community engagement and opinion of respondents on community engagement

1. Have you heard of community engagement in research?

2. If yes, what do you know about community engagement in research?

a. Consultation of elders

b. Providing information on proposed research

c. Community involvement in planning of proposed research

d. Community participation

e. Don't know

3. In this community, to what extent do you agree with the following statement on community engagement in the process of obtaining consent for research?

Process	1. Strongly disagree	2.Disagree	3.Indifferent	4.Agree	5. Strongly agree
Community leaders should be consulted before research can take place.					

Researchers should provide adequate information (such as risk/benefits).					
Community leaders need to be involved in the planning and carrying out of research.					
Permission of the community leaders is crucial in individual’s participation in research.					

SECTION C: KNOWLEDGE OF INFORMED CONSENT AND THE PROCESS OF TRUST BUILDING IN RESEARCH PARTICIPATION

3. What do you understand by giving consent to participate in research?
    1. Agreed to participate 2. Signing of form 3. Giving information, signing of form and agreed to participate 4. Don’t know.
4. What is /are things that motivate people to participate in a particular research?
    1. Trust 2. Incentives 3. Researcher is from the community. 4.Dont know.

5. What procedures are used to inform/ ask for permission/ document consent in research?
    1. Community entry 2. Community consultation. 3. Information sharing. 4. Verbal/ written consent. 5. Don’t know.

SECTION D: FACTORS INFLUENCING WILLINGNESS TO PARTICIPATE IN RESEARCH

6. Willingness to participate in research in your community based on the following factors:

Factors	Yes	No
If research is carried out in the community		
Attitude of the researchers		
If the community leaders agreed		
If research will be of benefit		
If information about the study is provided		
If the researcher is well known to me		
If the spouse agreed		

Thank you.

Focus Group/ Key Informant Guide

1. Have you heard of community engagement (probe-process of recruiting participants for research activities in your community?
2. Discuss the process of community engagement in informed consent process in research (probe – community consultation- providing information about the research , sensitization, involvement and participation in planning and carrying out research).
3. Trust building in research (probe on process of establishing trust between researcher and participants).
4. Participation in research (probe on willingness to participate in research, has the findings of previous research activities being shared).

QUESTIONNIARE IN YORUBA

Ìpín A: Ìmò□ nípa àwùjo□ àti àbùdá àdáni àwo□n olùdáhùn

Àmìn ìdáni mò□:

O□jó□ orí:

Obirin tabi Okunrin

Àdíré□è□sì:

Ipò nípa is□é□:

Ipò nípa è□kó:□

È□yà:

È□sìn:

Ìpín B: Ìlànà tówà té□lè□ tí afi n□ kó àwo□n olùkópa tuntun nínú is□é□-ìwádìí jo□

1. Njé□ o ti gbó□ nípa ìkópa àwo□n aráàlú nínú is□é□-ìwádìí rí?
2. Tí ó bájé□ bé□è□ni, kíni o mò□ nípa ìkópa àwo□n aráàlú nínú is□é□-ìwádìí?

a. Ìgbàmò□ràn àwo□n àgbà

b. Imú ìròyìn wá nípa is□é□-ìwádìí agbèrò

d. Ìkópa aráàlú nínú ìpètepèrò àti s□ís□e is□é□ ìwádìí

e. Ìkópa àráàlù

e□. Mi ò mò□

3. Nínú ìlú yìí àwo□n èniyàn a máa kópa nínú is□é□ ìwádìí nípa àwo□n liana wò□nyí.

Ìlànà tó wà té□lè□	Mi ò gbà	Mi ò gbà lódodo	Mo gbà	Mo gbà lódodo
Olórí ìlú ní láti gbó□ kí is□é□-ìwádìí tó ó le bè□rè□				
Àwo□n olùwádìí gbó□dò□ s□e àlàyé lé□kùnré□ré□ fún àwo□n èniyàn yálà nípa ewu tàbí àn□fààní tó wà nínú is□é□-ìwádìí náà.				
Ìkópa nínú is□é□-ìwádìí gbó□dò□ jé□ wò□tún wòsì nílò iyò□n□da látò□dò□ àwo□n ìlú				
Ìyò□n□da látò□dò□ olórí-ìlú se pàtàkì fún ìkópa e□nìkò□ò□kan nínú is□é□-ìwádìí				

Ìsètò àlàyé lé□kùnré□ré□ àti ìdí abájo□ is□é□-ìwádìí fún àwo□n aráàlú yóò sàlékún ìkópa wo□n nínú is□é□-ìwádìí				
Jíjábò□ fún àwo□n aráàlú nípa àbájáde èsì is□é□-ìwádìí tí wó□n ti kópa yóò sàlékún ìfirinlè□ è□mí ìgbàgbó□ wo□n nínú is□é□-ìwádìí.				

Ipin D:̀Etò nìpa ìfirinlẹ̀ ẹ̀mì- ìgbàgbọ́ nínú ìkópa ńinú iṣẹ́- ìwád̀ìí

3 Kí ni ìwọ mọ̀ sí láti kópa nínú iṣẹ́-ìwadìí?

i) Ìfarajin láti kópa

ii) Bíbuwọ́lu ààtò (fóònù)

iii) Fífun ni ní ìròyìn , bíbuwọ́lu ààtò àti ìfarajìn láti kópa

iv) Mi ò mọ̀ ọ́

4 Báwo ni àwọn olùwádií ṣe máa ń kó àwọn ènìyàn jọ láti kópa nínú iṣẹ́- ìwádìí ní́nú ìlú yìí?

i) Fífi ọ̀rọ̀ jẹwọ̀ pẹ̀lú àwọn olóyè

(ii) Ṣíṣe ìpolongo tàbí sísọ̀rọ̀ nípa ètò ìlara

(iv) Àwọn ìlànà méjèèjì

(iv) Mi ò mọ̀

5. Kí ni tàbí àwọn kí ni àwọn ìrètì àwọn ènìyàn kí wọn ó tó ó kópa nínú iṣẹ́-ìwádìí?

(i) Yóò tán àwọn ìsòro wọn.

(ii) Gbígba àwọn ohun amóríyá (owó, nǹkan èlò àti bẹ́ẹ̀ bẹ́ẹ̀ lọ)

(iii) Àwọn ìrètí méjèèjì

(iv) Mi ò mọ̀ ọ́

(6) Àwọn ìgbésẹ̀ wo ni ó yẹ kí olùwádìí ó gbé láti rí àwọn ènìyàn kópa nínú iṣẹ́-ìwádìí

(i) Lílọ sí inú ìlú

(ii) Ṣíṣe ìmọ̀ràn pẹ̀lú aráàlú

(iii) Ìròyìn àjùmọ̀lò

(iv) Ìbámu èrò nípa alákọ̀ọ́lẹ̀ tàbí aláfẹnusọ

(v) Mi ò mọ̀ ọ́

7. Ọ̀nà wo ni àwọn olùwádìí lẹ́tọ̀ọ́ láti ṣàlàyé èròǹgbà iṣẹ́-ìwádìí fún ìkópa aráàlú.

(i) Àwọn olóyè

(ii) Akéde ìlú

(iii) Àwọn ohun ìròyìn

(iv) Mi ò mọ̀ ọ́

8. Irú àjọsepọ̀ wo lóyẹ kó wà láàárín àwọn olùwádìí àti aráàlú kí wọ́n baà le kópa nínú iṣẹ́-ìwádìí.

(i) Gbẹ̀fẹ́

(ii) Àìgbẹ̀fẹ́

(iii) Tímọ́-tímọ́

(iv) Mi ò mọ̀ ọ́

9. Kí ni àwọn ohun amóríyá tó máa ń múkí àwọn èniyàn ó kópa nínú iṣẹ́-ìwádìí kan pàtó.

(i) Ẹmí ìgbàgbọ́

(ii) Àwọn ohun amóríyá

(iii) Àwọn olùwádìí jẹ́ ọmọ ìlú

(iv) Mi ò mọ̀ ọ́

Ìpín E: Àwọn kókó tó máa ń fa ìfirinlẹ̀ ẹ̀mí-ìgbàgbọ́

10. Báwo lose gba àwọn ìpèdè wọ̀nyí gbọ́ tó?

Àwọn kókó	Mi ò gbà	Mi ò gbà rárá-rárá	Mo gbà	Mo gbà tọkàn-tọkàn
Àwọn èniyàn yóò nígbàgbọ́ nínú iṣẹ́-ìwádìí kan nípa ìrírí wọn ṣẹ́yìn nínú irú iṣẹ́-ìwádìí náà.				
Ìwà ọmọlúàbí tí àwọn olùwádìí bá ń wù nínú ìlú yóò múkí àwọn èniyàn ní ẹ̀mí-ìgbàgbọ́ nínú wọn.				
Àwọn èniyàn máa nífẹ̀ẹ́sí iṣẹ́-ìwádìí nítorí ìwà ọmọlúàbí wọn.				
Ìsètò àlàyé lẹ́kùnrẹ́rẹ́ nípa ìmọ̀ iṣẹ́-ìwádìí yóò múkú àwọn èniyàn ó ní ẹ̀mí-ìgbàgbọ́ nínú rẹ̀.				
Ìpèdè lóòrèkóòrè pẹ̀lú àwọn olùkópa nínu iṣẹ́-ìwádìí lásìkò				

tí ìwádìí ń lọ yóò múkí wọn ó ní ẹ̀mí-ìgbàgbọ́ sí àwọn olùwádìí.				

Ìpín Ẹ: Ọgbọ́n-ìtọ́sọ́nà sí ìsètò ìlènà tódára jù láti mú kí aráàlú ókópa nínú iṣẹ́-ìwádìí

11. Báwo ni ó se rò pé ó dára jùlọ láti mú kí àwọn aráàlú ó kópa nínú iṣẹ́-ìwádìí

12. Ní èrò tìrẹ, ǹjẹ́ ọ̀nà tí wọ́n ń sàmúlò lásìkò yìí ní ìlú rẹ láti gba àwọn olùkópa tuntun sí iṣẹ́-ìwádìí ni ọ̀nà tó dára jùlọ.
    (i) Bẹ́ẹ̀ni (ii) Bẹ́ẹ̀kọ (iii) Mi ò mọ̀ ọ́

13. Tí ó bájẹ́ pé bẹ́ẹ̀ kó ọ̀nà tó dára jùlọ wo nìwọ yóò dábàá

Ìpín F: Ìhà-kíkọ sí ìkópa nínú iṣẹ́-ìwádìí

14. Màá kópa nínú iṣẹ́-ìwádìí tó bá wáyé nínú ìlú mi nìkan.

15. Màá kópa nínú iṣẹ́-ìwádìí tí ọkọ/ìyàwó mi bá yọ̀ǹda.

16. Màá kópa nínú iṣẹ́-ìwádìí tí olórí ìlú tàbí olórí ẹ̀sìn bá yọ̀ǹda
    (i) Bẹ́ẹ̀ni (ii) Bẹ́ẹ̀kọ (iii) Mi ò mọ̀ ọ́

17. Màá kópa nínú iṣẹ́-ìwádìí tí mo bá gbọ́ àlàyé lẹ́kùnrẹ́rẹ́ nípa ìdí abájọ àǹfààní àti ewu tí ó séése kówà nínú iṣẹ́-ìwádìí náà.
    (i) Bẹ́ẹ̀ni (ii) Bẹ́ẹ̀kọ (iii) Mi ò mọ̀ ọ́

18. Màá kópa ó bá jẹ́ wọ̀tún ni ìtẹ́lọ́rùn.
    (i) Bẹ́ẹ̀ni (ii) Bẹ́ẹ̀kọ (iii) Mi ò mọ̀ ọ́

Ẹ seun

CONSENT FORM

You are asked to participate in the research study either as a member or opinion leader in the community. This study is on community engagement in informed consent process in research. The process of informed consent involves the individual making an informed decision after comprehension but this decision can be influenced by community engagement.

The purpose of this research is to assess existing process of recruiting community members for participating in research and the process of trusting building. It will also examine the opinion of the community members on community engagement approach of informing and recruiting community members in research.

Your responses will be kept confidential and held in high esteem. Thanks for agreeing to participate.

Statement of person obtaining informed consent.

I have fully explained this study to ---------------------------------------and have given sufficient information, including about risks and benefits, to make informed decision.

DATE--- SIGNATURE-------------------------------------

NAME--

Statement of person giving consent:

I have read the description of the study or have had it translated into language l understand. I have also talked over with the researcher to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research to judge that l want to take part in it. I understand that l may freely stop being part of the study at any time.

DATE: ------------------------------------- SIGNATURE: ---

NAME--

WITNESS’ SIGNATURE (if applicable):--

WITNESS’ NAME (if applicable):---

If you have any questions about the study or there are things that you do not understand, please contact:

Esimai Olapeju

08037211457

Department of Community Health

Obafemi Awolowo University

08037211457

OR

UI/UCH Ethical Review Committee,

IMRAT Building

UCH, Ibadan

Ìlànà-ìtósọ̀nà Àkíyèsí-alátẹ́numọ́ Ẹgbẹ́

(1) Ìgbésẹ̀ ìsàmúlò fún ìkójọ àwọn olùkópa tuntun fún àwọn iṣẹ́-ìwádìí nínú ìlú rẹ̀

(2) Ki oríkì ìkópa aráàlú

(3) Jíròrò nípa ìgbésẹ̀ ìkópa aráàlú nínú iṣẹ́-ìwádìí (sàyẹ̀wò-fínní fínní-ìṣèmọ̀ràn pẹ̀lú aráàlú-ìsètò ìròyìn nípa iṣẹ́-ìwádìí, ìtanilólobó, ìdarapọ̀mọ́ àti ìkópa nínú ìpètepèrò àti ìmúṣe iṣẹ́-ìwádìí).

(4) Ìgbésẹ̀ ìfirinlẹ̀ ẹ̀mí-ìgbàgbọ́ nínú iṣẹ́-ìwádìí (sàyèwò fínní fínní lórí ìfẹ́ẹ̀nú láti kópa nínú iṣẹ́-ìwádìí, ǹjẹ́ àwọn àbájáde iṣẹ́-ìwádìí tó kọ́ja ti tànkálẹ̀, àwọn kókó tó ń fa ìwúrí tàbí ìrẹ̀wẹ̀sì ọkàn ìfinrinlẹ̀ ẹ̀mí-ìgbàgbọ́ nínú ìsàkoso ìgbésẹ̀ ìmọ̀dájú ìfarajìn nínú iṣẹ́-ìwádìí).

(5) Àwọn àbá lórí ọgbọ́n-ìtọ́sọ́nà tó dára jù láti kó àwọn aráàlú tuntun jọ fún iṣẹ́-ìwádìí.

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IMRAT)
COLLEGE OF MEDICINE, UNIVERSITY OF IBADAN, IBADAN, NIGERIA.
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E-mail: Imratcomui@yahoo.com, gfalusi@yahoo.com
Ag. DIRECTOR: **Professor Adeyinka G. Falusi**, *B.sc (Hons), M.Phil., Ph.D.*

UI/UCH EC Registration Number: **NHREC/05/01/2008a**

NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW

Re: Community Engagement in Informed Consent Process in Research in Osun State, Nigeria.

UI/UCH Ethics Committee assigned number: UI/EC/10/0055

Name of Principal Investigator: Esimai Olapeju

Address of Principal Investigator: Department of Community Health,
Obafemi Awolowo University,
Ile-Ife,

Date of receipt of valid application: 23/03/2010

Date of meeting when final determination on ethical approval was made: 29/07/2010

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and *given full approval by the UI/UCH Ethics Committee.*

This approval dates from 29/07/2010 to 28/07/2011. If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the* UI/UCH EC *assigned number and duration of* UI/UCH EC *approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC early in order to obtain renewal of your approval and avoid disruption of your research.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the UI/UCH EC. *No changes are permitted in the research without prior approval by the* UI/UCH EC *except in circumstances outlined in the Code. The* UI/UCH EC *reserves the right to conduct compliance visit to your research site without previous notification.*

UI/UCH EC
29 JUL 2010
APPROVED
COLLEGE OF MEDICINE

29-10

Prof. Adeyinka G. Falusi
Chair, *UI/UCH Ethics Committee*
E-mail:uiuchirc@yahoo.com

MAPS

Figure 1: MAP OF OSUN STATE SHOWING THE IFE CENTRAL AND IFE NORTH LOCAL GOVERNMENT AREA