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**FACTORS THAT INFLUENCE RESEARCH PARTICIPANTS' UNDERSTANDING OF INFORMED  
CONSENT: EVIDENCE FROM KAPSERET IN UASIN GISHU COUNTY, KENYA**

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**ABSTRACT**

This paper examines the factors that influence research participants' understanding of informed consent and their willingness to participate in health-related research. The paper is based on a study that sought to ascertain the extent to which research participants in Kapseret sub-urban in Uasin Gishu County understood informed consent in the researches they had already participated in at the time of the current study. The research was informed by the fact that although participants do often give uninformed consent, in some cases they seemed not to have understood the content of the consent forms they signed. There are instances when participants have taken part in research programmes whose aims they did not understand in the first place. In other instances, participants may not be aware that they are involved in a research for which they have given consent. Such cases are common in various parts of the world where health-related research is conducted and Kenya is no exception. The main objective of the research was to examine the factors that motivated research participants who had been involved in research to understand and sign informed consent. A cross-sectional study was done using in-depth interviews and qualitative data. Focus Group Discussion (FGD) was used for data collection. The target population was exclusively people who had participated in health-related research and who resided at Kapseret. Snowball sampling method was used to select 102 participants of both genders. They were divided into 12 focus groups discussion of 8 to 9 members each. To have homogeneous groups, gender, age and educational level were considered when forming the groups. To enable the FGDs to discuss intimate issues freely, participants of the same age group were placed together. Males and females were grouped separately. Collected data was transcribed and FGD-generated themes which were finally analysed. Participants showed evidence of having understood and given informed consent before taking part in health-related research. However, their consent seems to have been influenced by other factors which they gave more priority. As such, an IRB requirement demand that participants understand consent forms before signing, the reality at the research site is different. Before assenting to take part in a research, participants would want to know the benefits that would accrue to them. An example is that of participants' valuing money paid as transport refund so much that it seems to be compelling them into joining research. There is a greater need to educate research participants concerning research and benefits. As much as justice demands that participants should benefit from what they have participated in, it should be made clear to the participants that the said benefit comes if the research yields positive results.

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**INTRODUCTION**

Once participants have been identified, before they are requested to take part in any research, they have to be given information about the nature and purpose of the research then allowed to ask questions and answers given. This enables them to understand the research procedures well. They are then requested to voluntarily assent to participate in the research by signing a form and all this is a process. The entire process involves informing, comprehending, consenting and then participating in the research.

**Comprehension of Consent**

Comprehension of the research details and the content of the consent form by participants take place within the process of informed consent.

When a researcher is presenting information, participants may or may not comprehend what is being presented. There are at least four factors that contribute to understanding (or lack thereof): the language used; the level of education of the participants; exposure of the participant to various topics relating to the current one, cultural factors, influences and vested interests of the participant towards the research or researcher.

**Language**

Both CITI (2010, p. 78) and Oduro *et al.* (2008, p. 9) argue for the process of securing consent to be done in participant's primary language. This is aimed at protecting the participant by ensuring that they fully understand the nature and purpose of the research and what exactly is to be expected from them. CITI (2010, p. 78) and Oduro *et al.* (2008, p. 9) are of the view that if the language used during contracting stage is foreign to participants, there is a high risk they might not fully

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understand what they are expected to commit themselves to. Moreover, the use of a foreign language may make them shy off rather than admit their inability in understanding the language. Alternatively, such participants may resort to signing the consent, hence committing themselves to something they may not have understood. The Ethical and Policy Issues in International Research (2001, p. 39) argues against enrolling individuals in research who have not been given the opportunity to understand the important information represented in the research. The ideal situation is for the researcher to use the primary language to the participant. The realities on the ground differ and many at times researchers do not understand the primary language of the research site's community.

Boga *et al.* (2011, p. 3) argue that informed consent forms should be developed in English when being presented to an IRB, but translated to the primary language of the participant. The World Health Organization (2007, p. 31) urges researchers to hire a translator in cases where the researcher and the participant speak different languages so as to help the participant give knowledgeable consent. For instance, IREC (2010, p. 9) can only approve a protocol when the researcher presents two consent forms. The original one written in English and the other translated to language of the research site's community. A correctly translated consent form helps the participant to understand what the research is all about hence give knowledgeable consent. Naanyu *et al.* (2012, p. 1) state that when a participant was asked if he understood what he was giving consent to, he replied "you know I was very informed because we had the Kiswahili version.....". When participants are given consent forms in a language they understand, they in turn give knowledgeable consent. Translation of information from a different language to the primary language of the participant has its share of problems. In health related research, some of the problems encountered are mostly terminological because some medical terms may not have equivalent words in the primary language of the participants. Ethical and Policy Issues in International Research (2001, p. 7) argues that problems associated with medical interpretation include the inability to easily translate equivalent expressions across languages. The lack of equivalent words leaves the translator with the option of re-phrasing which results in omissions or erroneous substitution of terms resulting in misunderstanding.

One encounters problems when translating from English to African languages because most of the native languages spoken in Africa lack equivalent words to those of the English language. Kass and Hyder (2001, p. 220) argue that the word used in Africa to refer to research is the same as the one used for medicine. According to Escobedo *et al.* (2007, p. 3), Toucher and Larson (1998, p. 504), the lack of equivalent words causes misunderstanding in translation, hence wrong explanation of informed consent process because of drastic and erroneous changes in meaning. Even with the stated challenges, still a researcher must look for critical and innovative ways that are culturally responsive to the participant. The ultimate aim should be to secure knowledgeable consent from the participants. Another way of facilitating comprehension of translated information can be by use of pictorial flip charts or videos where possible.

Molyneux *et al.* (2004, p. 59) urges researchers to use visual aids. The use of visual aids can improve the participants' ability to remember facts much better than verbal presentation. Visual aids can strengthen the presented information. These visual aids can be developed during the pilot study. As Valley *et al.* (2010, p. 4) observed that the pictorials and flipcharts developed during a study in Mwanza, Tanzania during the pilot study became the main way of explaining the research content to the participants during recruitment. When a researcher uses visual aids, he/she still has the obligation to protect the identity of the person whose photo appears. The face could be covered to avoid identity or any other acceptable method that would protect identity of the participant.

### Education and Individual Exposure

The success of every programme depends on the way participants are trained. As such, the level of education of research participants influences their ability to perform the tasks assigned to ensure the success of the research programme. Kithinji and Kass (2010, p. 1) propose that the key issue in making a research presentation valid is a valid informed consent. Valid research findings imply that participants were given information; they understood it and voluntarily accepted to participate. But the major challenge to every individual giving valid informed consent has been the ability to comprehend the presented information. The high levels of illiteracy in many parts of the Kenyan society should not be used as an excuse for not giving participants adequate information when securing informed consent for research. As Preziosi *et al.* (1997, p. 372), Ekunwe and Kessel (1984, p. 22) posit, widespread illiteracy ought not to be a barrier to comprehension, since informed consent is more of an interactive process than, say, an exam that depends on the ability to read. By use of videos and flipcharts an illiterate participant can give informed consent when given proper information. Illiteracy in Kenya is on the increase in the rural areas compared to urban areas. However, with research that is carried out in the urban settings, participants have fewer problems with language because they can read and write in both English and Kiswahili. The urban group is made up of people who have had exposure through education and interactions with people from other communities. This exposure gained from formal education or from travelling widely makes one gain a wealth of experience. Marsh *et al.* (2008, p. 721) aver that exposure through formal education or interactions with various people improves one's ability to understand research information.

### Influences and Misconceptions

When researchers visit the research site they should take care not to influence participants into anticipating what they will get in participating more than knowing the aims of the research. Ngare (2007, p. 42) argues that when a researcher appears at the research site in a white coat, to the participants he symbolizes a medical doctor. People in rural areas rarely distinguish between different types of health personnel and to them people in white coats come to give medical care. Naanyu *et al.* (2012, p. 2) report a case in which a participant was asked if he understood what he had consented to and he answered: "what I feared was the fact that it was

research.....being a research I thought it would be risky because anything could happen". "I consoled myself that doctors are there to help not to kill or destroy". True, medical doctors are there to heal not kill; but depending on the nature of the research some medical experiments may be highly risky and require extreme caution. These risks must be made clear to the participants before they can give consent to participate. Moreover, participants should be made to differentiate between when doctors are in the field to give care and when they are conducting research. Doctors give care when doing their clinical treatment; but when doing research, they are out to prove something and they cannot mix treatment and research. They ought to explain the difference between research and treatment to the participants, especially if the research will involve some form of close personal medical examination or experiment.

Apart from the misconceptions, there are other influences such as the promise of free treatment for minor illnesses which may be given by researchers in health related fields. Such promises of reward or compensation could make one to consent to participate in research without proper understanding of the risks. Gikonyo *et al.* (2008, p. 6) report of a scenario in which they asked some of the participants to state why they took part in research; two of the participants said this: "what attracted us (was that) we knew that our children would receive treatment for a whole year in every disease they suffer". According to CIOMS (2002, p. 42), some participants are coerced into joining research by the benefits of treatment. They tend to believe that if they refused to join the research, the doctor would not treat them in future when they fall sick and need treatment. To clear such presumptions, the researcher must explain to the participants the differences between care and research. Any misconception or influence affects the volunteering of informed consent which raises doubt about the validity of that particular research. This then puts a heavy burden on researchers to ensure participants have understood the difference between research and care.

### Cultural Problems

Kuper (1999, p. 227) describes culture as a "symbolic system representing ideas, values, cosmology, morality and ethics shared by the community". For researchers to secure knowledgeable consents, they must take care of cultural issues. This calls for researchers to make effort to apprehend sufficient knowledge of the core values of the subject society. DeVries (2004, p. 279) believes that if a researcher will sufficiently get to understand the cultural background of his research site, he will be able to recognize the extent and significance of cultural difference in relation to morality and his research. He will be able to communicate his research content using a language that is morally acceptable to the community. In addition, researchers should also seek to know which individuals are culturally allowed to sign the consent forms. Ngare (2007, p. 47) argues that several ethnic communities recognize the man as the head of the household. As such, in cases where the household is sampled, the head of the family should sign the consent. A wife may be free in the legal sense, but in most cases she is considered a slave to her culture; hence the value of knowing the person authorized to give informed consent before asking her to sign forms. For one

to give informed consent, one must have the ability and the proper understanding of the research. Sensitivity to cultural norms entices the community into accepting and owning the research project. As Macklin (1999, p. 122) argues, the onus of getting valid consent rests on the researcher. As such, there is a need to carry out discussions with the community leaders so that participants can be authorized to give consent in a manner appropriate to their beliefs and understandings.

The other major cultural issues relating to health research are beliefs towards causes of diseases and their treatment. If, for example, an individual designs a research proposal to find out transmission outlets of HIV in particular community, he should first seek to know whether that community believes that HIV is a disease and not a curse, as is common in most superstitious societies. Some communities' believe that AIDS is not a result of HIV infection, but a curse. Kurgat (2008, p. 153) observes that most African communities view HIV as a curse from the spirits who have been offended in some way by humanity. Therefore, HIV being viewed as a curse, not a disease, requires ritual cleansing or purification but not treatment. A health researcher should thus suppress or eradicate his preconceived notions of scientific knowledge and facts and imbibe the thinking of the subject community if he is to secure participants for his work. Where possible, the researcher should shed light on some of their wrong views about the subject matter relating to research topic, although this may require time.

Society attaches great value to religious beliefs. Some groups do not allow their members to participate in things like donating blood. Pimentel (2002, p. 495) argues that groups such as the Jehovah's Witness are not allowed to donate or receive any blood transfusions or organ transplants. In such cases, if one's research touches on transplant of organs, the researcher should not anticipate recruiting participants from the Jehovah's Witness group. Even if one were to volunteer, it is important to understand that the group would not authorize him to participate. Moreover, Gikonyo *et al.* (2008, p. 6) report of a case in which the Kenya Medical Research Institute (KEMRI) researchers in Kilifi were branded devil worshippers. Associating researchers with devil worship created fear among participants and justified the community refraining from allowing researchers to draw blood from them. The participants misunderstood the researchers' act of pricking children's fingers to obtain blood samples for malaria test. According to Marshall *et al.* (2001, p. 241), the field assistants in Kilifi were counted as devil worshippers because nobody could explain where they were taking the blood samples to and for what purpose. The community's misunderstanding about the use of blood would have been avoided if the researcher had explained it prior to obtaining the participants. The community members in Kilifi could have been invited to visit the laboratory to witness for themselves their children's blood being tested for malaria.

Others accused the researchers of selling the blood samples while some were afraid that the blood might fall in the hands of witches and wizards. Valley *et al.* (2009, p. 17) observe that indeed some people believe that blood could fall into the wrong hands and be sold or be used for witchcraft purposes. Though researchers are faced with diverse cultural problems

when recruiting participants, they are still bound to secure knowledgeable informed consent. As the United Nations (1996, p. 5) says, "no one shall be subjected without his free consent to medicine or scientific experimentation".

### Statement of the Problem

Although it is a requirement to have informed consent before the start of any research, it is emerging that there are cases in which research participants are never given adequate information to enable them give informed consent. In some cases, research participants may not have understood the content and aims of the consent forms they sign. The study sought to examine research participants' view when giving informed consent in the researches they had taken part in. It is not enough to assume that, just because researchers attach signed consent forms to their study reports, their participants gave informed consent. The signed consent forms do not show the feelings and motives of the participants. They cannot be used to ascertain whether or not participants were given adequate information or even coerced to participate. Worse still, participants could have taken part in a research oblivious of the benefits and risks. The same form does not show whether the consent given was knowledgeable or not. For a participant to give informed consent, the consent process must be correct; having been presented with sufficient information to help them make decisions. The researcher must have answered all the concerns raised by the members of the target population and then request for volunteers. Since IRBs expect researchers to obtain informed consent that meets the aims and objectives of protecting human participants, any consent given by research participants that does not meet the IRB threshold should not be approved. Therefore, the present research sought to examine whether or not participants gave informed consent in the studies they had participated in.

### MATERIALS AND METHODS

The research was cross-sectional by design, aimed at assessing research participants' view of informed consent. Creswell (1998, p. 61-64), Strauss and Corbin (1998, p. 31) argue for qualitative methods when one intends to get data dealing with attitudes, understanding and feelings. Alzheimer Europe (2012, p. 2) describes qualitative methods as a means of uncovering the deeper meaning and significance of human behaviour, approaches, including contradictory beliefs, behaviour and emotions. From the above arguments, the qualitative method was preferred for the research, because it assessed knowledge-based issues. To implement the cross-sectional research design, a Focus Group Discussion (FGD) was chosen as a data collection instrument. Morgan (1988, p. 12) argues that FGD is a group interaction that produces data and insight that would be less accessible without the interaction found in a group. FGD was more effective when a homogeneous group had been formed and allowed to interact. Interaction itself generated data when answering specific questions from the interviewer. The purpose of specific questions was to guide the group in focusing on the research topic. The author had six guiding questions to guide the FGDs in this research. The study area was Kapseret Location in Eldoret town. The location has a population of 25,700 people composed of both men and women of all ages (District

Commissioners' Office – Wareng District). With every household estimated to hold 5 people, at the time of the study, the area had approximately 5140 households. Kapseret is a peri-urban area which attracts many residents because of its proximity to Eldoret town, good road network and cheap housing; the cost of foodstuff is cheap because Kapseret is surrounded by farms whose produce is sold to the residents. Kapseret is located along the highway of Eldoret Airport, Kapsabet and Kisumu. Majority of Kapseret residents are engaged in small-scale business; others reside there but move to Eldoret town for work during the day.

With such a set up, Pratt *et al.* (2000, p. 3) argue that young people moving from the rural areas to urban set up creates slums which become a high breeding ground for the spread of several kinds of diseases. This seemed to have been the case at Kapseret, hence the choice of the author to conduct the research there. Several people have participated in prior research conducted mostly by the staff and students of Moi University/Moi Teaching and Referral Hospital and AMPATH. Being peri-urban centre, residents get to know each other, because they maintain rural socialization in their midst. They even know who among them has participated in health-related research. In the research, a sample of 102 individuals, all of them residents of Kapseret, were recruited to participate in the research. Snowball sampling was used in recruiting research participants. The criteria for inclusion into the group were: people aged 18 years and above, being residents of Kapseret and having participated in health related research. Participants were identified through snowball sampling starting with the identification of an influential community worker to assist in the study area and culminating in the achievement of the required sample. The CHW identified as being influential was based on the fact that he was known and he knew almost everybody at Kapseret.

The total number of CHWs within Kapseret Health Centre was 9; only 6 turned up for the meeting. The author presented research criteria to CHWs; he requested for individuals who met the criteria for joining the research to volunteer. The CHWs who volunteered to join the research were asked to formalize their decisions by signing informed consent forms. The author collected the participants' information on age, level of education, phone number, place of residence and type(s) of the health related research they had participated in, and finally, the author requested them to continue recruiting new members. No group meetings were held until recruiting had reached saturation point, the point when the newly recruited members started coming up with the names of the already recruited ones (Fort Collins Science Centre, 2012, p. 2). The author thus completed recruiting participants before categorizing them into groups (FGD). Those recruited were provided with a phone number so that whenever they met a new recruit, the new member would text the researcher short message (SMS) about his/her willingness to participate in the research. They would then be called for a meeting. After 2 weeks, 72 members had been recruited. The author invited all participants for a meeting where he presented the purpose of the research and the selection criteria. After answering questions raised by the members, the author requested for volunteers to join and participate in the research. Ten (10) members were disqualified, remaining with 62 who, after

going through the consent process, volunteered to participate in the research. This brought the total number of recruited participants to 102.

### Procedure for Focus Group Discussion Formation

Based on personal details such as age, gender and level of education, the participants were grouped into FGDs. The respondents were also grouped according to their ages. Age-wise, the younger women and men are often reluctant to express their views in the presence of older men or women, hence the need to consider age. To achieve good results from the 12 FGDs, data was taped then later transcribed. Those aged 18 to 35 years were grouped together. United Nations (2013, p. 1) defines a youth to be a person aged 15 to 24 years. However, UNESCO (2013, p. 1) argues that young people are heterogeneous group who are constantly evolving and that their experience of being young varies enormously across countries. As such, the choice of youth as per this researcher was that aged 18 to 35 years, as argued by Wainaina (2012, p. 1). This was preferred because the Kenyan Constitution recognizes 18 year-old persons as adults. All respondents above 35 years of age were grouped into the 36 to 60 years category. This group of 36 years and above brings in a wealth of experiences because they have gone through several incidences and their reasoning is backed by their history.

Level of education was considered because it influences ones' ability to understanding, reason and communicate ideas correctly as well as fit in with the rest. For example, if an individual's level of education is not beyond Secondary School level and grouped with participants whose level of education is university, that individual will most likely be reluctant to participate during discussions feeling intimidated. The 12 FGDs had 102 recruited participants, 55 females and 47 males. Each FGD had either 8 or 9 members who were found manageable to the researcher. Ulin *et al.* (2005) argue that "For most purposes groups of eight to ten participants are sufficient to stimulate good but manageable discussion for the moderator, who must keep the discussion focused while encouraging everyone to take part" (p. 91). The author chaired all the FGDs of which each lasted for a period of one to two hours. To conceal identification, the tape-recording of discussions did not take place until after introductions.

### Data Analysis

The author identified a list of common themes from FGDs (Anderson, 2007, p. 1). This list was gotten from the transcribed conversations and patterns of experiences of all FGDs that participated (Aronson, 1994, p. 1). This was done by use of direct quotes or paraphrasing common ideas. van Teijlingen and Ireland (2003, p. 260-263) argue that themes can be identified and common ideas from the data can be interpreted without subjecting it to technical analysis. The researcher adopted this method by identifying themes and drawing implications directly. While identifying themes, there was the possibility of the researcher influencing the selection. The researcher was cautious to ensure the list was not influenced by his own views. Anderson (2007, p. 1) argues that a researcher must sort, name themes and, while doing that, must avoid interpretation; rather simply present the views of all FGDs members. Apart from that, research results were

subjected into members check as a control measure (Robert Wood Johnson Foundation, 2008, p. 1), for the FGDs to ascertain its correctness. The major themes anticipated within the process of securing informed consent were: language, education, influences/misconception, cultural problems, views on volunteering and waivers. Ulin *et al.* (2005, p. 92) argue for analyzing emerging themes in the light of the research context as a way of getting meaning from the words discussed by FGDs.

Coherence of ideas was based on the analyst who rigorously grouped FGDs' ideas to make meaning. Both Leininger (1985, p. 60) and Constan (1992, p. 253-266) suggest that it is upon the researcher to do all he/she can to bring out the true meaning of the transcribed data. The more rigorous the presentation is, the more meaningful the results are. After every FGD, the author would take about 5 hours to transcribe what had been taped. This was done immediately to avoid the loss of data through forgetfulness. Ulin *et al.* (2005, p. 81) argue that if data is not transcribed within the shortest time possible, the researcher might be vulnerable to lose of data, hence rendering the research unreliable. To avoid this, the author decided to have one FGD per day for twelve days. All the information was tape-recorded and transcribed before storing them safely so that it could only be accessed by the researcher and the supervisors. The transcribed data was grouped into themes. The findings were analysed and presented descriptively.

## RESULTS AND DISCUSSION

### Language

Some respondents said that in a study they took part in, the PI used the English version when making his presentations on informed consent. A male respondent aged 18-35 said "... understood the presentation because it was short, easy to understand and it was in English". But a female aged 18-35 years said "...when we were given the Swahili version it was easy to understand and I signed the form". The theme identified here was that of primary versus common language when writing and presenting informed consent forms. In addition, one male respondent aged 18-35 years said that he "...found it difficult to understand the English version, but when I was given the Swahili one, it was easy, I read and signed it". The theme identified here was that of translating consent form from English version to the common language at the research site. In both the Swahili and English consent forms, some female respondents aged 18-35 years said "...short, easy to understand..." They unanimously agreed that a short consent form is the best. One of them asked "...who will go through a ten page consent form?" The length of the consent form was the theme identified here.

Others talked of having been assisted to understand the research language by being shown a visual aid. A male respondent aged 36-40 years said "Our PI showed a video demonstrating the procedures of research, which enabled us to understand what we were going to do". The theme identified here was that of using visual aid when presenting informed consent. Another male member of the same age group said "...I do not remember being given any explanation or signing

any form; but I only found myself participating in the research". The theme identified was that of language and training of the presenters of informed consent.

### Education and Individual Exposure

From the participants' discussion about PI, a male member aged 36-40 years said that "A trained learned person can utilize the skills well". Another one said "... regardless of being a graduate, he could relate with everybody". The theme identified was that of training of PIs. A lady graduate aged 36-40 years said "we asked ourselves if anybody could see the benefit of the research to the community? Nobody responded". Another respondent in the same age group asked "...how can we discuss the issue of refund when the project cannot benefit the community?" However, a female member aged 36-45 years said "we wanted to know the amount we were to be refunded". The theme identified here was that of the value of greater level of education that when an individual is better educated he/she makes better decisions.

The use of technical language was discussed and a female respondent aged 18-35 years had this to say: "I had to seek explanation for words such as discordant couple". Another in the same age group said "they wanted to take a biopsy from me; I needed to be explained what it was". Research terminology was the theme identified here. However, a male member whose level of education was that of primary school class 8 said "I knew about biopsy because a veterinary doctor had taken a piece of meat (for laboratory test) from my cow; he called it a biopsy". Individual's exposure was the theme identified here. Participants had problems differentiating treatment and research. One female respondent aged 36-40 years said "I could not differentiate treatment and research in that the people who do these are all in white coats". Others understood the difference and one said "I knew that I was joining research". The theme identified here was that of level of education and exposure.

### Influences and Misconceptions

Among the participants, some saw the refund they were being given to cover costs of transport as a source of income. One male participant aged 18-35 years said "...the money we were given as reimbursement Ksh 1200 to us was a lot of money, enough to pay rent". Another female respondent aged 18-35 said "...the money we were given was good money which enabled me to meet my household expenses". Another participant aged 36-45 years talked of being given more (extra) money at the end of the research. She said "I thought that I would be paid more money as we got to familiarize ourselves (with the researcher)". The theme identified is that of influence that the money refunded is a lot. On the other hand, others were aware that the money they were receiving was purely a refund of the already incurred expenses. A female respondent aged 25-40 years said "...we were to be refunded Ksh 1200 to cover what we incurred in attending the project". The theme identified here was that of joining research under influence or misconception by the participants. Others viewed research as an opportunity for employment. A male participant aged 36-40 years said "when I joined the

research, to me I saw an opportunity to be employed". Other than employment, others saw it as an opportunity to be treated. A male participant aged 18-35 years said "when I heard that we were to be paid Ksh 1200, I took the research project to be both an employment as well as an opportunity for treatment". However, another one in the same age group said "I understood that participating in research was not resulting into employment neither was it to provide extra payment". The theme identified here was misconception.

Some participants talked of having joined research to avoid victimization. A female participant aged 36-60 years said "I feared to withdraw from the research because I thought that research doctors were from MTRH; they would mark me, hence when I go for treatment, they would not treat me". Other participants were aware of the difference between a researcher and a doctor. One of them said "I knew that they were researchers". The themes identified here were fear and misrepresentations that led to participants joining research. A female research participant aged 36-45 years talked of having signed a consent form without reading it. She said "I asked the researcher to show me where to sign because a doctor had referred me to the project that I would benefit from". Another respondent said "I was very sick and ready to do anything to get treatment." Others talked of having read the consent form and signed it. A female participant aged 25-40 years said "I was given adequate information and all my questions were answered, then I signed the form". The theme identified here was that of participants being referred by other researchers or doctors.

### Cultural Problems

Participants complained of being asked about sex-related questions by members of the opposite sex. A female participant aged 18-35 years said "...a researcher whose age was equal to my father's was asking sexual questions to me". An elderly participant aged 36-40 years said "...found it unusual to be asked sexual questions by a female". Another male participant in aged 36-60 years complained of not being explained about the use of the drawn blood. He said "I was not explained as to where they were taking the blood they had drawn from me". All participants agreed that visual aid can greatly assist when explaining research procedures. One said "when they showed us a video demonstrating research process, everyone said they understood what was expected of them". The theme identified in all of the above complaints was that of failure in not knowing the community's culture. In all the 12 fields, none reported having participated in research that observed community's culture. This shows that cultural issues were not understood by the researcher, hence not handled in a way that participants felt comfortable in answering questions. It also shows that participants assumed that researchers knew all about their culture, which implies that informed consent, was not understood.

## DISCUSSION

### Comprehending

Comprehension by the participants takes place within informed consent process. When a researcher is presenting

information, the participant will either comprehend what the researcher wants or fail to. There are at least four factors that contribute to understanding or lack thereof: they are the language used; standard of education of the participant; participant's exposure to various topics, cultural factors, influences, and vested interests of the participant towards the research or researcher.

### Language

Because language is the medium of passing information from the PI to the participants, it is necessary to choose the right one. When a PI uses a language that participants can understand, then securing consent becomes easy. There has been an assumption that the best language when securing informed consent is the first language of the respondents. However, the primary language has two challenges. First, not all PIs understand their own primary language, hence the need to seek a more common language. The choice of the common language has to be done in consultation with the participants. Once identified then it is a success in securing informed consent. Secondly, it might prove difficult for a researcher to recruit a group of participants who do not use the same primary language. This research was faced with the same difficulty. The only option was to go for a language that is common to all participants. Advocating for the use of common language to all the participants as well as the PI is contrary to using primary language of what both Oduro *et al.* (2008, p. 9) and CITI (2010, p. 78) recommend.

Instead it should be recommended that informed consent process be presented in a language that is common to both PI and participants. During this research, it was proved that common language (the language commonly used in that village daily) works. Primary languages are no longer commonly used. With migration from rural to urban centres, there are new adaptations of common language. According to Tucker (2003, p. 1), a common language should be used where primary languages in a group cannot be found. Since research groups are formed by participants having diverse primary languages, they ought to opt for a common language among themselves. It is true that visual aids assist the use of language to clarify the meaning of what the PI is talking about, as advocated by Valley *et al.* (2010, p. 4). Valley *et al.* (2009, p. 17.) encourage the use of video when demonstrating a procedure that is not clear to everybody.

### Education and Individual Exposure

The higher the level of education one has, the better for both the PI and participants. Even when a PI was going through training it was easy to train a learned person than an illiterate one. There is value in higher level education since participants with a higher level of education were able to ask a PI the value of the research to the community. The PI failing to respond may imply that the PI's level of education was low hence was unable to match the research objectives with the needs of the society. But participants were able to evaluate the community's needs against the research objective and they found them wanting. Tindana *et al.* (2006, p. 24) encourages PIs to recruit participants who are learned because they comprehend things easily. To affirm this, as the others were

discussing about their individual payment of Ksh 1200, the educated lady was evaluating the needs of the community. Although one might argue that asking questions in research was a way of seeking the truth, the quality of the questions reveals the level of understanding of the participant asking the question. For example, the question of if the research objectives would help solve the research community's problems, this shows the ability of the participants in revealing the facts to the researcher. In this case the participant was asking a very thoughtful question.

Nevertheless, even with higher level of education, the problem of translating consent form from English to Swahili still encounters missing corresponding words. The difficulty was in differentiating the word for clinical check-up of a patient to that of research. Kass and Hyder (2001, p. 220) point to the missing a corresponding Swahili words in some research; some were encountered in this research. One thing became clear when highly educated participants were compared to lowly educated ones; that the highly educated could differentiate treatment from research. The lowly educated had problems differentiating the two. This was a clear indication that education is a factor both to the PI and participant in giving knowledgeable consent. But exposure has a lot of influence in understanding an issue. Even a highly educated individual who is not yet exposed might have difficulties understanding issues. Even an exposed individual with the level of primary class 8 might be able to understand issues faster than a Form Four. A participant with primary class 8 level of education was able to understand what a biopsy was while Form Four and above participants were not. Exposure improves one's understanding and this is supported by Toucher and Larson (1998, p. 50). This was confirmed when one of the respondents said he learned of biopsy when a veterinary doctor took a piece of a dead cow's meat for laboratory test; meanwhile the others were still asking what a biopsy was.

### Influences and Misconceptions

Participants valued the refund of Ksh 1200, with some even calling it income. They even anticipated more payment at the end of the project. If an individual considered the refund as an income, then he was most likely influenced to join the project by this misconception. Probably, the individual joined and participated in the research expecting to be paid. Questions then arise as to whether or not researchers should still refund participants. If not, how should a participant be compensated for the time and effort he/she has spend taking part in research?

To be fair to both the PI and participants, the PI may refund participants a reasonable amount, that is, the amount that is reasonable to both the participant and PI based on research site's economic status. A CIOMS (2002, p. 34) guideline encourages PIs to base their refunds upon the economic status of the research site's community. It urges all PIs to avoid coercing participants. So refund should never be overstated to coerce participants; at the same time it must be reasonable to compensate the recipient. From the research findings, some of the respondents said they joined the research because they needed treatment from the doctors undertaking research. They

saw these researchers in white coats and believed that they were medical doctors out on field treatment. They were influenced to join the research in the hope that they would be treated by the white coat doctors. This amounted to coercion because the consent they gave was not informed; it was based on an expected benefit that did not exist.

Another participant said she decided to join research so that she could be treated in future at MTRH. She concluded that withdrawing would give her marked bad reputation. She joined that research to retain her friendship with the health related researchers. As such, fear was her main reason for joining research. Her consent was thus not knowledgeable. Others said they joined because they were encouraged to join with a promise that they would enjoy some other benefits, specifically from the activities of the research. These individuals did not evaluate the benefits and risks of research; instead, it had been done for them. To them, they based their faith on the one recommending them to participate. Their consent to join the research was not knowledgeable. Ngare (2007, p. 42) notes that appearing on research site with white coat influences participants to believe that one was a doctor out to treat. This was encountered in this research as well when a participant did not want to offend the doctors yet one would go back to the very doctor for treatment the next day. Participants were ready to do all that was requested by anybody in white coat. So researchers should always avoid anything that might influence participants into making decisions based on false impression. But there were those who understood that individuals in white coats were researchers. They had been given adequate information.

### Cultural Problems

From all the 12 FGDs, everybody admitted that in all the researches they had participated in, researchers had never shown any respect for their culture. It was reported that all researchers had never considered the fact that they offended the culture of their participants. They have always acted contrary to what DeVries (2004, p. 279) avers. They did not exhibit prior knowledge of the participants' culture, their morals and norms. Such, their actions might have offended participants. The PIs' lack of training or exposure on peoples' culture results in their abuse of the subject community's culture. Even without training one can seek participant's cultural understanding on how to approach issues that may prove too sensitive, like taboo subjects on sex among others.

This approach was used during this research and was found effective. But there is need to train all researchers about the value of knowing the culture of research site community. They should know that such knowledge will assist them in making participants feel part of the project. Another problem was the failure by PIs in medical related research to fully disclose to participants information on the use of blood samples drawn from them. Some feared that researchers would use the blood for witchcraft purposes. This was contrary to what Marshall *et al.* (2001, p. 241) encourage researchers to adhere to: that in such a research, they should give full disclosure to participants and, if still in doubt, take them to the laboratory to see how blood is being tested.

### Conclusion

From the study, it was noted that participants' volunteering to participate in research is influenced by a number of factors that one gives priority. As such, an IRB requirement demand that participants understand consent forms before signing, the reality at the research site is different. Before assenting to take part in a research, participants would want to know the benefits that would accrue to them. An example is that of participants' valuing money paid as transport refund so much that it seems to be compelling them into joining research. The current scenario at Kapseret is such that participants want the researcher to explain consent process and the anticipated benefits. The better the perceived benefits expected, the easier it is to recruit participants. They include (among others) cash payments, employment and treatment by the researcher. Research participants in their own cultural thinking and view believe that what is discussed on the consent form is not final. Other unwritten benefits will accrue once the researcher and the participant gets to know each other well. With this in mind, many choose to participate in research, but the anticipated benefits are known to the participants alone. The researcher may not necessarily be aware of what participants are anticipating. According to the researcher, the consent form is binding while to the participant the consent form is an introduction and more negotiations are yet to come.

### Recommendations

There is a greater need to educate research participants concerning research and benefits. As much as justice demands that participants should benefit from what they have participated in, it should be made clear to the participants that the said benefit comes if the research yields positive results. But the greater benefit that both researchers and participants aim at are what research will yield to humanity but not individual gain. It is therefore important to identify who should train the participants. The users of participants are the ones to train or meet the cost; these are researchers and IRBs. IRBs can commence research to find means and ways of raising funds for training research participants. Further research can be done to find out why Kapseret research participants hold such view; is it because of poverty, unemployment in the country or that they have commercialized participating in research?

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