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RESEARCH ARTICLE

AN ASSESSMENT OF THE EXTENT TO WHICH RESEARCH PARTICIPANTS ARE MADE TO UNDERSTAND INFORMED CONSENT IN KAPSERET, UASIN GISHU COUNTY, KENYA

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ABSTRACT

Ethical research demands that, among other things, the researcher obtains informed consent from the research participants before engaging them in research. This requirement is enforced by the Institutional Review Board (IRB) on behalf of the Government of Kenya through the National Council for Science and Technology (NCST). To enforce this, the IRB demands that consent form be attached to the proposal for it to be approved. The presence of a consent form is a reassurance that the researcher will provide adequate information to the participant. It seems that in most cases, research participants do give uninformed consent, as was evidenced by certain cases where participants seemed not to have understood the content of the consent forms they signed. There are instances where participants have taken part in research programmes whose aims they did not understand in the first place. In worse cases, some participants may not even be aware that they are involved in research for which they have given consent to participate in. Such cases are common in various parts of the world where health research is conducted and Kenya is no exception. The main objective of this research was to examine the extent to which research participants who had been involved in research before were made to understand informed consent before they accepted to participate in the research. A cross sectional study was done using in-depth interviews and qualitative data. Focus Group Discussions (FGDs) were used for data collection. The target population comprised exclusively people who had participated in health-related research and who resided at Kapseret in Uasin Gishu County, Kenya. Snowball sampling method was used to select 102 participants, both male and female. The respondents were divided into 12 focus groups discussion groups 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 were finally analysed and presented. It was established in this research that a trained researchers were able to deliver understandable informed content process. Research participants respected a trained research assistant. At the same time the trained PI respected the participants and this was demonstrated by the way the respondents of the study said such PIs ensured that informed consent process was well understood. The trained PI ensured that the informed consent form was short and easy to read. The trained PI created good rapport with the participants to a level that they were able to own the project. The appreciation accorded to them made the participants own the research. Participants give more value to what they individually perceive more than getting to understand the concept of informed consent with respect to the research they are being asked to participate in. It is thus recommended that they should be educated on the value of understanding informed consent as opposed to the view of seeking to know the benefit they will get from the research if they take part in it.

INTRODUCTION

The history of informed consent in the context of health research seems to have started at the same time with the advent of calls for regulation in health-related research. This was done in reaction to the Nuremberg trials of 1947 when Nazi physicians conducted abhorrent medical research on prisoners held within concentration camps (Emanuel *et al*., 2008). Regardless of publication of the Nuremberg Code and the trying of Nazi doctors for abusing of human rights, cases of other researchers still subjecting human participants to unethical research continued to emerge. This abuse of human rights resulted in the doctrine of informed consent (Emanuel *et al*., 2008). As such, informed consent evolved in response to failures by researchers to respect the dignity of human subjects. They failed to ensure that participants were given the full

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power to decide whether or not to participate in their researches.

For example, the Tuskegee research of 1932 to 1974 was started without following the proper ethical procedure of ensuring that human beings were protected. It never came to the attention of scholars in all fields of research to ensure that the humanity of participants was not subjected to unethical research until 1970s. Beecher (1966) points out that unethical research involving human subjects was still going on, even after the Declaration of Helsinki of 1964. In this Declaration, nothing much was achieved, just like the Nuremberg Code of 1947, because the regulations proposed lacked enforcement. It was not until after the release of the Belmont Report (Department of Health, Education and Welfare, 1979) that enforcement was found.

When all this was taking place, there were various worldwide complaints concerning the abuse of human beings in research. But the Belmont Report (Department of Health, Education and Welfare, 1979) created the Institutional Review Board (IRB) whose duty was to control research and protect human beings from unethical research. Faden and Beauchamp (1986) argue that IRBs have had a profound impact on the regulation of research and protection of participants, a view also held by both Levine (1986) and Veatch (1987). Although IRBs have tried their best, reports of research misconduct in the recruitment and handling of participants still exist, and Kenya is not spared in this. An example is the case between Otsyula and Oxford University concerning researches conducted at Nyumbani Children's Home in Kenya. In this case, Dr. Otsyula argued that research involving children had been going on at Nyumbani Children's Home even though the protocol for recruitment of those children had not been approved by any IRB in Kenya (Okwembah *et al*., 2004). This case was evidence of research misconduct in Kenya. No one could be held accountable because of the missing assent forms to show whether research participants at Nyumbani children's Home gave assent or not.

Faden and Beauchamp (1986) states that "regardless of the origin of informed consent, its moral purpose is to protect people against abuse" (p. 106). If all health-related researchers would ask their participants to give consent after presenting them (participants) sufficient and clear information about the research, there would be no need to raise alarm or complain of unethical research as well as misuse of human subjects. To date, informed consent is as important in health-related research as it was during the last century. Indeed, IRBs still insist on seeing consent forms attached to the proposal for it to be approved. When a proposal is approved, the onus of implementing informed consent moves to the researcher who has to take action; the process of securing consent from the target population.

Presenting Information

The stage of presenting information to the selected research participants is the start of informed consent process. This process is aimed at explaining what the research is all about; the procedures, risks and benefits. Pedroni *et al*. (2001, p. 6) encourage investigators to use this time not only to present information but also to provide relevant information aimed at promoting participants' understanding of the importance of the research. It implies that the investigator should use the opportunity to educate participants about the entire purpose of the research.

This stage may be the first time the investigator is meeting the target participants. It is important, therefore, that he establishes good rapport with them. How he/she establishes rapport will determine whether or not the researcher will be accepted by the research subject community. Winning the confidence of the research participants is the best outcome (National Bioethics Advisory Commission, 2001), a fact which calls for the investigator to be innovative and culturally responsive to the new environment and people he is approaching.

Some of the major things to be explained to the participants are the research procedures, the purpose, risks and anticipated benefits. If there are alternative procedures, they ought to be explained as well (CITI, 2010). As argued by Escobedo *et al.* (2007), the participant's rights must be respected. Investigators ought to promote the rights of every participant, treat each as an autonomous being, deserving to be treated with justice, beneficence and respect. The success or failure of a research depends on the co-operation of participants. This can be improved if they are made to understand what the research is all about prior to conducting investigations. Once they have understood the aims, procedures and benefits of the research, it becomes easy for them to own it and desire to be a part of it. By them owning the research, withdrawal rates of the participants will be minimized; they will also refer to the project as "our". Although the investigator may be time-pressed, one should not push or use coercive means to make the participants sign the consent forms. Rather, they should ensure that participants have understood the research procedures first (Lee *et al*., 2001). The next stage is to allow participants to internalize the information then encourage them to ask for clarifications on areas they may not have understood. Irvine and Hilton (2003) argue that it is the duty of the investigator to ensure that all information is provided whether written or oral. Both Sugarman *et al*. (2001) and Adams (2005) argue that disclosing of too much information about the potential harms might be alarming to the participants. The researcher may lose the participants altogether. Some concepts may be completely alien to some people and that might scare them away.

However, this should not be taken to mean that both Sugarman *et al*. (2001) and Adams *et al*. (2005) are advocating for the researchers to avoid disclosing possible negative issues to participants. Rather, they are encouraging researchers to seek for culturally acceptable words to use aimed at avoiding the danger of scaring them. Some technical words may be alien or taboo to the participants. As Upvall and Hashwani (2001) state, "some concepts are completely alien to the people"; the only way to be sure of passing correct information without scaring participants away is to contextualize the research within the cultural context of the participants. Once proper information has been passed over to participants and the researcher has clarified their concerns, participants can then be requested to

voluntarily join the research. Marshall (2003) argues that once the researcher has used an approach that ensures comprehension and understanding to participants. One can then be requested to make a voluntary decision to participate in the enrolment of the research group. As such, it is important to note that the request for consent comes after delivery of information.

This stage should not be geared towards securing consent to merely meet the legal requirement, but rather as a moral obligation of the researcher owing duty to the participants by making them understand what they are consenting to. Chadwick *et al*. (2011) argue that researchers should be concerned with securing effective informed consent but not only to meet the rigid compliance of IRB requirement. Researchers should view the consent given as a genuine partnership between him (researcher) and the participants. Both Nuffield Council on Bioethics (2005) and World Medical Association (2000) argue for a written informed consent as being accepted by International Guidelines. One can request IRB for a waiver of written informed consent in order to use a verbal consent. The design of the consent form and content should be simple and brief to the point because voluminous documents easily distract participants. Participants are not ready to read a ten-page document; so they should be made as brief and accurate as possible. Some participants may tend to sign the consent forms without reading through (Naanyu *et al*., 2012).

When participants sign the consent forms without reading, it means that the process of passing information was faulty. Such participants perhaps failed to understand the information given because it was unclear or too lengthy and they never had time to read through. Apart from being lengthy, the consent form might also be written in technical language. Irvine and Hilton (2003) argue for consent forms to be written in a non-scientific simple terms that the research participants can readily understand. Naanyu *et al*. (2012) abhor consent forms that contain too many details and are too long for anyone to read and understand easily. For a consent to be well understood, argues CIOMS (2002), it must remain clear that no researcher is allowed to initiate research involving human participants without obtaining each participant's informed consent. This can only be done if that particular researcher has received explicit approval (waiver of informed consent) from the IRB.

Volunteering

The sole aim of informed consent process is to secure volunteers to participate in the research. By giving consent, a participant is accepting to take part out of his own free will. Irvine and Hilton (2003) aver that the authorization of informed consent must be written in the language understood by the participant. When participants sign consent forms they are given a copy and the original remains with the researcher. The one that remains with the researcher is considered a legal requirement. The American government requires that informed consent be written and signed by the participant (45 CFR, 46, p. 117). For all the researches funded by the US government, a written signed consent form must be obtained. While Loue and Okello (2000) argue that Ugandan Guidelines for Conduct of Health Research do not require a written documentation when obtaining informed consent from research participants, from their past, people had been tortured by the previous regimes and forced to sign documents denying that they have gone through torture. Hence the sensitivity that, if researchers request participants to sign informed consent forms, participants could recall their past. To avoid this confusion, the Ugandan government has waived the need to sign anything for research. Nevertheless, the researcher has to secure valid verbal informed consent.

The Kenya National Council for Science and Technology (NCST, 2004) urges researchers to obtain informed consent. But it does not state whether written or verbal, a decision which seems to have been left to the IRBs to decide the one to enforce. The IREC of Moi Teaching and Referral Hospital/Moi University, having the delegated authority from NCST, demands that a written informed consent be obtained unless authorized not to do so in writing as per their Standard Operating Procedures 9.0 (IREC, 2010, p. 9). Though not explicitly expressed, when one submits a proposal, if consent form is not attached, it will be returned to the researcher to attach it before it is handed in for review. The (voluntarily) written consent becomes an agreement between the researcher and the participant in that research. Belmont Report (Department of Health, Education and Welfare, 1979) and the National Commission (1979) urge researchers to go for the spirit but not just to get a paper signed as a legal requirement, but to seek for the spirit of voluntariness. Consent represents the determination of one's own will. Good Clinical Practice (1996) argues for this spirit by pointing out that informed consent is a process by which an individual voluntarily expresses his or her willingness to participate in particular trial. If one cannot secure a signed or a thumb printed informed consent, the World Medical Association (2000) recommends that a researcher can request an IRB to allow him/her use verbal consent. Macklin (2004) laments the misuse of participants by researchers, even after securing approval of the proposal by an IRB. The consent secured by such researchers cannot be considered informed in that participants do not know the aims and procedures of the research they are taking part in.

Waiver

A waiver of securing informed consent from research participants can only be issued by IRBs. No other person or group is authorized to issue informed consent waiver to a researcher (CITI, 2010). When it comes to IREC, a waiver of informed consent should be sought at the point of submission of the proposal, that is, at submission stage as per SOPs 9.0 (IREC, 2010). Though it is not explicitly stated, if the researcher does not attach the proposal with consent form, they should then attach a requisition for a waiver of informed consent, giving reasons for that. A number of proposals can be given waiver of informed consent. For instance, if the proposed research has minimal risks; CITI (2010) and Brody (1998) argue that minimal risk means that the probability and magnitude of harm or discomfort is not greater than those ordinarily encountered on daily basis during performance of routine examinations, test done physically or psychological. In so doing, IRB is pointing to the fact that the research procedure is not unique from the day to day procedures.

Titus and Moira (1996) argue that research which spells potential risks to the participants should not be approved. For example, if a research was done to establish the number of people owning unlicensed guns, one signing a written consent invites risk by claiming to have such information. However, in cases where written consent cannot be approved, verbal consent must be sought. A waiver of informed consent can be given when participants are in a medical research which has an emergency situation. Brody (1998) argues for a waiver when it comes to research being done to somebody who is at risk of getting sudden heart attacks because time is of essence. If there is any research that can be tried to make such a patient recover, then it should be done without having to wait for the next of kin to give consent.

Another waiver for securing informed consent can be given when observation of individuals is to be done in their natural environment. This applies to individuals who may change their patterns of life if they are informed of what is happening, thus distorting the research findings. An example of this would be when a company wants to know the number of employees who report to work late. CITI (2010, p. 77) argues for the participants to be debriefed before writing the report and given the option to withdraw the data from being included in the final report.

Moreover, when a researcher conducts research from records (only) in a hospital of people who left or died long ago, IRB waives the requirement for informed consent because the owners of such records are deceased.

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), Strauss and Corbin (1998) argue for qualitative methods when one intends to get data dealing with attitudes, understanding and feelings. Alzheimer Europe (2012) 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) 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) 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 indentified 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). 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) defines a youth to be a person aged 15 to 24 years. However, UNESCO (2013) 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). 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). This list was gotten from the transcribed conversations and patterns of experiences of all FGDs that participated (Aronson, 1994). This was done by use of direct quotes or paraphrasing common ideas. van Teijlingen and Ireland (2003) 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) 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), 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) 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) and Constas (1992) 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

Understanding of Informed Consent

Majority of the members reported having understood the content of the consent forms they had signed. They said the person who had presented information to them had made it easy to understand. According to the respondents, the Principal Investigator (PI) was approachable, willing to respond to their questions, and also ready to attend to all of the concerns they raised. A female respondent aged 36-60 years said "… when we were being taken through group training, our facilitator talked of the way he himself was trained". Unfortunately, some of respondents said their PI was unable to communicate clearly. A female respondent aged 25-40 years said "He could not express himself". Another respondent, male aged 18-35years, said "He neither trained us; nor talked of himself being trained". The theme identified here was that of training of both participants and the PI. One of the male respondents aged 36-60 years said "Our researcher was willing to spend time with us". Others talked of the researcher being ready to discuss with every participant about their concerns. Another participant, female aged 36-60 years, said "…he had enough time for everybody". However, another respondent talked of their PI being in a hurry always: "…always in a hurry, having no time to answer our questions". The theme identified here was that of spending time with participants. The FGD members further reported of a PI who was friendly to everybody. One could not resist listening to what he was presenting, they said. A female participant aged 18-35 years exclaimed "How can one fail to listen at the presentation of such a welcoming person".

Moreover, a male respondent aged 36-60 years said "Our PI was not welcoming; was such a serious person who could not entertain petty questions from us". The theme identified here was that of a PI not building rapport with participants. There was the presentation of information using unfamiliar words/language or concepts during the informed consent process. Some words or concepts were being encountered by the respondents for the first time. A female respondent aged 36-45 years said "I was told to cover my face so that my photograph would be taken as I explained my health condition"; but another female member in the same FGD interjected "…that was meant for confidentiality to the participant". The theme identified here was that of alien words or concepts in the presentation of informed consent.

Volunteering

Among the participants, there were those who appreciated information given to them. One female member aged 36-60 years said "I can still recall the way I was explained about the research process. ….then I signed it". Another in the same FGD had this to say: "…I do not remember being given any explanation or signing any form" (Personal Communication, FGD 4). At the same time, the participant said "I just found myself participating in research". The theme identified here was that of unknowledgeable/knowledgeable informed consent.

Waiver

None of the participants talked of having participated in a research that informed consent was not required. They said "I have never been in research which I was not asked to give consent". The theme identified was that of protecting research participants.

DISCUSSION

It was established in the research that trained researchers were able to deliver understandable informed content. From the reviewed literature, training improves communication skills, and provides exposure to the researcher enabling him/her to appreciate research community's culture. Research participants respected a trained research assistant. At the same time the trained PI respected the participants and that was demonstrated by the way the respondents of the study said such PIs ensured that informed consent process was well understood. The trained PI ensured that the informed consent form was short and easy to read. The trained PI created good rapport with the participants to a level that they were able to own the project. The appreciation accorded to them made the participants own the research. According to Lee *et al*. (2001), a successful research is the one in which the PI succeeds to win the confidence of the participants to the level where they refer to the research as 'ours'.

Other than training, time was another factor that determined the success or the failure of informed consent process. A PI willing to spend time with participants succeeded in ensuring informed consent process was understood. But those who acted in a hurry failed to attract participants and even if they managed to recruit, then the recruited group are the same group who could not remember signing consent form. Instead they remember finding themselves participating in research contrary to what CIOMS (2002) says, that nobody should be made to join research without his/her consent; the reason being that these participants never gave knowledgeable consent.

Because PIs might be meeting participants for the first time, PIs should not use technical terms. From the study findings, it was reported that alien words scare off the participants, especially when it is coming from an individual not familiar to participants. When researchers use alien words or language without making an effort to domesticate, then participants remain in dilemma, not knowing whether to join the research or not. Every effort should be made to domesticate the alien words. But if not possible, it should be clearly explained in detail (Upvall and Hashwani, 2001). With or without alien words, a PI is not allowed to enlist individuals in research without his/her consent. To reduce the sensitivity of the alien words, a visual aid to demonstrate what the research is all about can be used. And Molyneux *et al*. (2004) support that, and participants talked of its effectiveness.

Volunteering

Some participants reported that they volunteered and joined research after having evaluated the benefits and risks. This showed that PIs obtained informed consent from participants

following the right procedure. Macklin (1999) encourages researchers to secure consent correctly. Nevertheless, others accepted finding themselves in a research for which they could not remember giving consent. The PIs might have gotten consent through coercion or influence. Such PIs do satisfy the IRB's legal requirements. According to Gikonyo *et al*. (2008), researchers should be discouraged from coercing participants into taking part in research without proper knowledge. This should not be happening when bioethics courses are being taught. Macklin (2004, p. 31) is right when she laments the misuse of participants by researchers.

Waivers

None of the participants talked of having participated in a research that never sought consent. The fact that none of the respondents had taken part in a research without a request of consent indicates that the IRBs regulations are being heeded. It shows that the informed consent attached to the proposal is always implemented by researchers, even though the consent form obtained by the PIs at times is meant to simply satisfy the requirements of the IRBs. Chadwick *et al.* (2011, p. 115) see this kind of securing consent, for the sake of regulations, form as misusing participants. Such PIs want to achieve the requirements of the IRBs, but do not care about the feelings, culture or specific needs of the participants. Training of the PIs might bring this kind of practice to an end; the misuse of participants. The fact that IRBs have succeeded in securing consent in almost all research done in Kapseret shows that the practice of coercion has receded.

Conclusion and Recommendations

The evidence obtained from the study shows that participants in health-related research mostly understand and give knowledgeable consent according to their own view. The respondents fully comprehend what the research is all about, the risks involved before volunteering to participate in the research. The requirement to use informed consent form as a protection tool to research participants by IRBs still remains the best option. Because IRBs cannot speculate on the thoughts of participants or their beliefs, it is difficult for IRBs to control anticipated benefits which are not documented in the consent form. Since both the researcher and the participant still recognize the consent form as a contract deed, IRBs should continue to enforce it as a protection tool to research participants.

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