Understanding Informed Consent: An in Depth Analysis

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Abstract:

Introduction: The history of informed consent 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. Despite the publication of the Nuremberg Code and the trying of Nazi doctors for abuse of human rights, cases of other researchers still subjecting human participants to unethical research continued to emerge. 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 power to decide whether or not to participate in their researches.

Objective: This study sought to examine research participants' views when giving informed consent in the researches they have taken part in.

Methods: This was a qualitative study done using in-depth interviews and Focus Group Discussion (FGD) 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 analyzed.

Results: 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.

Conclusion: 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.

***Key Words*: Informed Consent; Health research; In depth analysis**

I. BACKGROUND

The fact that humanity invented a way of lighting fire and the use of honey as a preservative when storing meat for future use is a pointer that humanity has been conducting informal research ever since the dawn of human history (Middle Ages Food Preservation, 2012). Then came the Greek era when medical research was part of learning and treatment guided by the Hippocratic Oath which required physicians to benefit their patients to the best of their knowledge (Middle Ages Food Preservation, 2012). But it was not until the 1900s; the era of modern science which was accelerated by research in medical field (Medicine 1900-1949, 2012).

As health-related research progressed resulting in discoveries that improved treatment, eradication and control of diseases, it was reported that researchers misused vulnerable groups such as prisoners. An example of this was Celsus who justified the use of death row criminals in Egypt by saying "It is not cruel to inflict on a few criminals sufferings which may benefit multitudes of innocent people through all centuries" (CITI, 2010). This shows that Celsus was not asking for consent from the research participants. He viewed death row prisoners as research tools without feelings in that the very individual would soon be put to death. But it should be noted that every individual has rights regardless of his/her current or future circumstances.

This concept of using prisoners for health-related research was perfected by the German Nazi doctors. They made the prisoners go through awful research procedures, which made the League of Nations come up with regulations to govern research on human beings. The regulations were published in 1949, known as *Nuremberg Code* (Bulger, 2002).

The gross violations investigated at Nuremberg were gradually perceived by the medical community as a general threat to the reputation and integrity of health related research. In response, the medical community drafted regulations to differentiate an ethical research from an unethical one; which resulted in the *Declaration of Helsinki in 1964* (CITI, 2010) which sought to ensure researchers adhere to research ethics.

According to Bulger, the *Nuremberg Code* was published as a standard for judging the Nazi doctors during Nuremberg trials. It established ten basic principles to be followed by every researcher conducting research using human participants.

However, the *Nuremberg Code* did not establish the method to be followed in ensuring that physicians follow the ten rules conducting health related research. As such, misuse of research participants continued generating debate on the way to enforce the code. In 1964, the *Declaration of Helsinki* insisted that research participants must give consent before participating in health related research. But, there was no change because it lacked an enforcing agency.

Beecher (1966) published an article indicating that unethical research was still in practice. Because of that revelation, the United States of America Congress in 1974 authorized the formation of the National Commission for the Protection of Human Subjects in Biomedical and Behavioural Research (Beecher, 1966). According to CITI, the National Commission met in 1979 and published the *Belmont Report*. This report identified three basic ethical principles, namely respect for persons (autonomy – this is where informed consent is required), beneficence and justice (CITI, 2010). Respect for persons (autonomy) means that individuals must be allowed to choose for themselves whether to participate in the research or not.

It was the *Belmont Report* that came up with ways of enforcing regulations in research participation. It was made mandatory that all proposals dealing with health related research must be approved by an Institutional Review Board (IRB) before the start of research. IRBs were mandated to ensure that no researcher recruits research participants before his/her proposal is approved. To ensure that humanity is protected, according to NCST, IRBs ought to ensure that all proposals are of value by ensuring that the proposed research will be of benefit to humanity; has scientific validity or practical feasibility and involves fair selection of research participants. IRBs must check on the risk-benefit ratio, which means that the benefits should outweigh the risks. Once the IRB is satisfied that the above has been achieved and that the proposal has a consent form, it issues approval for the researchers to proceed (NCST, 2004).

To enforce the code, some publishers of research journals demand that researchers attach IRBs' letter of approval to enable them publish the article. This method has proved effective since publishing of research findings is one of the major goals of researchers.

In 1979, Kenya decided to regulate research and, to this end, formed the National Council for Science and Technology to handle the regulation of research in the country. To date, NCST has delegated her responsibilities to 14 IRBs in the country such as Institutional Research Ethics (IREC) in Moi University/Moi Teaching and Referral Hospital, Kenya Medical Research Institute (KEMRI), Aga Khan Hospital, Kenyatta National Hospital, among others.

IRBs have thus made it mandatory that all human related research proposals must be accompanied by informed consent forms in the hope that researchers would seek knowledgeable consent. However, a story featured in *The New York Times* (1997, p. 5), states that the women who participated in the study of Zidovudine aimed at preventing prenatal HIV transmission in Ivory Coast did give informed consent. Several of the participants were confused about what the research was all about. One woman believed that she received medicine to treat Malaria fever or AIDS (Mariner, 2003). This raises a lot of doubts as to whether the women who took part in that research understood the meaning and content of informed consent they gave.

From the above discussion, the aim of this research was to assess the extent to which research participants in a study area gave informed consents and, if they did, how much they understood the content of the specific informed consents they gave.

Problem Statement

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. This study sought to examine research participants' view when giving informed consent in the researches they have taken part in.

It is not enough to assume that just because researchers attach signed consent forms to their study reports, then 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 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 researcher saw a need to examine whether participants do give informed consent in the study area.

Objective

Objective: This study sought to examine research participants' views when giving informed consent in the researches they have taken part in.

Justification of the Study

This research aimed at examining research participants' views when giving informed consent. Taking the example of the

Ivory Coast woman who joined a research thinking that the drugs given would treat, among others, malaria infection, this research highlighted some of the causes of misunderstanding of the concept and content of informed consent by both researchers and research participants. It is possible that this misunderstanding emanates from the fact that participants are not given proper explanation on the nature and purpose of the research, or in some cases, the language used in the consent form is too technical to understand.

In some cases, research participants consent to take part out of ignorance. This research examined and discussed such misunderstandings and the reasons for it. This means that people should join research as participants out of their own will. The only way of knowing the way research participants were recruited is through the signed informed consent form. But signatures do not reveal whether the participant understood research procedures and risks involved. So this study highlights the participants' view of informed consent given by participants in previous health related research; then assesses whether the given consent was knowledgeable or not.

As stated earlier, the aim of an IRB is to help protect the rights and welfare of human research participants "IRBs have had a profound impact on the regulation of research with human participants". In doing this, IRBs have been demanding that all researchers attach consent forms to their research proposals with the hope that during recruitment of researcher participants, researchers would use the attached consent forms to secure knowledgeable consent. As such, it is hoped that the findings of this study can help the IRBs evaluate their ways of approving proposals.

II. LITERATURE REVIEW

The History of the Concept of Informed Consent

The history of informed consent 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.

Regardless of publication of the Nuremberg Code and the trying of Nazi doctors for abuse 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 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 (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 (1979) created the Institutional Review Board (IRB) whose duty was to control research and protect human beings from unethical research. Faden and Beauchamp argue that IRBs have had a profound impact on the regulation of research and protection of participants.

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, state "regardless of the origin of informed consent, its moral purpose is to protect people against abuse". If all health related researchers would ask their participants to give consent after presenting proper 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. Still a key issue that IRBs 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.

The Process of Securing Informed Consent

Once participants have been identified, before they are requested to take part in the 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 the participants 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.

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) encourages 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 a good rapport. How he establishes rapport will determine whether or not he 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). 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 and 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. It is the duty of the investigator to ensure that all information is provided whether written or oral. 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.

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 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 (Marshall, 2009).

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. 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.

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. Consent forms should be written in a non-scientific simple terms that the research participants can readily understand. For a consent to be well understood, 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.

III. METHODS

Research Design

This was a qualitative research design, In depth analysis and Focus Group Discussions (FGD) were chosen as a data collection method.

Study Area

The study was conducted at Kapseret Location in Eldoret town. The location has a population of 25,700 people composed of both men and women of all ages. Kapseret is a peri-urban area which attracts many residents because of its proximity to Eldoret town, good road network and cheap housing

Target Population

A population is the collection of individuals spread throughout the research area who meet the criteria for participating in the research.

Sample Size

A sample size of 102 individuals, all of them residents of Kapseret, were recruited to participate in the research.

Sampling Procedure

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 were 9; only 6 turned up for the meeting. The researcher 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 researcher 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 researcher 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 researcher 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. With the assistance of CHWs, 40 participants were recruited in the first week. In the second; 72 prospective participants were invited for a meeting; where the researcher presented the purpose of the research and the selection criteria. After answering questions raised by the members, the researcher requested for volunteers to join and participate in the research. Ten (10) members were disqualified because they had not participated in health related research, remaining with 62 who, after going through the consent process, volunteered to participate in the research. The 40 participants recruited in the first week, plus the 62 recruited in the second week, brings the total number of participants to 102. 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 (data) from the 12 FGDs was taped then later transcribed. Those aged 18 to 35 years were grouped together. 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. The 12 FGDs had 102 recruited participants, 55 females and 47 males. They were from various tribal background, but all understood Swahili. Each FGD had either 8 or 9 members who were found manageable to the researcher. The researcher 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

Thematic analysis was used to analyze the data collected during FGD's. This themes were derived from the transcribed conversations and patterns of experiences of all FGDs that participated. This was done by use of direct quotes or paraphrasing common ideas.

Ethical Considerations

Permits: Ethical approval to conduct the study was sought from the Institutional Research Ethics Committee (IREC) at the Moi Teaching and Referral Hospital/ Moi University School of Medicine on behalf of the National Commission of Science, Technology and Innovations (NACOSTI). Permission to conduct the study was obtained from the appropriate officers in the Sub-County and the County where the study was carried out.

Consent: Written consent was obtained from all the study participants. At the conclusion of the study, any information that could be used to link the respondents to the research data collected was destroyed. Only individuals who freely consented were allowed to participate in the study, and no one was coerced to participate. Participants were informed that they have the right to withdraw at any point of participation in the study. Participants were informed that they could decline to answer any question or stop talking at any time they wished during the interview process for any reason.

Confidentiality and Anonymity: The identity and replies of respondents was confidential. Participant logs, the only link between identifying information and code numbers, and all data was kept in a locked file cabinet. Only the researcher had access to the files.

IV. RESULTS

Demographic Characteristics of Respondents

The demographic characteristics of study participants were as represented in Figure 4.1 below.

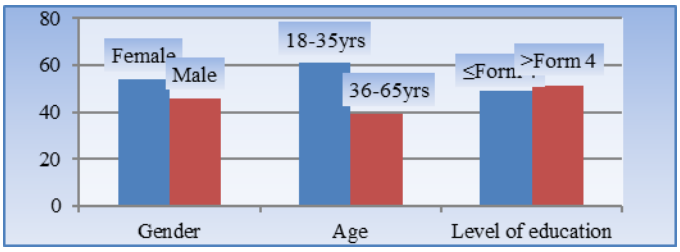

Figure 1: Demographic Characteristics of Participants

As shown in Figure.1, with respect to gender, 47(46.08%) of the respondents were male and 55(53.92%) were female. On age, 40(39.22%) were aged 18-35 years and those aged 36-60 years were 62(60.78%). Lastly, on the level of education, 52(50.98%) of them had attained Form Four and below and the other 50(49.02%) had their level of education above Form Four.

Using their level of education, the researcher brought together FGDs 1, 2, 7, 8, 9 and 10. All the members of these FGDs had diploma and above as their level of education. They were all trained together by the researcher. FGDs 3, 4, 5, 6, 11 and 12 were trained together because the levels of education of their members were that of secondary Form Four and below.

The training covered areas of basic group guidelines of having to respect every individual's contribution during discussions. Every member was expected to have an active listening to avoid redundancies. To maintain confidentiality, an agreement was reached that whatever was discussed in the FGD should never be disclosed elsewhere outside the circle of those who participated.

The data collected was put in themes identified through regular repetition during discussions. A theme was a title given to a factor contributing to the understanding (or lack there of) of informed consent.

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 aged36-45 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 36-60years 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 are search 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.

V. 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*., 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' (Lee, Fairclough, Antin, & Weeks, 2001).

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 says, that nobody should be made to join research without his/her consent; the reason being that these participants never gave knowledgeable consent (CIOMS, 2002).

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 & 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*. support that, and participants talked of its effectiveness (Molyneux, Peshu, & Marsh, 2004).

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 encourages researchers to secure consent correctly (Macklin, 1999). 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*. researchers should be discouraged from coercing participants into taking part in research without proper knowledge (Gikonyo, Bejon, Marsh, & Molyneux, 2008). This should not be happening when bioethics courses are being taught. Macklin is right when she laments the misuse of participants by researchers (Macklin, 2004).

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*. 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 (Chadwick, Have, & Meslin, 2011). 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.

VI. 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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