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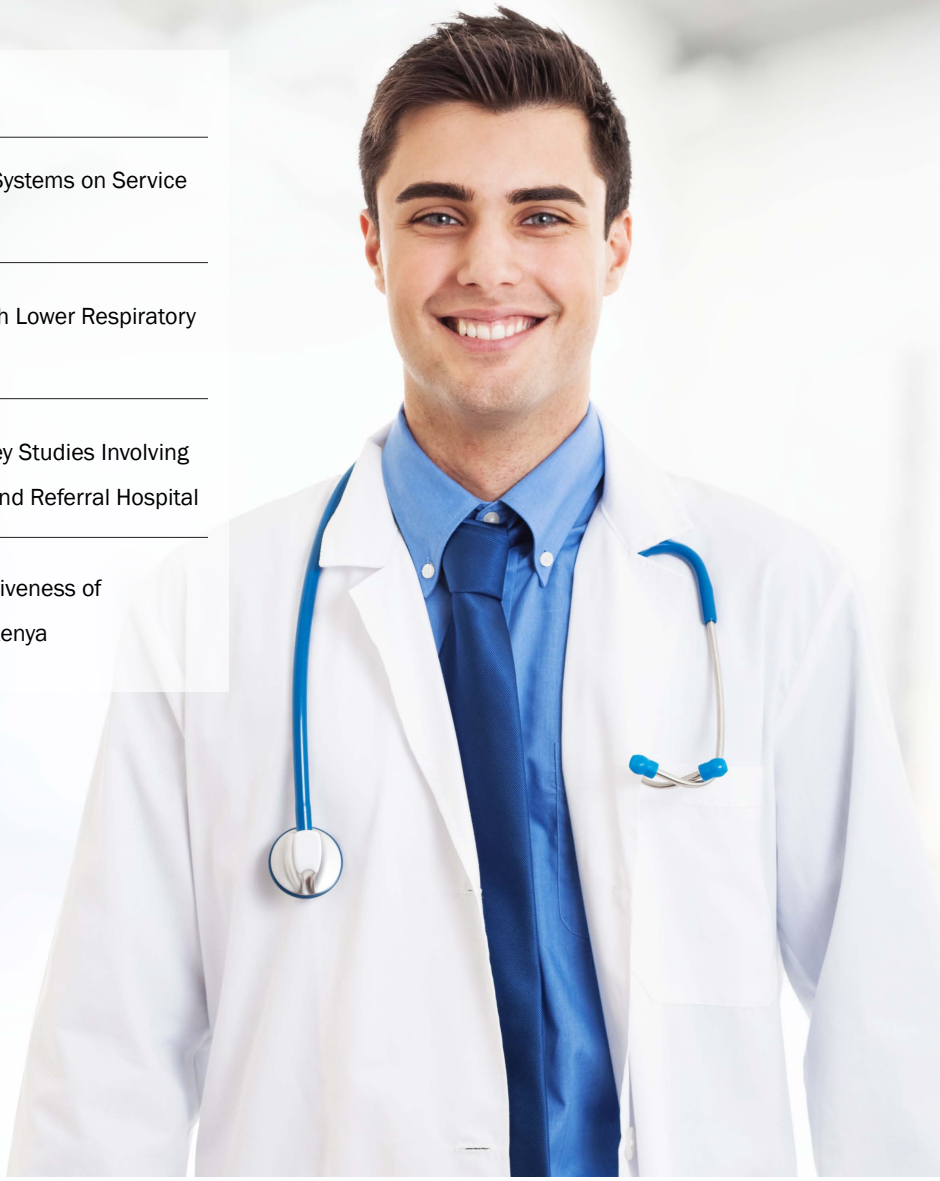

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The Practice of the Informed Consent Process on Survey Studies Involving Healthcare Providers as Participants at Moi Teaching and Referral Hospital

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Abstract

Background: The informed consent process is an ethical pillar whose implementation enhances the ethical principle of respect for individuals. It was formulated after discovery of inhumane historical events in research with human subjects. It has seven steps, namely; i) determination of authority to consent; ii) provision of standard information; iii) confirmation of understanding; iv)giving opportunity for questions; v) confirmation of consent; vi) documentation of consent; and vii) implementation of post-consent follow-up. In routine survey studies, healthcare providers have been found to have limited knowledge on the informed consent process. Yet they are expected to be the most conversant. This study assessed the understanding of the steps in and the practice of the informed consent process on survey studies involving healthcare providers as research participants.

Methods: The study employed a descriptive cross-sectional research design, generating qualitative data from healthcare providers who included medical specialists, medical officers, clinical officers, nurses and IREC members as key informants. Quota and purposive sampling was carried out for the healthcare providers and key informants respectively. Data was collected until a saturation point was reached, having interviewed four key informants and presented 54 open-ended researcher administered questionnaires to the health workers. Thematic analysis using SPSS program that involved frequencies, non-parametric correlation techniques of Multiple Correspondence Analysis (MCA), and nonlinear canonical correlation analysis (OVERALS) was performed.

Results: Most respondents were aged 31 to 40 years (n=31, 53%). None (0%) was above 60 years, with more females (n=40, 69%) relative to males (n=18, 31%). Approximately three quarters were married (n=46, 79%), and a few were single (n=8, 14%) or widows/ widowed (n=4, 7%). Their understanding of the consent process was limited; of the 54 (100%), none understood all the seven steps, especially on the first (determining authority) and last step (follow-up).

Conclusion and Recommendation: In survey studies, consent takes place without adherence to the required steps. Hence it is not valid. There is a limited understanding of the process among healthcare providers, of whom the majority are middle-aged. IREC should make researchers responsible in due consent procedures.

Key Words
Informed Consent; Healthcare Providers

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Introduction

Informed consent process is an ethical pillar in research with human subjects. Its implementation enhances the principle of respect for individuals. This promotes autonomy and self-determination of potential participants, improving research, regularizing relationships between investigators and subjects, and protecting privacy rights[1]. The process is about what participation means, particularly on potential harms and anticipated benefits of a study[2]. Most consenting processes end up with legal agreements between concerned parties and are verbal, written, or both. It may be expressed, e.g. via a signed consent form, commonly done in research and hospitals in relation to specific procedures. It can be implied, e.g. when a patient goes voluntarily to a doctor's office for check-up or treatment[3].

Its formulation came as a result of inhumane nature of historical events in research with human subjects. For instance, in Germany, Nazi physicians conducted involuntary experiments in which subjects were forced into participation. One of the international guidelines that was developed as a result of this injustice is the Nuremberg code of 1949 which states that there should be voluntary participation in research. Another code of ethics

used by many regulating research agencies is the Belmont report of 1978/1979. It highlights three main guidelines: respect for persons (participants be treated autonomously and those with limited autonomy given protections and considerations); beneficence (the need for the benefits of the study to outweigh any potential harm). The researcher's responsibility is to balance risks and benefits in a favourable manner. This means, low income populations cannot be used in research and then the findings transferred to benefit a different population.

Various issues have been found to undermine the informed consent processes in the developing countries. They include:
i) Limited exposure through formal education to research concepts and procedures and lack of local terms for key elements of research.
ii) Lack of in-depth understanding of research or research ethics among those responsible for examining research activities.
iii) Difficulties for potential participants or their guardians in listening to or understanding large volumes of research related information[4].

Active debate continues among clinicians, researchers and ethicists about exactly what forms of consent are necessary in various situations, for example social scientists consider adding the collection of bio-specimens to their surveys would make informed consent a much more complex process than is the case for surveys that involve collecting only self-reported psychological, social or economic data[5].

However, the Institutional Research and Ethics Committees (IREC) of Moi Teaching and Referral Hospital (MTRH) and Moi University, have the mandate to safeguard the dignity, rights, safety and wellbeing of research participants by ensuring that research is conducted according to the highest ethical and international scientific standards.. One key function of ethical review is to ensure that consent for participation is properly obtained and documented[6]. IREC reviews the scientific design and conduct of the study. For example, how participants are recruited, cared for, how their confidentiality is protected and consideration of the community's culture[7]. Apart from IREC playing an oversight role to ensure that the conduct of research is ethically sound, other research stakeholders including researchers, research institutions and regulatory bodies also have an ethical responsibility[6].

Healthcare and research are interrelated; one cannot function without the other. For example, due to lack of research on women, their health was compromised for a long time until 1986 when the National Institute of Health (NIH) policy in the United States of America (USA) encouraged the inclusion of women in clinical trials. Human rights activists also played part in these developments[1]. Healthcare providers therefore participate in different research that includes experiments and observations. In survey studies they become researchers, participants or research assistants hence they are expected to be involved with the informed consent process in one way or the other. In healthcare institutions, they commonly participate in employee surveys aimed at measuring and monitoring the extent that personnel are aligned with the management's business goals and objectives. Most of which are non experimental, descriptive methods used to gather information on peoples' opinions, feelings and thoughts by use of questionnaires and interviews. Hence, is a means to an end where the healthcare for the general public is improved[6]. Competent persons can only give informed consent. This is a process that has its place in relationships "between consenting adults", and it is only possible when they are knowledgeable or, as John Stuart Mill puts it, "in the maturity of our faculties,"[8].

Practice of Informed Consent Process

Healthcare Providers are perceived to understand the importance of research and are expected to be conversant with the process. Yet their knowledge may not be greater than other research participants. On the grounds that they are informed on consent matters, it is possible that they may be predisposed to more research participation than other groups of workers[9].

Healthcare workers are potential participants in different studies including employee surveys that are aimed at measuring and monitoring the extent that personnel are aligned with the management's business goals and objectives. Surveys are non-experimental, descriptive methods used to gather information on peoples' opinions, feelings and thoughts. They are easily conducted and can be used on some specific group of people using questionnaires and interviews. They can be specific and limited, or have more global widespread goals, promoting utilitarian theory that states, The 'right' thing to do is that which maximises the 'good' for many (Berglund, 2007).

According to Cornell University (2007), it is the investigator's responsibility to document that the process has taken place by use of an informed consent form as a standard for the documentation process. This is in line with what deontologists suggest, that "what is important is the obligation vested on individuals[10]. Institutional Review Boards (IRB) have standards operating procedures (SOP) on the informed consent process which require

that: The forms should be written in a language understood by participants avoiding technical terms and complex sentences even for the educated group of participants so as to aid their comprehension process. Explanation of the purpose of the study, what happens to the participants during the study period, description of risks, side effects or any discomforts in the study procedures while giving information in case there are no anticipated risks i.e. "we do not anticipate any risks in this study except those encountered in daily life". Benefits including those that indirectly benefit society or for scientific knowledge have to be stated well i.e. "information from this study will benefit other people now or in the future". Other statements include provision of information on the voluntary nature of the study. That they are free to refuse participating from the beginning of the study, discontinue at any level, skip some questions and that no penalty will be imposed on them. They should be informed that they are free to ask questions, be assured of how their participation will be made confidential, what will happen to the data after the study is over and how audio or visual recording devices used will be kept at the study completion. A separate signature line on the consent form should be provided if the participant is to be taped/audio or photographed. An indication that the participant shall receive a copy of the signed and dated consent form with the name(s) of investigator(s) and contact information. Information on the possibility of the participant contacting IRB with any concerns or complaints has to be provided e.g. IRB email address or telephone numbers. A "statement of consent", the name and signature of the participant together with the name and signature of the person obtaining the consent have to be given. At the end of the consent form, a statement on the duration of time that the consent form has to be written (Cornell University, 2007).

Research is key to healthcare practice and the health of human population. However in developing countries, research regulations are either in their initial stages or not in existence[11]. Therefore, the implementation of the consent process ought to be well guided to ensure that the right ethical practice is in place. The role of informed consent in human subjects research is central to ethical regulation and conduct, guided by existing guidelines[12]. When this is done, human subjects are protected from harm and risks that are associated with research activities, self-determination (autonomy) of researched individuals is promoted, and justice prevails. The rights and dignity of research subjects is safeguarded and guaranteed.

Informed consent has been defined as an autonomous authorisation by individuals of a medical intervention or of involvement in research. For it to be validly obtained, it must have disclosure of information, understanding, voluntariness and competence built into the consent process. In oral or written consent, determining whether it is truly informed, a researcher should ascertain if at all participants actually understood the information and their believe that they gave consent voluntarily for the study[11]. A lot depends on what information is conveyed and how it is done. Researchers should understand information needs of the group they want to study so that they can use the same knowledge in delivering information in a way that enable potential participants understand what participation will involve[13].

Competence (capacity for decision making) comprise of four functional abilities. These are: the ability to understand relevant information, the ability to appreciate the nature or situation of events and its related consequences, the ability to reason through the given information and to weigh options in a logical manner as well as communicate the choice[11].

Healthcare workers participate in different types of survey studies, including employee surveys by human resource departments. For example, due to serious human resource crisis in the health sector in developing countries, especially in Africa, on low motivation of health workers, a study was conducted in Benin and Kenya. It assessed the role of non-financial incentives for motivation revealing that mixture of non-financial and financial incentives help maximize health worker motivation. Many studies have also shown that most participants do not understand the research process they are involved, some are even unaware of participating in research. In Nigeria, participants in an oral health research did not adequately understand the studies they were invited to join or their rights as research subjects. This limitation called for training of researchers on research ethics and inclusion of bioethics in the curriculum of dental schools[11]. With training on the consent process, the interests of the research subjects would prevail over that of third parties as recommended by the Declaration of Helsinki[14].

Healthcare and research are interrelated, one cannot function without the other. For example, due to lack of research on women, their health was compromised for a long time until 1986 when the National Institute of Health (NIH) policy encouraged inclusion of women in clinical trials[1]. The growing need for human subjects participation in research so as to promote their health also arose with human rights activists taking lead. With the inclusion of healthcare providers in different researches as participants, they are expected to be

taken through informed consent process whose functions are: To promote autonomy and self-determination, improving research, regularizing relationships between investigators and subjects and protecting privacy trials[1]. For these purposes to be accomplished, knowledge and practice of the consent process should be exercised, reinforced and emphasised among all researchers and the researched persons.

Healthcare workers have been found to lack adequate knowledge on the informed consent process i.e. on how to asses capacity and treat people who either refuse treatment or those that lack ability to comprehend any given information. Findings from a study to investigate what and how much information dental patients perceived after oral health workers informed them about treatment, benefits, risks and management alternatives in order to make decisions and give informed consent on their treatment showed that there they had limited knowledge on the consent. Therefore, if they are not able to take patients through correct consent process, how are they managing to undergo the same process as participants in survey studies?

There are barriers associated with understanding consent process. The barriers lead to ineffective communication between researchers and participants. These include language barriers, religious influences and false expectations.

Methods

A descriptive cross-sectional qualitative research design was used in this study to determine the understanding of the steps and practice of informed consent process on healthcare providers in survey studies at MTRH. The study looked at variables at a specific point in time from the potential participants.

Research participants were recruited from the clinical healthcare team using quota sampling technique based on four categories of the workers, mainly medical specialists, medical officers, clinical officers, and nurses. IREC members as key informants were sampled purposively, where identification was done using a list obtained from IREC office.

Saturation point during data collection determined the sample size. Data saturation was reached when the ability to obtain additional information was achieved; no additional data was found to give newer properties of categories and relationships and further coding was no longer feasible. This was with in-depth interviews of four key informants and by use of researcher administered questionnaires (unstructured) of 54 healthcare providers. The data was subjected into SPSS software program where repetition of themes became even clearer.

Quota sampling was used in recruiting the healthcare providers drawn from various departments of the hospital, where quarters were obtained as per their various categories, then purposively sampling potential participants from each quarter. Purposive sampling was used to recruit the key informants; the researcher sampled the participants from their work offices in the hospital guided by a list of the institutional research and ethics committee members obtained from IREC office. These non-probability sampling techniques allowed the researcher to use cases that had the required information with respect to the objectives of the study.

Data Analysis

Thematic analysis of data with the help of a Special Program for Social Scientists (SPSS) was done. The process followed the following six phases; familiarization of data; generating initial codes; searching for themes among codes; reviewing themes; defining and naming themes; and producing the final report. This was with the aid of frequencies and non-parametric correlation techniques of Multiple Correspondence Analysis (MCA) and nonlinear canonical correlation analysis (OVERALS). Non-parametric techniques were chosen because the data was nominal or ordinal. The methods of MCA and OVERALS were used because the data was either nominal or ordinal and the methods do not require stringent assumptions about the data, such as, randomness of the data (the study used non -probability sampling), as in classical statistical techniques[15]. They also present the correlations in an aesthetically appealing graphical form. The methods transform observed data in a nonlinear way in order to obtain transformed objects, which are as much homogeneous as possible. MCA analyse variables which are in a single set, while OVERALs analyse variables in two or more sets. However, when the multiple sets in OVERALS contain just one variable, as was the case in this study, the output of OVERALS and MCA are essentially the same[16]. Thus, this study used both techniques every time, choosing one over the other on the basis of the best fit of the model. The fit of the model was measured by the amount of variance (also, referred to as inertia) the model could explain in the original values (lowest: 0% and highest: 100%). The eigen value indicates the level of relationship shown by each dimension. In addition, MCA also computes a Cronbach's Alpha for measuring the reliability of the model (Minimum: 0 and Maximum: 1). On the other hand, for OVERALS the amount of

unexplained variance is labelled as 'loss' whereas explained variance is the 'fit' (Gifi, 1990). The degree of correlation in both techniques is measured by the closeness of the variables on the graph; the closer the higher the correlation[15].

Results

The study consisted of 54 healthcare providers and four key informants (n=58, 100%). Descriptive results showed that most of the respondents were aged between 31 and 40 years (n=31, 53%), followed by those aged between 41 to 50 years, and 51 to 60 years (both, n=12, 21%)

The ages of three participants (5%) were between 21 and 30 years, while no (0%) respondent was more than 60 years, suggesting that a relatively youthful and middle-aged workforce was among the healthcare providers.

How Was Informed Consent Process Obtained in Survey Studies?

The respondents were asked how informed consent process was obtained from them in survey studies at MTRH. This information is presented in Table 1 below.

The results indicated that, overwhelmingly, no consent is sought from participants before being asked to participate in research studies. All 14 (100%) clinical officers, 20 (95%) nurses, 8 (80%) medical specialists, and 7 (70%) medical officers, had never taken through the contents of consent forms before being asked to participate in studies. For instance, in response to this question, most participants answered that, "I was requested to fill a questionnaire" which was done by a friend or a member of staff, "I was just asked to fill a questionnaire", or "I was given a form to fill brought by Head of Department who said we should". In fact, the results suggest that there could be some element of coercion in the recruitment process. For example, some nurses answered, "I was given a questionnaire and told that all nurses should participate". Some medical practitioners stated that consent had been sought from them, "I agreed to participate upon agreeing to go through the consent form", "there was some form of selection criteria" whereas others said, "I was informed what the study involved and its purpose". Some medical specialists declined to participate in the studies" I declined to participate because of lack of time", which implied that they appreciated the consent process, which gives a potential participant the right to refuse to participate in the study.

The results suggest that the informed consent process was unlikely to take place as expected among the healthcare providers. The process was characterised by requests to fill questionnaires and orders from higher level of authorities. There could be elements of coercion into participation, no researcher responsibility and a cultural practice of lack of informed consent process appeared to be embedded. The participants confirm the same since they had even taken the malpractice as a routine. It is germane to reverse these wrong practices in order to safeguard human dignity.

			Profession				Total
			Medical specialist	Medical officer	Clinical officer	Nurse	
Consent	No consent	Frequency	8	7	14	19	48
		%	80.0	70.0	100.0	95.0	88.9
	Some consent	Frequency	2	3	0	1	6
		%	20.0	30.0	.0	5.0	11.1
Total		Frequency	10	10	14	20	54

Table 1: Involvement of participants in survey studies

Survey Studies in which the Healthcare Providers Had Previously Participated

The respondents were asked about the type of survey studies, in which they had participated in the last one year at MTRH. This information is presented in Table 2 below.

The number of responses for this question was 55, which was more than the number of participants (54) in the study. This was because some respondents had participated in more than one type of study. In other words, the question was a multiple response type. The study found that the type of studies in which respondents had participated could be divided into five broad types: alcohol and drug abuse; general healthcare, quality assurance/satisfaction studies; student-related studies; and nursing.

The results showed that the studies in which most respondents participated were quality assurance/ staff/customer satisfaction (42% of the 55 responses), general healthcare (36% of the 55 responses) and studies related with nursing (13% of the 55 responses). Very few health workers participated in alcohol and drug- abuse (2% of the 55 responses) and student-related research studies (7% of 55 responses). General healthcare involved an assortment of studies, for instance, diabetes, reproductive health (erectile dysfunction and family planning), surgery (ankle brachial pressure and cervical cancer evaluation), and diarrheal diseases (benefits of zinc in treatment of gastro-intestinal diseases). Others were infection prevention, malaria, and mental health studies. Nursing related topics included nursing process, nursing care, and effects of nurses' duties on their health, especially those that are back related and effectiveness of 12 hour shift for nurses at MTRH.

Medical officers mostly participated in general healthcare studies (seven (64%)), while medical specialists participated equally (four (44%)), in general healthcare and quality assurance studies. Although many (seven(47%)), nurses participated in quality assurance studies, they are the ones who are more 5(33%) likely to take part in nursing-related studies compared to any other group. Clinical officers, on the other hand, were found to take part in all (alcohol and drug abuse: one (5%); healthcare: seven (35%); quality assurance: 1(5%); nursing-related studies: one(5%)) the five types of studies, suggesting that they could be the most versatile.

		Responses		Percent of Cases
		N	Percent	
Type of Studies	Alcohol and drug abuse	1	1.8	2.2
	General healthcare	20	36.4	44.4
	Quality assurance	23	41.8	51.1
	Student-related	4	7.3	8.9
	Nursing	7	12.7	15.6
Total		55	100.0	122.2

Table 2: The type of survey studies in which the respondents had participated

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			Profession				Total
			Medical specialist	Medical officer	Clinical officer	Nurse	
Type of Study	Alcohol and drug abuse	Frequency	0	0	1	0	1
		%	.0	.0	5.0	.0	
	General heathcare	Frequency	4	7	7	2	20
		%	44.4	63.6	35.0	13.3	
	Quality assurance	Frequency	4	2	10	7	23
		%	44.4	18.2	50.0	46.7	
	Student related	Frequency	0	2	1	1	4
		%	.0	18.2	5.0	6.7	
	Nursing	Frequency	1	0	1	5	7
		%	11.1	.0	5.0	33.3	
Total		Frequency	9	11	20	15	55

Table 3: Cross tabulation of respondents' profession and types of studies

Discussion

The practice of informed consent process

There was no due process of informed consent being followed in the survey studies involving healthcare providers at MTRH. Therefore, the process is not valid as Emanuel and Flory (2004) argued that, for informed consent to be ethically valid, more than disclosure of information is demanded; participants should also understand the disclosed information. All (100%) clinical officers in the study, and nurses (95%), medical specialists (80%), and medical officers (70%), were not taken through the contents of consent forms before participating in studies.

The study also found that the process is characterised by requests to fill questionnaires and orders from higher level of authorities and hence there could be elements of coercion. This was despite the fact that most respondents had participated in one to two studies in just the past year, hence, providing ample opportunity for the implementation of the informed consent process. In fact, the group, which scores the worst on the consent process – the nurses – had participated in as many as five to six studies and over six studies, with one having participated in as many as 20 studies, in just a year.

The respondents also participated in wide-ranging research studies, which provided, once again, sufficient opportunities for the application of the consent process, but was not done. Research findings indicated that healthcare providers participated in many quality assurance/staff/ customer satisfaction studies, general healthcare, and studies related to nursing. A few also took part in alcohol and drug-abuse and student-related research studies. Many of these studies, especially on general health, for instance, erectile dysfunction, ankle brachial pressure surgery, cervical cancer evaluation, are fairly invasive, and hence, the process of informed consent is expected to be rigorous[17]. However, the actual practice at MTRH suggests that the consent process could be slack.

Conclusion

Conclusion was reached through analysis and interpretation of the study findings with guidance of the research question. The study determined the understanding of steps and practice in informed consent process on survey studies involving healthcare providers as participants at MTRH. It also studied the practice of Informed consent Process by determining how IREC members as key informants implement follow-up of the informed consent process.

Despite the workers having gone through formal education on research ethics in their former institutions of higher learning, they did not understand all the steps of informed consent process. Consent takes place without adherence of required steps, hence not valid. The workers had plentiful opportunities for participating in survey studies and the sources of information on consent process were mainly class and workshops.

IREC do a conscientious job in reviewing studies but proper implementation of approved informed consent forms is not up to date due to challenges

on follow up and in ensuring that participants have adequate understanding of the consent process. Although IREC has mechanisms such as monitoring and evaluation subcommittee, having researchers, reports and use of whistle blowers to monitor implementation of research projects, they have not effectively facilitated follow-up of approved consent forms. Most of the steps taken are merely *ad hoc* measures. IREC is required to make researchers responsible in due consent procedures if ethical standards of research are to upheld.

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