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ORIGINAL ARTICLE

Value and importance of informed consent to researchers at Makerere University

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ABSTRACT

Background: Respect for persons requires that research participants be given the opportunity to make choices about what should be done to them. Many times, the process of informed consent is abused to the benefit of researchers while exploitation and harm to the research participants may occur. In Uganda, issues of questionable research ethics have been highlighted in the past. **Objective:** To determine the Value and importance of the informed consent process among researchers at Makerere University. **Materials and Methods:** This was a qualitative descriptive study design involving faculty and graduate students in the faculties of Medicine and Social Sciences. **Results:** Of the 37 respondents 68% were faculty while 32% were graduate students in the fields of social sciences, clinical and basic sciences. Mean research experience was 8.5 years. More than 70% of the respondents have had no formal training in research ethics. Only 22% of the respondents appreciated the need for research participants to comprehend the informed consent; 38% thought it is not always the case and in many cases their subjects do not have to comprehend, while the remaining 40% believe that research subjects' understanding of the informed consent process may not be necessary. All respondents appreciated the importance of confidentiality although data management procedures were lacking by many. **Conclusion:** Most researchers appreciate the importance of confidentiality, but have limited understanding of the process of informed consent, information handling and the importance of feedback.

Key words: Importance, informed consent, Makerere university, researchers, value.

Introduction

Respect for persons requires that research participants be given the opportunity to make choices about what should be done to them. Consent is not just a form, a signature or mark but a process of information exchange between the researcher and research participants on the whole research process. Information provided should be adequate, clearly understood by the research participant with decision making capacity and the research participant should voluntarily decide to participate.[1-4]

Many times, the process of informed consent is abused to the benefit of researchers while exploitation and harm to the research participants may occur. Results from studies of informed consent, both in the economically developed as well as low resource setting, indicate that many research participants might fully understand neither the study in which they are enrolled nor their rights as participants, despite having signed a consent form.[5-13]

In Uganda, issues of questionable ethics during research have been highlighted in the past.[14-15] Therefore, there was a need to study the value and importance of the informed consent process among Ugandan researchers as they view it during their research.

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Objective

To determine the value and importance of the informed consent process among researchers at Makerere University.

Materials and Methods

This was a qualitative descriptive study of researcher's

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appreciation and application of the informed consent process during research involving humans as participants.

Sample selection was done purposively. Selection of the respondents was based on being a researcher in the field of medicine or social sciences and affiliated to either the Faculty of Medicine or Social Sciences of Makerere University. The participants included both academic staff and postgraduate students.

Respondents were interviewed using unstructured questionnaires. Other respondents took part in key informant interviews and these were drawn from the Uganda National Council for Science and Technology, faculties of social sciences and medicine, respectively. Theoretical sampling, a qualitative sampling technique was employed. This meant collecting data until no new information was being added by additional study respondents.

Methods of data collection included personal interviews, key informant interviews and observations. Primary data were collected using research instruments including unstructured questionnaires and interview guides.

Secondary data were collected by systematically reviewing relevant documents and records on research practice and research ethics. A document checklist stipulating major issues to search from documents was developed to guide and expedite the collection of secondary data.

Data were collected and recorded in a note form. This was done with the consent of the relevant study respondents. Data were checked in the field to ensure that all the information had been properly collected and recorded. This process was repeated to ensure completeness and internal consistency. Thematic and content analysis was carried out whereby field notes were categorized according to the research themes and interpreted in line with the study objectives and research questions. Relevant comparisons were made between the different groups of informants.

Ethical review and approval was sought from the institutional review board of the Faculty of Medicine before commencement of the study. Adequate informed consent was obtained from all the respondents and, where applicable, their institutions before recruitment [Table 1]. All data were kept in a secure location and stripped of identifying information.

Table 1: Respondents understanding of the informed consent process.

Variable	Respondents with adequate knowledge	Some knowledge	No knowledge	Total
Understanding of informed consent	11	16	10	37
Importance of informed consent	10	8	19	37
Process of consent	11	6	20	37
Importance of confidentiality	23	3	11	37
Importance of participant understanding of consent	8	14	15	37
Information handling	7	14	16	37

Results

Out of 37 study respondents, 68% were faculty while 32% were graduate students with research experience ranging from 1 to 34 years. They were mainly involved in conducting social science, clinical and basic science research. Less than 30% of the respondents admitted having had any form of training in research ethics.

Regarding informed consent, only 30% of the respondents appreciated the importance and understood the process of informed consent.

When they were asked what they understood by informed consent, the respondents made several remarks including the following:
"I have no idea" (senior researcher),
"the group researched on should be assured of confidentiality especially if information is sensitive",
"when participants should participate knowing the outcome",
"accepting the information given by the researcher",
"when someone with enough information delivers",
"when the respondent agrees and cooperates to give information".

This highlights the magnitude of limited knowledge about informed consent, which is an important component of research ethics.

Asked how they go about obtaining consent, respondents made the following responses:
"By persuasion",
"Select the sample group and know how to deal with them",
"Greets, asks for permission to interview or collect

samples of plant material",
"When the participants accept to take part in the research"

On whether informed consent is sought all the time before conducting research, our respondents gave varying responses:
"Not all times",
"To a great extent",
"For some",
"Rarely but I have tried",
"Taken for granted".

Our respondents were asked what they thought to be the importance of informed consent. They made the following remarks:
"So subjects are not biased and give all information necessary",
"Part of requirement for research ethics",
"The researched have rights which should be respected",
"To avoid back-lash on research and generation of knowledge".

All respondents appreciated the importance of confidentiality although data management procedures were lacking in many of the responses.

On comprehension, 22% of the respondents appreciated the need for research participants to comprehend the informed consent, 38% think it is not always the case and in many cases their research participants do not have to comprehend, while the remaining 40% believe that research participants understanding of the informed consent process may not be necessary.

Asked if their participants understand and appreciate the research process, the respondents varied in their responses as indicated below:
"Depends on category of participant, i.e. literacy",
"Not necessary… depends on nature of process and level of literacy and study itself",
"They may and normally do. Some genuinely appreciate once they have understood. Others don't want since they are fatigued; don't want to be guinea pigs. Also if there are no benefits",
"Yes and no. They are not interested",
"Sometimes they don't since they never get to see the results of the research".

Majority of respondents (65%) never give feedback to research communities unless the funding organization makes it one of the mandatory requirements before funding is approved. Asked what the researchers do in respect to their participants following the completion of research and compiling research reports, they made the following remarks:
"No feedback given",
"Nothing because they do it for purely reading purposes",
"Nothing due to lack of funds",
"Only if they ask for findings",
"I treat those who have problems and follow them up on a scheduled day",
"if asked by the funding agent",
"Not necessary in my type of research".

Asked what areas of research ethics needed revision or improvement in order to make research better they suggested the following:
"The whole course is required",
"Should be taught at undergraduate and graduate level as many medical officers are doing research",
"Need to study the whole subject".

Discussion

Of the 37 respondents, only 30% had adequate knowledge and understanding of the informed consent process; 43% had some inadequate knowledge while 27% had no knowledge despite admitting to conduction of research. This implies that many times our respondents conducted research involving humans as participants without adequate knowledge of the principles and practices that should be adhered to when doing research. It is not surprising that a good number admitted to conducting research without seeking informed consent.

On the importance of informed consent, 27% of the respondents knew and appreciated its importance during conduct of research. This means that more than 70% of the respondents may not value or respect the requirement for informed consent, hence are unlikely to adequately apply it.

About the process of informed consent, more than half or 54% had no knowledge of the process involved in obtaining consent and many times violated this process as evidenced by some of the quotations in the Results section. It should be noted that informed consent may not be valid unless the process of obtaining it is right. Signing a consent form neither necessarily implies an informed consent nor does it exonerate the researcher of misconduct.[5-13]

Participant understanding of the details of the study in which they are supposed to participate as well as being given ample time to reflect on the importance as well as risks involved in the study before signing the consent

form as an important aspect of the informed consent process. In addition, regular updates on any emerging information even after completion of the study are part and parcel of the consent process. However, only 23% of our respondents knew the importance of why their participants should understand the informed consent. The remaining 77% of the respondents either had little of no knowledge as to why participants should understand the informed consent process. This means that many of these respondents would allow their participants to sign a consent form or participate in a study even if they did not understand what the study is all about. This finding is similar to findings of studies done elsewhere.[5-13] Therefore, when questioned on comprehension, many researchers believe that research participants can understand if the study is simple or when they actively participate, although others still think that promising incentives to participants makes them accept even without understanding.

Asked about confidentiality, 62% of our respondents stressed the necessity and importance for confidentiality during research involving humans as participants. However, only 19% had good understanding of how to handle research related data including maintenance of privacy and confidentiality.

Conclusion

There is still considerable lack of appreciation and understanding of the informed consent process among researchers. Overall, more researchers from the medical faculty had a relatively better understanding and appreciation of the informed consent process as compared to their behavioral sciences counterparts.

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