

## Perception, Understanding and Practice of Ethics during Research on Humans.

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**Background:** Scandals have occurred over time involving conduct of research in different parts of the world. This study was aimed at exploring researchers' perception, understanding, appreciation and practice of research ethics during research on human subjects.

**Methods:** A qualitative approach using the exploratory and descriptive designs was used. Participants in the study academic staff 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. Research experience ranged from one to thirty four years. 27% had had formal training in research ethics; the remaining 73% had a vague idea about research ethics. All respondents appreciated the importance of confidentiality although data management procedures were lacking in many. A total of 22% of the participants appreciated the need for research subjects to understand the informed consent, 38% think it is not always the case and in many cases their subjects do not have to understand, while the remaining 40% believe that research subjects' understanding of the informed consent process may not be necessary. Sixty five percent of participants have no knowledge and usually give no feed back to research communities unless the funding organization request so.

**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.

### Introduction

The pace at which conduct of research grows seems not synonymous with the increase in knowledge and practice of research ethics thus posing a number of issues about the ethics involved in the studies being conducted. Ethical requirements for human subjects research aim to minimize the possibility of exploitation by ensuring that research subjects are not merely used but treated with respect while they contribute to the social good<sup>1,2</sup>.

Scandals have occurred over time involving conduct of research in different parts of the world<sup>3-11</sup>. And In the recent past, some studies conducted in Uganda have raised questionable aspects of ethics<sup>12-13</sup>. It was out of concern about these ethical issues that prompted the need to carry out a review of how the researchers in Uganda conduct research in order to avoid similar situations in the future.

The main objective of this study was to assess the researchers' perception, understanding,

appreciation and practice of research ethics during research on human subjects at Makerere University, Uganda.

### Methods

This was a Cross-sectional descriptive study that employed qualitative methods. It established needs of researchers by investigating and analysing the current knowledge and practice levels of research ethics and comparing them against the recommended research ethics and practices. Sample selection was done purposively. Selection of the study participants 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. Purposive sampling was employed and a total of 37 study participants were selected and interviewed using un-structured questionnaires until saturation occurred. Other study participants 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 additional study participants were adding no new information.

Methods of data collection included personal interviews, key informant interviews and observations. Primary data was collected using research instruments such as unstructured questionnaires and interview guides. Secondary data was 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 was collected and recorded in note form. This was done with the consent of the relevant study participants. Data was 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. A written informed consent was obtained from all the research participants and where applicable their institutions before recruitment. All data was kept in a secure location and stripped of identifying information.

## Results

Table 1 summarizes the findings. Of the 37, 68% were faculty staff while 32% were postgraduate students with research experience ranging from one to 34 years. They mainly conducted social science, clinical and basic science research. Only 27% had had formal training in research ethics while the 73% had either a vague idea, done it as a unit of

research methods, learnt during research experience or had no idea at all.

When participants were asked if they had had any formal training in research ethics, the answers they gave included “No”, “not formally”, “Minimal”, “Yes in research methodology.” Only 30% of the participants understood the concept of research ethics, appreciate the importance of informed consent and understand the process of informed consent. Asked what they understand by informed consent, study participants made several remarks including “*I have no idea*” by a senior researcher.

More than 50% of researchers especially those from the Social Sciences reported not to have sought approval of their research protocols from a recognised and functional Institutional Review Board (IRB). Unlike the Faculty of Medicine which has an IRB that is accredited by the National Council for Science and Technology (UNCST), the Faculty of Social Sciences has a ‘science committee’ which mainly handles the technical aspects of graduate students research and research directly funded by the university. This committee has little or no control over externally funded research carried out by individual members of the faculty. However, effective monitoring of the study sites to evaluate the extent to which researchers adhere to what is stated in the approved protocols is still lacking.

All respondents appreciated the importance of confidentiality although data management procedures were lacking in many. Twenty two percent of the participant appreciated the need for research subjects to comprehend the informed consent, 38% thought it was not always the case and in many cases their subjects did not have to understand it, while the remaining 40% believed that research subjects understanding of the informed consent process might not be necessary. More than 65% of respondents never give feed back to research communities unless the funding organization made it a mandatory requirement. However, there was a tendency to give feed back to communities where action research was conducted.

**Table 1.** Summary of Research Findings From the Unstructured Questionnaires

| Variable   | Adequate knowledge | Some knowledge | No Knowledge | Total |
|--|--------------------|----------------|--------------|-------|
| Understanding of research ethics                   | 11                 | 16             | 10           | 37    |
| 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 privacy/confidentiality              | 23                 | 3              | 11           | 37    |
| Importance of Participant understanding of consent | 8                  | 14             | 15           | 37    |
| Information handling                               | 7                  | 14             | 16           | 37    |
| Ethical review approval                            | 18                 | 7              | 12           | 37    |
| Feedback to participants                           | 5                  | 8              | 24           | 37    |

This was mainly because feed back to communities was inbuilt in the design and budgets of the action research projects. All participants stressed the need for formal training in research ethics in order to improve their understanding and appreciation of research ethics and this issue was re-enforced by the fact that the majority 73%of participants have never had formal training yet they continued conducting human subjects research.

### Discussion

Only 30% of the respondents understand what research ethics is, appreciate the importance of informed consent and understand the process of informed consent. Many did not seek approval of institutional review board before conducting research nor did they seek consent. This lack of appreciation of research ethics has affected many and caused scandals in different parts of the world.<sup>3-11</sup>.

On understanding of the study by prospective research participants, many researchers believe that research subjects 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. This situation is not limited to Uganda, as many studies around the world have been questioned especially concerning recruitment of subjects who have turned out to have no or little understanding of the study in which they happen to have participated in<sup>11, 14-17</sup>. And this further stresses the limited understanding and appreciation of

research ethics by the researchers especially in execution of their research projects. Majority of researchers do not usually give feed back to research communities unless the funding organization request so. Similar arguments about whether researchers have and or fulfil their ethical obligation to give feedback to the study participants have been raised in the past<sup>12,13</sup>.

Lack of feedback might breed mistrust and suspicion by the communities in which research is carried out. Regular feedbacks and inclusion of community representatives on Institution review boards where they exist as well as community advisory boards can contribute towards solving such issues. However, most of those who conduct action research do give feedback immediately which is also donor dependent. This suggests that there has been limited effort to educate researchers on the need for feedback to study communities as an ethical obligation.

It was observed that most of the research activities in the social sciences are donor driven, and the practice of research ethics is dependent on the demands placed upon researchers by the funding agencies. This is not unique to the Ugandan context since similar trends have been observed elsewhere in many institutions world over, most of the research is donor driven<sup>15,18</sup>. Sensitisation and advocacy for research ethics among donors may create an opportunity for scaling up the practice of research ethics among researchers. Functional institutional review boards exist in some institutions but even where they exist, there are variations in their

competence, performance and capacity to monitor adherence to what was stated in the approved protocols.

There was still considerable lack of appreciation, understanding and practice of research ethics from the majority of our respondents mainly due to lack of training, attitude or both. This was highlighted in situations where some respondents believed that their research subjects either did not understand or need not understand the informed consent but could be lured into accepting to participate by a mere promise of incentives.

Overall, more researchers from the medical faculty had a relatively higher understanding and appreciation of the practice of research ethics than those in the behavioural sciences. This is probably attributed to higher demands for ethical practice during clinical research, continuing education on research ethics during a particular study and a more rigorous review process in the medical faculty as compared to the social science faculty.

#### **Limitations of the study**

We did not have the time and resources to look at the documents and research reports of the study participants to assess how they had handled the issues of research ethics in practice. We largely relied on the interviews and some secondary sources.

#### **Conclusion**

There is still limited knowledge among researchers of the informed consent process during human subject research. Considerable lack of appreciation of the importance of informed consent is still a major problem particularly in the areas of research involving behavioural studies. And feedback to research communities is seriously ignored in most forms of research with exception of the action research in which feedback is part and parcel of the whole process.

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