KEMRI Bioethics Review

Vol VII, Issue 1

Research Ethics in Qualitative Research

Contents

A word From the Chief Editor

Prof Elizabeth Bukusi

I am pleased to bring to you the first issue of the seventh volume of the KEMRI Bioethics Newsletter. This issue focuses on the Ethical issues of conducting qualitative studies. Inside, Dr Dorcas Kamuya, a researcher from the KEMRI Welcome Trust Program highlights the ethical challenges in conducting observational studies. Ms Safari, a Research Officer at the KEMRI Center for Public Health Research writes on the ethical issues in qualitative research. Last but not least, Mariam and Cornel, both from SERU Secretariat shed light on ethical in issues in conducting research with prisoners and Ethics of observational research respectively.

In studying human attitudes, beliefs, and behaviors, researchers sometimes researchers rely on qualitative methods in their research. Qualitative studies may seem minimal risk to researchers compared to experimental studies. However, researchers should be cognizant of the fact that qualitative studies present its unique risks. These risks include psychological stress, social harm, economic harms and sometimes political harms. Additionally the risks of qualitative studies are difficult to predict, varied and may be difficult to deal with compared to physiological harms. It is thus vital that researchers understand the ethical dynamics of qualitative studies including the risk and benefits. Researchers must ensure that measures are in place to minimize risks through adequate informed consent, proper data management and even debriefing in case where deception is used.

Enjoy reading.

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The **KEMRI Bioethics Newsletter** is published every 3 months on the KEMRI website. We publish articles by KEMRI affiliated authors and from other contributors from all over instituitions within and outside Kenya. The scope of articles ranges from ethical issues in biomedical science, healthcare, technology, law , religion and policy.

The chief editor encourages submisssion of articles as a way of creating awareness and discussions on bioethics. Please get in touch by writing to ddrt@kemri.org

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A word from the Ag DDRD

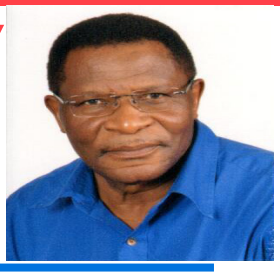
Dr Evan Amukoye

Welcome to this issue on the Ethics in qualitative research. Qualitative methods involve the use of several different ways of data collection including direct participants' observation, in depth interview, focus group discussion and other methodologies that have been refined by anthropologists and other social sciences over the years. Research studies that adopt qualitative method studies play a crucial role of complementing the experimental studies and answering research questions that experimental studies cannot. In social science, this methods are key in unearthing the social determinants of diseases and also evaluating human behavior in relations to prevailing health challenges of the populations. Qualitative research presents unique ethical challenges for researchers. For example, one common method of studying human behaviors is through direct observation of participants. In observational studies, researchers always run the risk of potential breach of confidentiality and privacy through inadvertent disclosure. Do you get permission to observe a person in a public set up? And if you do, does it alter their behavior when they know they are watched? The classic 'Hawthorne' effect? And if the behavior is altered, then the goal of the study may then not be achieved. Another example of the complexity of qualitative research is demonstrated in focus group discussions, another commonly used data collection method. In these discussions, the questions are not directed at individuals but at the common community views and behavior and practices. But this may inadvertently provide disclosure. For example, women in an FGD may realize that the questions are linked to being HIV positive. Or linked to thoughts about male medical circumcision for HIV prevention. This is further complicated by the nature of such studies that focus on behavioral and social issues because they could potentially put participants at the risk of being stigmatized- if a medical or social condition is associated with participation. This therefore calls for extra measures by the researchers to ensure that fidelity is maintained and that the researchers promise of maintaining privacy is upheld and assured- and where not possible that participants are informed of the likelihood of breach of confidentiality or information by their participation so that they participate fully aware of the risks they may encounter. Researchers conducting qualitative studies in KEMRI have the SERU at their disposal at all times for advice on such dilemmas and are advised to always consult with the unit when faced with questions or ethical dilemmas in the course of their work. The capacity of SERU has been enhanced, currently most committees have at least one expert in social science matters to help review studies that focus in this area. Ultimately researchers are held responsible for the safety and well being of the participants and therefore they should always be proactive and put the interest of participant at the forefront to ensure research is done at the utmost high ethics and scientific standards since the first rule in research and medicine is ' do no harm'. Qualitative research remains an integral and important part of biomedical science and research because much of prevention and treatment starts and ends with behavior. And interventions that provide for either promoting or preventing or treating any disease will be linked to the ability of participants and patients to utilize the innovation and incorporate it into their daily routines.

Ultimately researchers are held responsible for the safety and well being of the participants and therefore they should always be proactive and put the interest of participant at the forefront to ensure research is done at the utmost high ethics and scientific standards since the first rule in research and medicine is ' do no harm'.

A word from the Ag Director, KEMRI

Dr Yeri Kombe



Welcome to yet another issue of KEMRI Bioethics Review under the theme: *'Ethics in Qualitative Health Research.*

Qualitative approaches in health research have gained increasing popularity among health researchers globally and nationally including researchers at the Kenya Medical Research institute (KEMRI). This is due to: their ability to enhance the understanding of people's norms, beliefs, attitudes and behavior; as well as the recognition that interdisciplinary approaches have the potential to provide additional understanding to the complex health problems at stake.

Qualitative research methods involve a systematic collection, organization and interpretation of material derived mainly from talk and or observation. These research methods can be applied independently in a single study or jointly with quantitative methods where mixed methods designs are applied. Qualitative methods mainly include: in-depth interviews, focus group discussions and participant or non-participant observation.

Ethical consideration is critical for the qualitative studies as they present unique and complex scenarios that may be poorly understood by both researchers and research ethics boards. This is because the methods employed: are more intrusive into the everyday world of the study informants or participants; present a greater role of the researcher and study informants or participants' relationship hence, the need for ethical interaction. This necessitates a sound knowledge of the nature of qualitative research studies alongside appreciation of ethical consideration by both the researchers and ethical review boards for rigorous research and reviews to be conducted.

Risks to the participants in these studies may occur during data collection and after the data is collected.

KEMRI continues to strengthen the Scientific and Ethical Research Unit through incorporation of social scientists in the review sub committees to provide expert review of social science research. This measure is meant not only to protect the well-being of the research participants and informants but also to ensure that KEMRI remains an institution where research is carried out at the highest ethical standards.

Some examples of these risks are: during data collection, the use of in-depth interviews can delve into participants personal and sensitive matters that are either audio recorded, noted down or already transcribed data. If such material is handled inappropriately it may lead to the revelation of private and confidential information, which in public domain may be harmful to the participant. Secondly, ethical concerns on privacy and consent may be raised during naturalistic observation methods whereas, potential to the identifiability of the results in the write-ups by the study participants or other people. This calls for extra efforts to maintain confidentiality.

It is important for research scientists to be aware that the ethical issues in qualitative research are just as important as those in quantitative research. Hence, conducting this kind of research ought to be done responsibly whilst ensuring that all ethical principles are applied and followed This can be done by ensuring that participants are protected and respected, study informants or participants are treated equitably, benefits are maximized and any harm minimized at all

times. When considering ethics in qualitative health research, scientists ought to be cognizant of two fundamental questions that address the following: how to interact with the subject during the procedures in the research and how to collect, manage, analyze, interpret and report the data.

How researchers interact with their participants depends on the level of professionalism, their knowledge on ethical conduct and the prevailing ethical code of conduct that regulates research in that context. There are rarely any black and white answers for ethical dilemmas therefore researchers need to understand their foundational scientific and ethical principles that anchor their professional conduct for research on human subjects.

All ethical codes of conduct that regulate biomedical research at KEMRI also apply to social and behavioral research studies, however, if there is qualitative research protocols that presents other unique challenges that may be linked to cultural and social values, it therefore calls for the researcher to work in close consultation with the Scientific and Ethics Review Unit (SERU) to navigate such cases together and critically evaluate the implications of the conclusion to ensure that the best decision is reached for the wellbeing of study participants.

Ultimately, sound knowledge in the nature of qualitative research for rigorous scientific and ethical review is needed to address the needs arising from diversification of research portfolios that include fields like social science and behavioral research. KEMRI continues to strengthen the Scientific and Ethical Research Unit through incorporation of social scientists in the review sub committees to provide expert review of social science research. This measure is meant not only to protect the well-being of the research participants and informants but also to ensure that KEMRI remains an institution where research is carried out at the highest ethical standards.

I wish you enjoyable reading.

Dr. Yeri Kombe

Ag. Director & CEO, KEMRI

Ethical issues in qualitative observational research: Experiences from Coastal Kenya

Dr Dorcas Kamuya and Vibian Angwenyi
KEMRI Wellcome Trust Program-Kilifi

The role and contribution of observation methodology in qualitative research is widely acknowledged [1, 2]. While observational research is used to refer to different types of health research including audit, epidemiological and clinical studies [3-5], in this paper, we focus on observation as a social science method used in qualitative research [6]. Observation refers to a methodology where the researcher observes naturally occurring processes, behaviours and practices, and makes sense of the lived social life [1]. Observation is sometimes lauded as the equivalent of Randomized Controlled Trials (RCTs) in epidemiological studies [1], due to the ability to observe things as they happen naturally, as opposed to interviews where social desirability - the ability of the respondent to give responses a problem. There are diverse observation methodologies, ranging from formal once-off checklists to ethnographic observations where the researcher lives and is immersed in the daily lives of the community/group being studied for long periods of time (sometimes years) to develop a deeper understanding of the phenomenon. Between these two end of the spectrum, many social science researchers incorporate observations into their studies, spending variable periods of time (days, weeks, months) [2] observing activities and interactions. Mays and Pope (1995) summarised the different types of observation as shown in box 1 below. Each of these types of observations has pros and cons which need to be carefully considered in advance.

Box 1: Observational research roles [2]

Type of observation	*Key Features*
Complete Participant	Researcher is fully involved in activities of those being observed, and participant may not be aware that they are being observed (also called covert observation)
Participant observation	Mutual awareness of the research; participants are aware of the researcher's activities (also called overt observation).
Observer as participant	Essentially a one shot interview with no enduring relationship based on lengthy observation
Complete observer	An Experimental design research is not at all involved in the activities of the participants and tries to be objective in their observation.

In this article, we draw on our experiences of undertaking observation in different forms of observations in social science studies that were examining practice in biomedical research, to discuss some of the ethical challenges that researchers may experience. We also draw on our knowledge of how we handled these challenges to suggest ways to address them. As shown in Box 2 below, in each case, our observation work was part of wider social science studies, and hence the data we collected fed into and complemented information we collected using additional methodologies (such as individual and group interviews of various forms, and semi-structured surveys).

Box 2: observation work informing this paper

Dorcas carried observation as a part of wider set of a social science study which aimed at exploring the nature of interactions between fieldworkers and research participants in community-based studies, the challenges that fieldworkers faced, and if and how these challenges were resolved. This work has been published elsewhere including details of the observation method used [8]. Two different community based studies were purposively selected for the social science study; an observational basic science study involving examining respiratory syncytial virus transmission patterns (case study 1- CS1) involving entire households (n=47); and a malaria vaccine trial involving 900 children from Kilifi(case study 2- CS2). Participant observation was used in both studies as a first set of data collection method to provide first-hand information of the context in which FIELDWORKERs worked and the type and nature of interactions between fieldworkers and different householders. Dorcas carried out participant observations for a total of 4 months in the CS1 and 1 month in CS2. Considerable time was spent CS1 to get deeper understanding of the range and depth of issues in fieldworker-participant interactions. Less time was spent in CS2 as the aim was to explore the extent to which findings from CS1 were generalizable to CS2.

Vibian carried out observations as part of social science study (see [9]). The study aimed at documenting consent and community engagement processes for a multi-centre malaria vaccine trial (same as case study 2 described above), and describing stakeholders perceptions and understanding of trial activities/implementation process. The type of observation adopted for this study was in-between non-participant and participant observation (depending on activity being studied), and was carried out by a team consisting of Vibian and 2 to 3 social science fieldworkers. Since this social science study was embedded within the trial running for six years, observation lasted for weeks/months depending on the activity being studied. These activities included: study planning meetings; community entry and sensitization meetings; recruitment and informed consent processes; study procedures including vaccination, follow-up visit at health facilities and homes; feedback and dissemination activities; and trial closure. For each activity a semi-structured observation tool was developed. Brief training sessions were held with data collection team on how to capture and document information in the tools i.e. both verbal and non-verbal. The tool had a section capturing observers' reflection of the activity including ethical issues emerging and how these were handled

Ethical considerations while undertaking observation research

Hawthorne effect on observation work

As we have mentioned above, if people are aware that they are being observed as part of research, they are likely to modify their behaviours and practices; often referred to as the Hawthorne effect [1]. This is a core issue for consideration in observation. There are ways in which the Hawthorne effect can be minimized including undertaking covert observation (in which participants are not aware they are being observed) and spending extended time with those being studied and participating in their daily activities to the extent that they recognise the researcher as one of them; over time people often revert to their normal behaviours and practices [2, 10]. Our observation work carefully considered the effect we may have on behaviours and practices of those we were observing. For example, Dorcas spent a considerable amount of time with fieldworkers particularly in the Case study 1, worked alongside fieldworkers, and was immersed in the fieldworker roles and activities to the extent that she was often referred to as one of the fieldworkers. The fieldworkers appeared to identify her as one of them, for example, when assigning roles and discussing issues. She helped/worked in non-technical parts of the study, and walked with fieldworkers to households as per scheduled appointments, sometimes as early as 5.30am in the morning - the times that most household preferred to be visited as all members would be home. Due to this immersion and living the life of a fieldworker, she gained insights into the daily work-life for a typical fieldworker, including challenges and dilemmas they faced. These were important information for her study and helped in the development of question guides for use in interviews with participants in her social science study.

For Vibian, early phases of observation involved a short stay in the field with the fieldworkers, shadowing them in their chores, and visiting households to invite parents of potential study participants to meetings. In addition, she spent numerous amount of time documenting the trial community engagement activities, tagging along with the study team to meetings with stakeholders and communities. During this visits she would take notes of the meeting proceedings and share these with the trial team. These visits gave her first-hand experience of issues of concern

for fieldworkers and for community engagement activities, and of study teams addressed these issues. The observation provided an opportunity for Vibian to immerse herself in the world of fieldworkers, and to be accepted within their group. This was necessary as it enabled her to continue carrying out work including accompanying the study team (fieldworkers and clinicians) to households where there were refusals, observing and unpacking the dynamics in interaction between the fieldworkers, study participants and the study team Principal Investigators; which would have been difficult to unpack using other methodologies.

This process of being immersed in the daily lives of the people we were studying was important in creating relationships with our key informants, which facilitated our deeper understanding of the lived social world of the participants. These relationships seemed to matter to all of us, formed the basis by which those we studied felt free to open up and invite us in to their social worlds. As we discuss below they also presented challenges when it was not very clear to us which of the many roles (that of being a researcher, a colleague, a mentor, a friend) would be appropriate for different situations we encountered. However, the relationships helped minimise the Hawthorne effect we would otherwise have experienced had we conducted rapid observation work.

Informed consent: if and when is it appropriate

An area of considerable debate in the literature is about when and what type of consent would be appropriate when undertaking observation [11]. The dilemma with consent forms and information is that, once people are aware that they are being studied they are likely to change their behaviour and practice to what is desirable [7], which has the potential to affect the results of the study e.g. masking unethical practices which could have implications on policies about practices that might otherwise be assumed to be working well. On the other hand, it is the right of the participants to be informed of their involvement in research and to give consent for the research to go on. While we recognise the appropriateness of informed consent for observation research can vary depending on what the research is about, in our case, consent was sought from those who were directly involved in the research. This is because the type of social science studies we were conducting (and the practices we were observing) were particularly not sensitive. Right from the beginning, we made sure that the study teams and the respondents for our research were aware that we were researchers; and we sought consent from all those who were involved in our research. This was essential in building appropriate levels of trust with our participants and for our research to be successful.

Whom to seek consent from

Observation inevitably includes considerable interactions between the research team and those primarily being studied, as well as others. A concern related to informed consent is the extent to which consent can be sought from others who interact with the primary participants but are not themselves the focus of the observation work. We noticed for example that in the households we visited, guests, neighbours, other relatives dropped in all the time, particularly during research procedures (such as collecting nasal swabs, or filling in questionnaires). Those of us observing trial activities and responses to them were often considered visitors who had come to the household and people were curious to know of our intentions. At that point, we had no power or authority to determine who interacted with the household and what information got shared. The way the visitors interacted with the household and with fieldworkers we were observing was particularly informative of our research e.g. in informing us what neighbours thought about the work of KEMRI and the research that goes on (with implications for whether study team needed to be refreshed about these kinds of information). It also contributed to deeper understanding of the dynamics between frontline research staff, participants and communities hosting a research, as we have published elsewhere [9, 12]. While we did not seek consent from the visitors who came to the households, we were careful in our documentation to focus on our primary respondents. Where given the opportunity, we requested the household head or family member to introduce us to the visitors and inform them of the reasons for our visit. We also noticed that after a few minutes, the visitors would leave.

Handling Sensitive and confidential information

It was inevitable that close relationships developed and evolved between the researchers and the primary respondents in the studies we conducted. Fieldworkers and research participants felt free and considered us their colleagues, peers and sometimes mentors and felt that they could open up and share some deeply private and confidential information they had [12]. These ranged from family issues, marital, career advice and social issues that they were facing. Others were more specific to the studies for example, instruction that they felt were difficult to implement in practice but were concerned that if they pointed this out to their superiors they may be seen as incompetent or resistant to change. We also observed practices that we felt might not have been appropriate, for example, a fieldworker filling part of the information forms and indicating that they will fill the rest when comfortably seated in offices. In those moments, we the researchers had to weigh out what the appropriate way to respond would be. Simply observing and not doing anything about such behaviour did not seem adequate. We were also aware that if we acted hastily and forwarded these issues to the superiors without first understanding what led to these practices may not be help in addressing the underlying factors. It helped that we were working with teams of social scientists with whom we discussed these issues and possible ways to respond/address, while also not jeopardizing our research. These included;

- *Gathering advice from other more independent people; social science researchers at the research centre who were not part of the study teams we embedded our research.*
- *Reflecting on the issue with those being observed, to find out what contributed to the practice.*
- *Encouraging fieldworkers to discuss with their supervisors and PIs some of the challenges that contributed to these practices, and to suggest ways to resolve them.*

We were also part of an institutional team set up for each study to advice on practical and ethical issues encountered during research implementation. Through this system we had opportunities to follow-on and see if the actions were implemented, as reported during weekly study team meetings. In doing either of these roles, we were aware that we stepped out of the researcher role onto an interventionist role, but felt this was justified by the potential implications if such issues/practices were not addressed.

When to feedback research results

Wherever possible, it is expected that research results will be fed-back to those who contributed or were involved in the research [13]. This is one of the markers of ethical research conduct. During our proposal development we carefully considered the implications of feedback of research results to the participants (study teams and host community) of our study, and provided such feedback at the end of our research. However, a particular challenge we experienced was whether to feedback to individual study teams in which we had embedded our research immediately after data collection and before proceeding to another data collection/subsequent case study. The study teams seemed to expect this as they felt that the immediate feedback would be useful in highlighting areas that needed to be considered/addressed immediately; waiting longer (e.g. for months or years) to get the feedback seemed redundant. They also felt providing immediate feedback to the study would be our way of reciprocating to them (showing appreciation and being useful to the team) for allowing us to embed our research in their studies. We were aware of these expectations, and tried to address them as early as possible at the time we introduced our research to the teams. However there were particular concerns with giving feedback that is specific to a study team immediately after our data collection. To start with, the data was likely to be raw since systematic analysis would not have been done. Secondly some of the issues would be very specific to that study team and to particular individuals, including private and confidential information that we got insights of –information we found useful in helping us understand underlying issues affecting study teams. Sharing such information early on, however, risked compromising the confidentiality bestowed on us as researchers. In addition, we were aware that the carefully established relations with the study team may be compromised and that we may be seen as study monitors and evaluators of ethical research conduct, rather than as researchers interested in understanding everyday issues that study teams encounter. These are some of the issues that we need to consider and weigh carefully. In the end, we fed-back research results to all the study teams, and ensured that we generalised findings as much as possible. We also provided feedback to individual teams as soon as we finished data collection in the specific studies and were careful to emphasize that these were preliminary findings.

The value of reflexivity

One of the markers of good qualitative research is the researcher's awareness of how her position, knowledge, perceptions and biases shape and influence the research she undertakes. This is inevitable. However, it is particularly important that in addition to this self-awareness, the researcher is honest and transparent about this upfront and throughout the research cycle, that is, reflexivity is in-build throughout the research [14]. In addition, the researcher needs to be aware of situations that need her objective and distanced view, and those which require her to identify with and add her subjective views. These are positions we identified with throughout our observation work, as alluded to in the previous sections. Throughout our observation work, we had numerous sessions of self-reflection with our supervisors and mentors. This we found useful as there was potential to be immersed in our research and to lose the researcher focus. We were aware of the multiple roles we played and the different expectations these placed on us (expectations from others and from ourselves). Being articulate about our different roles and identities upfront was helpful in managing these expectations, and in unpacking the multiple layers of the phenomenon we were studying. An aid to this process was the continuous use of diaries and journals, and semi-structured observation tools.

Conclusion

Qualitative observational research is argued to be one of the best research designs used to study unfamiliar areas/topics which other 'traditional' study methods cannot reach. Further to this, it is valuable at the formative stages of research through gaining deeper perspectives of a topic which helps in designing other research instruments such as interview topic guides. However, researchers intending to use this method would have to carefully weigh the strengths and limitations of this design. As in any social science research, observation data needs to be triangulated with data from other sources to increase rigour and depth and to aid in the interpretation of study results.

A grey area for most researchers using observation is that there are no equivalent 'good clinical practise' guidelines or even standard operating procedures on several ethical issues, some of which we have discussed above. For instance, at the ethical review stages, the need to justify in protocols how consent will be obtained for observation methods, from whom and how it will be documented maybe required. Equally such requirements maybe needed

during publication and peer-review processes. In addition, the drive towards open-access data sharing adds another layer of complexities for researcher working with observation data, balancing between sharing anonymised raw data and adhering to confidentiality and privacy clauses. All these factors place certain responsibilities on primary researchers to consider carefully at the outset the type of observation method that will be most appropriate for particular research question they are interested in, and to justify if, when and from whom consent will be sought. It also requires that research anticipate some of the ethical challenges that their observation work may present and device approaches to address these. It necessitates researchers to be transparent about the dilemmas they encounter and to share experiences about how they addressed these, and of the challenges that could not be addressed, because such information can inform ethics review processes, and can contribute to strengthening ethical conduct of research.

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Research Ethics in Qualitative Research

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Qualitative approaches have gained their rightful place in health research. Whereas quantitative approaches present phenomena in numerical form giving a snap shot of situations, qualitative approaches tell us why these statistics present themselves in the way they do. Qualitative researchers argue that this is the core of problem solving as the 'why' and 'how' of an issue highlighted sets the stage for effective interventions in public health. A commonly held prejudice is that qualitative research is unlikely to cause significant harm to participants. This has lead to the lack of discourse on ethical issues specifically surrounding qualitative research and how the basic principles of ethics should be applied in qualitative research.

Researchers who work with human subjects are faced with a myriad of challenges and issues be they individual, regional and or international, societal issues, human rights, health & safety in political as well as legal arenas. As the sole purpose of ethics in health is to protect the participant from possible harm or risks, ethics is a requirement of health research and yes qualitative (observatory) research too. "Primum non nocere" or first do no harm is just the foundation for building of ethics in health research.

By its very nature, more complex ethical issues permeate qualitative studies. This is because qualitative research methods involve in depth investigation of a subject hence more interactions and relationship building with participants; the researcher is more intrusive than in quantitative studies. Potential risks to research participants in qualitative research include anxiety and distress, exploitation, misrepresentation and damage of reputations. Express identification of the participant is a possibility as audio recordings and transcripts although made 'anonymous' may reveal clues as to who the participants are and or their social groups.

Application of ethics in qualitative research involves a delicate balancing act with the dignity, rights, safety and well-being of participants being the primary consideration and achievement of study goals. By nature, qualitative research deals with in depth probing of issues and can pose emotional and other risks, discomforts and inconveniences to both participants and researchers. Unfortunately, these risks are often underestimated. The 3 core principles of human research (beneficence, justice and respect for others) are still applicable.

Beneficence

Beneficence has always been seen as fundamental to human morality; the word itself implies mercy, kindness, charity and the promotion of the greater good of mankind. In research, it highlights moral obligations of researchers to act for the benefit of participants. The role of a researcher demands beneficence through harmonizing anticipated benefits with potential risks, promoting good and preventing harm of participants.

The responsibility of the researcher in ensuring this principle is applied beginning with the design of the study all through to its subsequent articulation. Meeting study goals is key however addressing the welfare of the participants in the case of any malpractice, protection from any potential risks and identification of potential benefits is paramount. Anticipating and identifying risks and planning to mitigate them sets the platform for an ethically sound study. Researchers should provide clear procedures for dealing with anxiety, distress or discomfort so that both parties involved in research can use them if it becomes necessary.

The likely benefit of the research must justify any risks of harm or discomfort to participants. During a study where risks to participants are no longer justified by the potential benefits, research must be suspended for considerations into any modifications required before the study can proceed. With qualitative studies, there is constant involvement and for prolonged periods with participants which may vary situations, hence the need for researchers' understanding and flexibility in venturing into new evolving directions.

Justice

Justice calls for fair treatment of participants with no exploitations related to age, gender, sexual orientation, race or religion. Consideration to be made on vulnerability of some persons in the society as well as equitable distribution of risks, benefits, any inconveniences, opportunity costs involved and equal chances of participation are given. Some of the inconveniences experienced include interviews lasting for at least an hour, group discussions lasting longer and the need for the participant to travel to a central place for the interview or participants allowing the interviewer into their home for which participants need to be compensated. Compensation presents direct benefits of the study to participants.

Arguments against compensation of participants postulate that reimbursements introduce some bias and that incentives in research are unethical presenting undue influence. Proponents of participant compensation present evidence that shows that 'paying' respondents in surveys increases response rates, addresses financial burdens of participants and equalizes the power play between researchers and respondents. Despite such arguments, there does exist some kind of compensation for participation in qualitative studies however the question often asked is how much?

In considering this, justice details that the needs of research participants should always come before the objectives of the study. Amount of time taken or inconvenience caused, levels of participation required, area of study as well as difficulty of recruitment of participants for the study are key in decision making for compensation. Researchers could also consider other incentives other than money such as branded items, payment in kind etc. Either way this compensation shouldn't be the rationale for participation in the study.

Other considerations to participants include researchers keeping time; don't be late or early. People have given up their time to participate in the interview/ discussion so be thoughtful and courteous. Conduct sessions in a sufficiently structured way so as to start and end sessions on time. Observe time management during sessions by breaking down discussion guides and interviews schedules into manageable minute by minute sections and use a clock to monitor these times. Time management is a skill that most people have to learn so take time to practice.

Respect

Interpersonal respect in qualitative studies plays a significant role in the esteem felt within the research relationship. For qualitative researchers, the capacity to respect their participants should be at the forefront of their research practice as it demonstrates high regard for participants and their contribution (s). Actions that show respect include courtesy, listening, and sensitivity to participants' concerns.

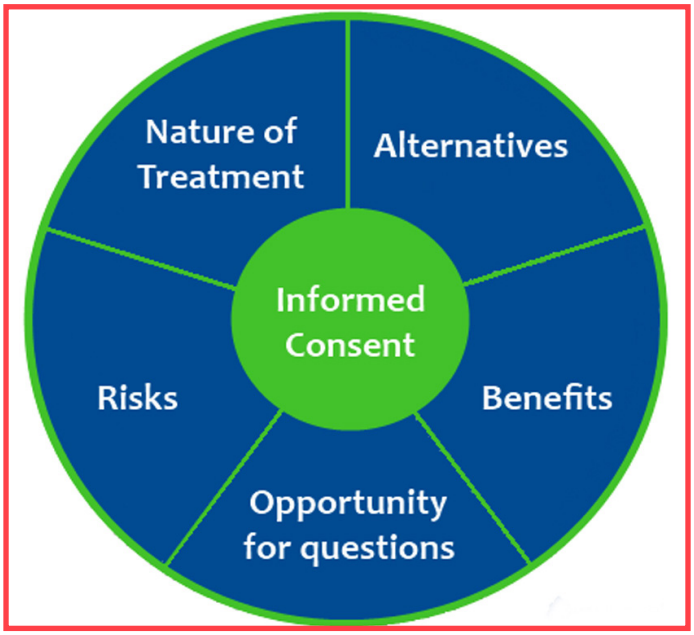
As respect means different things in different social settings, it requires having due regard for the welfare, beliefs, perceptions, customs, privacy, confidentiality and cultural sensitivities of the participants and, their communities. It is through respectful interactions between researcher and participant that trust and mutuality can be cultivated. How respect is evidenced can vary from person to person, however, the continual cultivation of respect between two people in a relationship (in this case researcher and participant) can help to foster trust which in turn will elicit honest responses in a qualitative study. To be avoided is unequal involvement of participants which can prevent the growth of trust and weaken research relationships.

Respect does inculcate trust; futuristic trust. Ongoing trust in health research is paramount for participation in future research. This justifies the need and use of Informed consent even where minimal risks are anticipated. Any specific agreements made with the participants or the community should be fulfilled. Always recognize the capacity of participants to make their own decisions but where this is not possible for any reason, empowering them where possible and providing for their protection is key in evidencing respect. Qualitative researchers have an immense responsibility to avoid misrepresentation

of participants, evaluate what he or she observes and to interpret it correctly to better extract reliable information. Researchers can evaluate if they was sufficient reciprocal respect and maintain emotional distancing during the session through explicitly seeking feedback from participants at the close of the session. This in turn may offer researchers the opportunity to monitor their capacities to respect others which can only lead to improvement in the practice of interviews and discussions.

Informed Consent Form (ICF)

Consent has been seen as a state of mind; a conscious decision to participate or not to participate in a study. Participants make their decision based on a description of the study given in the ICF, hence the need for the description to be as detailed as possible. The ICF needs to adequately address the above principles of beneficence, justice and within the context of the research. More so qualitative researchers are obligated to obtain informed consent from all those who are directly involved in research and in some instances other relevant persons. Relevance is considered where there is power play between participant and researchers for example with students and teachers who may feel duty-bound to participate. In such a case a higher authority 'equal' to the researchers' perceived power position would also give consent in addition to individual participant consent(s) example the head teacher. In qualitative studies consent should be a process rather than an event; it needs to be negotiated throughout the course of the project as events emerge.



A summary of obligations, risks and benefits involved in the study are articulated in the ICF or a separate sheet attached to the ICF. The use of consent adheres to principles that pronounce that respondents are not coerced into participation and have access to relevant information prior and during the study. Consent gives assurance of confidentiality of information shared, options for withdrawal from the study, anonymity by not revealing the identity of the individuals and institutions involved outlines of risks and benefits involved.

Consent is seen as valid if the participant is *informed* in detail of the study, is able to *understand* the descriptions given and agrees to *freely* (autonomy) participate in the study. The necessary elements of consent for a study are identified by review committees. Lack of informed consent can be used to establish negligence and malpractice in research and inaccurate description of the study can be construed to mean that there is no consent.

Conclusion

Ethical issues are therefore an integral part of the qualitative research design. As qualitative research attempts to generate knowledge which is rooted in the reality of individuals, communities and societies, the importance of reducing inequities, biases and applying sound ethical principles should not be underrated. Application ethical principles will assure quality of study, scientific rigor, dependability and credibility. There is therefore a need for standards of best practice to guide how best to apply these principles into qualitative research.

Research Ethics in observational research involving prisoners

By Mariam Macharia
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Who is a prisoner?

According to the Merriam-Webster dictionary a prisoner is: a person deprived of liberty and kept under involuntary restraint, confinement, or custody; especially: one on trial or in prison. In US Code of Federal Regulation (CFR) 45 Subpart C defines a prisoner as follows: "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing." (45 CFR 46.303(c))2. It also includes those confined to drug or alcohol rehabilitation centers.

From history, research involving prisoners has had episodes characterized by controversy, cruelty and exploitation. It is in this context that brought light to the need for research regulation guidelines to avoid a repeat of the historical atrocities. Some of the atrocities highlighted within history of medical research include but not limited to: In Germany, during the WWII, German doctors carried out experiments on Jewish prisoners by subjecting them to pain, extreme temperatures, torture and their bodies observed on how they reacted to the various forms of torture. The 1998 experiments at Holmesburg, Philadelphia where Prisoners were used to test the toxicity of cosmetics instead of the use of laboratory animals for testing and the atomic experiments where prisoners were irradiated in research conducted by the United States Atomic Energy Commission, rendering some sterile and others badly burned.4

In historical times and even today, prisoners are the easiest study participants to access. This is due to the fact that they are confined thus it's easier to observe them. Unlike free people, they are also easy to follow up for a re-assessment of the study findings. Free people can easily move from the study site or withdraw from a study. Prisoners can also easily be forced to participate in a research by the authority to which they answer to. This is mostly what led to the Government of the USA using prisoners to test the atomic energy impact. Eventually human rights groups and prisoners rose up to file a suit against doctors, governments, pharmaceutical companies who were involved in these experiments. The suits were part of the seeds that eventually gave birth to various ethical guidelines to protect prisoners from harm and involuntary participation in research.

The Nuremberg code gave prisoners the right to be informed on all aspects of the study and a right to decide whether to participate and also withdraw from any study. The Department of Health and Human Services (HHS) regulations at 45 CFR Part 46, subpart C details guidelines on review of the documents and protection of the prisoner. The guidelines also classified Prisoners as vulnerable populations. This is due to the fact that they can easily be coerced to participate in research and the fact that they are incarcerated might affect their decision to give informed consent.

REVIEW PROCESS AND ETHICAL CONSIDERATIONS

Observational research using prisoners focuses on behavior characteristics and modification. Behavioral characteristics seek to understand factors that lead to crime such as racial, family background, level of education, social class. Behavior modification looks at the effects of prison offered services e.g. counseling, drug addiction rehabilitation on the prisoner and their effectiveness.

The review process of a proposal with prisoners as research subjects requires special consideration considering the diminished autonomy of the Prisoners. The principal investigator has to get ethical approval first and clearance from the prison authorities of the specific facility that he/she is going to carry out the study. The IRB has to identify a prison representative i.e. prison warden, penitentiary officer and any suitable representative who is not in charge with prison affairs in a way that they can influence the decision of the prisoners. Additionally the representative must have both experience and appropriate background to review the proposal and sit in the IRB meeting where the proposal will be discussed. The prison representative will sit at the convened IRB meeting during the full life of the proposal including; initial review, continuing review, full-board modifications, and reportable unexpected or unanticipated problems. The majority of the IRB members must disassociate themselves with prisons or if having any association e.g business or leadership roles with prisons declare conflict of interest.

The study must be no more than minimal risk. This means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. The IRB must weigh the risk benefit ratio and ensure the risks do not surpass the benefits. The benefits must also be very specific to the prison conditions. The IRB must ensure that the objectives can only be met if the study is only carried out in prisons. The Office for Human Research Protections (OHRP) – in the USA, sets the criteria for studies which can be allowed using prisoners. For behavioral science, the study may focus on criminal behavior, its possible causes, effects processes of incarceration, and of criminal behavior or the prisons as institutional structures and the conditions particularly affecting prisoners. The study findings must be aligned to help improve the wellbeing of prisoners within the federal system.

Participation should be fair and voluntary and selection should be random. The IRB must ensure that the benefits indicated are not used to lure prisoners to participate in the study. Some behavioral incentives include that may be used to lure prisoners to participate include; flexible sentences, indeterminate sentences, behavioral therapies during imprisonment, and parole and probation based on evidence of rehabilitation etc.6 The principal investigator should also ensure that prison wardens do not force prisoners to participate as they are the authority.

Each prisoner must be consented as an individual. All study procedures, risks; benefits should be explained to be prisoner prior to participation in a language he/she understands. The prisoner despite being incarcerated must also sign or append a thumb print to his copy of the consent form. The Prisoner is also at will to withdraw from participation in the study. The Prisoner should be at liberty to ask any question regarding the study which the principal investigator should answer without withholding any information.

Confidentiality of both the prisoner's personal data and information given regarding the study should be maintained. The Principal investigator should seek to protect the participant from any discrimination that may occur due to them participating in the study. Interviews should be conducted in privacy. The information gathered should not contain the prisoners name or bio data that can lead back to identification of the participant. The data should be de-identified and code names used instead of real names. The data gathered should only be accessible to the principal investigator or the study coordinator.

Adequate provisions must be made for the prisoners to be able to access the right standard of care. This is to ensure that despite their incarceration, their dignity as a human beings is maintained. Counseling should be provided without charges in case of depression during participation. In case of injury due to participation in the study, the prisoner has a right to access medical care. In case of clinical trials, the principal investigator must ensure that the study drug is accessible to the prisoner even after completion of the study. This stipulation should be made in the proposal.

In situations where a study participant has been arrested and sentenced to prison, the Principal investigator should withdraw him from the study. In case where his withdrawal will cause more harm than good, the principal investigator should inform the IRB. The IRB should then re-review the proposal and enlist a prison representative as required by CFR 45 Sub part C. Prisoners are humans. Their imprisonment shouldn't be taken as an opportunity by researchers to use them as their guinea pigs in their experiments. They should be respected, protected from harm and injustices. All scientists be it social, behavioral and clinical should always remember to abide to the three universal research guidelines highlighted in the Belmont report; respect for persons, beneficence and justice.

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Research Ethics in observational Research.

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Observational studies are invaluable to to human health. By using personal information for public good, observational studies points out the vital evidence about our health and how best to protect and improve life and health. For this to be achieved, observational studies must uphold high ethical standards.

Observational studies are relatively low-risk, and this is because, first, the investigators observe and analyze information about health or malfunction but do not alter the care or services that people receive. Secondly, a potential for conflict between the investigator role and the clinician role is greatly decreased. Observational studies differ from intervention studies, in which investigators intentionally alter people's care or services to study the safety and benefit of doing so. The term 'observational studies,' refers to epidemiological and clinical observational research including audits and related activities which also share ethically relevant characteristics with observational research. Most observational research is epidemiological or health services research, however some observational studies, including most case series and case studies, are conducted by clinicians in personal care settings. Observational studies may involve recording, classifying, counting and analyzing of data takes place while intervention studies include randomized controlled trials.

Types of observational research

Adapted from:Ethical Guidelines for Observational Studies Revised edition, 2012

The purpose of observational studies is to contribute to generalizable knowledge about a life or health issue. This objective can be achieved by the different categories of observational studies as discussed below:

Case control: these studies examine the relationship between an attribute and a disease by comparing those with and without the disease on the presence of the attribute or level of exposure to it. *Cohort studies:* they examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease (or other outcomes) by observing scores of people over a period and comparing incidence rates of the disease (or outcome) about exposure levels. A cohort study may be a clinical cohort study (for example, where a group of patients with a given disease is followed to examine the prognosis). *Cross-sectional:* these studies examine the relationship between diseases (or other health-related characteristics) and other variables of interest in a defined population at one particular point in time, by collecting health and other information concerning members of the population. These include questionnaires or surveys done for research purposes. *Case reports:* they are detailed reports of cases from health or disability services or research settings. Case series: describe a set of cases of a disease (or similar problem). For example, a clinician may assemble a case series on a topic of interest, such as an unexpected adverse effect experienced by patients taking a particular medication. *Descriptive studies:* examine the existing distribution of variables in populations, for example, analyses of cancer registry data or emergency department data by person, place or time. Audits and other related activities which can be considered "observation studies" include program evaluation, evaluation studies, quality assurance activities, outcome analyses, benchmarking, public health investigations, public health surveillance, pharmacovigilance (post-marketing surveillance) and resource utilization reviews.

Ethics of Observational Studies

Investigators overseeing the implementation of observational studies are responsible for ensuring that their studies meet ethical standards. This is a necessity whether or not review from an ethics' committee is required. When there is more than one investigator, the principal investigator has the overall responsibility for the ethics of the study. Greater care is needed in assessing and addressing the ethical issues of the more than minimal risks associated with observational studies. Some observational studies such as the public health investigations do not require ethics committee review. This is because they are necessary for the protection of public health as a central part of healthcare practice, and they are often of an immediate or urgent nature, and legislation often requires them. However, it is not at the discretion of the investigator to determine whether an observational study requires an ethics committee review or not. Investigators should, therefore, submit the studies to ethical review committees for review either as an exempt, expedited, or full board review studies. The underlying general ethical considerations for observational studies include the three general ethical principles; respect for persons, justice, and beneficence. Other considerations for the conduct of the observational studies are integrity, diversity, and conflict of interest. *Respect for persons* involves the two fundamental elements of autonomy which requires that people who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination, and protection of people with impaired or diminished autonomy, which requires that people who are dependent or vulnerable be given additional protection against harm. *Justice* is an obligation that, within a population, there is a fair distribution of the benefits and burdens of participation in a study, and for any participant, a balance of burdens and benefits. *Beneficence and non-maleficence* is an obligation to avoid or reduce risks and harm. The risks of a study should be reasonable in the light of the expected benefits. Investigators should consider the features of a proposed study in the light of ethical considerations, and satisfactorily resolve ethical issues raised by the study. Not all ethical considerations weigh equally. *Integrity* obliges an investigator to commit to the advancement of knowledge by conducting an honest and thoughtful inquiry and rigorous analysis and to be accountable for the activities in a study. Investigators should understand, respect and make due allowance for diversity among participants and their communities in regards to the diverse needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values when conducting or implementing observational studies. Investigators should reveal to co-investigators, sponsors, employers, participants and, where applicable, ethics committees any perceived, potential or actual conflict of interest about the study. Such conflicts of interest can compromise the design or conduct of a study or the credibility of its results, thereby exposing study participants or others to unnecessary risk, harm or inconvenience. Conflict of interest should be minimized at all cost and times.

Risks associated with Observational Research

Adapted from:Ethical Guidelines for Observational Studies Revised edition, 2012

As adopted from the "National Ethics Advisory Committee. 2012. Ethical Guidelines for Observational Studies: Observational research, audits, and related activities. Ministry of Health, New Zealand": Any observational study that has one or more of the features identified in the table below can be considered as a more than minimal risk observational study. A more than minimal risk observational research requires ethics committee review.

DEPARTURE FROM NORMAL CARE	
Something withheld from or done to a patient that deviates from normal health care constitutes more than minimal risk (for example, when extra blood samples or biopsies are taken).	
Use of stored samples	Exception
Use, collection or storage of human tissue without informed consent and use of stored samples for study purposes other than those for which they were originally collected constitutes a more than minimal risk activity.	Exceptions to this rule include: • Where the individual has consented to the use or disclosure • Where the information is not identifiable • Where a statutory exception to the need to gain informed consent applies • Where secondary use of data is for the purpose of quality assurance or outcome analysis • Where resource review is undertaken by those employed or contracted by the health or disability support service provider holding the information. The justification for this is that the use is related to the primary purpose of the data collection, and in such settings only individuals bound by a professional or an employment obligation to preserve confidentiality should have access to identified or potentially identifiable information
Vulnerable participants	
A study poses more than minimal risk where one or more participants are potentially vulnerable. Vulnerability participants have a restricted capability to make independent decisions about their participation in a study or lack the ability to consent freely. Non-exhaustive examples of potentially vulnerable people include: Children, pregnant women-fetuses-neonates, prisoners, and people with mental illness/ serious intellectual disability.	

National Ethics Advisory Committee. 2012. Ethical Guidelines for Observational Studies: Observational research, audits and related activities. Revised edition
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