At present, it is observed that a notable proportion of research projects particularly targeting public health outcomes employ mixed methods, a combination of quantitative and qualitative research methods across the globe (1-4). This trend is evident in Sri Lanka too, where a research culture and the need for evidence based decision making are slowly attracting recognition.

Qualitative and quantitative research methods stand on distinctly different theoretical underpinnings (5). Owing to their training, health professionals are mainly oriented to look and understand the world through quantitative lenses. Only a limited number of health professionals are adequately trained and experienced in the use of qualitative methods (6). On the other hand, many professionals with social science background show interest in health research, some of whom are well-equipped with knowledge and skills on qualitative research, but lack or have extremely little understanding on the health systems functioning, and therefore less sensitivity on the nature of health-related topics. Both expert qualitative researchers and those who do not possess knowledge and skills necessary for undertaking qualitative research submit proposals for ethics clearance. On top of this, ethics review committees (ERC) are predominantly led by health professionals who have little or no training in qualitative methods (1), thus finding it difficult to review qualitative study proposals (6). It is therefore important to consider the shift of research landscape in the field of health, when constituting ERC and defining parameters for reviewing qualitative research proposals.

Qualitative health research and ethics

Qualitative health research explores and explains human behaviour for improving the wellbeing rather than as a mere attempt to describe attributes of health. It explores why/how and under what circumstances certain behaviours occur; seeks depths of understanding and social phenomena holistically; and provides insights into meanings of decisions and action (5, 7). Qualitative methods are warranted for in-depth understanding of the context, interactions and behavioural attributes that contribute to dynamics of the society (8). Existing issues across the health sector involve complex behavioural and interaction mismatches that need to be understood for successful action.

Qualitative approach is extremely valuable when the issue is not clearly defined, largely unfamiliar and insufficiently studied. Understanding complex human interactions needs utmost care and patience. Research should be geared to yield the maximum benefits, while minimizing harm at the individual as well as population levels. Thus, the emergence of qualitative health research as a unique discipline emphasises the need for guidance on ethics, conducting fieldwork and other considerations in the research process (4).

Planning should begin with the framing of ethical research questions that can be studied (7-8). If the research question is not ethically sound, methodological rigor will not justify the end. Nevertheless, as Mason (8) elaborates “However much the research questions are framed, any research project is likely to involve a range of interests, some of which may be competing”.

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Any research including qualitative should adhere to well-established ethical principles; autonomy, beneficence and justice at all stages of the research (9-10). However, there can be differences in application during the actual practice of those principles, compared to quantitative research. Those differences need acceptance to preserve basic premise on which qualitative methods are built on. Hence, in reviewing a research proposal, certain flexibilities need to be allowed to retain the nature of qualitative inquiry while maintaining a balance on ethical aspects.

**Autonomy**

In any type of research, the participant has the right to excise their autonomy by consenting or refusing to participate; and being informed of the purpose and process of the study and the expected involvement of the participants. Consent is negotiating trust between the two parties, researcher and the participant. Respecting participants as ‘persons’ including those who are dependents such as children and mentally retarded, is essential (7). Negotiating the process and establishing trust for a qualitative inquiry show certain differences from a quantitative assessment where the philosophical underlings differ (4-8). In a questionnaire survey or a clinical trial, parameters for which the researcher seeks information from a participant are consistent – strictly based on the prior agreement. However, in the case of qualitative techniques such as in-depth interview or participatory observation, exploration is usually dynamic. Emerging information from one interview or observation will shape the trajectory for subsequent interviews and observations. Hence, it is practically impossible to state the specific nature of the information sought from participants at the outset (4-5, 8). This is the very nature of the qualitative research process; thus, the researcher needs to be given more flexibility to reveal the overall purpose of the study to participants than providing specific details during the process of obtaining consent. In addition, qualitative methods rely on the interaction between the researcher and participant or interaction among the participants to generate data. This interaction is built upon trust and needs to be sustained for a relatively longer period than in the case of most quantitative research methods (4). Success of the study more or less depends on this crucial factor. Trust per se cannot be established by a written document such as consent form, but on the nature of the interaction itself. Field experiences of many working in this part of the world reveal that obtaining signature/thumb print on a consent form at the outset of engagement with the participant, may actually induce suspicion than trust (5, 11-12). This is primarily because most communities feel that placing signature on an official document makes them vulnerable. This fact needs to be given due recognition in qualitative studies, and ERCs need to be flexible in their scrutiny allowing ‘informed verbal consent’ wherever necessary than pressing for written consent.

Issues of autonomy and consent can also arise in the use of participant observations. Naturalistic observations are done during normal day to day affairs of a community or in a setting. There will be multiple participants contributing to a given interaction in a community where the observations are made. Most would be incidental participants depending on the interaction being observed. It is not practical to obtain consent from all possible participants of an event/interaction observed. In such situations, the researcher has to be satisfied with obtaining informed consent only from the primary stakeholders or participants. Ongoing consent with participants may be a way of ensuring their privacy (1). For example, when care delivery is observed in a hospital ward, it is not possible to obtain consent from all possible parties that will be part of the interaction; all patients in the ward, bystanders, visitors, health workers from other units, etc. Consent obtained from the authority of the ward with concurrence from ward staff will be the maximum that can be achieved at the beginning. If the researcher continues to observe specific events, consent could be obtained from those involved at a later stage. Obtaining community consent from an authority or a representative of the community may be the only option available when using community-based qualitative techniques, such as participatory rural appraisal or using participatory action research and ethnography. Hence, the issue of consent is challenging when techniques such as participatory observation are employed (13).

Most qualitative researchers use devices to record interviews. Photographs are also taken such as photo voice. It is mandatory to request consent from the participants for audio or visual recording at the time of obtaining consent. This is particularly relevant if public text will include visual recordings that could retain identifiable clues of participants (4). If consent is not granted for audio recording, the researcher should be prepared to take notes verbatim. Photo-
graphing of group or individual interviews should be avoided to prevent identification of the participants. When using photo voice as a technique, all possible precautions should be taken to prevent the identification of individual participants in the public text (4).

**Beneficence**

Beneficence is understood as ‘doing good and preventing any harm’ (9). As with any other approach, intention should justify benefits over the potential risks to the society and participants in qualitative studies. This needs to be clearly given in the objectives, methodology and the process of conducting the study. The study protocol should inherently justify the use of qualitative methods in the study and rigor of application to yield the intended objectives. The author observes that many studies currently submitted for higher degrees and research grants in Sri Lanka propose qualitative methods (i.e. focus group discussions, key informant interviews) without any rationale, simply to show that multiple methods are used and the larger quantum of work. As Mason and Miles et.al (7–8) have elaborated, the use of qualitative techniques in a study should justify their use adequately. This is necessary because of the potential risks that could arise due to close relationship the researcher may develop with the participants, and sensitive information that can be elicited. Hence, ERCs have a responsibility to conduct a proper methodological evaluation prior to approval.

Qualitative methods warrant close and active engagement of participants in the research process (7). Therefore, participants will be more exposed to the research team compared to quantitative methods, as the analysis of qualitative data is grounded in the context that generates such data. Obtaining contextual information will be part of the data collection process while anonymity will be difficult to hide during the research process. Therefore, it is necessary to take additional precautions to maintain confidentiality of the collected data. Measures should be taken to use pseudonyms or non-identifiable tags to verbatim quotes, thus participants cannot be traced even with accompanying contextual information in the public text. This is especially important when the study population is unique and easily identifiable (1).

In certain qualitative methods such as in-depth interviews employed on sensitive topics, utmost precautions need to be instituted. The interviewers should be mindful not to dig into participants’ inner world than what the participant feels comfortable in revealing and what is necessary to achieve the study objectives (9). The researchers need to be well-trained in the techniques and skilled enough to understand the limits of the comfort zone of participants to prevent emotionally exhaustive interviewing on sensitive topics. Interviews of sensitive topics need to be planned well to provide adequate time for the participants to adjust, schedule subsequent interviews with adequate time gaps in between and pre-arrange facilities for counselling if the need arises. The researchers should be prepared to abandon an interview at any point if they feel the participant could be emotionally disturbed by continuing it. All interviews should allow adequate time at the end for making participants comfortable and emotionally stable (4, 9).

**Justice**

Justice means ensuring reasonable non-exploitative and carefully considered procedures and their fair administration, fair distribution of costs, and benefits among persons and groups (7). Qualitative research fundamentally identifies that obtaining the total spectrum of data in relation to the topic is important in establishing the social reality and reality could be multiple. Thus, it differs from quantitative approach of cleaning the data for outliers and excluding deviance. Consistent with the philosophical underpinnings, in qualitative research projects, all efforts need to be taken to include the possible spectrum of participants to showcase their voices in the data collection, analysis and interpretation, thus acknowledging their contribution (9). Hence, vulnerable segments in the population, those who dissent from the community norms and other special groups need adequate representation in the selection process depending on the objective of the study. Further, the researchers should provide visibility for the deviant findings in the public text ensuring safety of those who contributed both in reporting and instituting action on those findings.

**Responsibility of the research teams and ERC committees**

Research teams need to demonstrate adequate expertise in conducting a qualitative research. If the principal investigator does not have any expertise in qualitative methodology, a supervisor or another
member should possess such expertise. It is not adequate to mention in the proposal that the investigator or the team will be trained. It is the duty of the team to demonstrate their competencies in using qualitative methods during the proposal development and submission for ERC. It is not justifiable to experiment with sensitive tools/research techniques that could inflict harm on the participants due to lack of expertise or ignorance of the investigators. Hence, apart from reviewing the proposal, ERC should scrutinize the capabilities of the research team to plan and conduct a study using qualitative methodology (7). ERC should solicit expertise in qualitative methodology and field experience in the review process.

Implications for research ethics policy

Qualitative research needs specific considerations on ethics apart from the general rules applicable in research. Those who wish to include qualitative methods should ensure that the research team satisfies such specific requirements from the selection of study topics till the end of reporting of findings. This key responsibility lies with the ERC to look into these aspects closely during the review. ERC need such expertise to ensure proper scrutiny. However, all researchers as well as ERC members should be aware that ethics review process is to facilitate innovation and generation of knowledge while keeping a balance between the benefits and negative effects to the society.

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