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Original Paper

An Institution-Based Ethics Review Committee Model for Research on Human Subjects in Eswatini: Composition, Duties and Operations

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Abstract

It is becoming increasing apparent that Universities in Eswatini need to establish effective ethics review committees to review applications from students and from faculty researchers. As the establishment of postgraduate programmes continue to increase, the volume of applications expected to be reviewed by the national Eswatini Human and Health Research Review Board (EHHRRB) continue to increase. The capacity of the EHHRRB is in itself not adequate for the load. High load of reviews suggest that not enough time is spent on each application. Hence universities have to carry some of this burden by reviewing their student applications or even applications from researchers in the country. It has been observed that universities themselves have either poorly constituted ethics committees or ones that are non-functional. This paper attempts to review different models of university-based committees that may be adopted by universities in Eswatini. Three models are discussed, the single central committee model, the devolved committee model and the rotating committee models. The paper discusses strengths and weaknesses of each model. The rotating committee model encapsulates the strengths of the former two models while suggesting how this model may avoid their weaknesses. The paper does not in any way entail to prescribe any model for any university but merely elucidates on the pros and cons of each in order to assist universities make informed decisions on which model best suites their set up.

Keywords

Institutional Review Board, IRB, IRB Composition, Research Ethics, Human subjects research

1. Introduction

According to the Declaration of Helsinki, all biomedical research involving human subjects, including research on identifiable human material or data, should receive review and be approved by an Institutional Ethics Committee (The World Medical Association, 2000). To make this requirement effective and quicker, institutions engaging in research may have an independent Research Ethics Committee that overlays high-level guiding principles and expectations that the institution or university generally expects its researchers to observe (Ansert et al., 2024). Both postgraduate and undergraduate research should be reviewed to protect subjects' welfare, ethically and legally protect researchers, enhance the reputation of psychological research, and enrich the educational experience of student researchers (Kallgren & Tauber, 1996; Nesom, Petrof & Moore, 2019). Institutional Review Boards (IRBs) and comparable entities, such as research ethics committees and ethics review boards have been established for the primary purpose of protecting human subjects participating in research (Tsan & Puglisi, 2023). Therefore, all ethical review processes should produce the same outcome regardless of the IRB conducting the review (Friesen, Yusof & Sheehan, 2019). Following a review of 53 undergraduate researchers, Kallgren and Tauber (1996) recommended the Institutional Review Board (IRB) process for all undergraduate research. Their study revealed that undergraduate researchers claimed to have learned more by going through the IRB processes, produced a better product, viewed instructor feedback more positively, saw the instructor as more of an ally, treated their research more seriously, and were sensitized to ethical issues. This assertion holds true for many institutions in Eswatini that train more undergraduate than postgraduate researchers and are of the false view that their research does not require ethical review. Institutions should therefore stress the point that the IRB process provides the students essential learning processes of ethical review requirements and processes, and does not police researchers. The institutional or university research ethics committee is the overarching committee at the institutional level for the consideration of ethical issues arising from research that involves human participants and personal data. Research Ethics Committees have two main functions: 1) to protect the rights, dignity and well-being of research participants; and 2) to facilitate and promote ethical research that is of potential benefit to participants, science and society. In line with this requirement, it has been clearly apparent that institutions involved in research in Eswatini need to establish systems of ethical review for both students and staff researchers involving human subjects. The need has been recognized by universities, the Ministry of Health and the wider public, because of the possible harms and unethical behaviour which can occur in the process of social science research (Holm & Irving, 2004). It is also driven by increased requirements of journals for human subject's research to have received appropriate ethical approval, and requirements from funding organizations that projects should receive appropriate ethical approval before monies to support research are released. This is especially the case since the Eswatini Human and Health Research Review Board (EHHRRB), which also oversees that all research on human subjects is safe, necessary

and follows appropriate scientific theory, was established. The EHHRRB has announced a new Research Ethics Framework for social science research that looks to establish research guidelines aimed at ensuring the safety of research participants. Concerns over the quality of the functioning of Institutional Review Committees have increased worldwide. As such, the relatively informal processes that have been engaged in the review of student's protocols at most universities in Eswatini need to be strengthened and formalized into full-blown University Ethics Committees. A survey conducted by Indian Council of Medical Research (ICMR) among 200 institutions revealed that many IECs were unsatisfactorily constituted or structured, hence were not functioning adequately (Muthuswamy, 2005).

Universities in Eswatini have grown in number and stature such that some offer post-graduate programmes that require students to conduct in-depth research as a requirement for graduation. The EHHRRB does not have adequate capacity to review all protocols from local and foreign student's researchers, hence some of the burden should be borne by trained research ethics experts in the universities in Eswatini. However, while the Research Ethics Framework does give guidelines on the processes that should be involved during the review of research protocols involving human subjects, the Framework is intentionally non-determinant in terms of how this review ought to be implemented by the universities, including the structure of university-wide ethics review committees. This leaves the universities with the liberty to ensure that they establish structures and processes that comply with the guidelines; although these do, for example, give some requirements concerning the membership of the institutional research review committees at whatever level they are established. Thus, there is widespread debate about the most effective or appropriate way to set up ethical review processes at universities in Eswatini. This paper aims to contribute to this debate, while offering information on effective models implemented elsewhere.

2. Single Central Committee Model

The classic model for the review of research involving human subjects involves the assessment of each application by one central university-based research ethics committee. This model has been implemented in several universities in New Zealand, Australia and the United Kingdom (Tinker & Coomber, 2004). The strengths of this model are that each application receives a full review by a properly constituted ethics committee, and that it would build on already existing practice in other universities (Tinker & Coomber, 2004). This model is likely to receive university attention, hence is commonly made up of the best experts in ethical review. The single central committee model also ensures that all proposals are reviewed by the same committee and there is no inter-committee review variation for similar proposals. What drawbacks exist for this model? Commonly, members serving in the single central committee are overloaded because of the large volumes of research conducted in the social sciences. Because members of the committee find themselves under pressure to review all applications received, most members do not get the opportunity to read all applications thoroughly. The

pressure also reduces interest in serving in this committee, such that maintaining and staffing the committee becomes a difficult task. Interest is further reduced by that most academic institutions do not place any formal value to serving on research ethics committees, and the time in being on a committee that operates in such a fashion is a large commitment. Finally, there are concerns about the efficiency of such a committee, potentially at least, it is difficult for a single sitting to effectively review all applications promptly and adequately, thus creating a backlog. This is exacerbated if many applications come in at one particular time of the year (for example, when students attempt to meet set deadlines for their project applications). A majority of undergraduate students in Eswatini submit their protocols for ethical review just before or on the deadline day. However, these problems are not insurmountable, and unquestionably some single central university research committees do function well. Where inefficiencies are experienced, universities may consider adopting alternative models.

3. Devolved Committee Model

The devolved committee model involves establishing research committees at the School or Faculty level, as opposed to a single central university-wide committee. Committees at school or Faculty level may function as full blown ethics committees, or they can serve as limited ethics committees with power only to review and approve some applications while the more contentious applications are referred to the university-wide central committee. In Eswatini, individual institutions could establish their own ethics committees and a larger central committee made up of members from the different institutions and the public. Faculty committees could primarily be constituted by members of that faculty or school in which they are based, balanced perhaps with a few members either from other faculties or members of the central university-wide committee. The devolved committee model has an advantage in terms of turn-around time for review and approval of proposals. However, there are four potentially-serious shortcomings of this model:

1) *Conflicts of interest*: The devolved committee model may create grounds for serious conflicts of interest. Members of a faculty or school are largely, or partially likely, to have interest in the sort of research being proposed in that faculty because it is likely to be in their own research interest. Furthermore, declining or passing on certain edgy research may set an unwelcome precedence, jeopardizing their own work by making it go through the full review process. In other words, there is a risk with devolved committees that *Dracula will be put in charge of grading the blood bank*, to put it in Christopher Mitchell's words. While adding lay persons in the devolved committee could allay these concerns, many universities have more than one devolved ethics committees, and finding and maintaining this number of lay members would pose significant difficulties.

2) *Ethical expertise of devolved committees*: It is unlikely that too many schools or faculties will have ethicists on their board. The Eswatini Human & Health Research Review Board (EHHRRB) research ethics policy emphasize the importance of appointing persons with formal training and qualifications in ethics (MOH 2020-2030 pg. 9). Ethical experts are not only useful for aiding the identification of ethics issues but also, from the perspective of university liability, should gain trust for members of the public and research community both nationally and internationally. Unless there is a fully trained ethics committee with varied membership, involving ethical experts, laypersons, representatives of vulnerable groups, etc., how can the committee be expected to identify the possible ethical issues/risk involved in research?

3) *Potential for methodological blindness to problems or bias*: Certain groups and disciplines have a set of views or ways of looking at the world which may blind them to certain ethical issues. While this could, to some degree, be alleviated by having members from outside the faculty or school, there is still no guarantee that this will not occur. For example, in some universities, psychology departments see no conflict between informed consent and requiring students to participate in their research as part of their coursework. However, typically this is seen as an ethically-worrisome practice by those outside of psychology. Inclusion of members from different faculties also pose logistical problems when meetings of the committee have to be held and for collaboration of committee members.

4) *Inconsistency between devolved committees' decisions*: Another serious concern is that the various devolved committees will review applications inconsistently, so an application in one faculty or school may get rejected, while a practically identical study may be approved in another faculty or school. While this may be justified, it may not be *prima facie* to be unfair. It also opens the whole ethics review process up for attack by those displeased with either their treatment at its hands or by those who see it as just another bureaucratic hoop to jump through (Edwards et al., 2004). Some researchers may end up shunning one committee and preferring their protocols to be reviewed by the one that guarantees them clearance without in-depth review or questioning. This problem could be exacerbated by multidisciplinary research which could face difficulties both in determining which committee to apply to, and in getting approval. While, again, these difficulties can be dealt with, and no doubt some devolved models do function well, this model is nonetheless generally troublesome.

4. Rotating Committee Model

The strength of the single central committee model is that applications are reviewed by the same properly constituted team of experts in ethics, which in principle, ensures the best level of protection to research participants and to offer consistency. Unfortunately, such benefits are achieved at the expense of efficiency. In contrast, the devolved committee model arguably achieves high level efficiency but does this, unfortunately, at the expense of the best ethical review. Hence, it makes good sense to combine the single central committee and the devolved committee models by instituting several-centrally based research ethics committees within a single university. So, suppose four centrally-based committees are established, it will be much easier to ensure that they are properly constituted than in the standard devolved committee model system. The smaller number of committees should make it easier to ensure that that both ethics experts and laypersons are recruited. The central location of the committees, drawing their membership from a wide base across the university, should remove serious concerns about conflicts of interest or methodological bias. If the committees meet once a month on a staggered basis, then there should be a very quick turnaround for research applications because one of the committees will be meeting once every week. Also, the burden on each individual committee is lightened because each committee will only meet once a month.

5. Composition

By nature, IECs should be multidisciplinary and multi-sectoral in composition. Hunter (2007) suggests that membership of IECs should include members who are familiar with the research areas and methodologies likely to come before them, which ensures easy identification of methodological issues and implications that the researchers might have overlooked or not have identified. Also, IECs ought to have representatives from those groups who are commonly recruited as research subjects (Hunter, 2007). Such members are likely to have the awareness to identify specific concerns raised through researching these particular groups, which many researchers might not have picked up. They provide the IEC a fresh perspective, from the point of view of the participant, and they may be sensitive to concerns that the committee might otherwise neglect. The laudable objective of ensuring that various facets of society are represented by the inclusion of non-medical personnel in the IECs, and mandating that a lawyer, judge or social scientist or representative of a non-governmental voluntary agency, a philosopher/ethicist/theologian and a lay person from the community should all form part of an IEC. Members from diverse backgrounds can be useful in identifying specific ethically related issues in the applications. Lay members, in general, can be helpful in identifying issues that experts might not be sensitive to, for example complicated information being presented only in confusing scientific jargon in the information sheet. While familiarity is very useful for IECs, it can easily blind them to the issues that lay members could identify. The inclusion of a statistician ensures that the committee has capacity to identify applications that intend to recruit more participants than is actually required, which

unnecessarily exposes more participants to the research risks. Statisticians also make sure that the suggested number of participants is adequate to allow a meaningful analysis. Members with experience of working with children, such as pediatricians, teachers, social workers, etc., could be very useful if participants of a study are children. Members with a legal background can be useful in identifying any potential legal issues posed by an application. Finally, members with some formal knowledge of ethics issues can easily identify such issues, for example, those related to justice. Since there are a variety of ethical theories, it may be suggested that all members of the committee be made to go through some formal background training on ethics which would be helpful in highlighting the ethical issues from a variety of ethical perspectives, whether or not they themselves identify with those particular perspectives.

6. Monitoring Effectiveness of Institutional Research Ethics Committees

Fifty-five years since Eswatini became independent, the country should be having adequately functional institutional research committees and ones that are well constituted and structured. Independence and competence are the two hallmarks of an IEC. Despite the importance of Institutional Review Boards (IRBs) in protecting human subjects participating in research and the well-known benefits of performance measurements, in Eswatini and in many other countries (Tsan, 2018; Lynch & Rosenfeld, 2020; Lynch, Eriksen & Clapp, 2021), there has been no systematic assessment of the quality and performance of IRBs.

Some studies have acknowledged that it is important to conduct empirical research on the effectiveness of IRB review and oversight but the studies that have been published so far do not directly address this question because they do not attempt to measure the impact of the IRB on the welfare or rights of human subjects (Resnik, 2015). Commonly, data on the welfare and rights of human research subjects is unavailable, which hampers the supervisory or evaluatory responsibilities of any body in charge of overseeing the operations of IRBs. Nevertheless, the ethical governance of research assumes the existence of a national entity (or subnational if applicable, according to the constitution of a country) in charge of supervising the Research Ethics Committees (RECs) that review and monitor research with human subjects. This supervision includes the accreditation of the RECs that authorize them to operate in the jurisdiction in question. The EHHRRB is well positioned to take up the supervisory and accreditation tasks of institutional research ethics committees in Eswatini. Its task would not be to take decisions, though it might in exceptional cases—such as over multicenter trials—but to ensure that the workings of local ethics committees are standardized and monitored as well as running training courses for their members in order to improve capacity and quality performances and to standardize operations across different IECs. It appears that capacity building, developing and encouraging expertise in the field of research ethics is urgently necessary in Eswatini. To strengthen research ethics systematically, the EHHRRB must develop research ethics indicators that address the core components of a national

research ethics system. These indicators would allow identification of advances on each component, evaluation of progress toward strengthening systems, and develop a plan of action for each institution based on indicators not yet reached. This indicator-based strategy could be useful beyond the institution and become a model for the country in case any new institution is established and wants to undertake research ethics duties. The EHHRRB has to develop tools for its use to ensure that the accreditation of RECs is carried out in accordance with international ethical standards and that the accreditation process does not vary from one institution to another. Currently, Eswatini does not have an accreditation system in place to ensure quality assurance issues and control of the conduct of clinical trials and other types of research. Complaints, or the expression of concern about research ethics at an institution, can also be made to the EHHRRB, which would have the mandate to refer cases to the EHHRRB's misconduct procedures when appropriate. The EHHRRB, to achieve this mandate, should welcome approaches from whistleblowers with information concerning research ethics at an institution.

7. Monitoring of Approved Studies

Once an IRB gives a certificate of approval, it is the duty of the IRB to monitor adherence of the research process to the approved protocol, which is regardless of whether the study occurs in a medical institution or private institution/clinic. The purposes of monitoring are to verify that: (a) the rights and well-being of human participants are protected, and (b) that the reported data are accurate, complete, verifiable from source documents and that the study is conducted in compliance with the study protocol. IRBs in Eswatini have to develop capacity to undertake such monitoring requirements as per the ethics guidelines of the EHHRRB. However, such additional monitoring roles could suggest that some members of the IRB should work full-time to be able to effectively monitor trials, especially where large sample sizes and a wide geographical coverage is involved, e.g., country-wide trials. The IRB may delegate monitoring to a special committee that reports its findings to the main research ethics committee. Among other documents or methods that may be used to monitor progress of approved studies, the IRB or post-approval monitoring sub-committee may review periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the sponsor, or reports compiled from study site visits. Some studies have identified issues related to informed consent, protocol deviation, and reporting of study progress to the IRB, recruiting additional participants without IRB approval, and reporting of serious adverse events (Davies, 2018).

Lack of administrative infrastructure, a clear framework for undertaking monitoring (Pickworth, 2000), difficulty in motivating members to conduct audits of ongoing studies (Davis et al., 2016), inadequate workforce, lack of training of IEC members on how to conduct monitoring and inadequate funds were identified as major hurdles for conducting site monitoring (Tripathi et al., 2016). Many IECs spend a substantial amount of time in reviewing and approving protocols and reserve time only for passive monitoring of ongoing studies, which includes reviewing data such as Serious Adverse Events (SAEs)

(Tripathi et al., 2016), protocol violation (Jalgaonkar et al., 2016), progress reports, and protocol amendments at pre-specified regular intervals according to the guidelines (Smith et al., 1997), but almost none for site visits yet it forms an important component of the monitoring exercise. If IECs have to look into human subject protection in its entirety, then they need to conduct active monitoring which requires IEC members to visit study sites where studies approved by them are ongoing. Apart from pre-specified standard operating procedures which will enable sites to conduct on-site monitoring visits, another useful tool could be brief checklists that can be used at the site to record observations.

8. Structures, Processes and Resources

Concerns have been raised that the intensification of research activities has not been accompanied by a corresponding increase in institutional research ethics capacity, including well-functioning ethics review systems (Hyder et al., 2004; Bhuta, 2002; Nuffield Council on Bioethics, 2002). In general, commentators have voiced concerns that research ethics committees in developing countries might not be able to promote high standards of human subject protection due partly to inadequate financial and material resources, lack of adequately trained personnel to be appointed into research ethics committees, insufficient diversity of membership, lack of independence of research ethics committees, and inability to monitor approved protocols (Hyder et al., 2004; Sumathiapala, Siribaddana & Patel, 2004; Kass & Hyder, 2001; Kass, Dawson & Loyo-Berrios, 2006; Arynchyna, Putney & Iafrate, 2019). Other researchers have reported poor working relationships between IRBs and themselves (Dyrbye et al., 2008), probably suggesting lack of understanding of what IRBs require for a research ethics application to go through. While the EHHRRB has coordinated the establishment of research ethics committees at various institutions in Eswatini, the quality and consistency of ethical reviews remains unclear. Specifically, little data are available regarding processes of ethics review, member composition, training of members, workload and resource needs of Research Ethics Committees (RECs), including challenges that RECs face in African research institutions (Milford, Wassenaar & Slack, 2006; Moodley & Myer, 2007). Variabilities in the timelines and consistency have been reported even among IRBs in some studies conducted in developed countries (Drbye et al., 2007).

Even though RECs are established by the administrators of institutions, support of RECs by appointing institutions remain largely unclear. However, appointing administrators of institutions need to understand that even though they are expected to provide support to their RECs, such support should not compromise the independent operations of the RECs. Institutional officials should be continuously made aware of the needs of RECs in Eswatini, and constructive dialogue is encouraged on how capacity of RECs may be stabilized through adequate financial and material resources. With advanced technologies for the review of studies involving human subjects becoming available, resources should be availed in order to improve the quality of review processes as well as reduction in variability of these review processes between reviewers or reviewing institutions. Mechanisms to raise funds for the

support of operations of IRBs should be devised by IRBs themselves in order to reduce over-reliance on institutional support, which often cannot be guaranteed.

9. Conclusion

Low and middle-income countries are increasingly demonstrating capacity to put into practice concrete mechanisms for enforcing ethical requirements. However, while no assessments have been conducted to determine the effectiveness of structures and functioning of IECs, the need to develop guidelines for the structure and functions of IECs cannot be overemphasized. Research protocols reviewed by different IECs have to almost produce the same response irrespective of the country, institution or locality. As research ethics is relatively a new subject in Eswatini, and for that reason is not dealt with sufficiently, in the media, adequate sensitivity and information have not so far been shown either by the medical research and education institutions or the public. Strong and well constituted institutional research ethics committees can also play a central educational role in helping researchers and students to be aware of moral problems and that these institutional research ethics committees can have a complimentary function in respect of medical ethics education to physicians, nurses, public health practitioners and such. Likewise, committees within institutions or universities in Eswatini should be constituted in an appropriate fashion. If they are not constituted according to clearly set guidelines, then these issues may have implications on their ability to function appropriately and independently or conduct quality of reviews.

Conflicts of Interest

The authors report no conflicts of interest related to this paper.

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