TOWARDS THE DEVELOPMENT OF A CAPACITY DEVELOPMENT FRAMEWORK FOR RESEARCH ETHICS ADMINISTRATORS: LESSONS FROM SOUTH AFRICA

by

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DECLARATION

I hereby declare that the compilation of this doctoral dissertation and interrelated, publishable manuscripts/published articles that are herewith submitted for the Philosophiae Doctor in Health Professions Education and Community Health are the result of my own, independent investigation. I have endeavoured to use the research sources cited in the text in a responsible way and have given credit to the authors and compilers of the references for the information provided, as necessary. I have also acknowledged those persons who have assisted me in this endeavour. I furthermore declare that this work is submitted for the first time at this university and faculty for the purpose of obtaining a Doctoral Degree in Health Professions Education and Community Health (Interdisciplinary PhD) and that it has not previously been submitted to any other university or faculty for the purpose of obtaining a degree. I also declare that all information provided by study participants will be treated with the necessary confidentiality.

MA Mulondo	30 November 2021
Ms M.A. Mulondo	**Date**

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DEDICATION

To my wonderful mother Ntsundeni Florah Nemanashi (née Mavhina-Masuvhelele), thank you for being an unending source of support and love. It is impossible to imagine having come so far without your enduring dedication to my success. Thank you for the sacrifices and the care. I love you completely. Thank you.

To my late father, Thomani Jeffrey Mulondo, it is unfortunate that you are not present to witness me achieve this wonderful milestone. Thank you for instilling in me a love for learning, reading and education. I am confident you would have been immensely proud of me. Thank you.

Write the vision and make it plain on tablets, that he may run who reads it.
For the vision is yet for an appointed time;
but at the end it will speak, and it will not lie.
Though it tarries, wait for it; because it will surely come, it will not tarry.
Habakkuk 2:2–3

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LIST OF ACRONYMS

ARESA:	Advancing Research Ethics Training in Southern Africa
CIOMS:	Council for International Organizations of Medical Sciences
COHRED:	Commission on Health Research for Development
EDCTP:	European and Developing Countries Clinical Trials Partnership
GCP:	Good clinical practice
HPE:	Health Professions Education
HRWeb:	Health Research Web
IACUC:	institutional animal care and use committee
IRB:	Institutional review board
LMIC:	Low- and middle-income country
MARC:	Mapping African Research Ethics Capacity
NIH:	National Institutes of Health
NHREC:	National Health Research Ethics Council
REC:	Research ethics committee
SARETI:	South African Research Ethics Training Initiative
SARIMA:	Southern African Research and Innovation Management Association
TRREE:	Training and Resources in Research Ethics Evaluation
UFS:	University of the Free State

SELECTED DEFINITIONS AND TERMS

Research ethics administrators: "These are the professionals who usually manage the operations of Research Ethics Committees (RECs) and implement review administration within RECs" (Kasule, Wassenaar, IJsselmuiden & Mokgatla 2016:13).

Capacity development: Capacity building (or capacity development) is the process by which individuals and organisations improve and retain the skills, knowledge, and other resources needed to do their jobs competently. This definition is specifically focused on specific skills required to do a specific job. This term is quite different from staff development, which has broadened over time, and which focuses not only on improving teaching effectiveness, but also considers other focus areas within academia, e.g., research and administration (Steinert 2014:4).

Framework: A framework provides structure that guides the development of a study and on which detailed methodology, such as data collection and data analysis, can be illustrated (Creswell 2003:3).

Research ethics: Ethics refers to general moral principles and standards of right and wrong, while research ethics refers to the moral conduct of researchers within the world of research (Onyebuchi 2011). There is no known individual founder of research ethics, though the Nuremberg Code was the first law to advocate for ethical conduct in research.

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ABSTRACT

Introduction: Currently, research ethics capacity development is limited to research ethics committee (REC) members, and little research has been done on research ethics administrators, leading to lack of standardised requirements for this role, its responsibilities, and training requirements for fulfilling the supportive role for RECs. Although the role is administrative, research ethics administrators' duties exceed those of just simple administration, and include complex demands such as preparing for audits. This study proposed and validated a capacity development framework for research ethics administrators in South Africa.

Methods: A scoping review was done to gain deeper insight into the history and current status of REC administration, with a specific focus on capacity development programs available for research ethics administrators. A questionnaire was then distributed to 36 research ethics administrators to determine the current responsibilities, training requirements and needs of the role, focusing on the local situation of REC capacity development. The first draft of the capacity development framework was developed through triangulating findings from the scoping review and questionnaire. A Delphi survey of the designed framework, completed by 13 experts from South Africa and abroad, was then conducted until consensus was reached.

Results: From the 22 studies synthesised in the scoping review, two reported that there had been two capacity development efforts for administrators in Africa, namely the African Conference for Administrators of Research Ethics Committees, and the West African Bioethics Training Program. Thirty-six (36) administrators from National Health Research Ethics Council-registered ethics committees in South Africa participated in the online cross-sectional survey. Nearly 49% of the participants indicated that they had only received informal research-ethics-related training – not targeted formal training. Of the 23 research ethics experts approached, 13 participated in the Delphi Survey, and results show that 67% of them confirmed that research ethics administrators require basic, entry-level training at the level of a Bachelor's degree to be able to fulfil their duties.

Conclusion: Research ethics administrators need to have a Bachelor's degree and be capacitated in ways comparable to the training received by research ethics committee members. The world of research is evolving fast and requires every role player in the research ethics committee to be adequately capacitated.

Keywords: research ethics committee, institutional review board, capacity development, research ethics administrator(s), health professions education, community health, bioethics, framework, REC administrator, health research

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CHAPTER 1

ORIENTATION TO THE STUDY

So I will restore to you the years that the swarming locusts have eaten…
I am the Lord your God and there is no other. My people shall not be put to shame.
Joel 2:25–27

1.1 INTRODUCTION

In this research project, an in-depth study was undertaken to design a framework aimed at providing capacity and enhancing research ethics administrators' ability to do their work. The purpose of this study was to design a capacity development framework for research ethics administrators.

The Declaration of Helsinki has as its main objectives; autonomy, justice and beneficence (Malik & Foster 2016:184) which the research ethics committee (REC) is mandated to oversee. Research ethics administrators remain an overlooked resource, providing administrative support and being the key role players around whom a REC operates (Kasule, Wassenaar, IJsselmuiden & Mokgatla 2016:18). Most research ethics administrators indicate that their daily tasks are more complex than simple administration, as they experience demands that exceed the competencies provided to them through educational training (Kasule *et al*. 2016:15).

Although the position and role of research ethics administrators have been well documented in developed countries, for example, Euro-American contexts (Dunscombe 2008; Bankert & Amdur, 2006:68–72), there is a dearth of empirical knowledge about the role and responsibility, professional identity and career trajectory of research ethics administrators (Kasule *et al*. 2016:13) in developing countries. The literature review in this study is therefore biased towards REC members and not administrators as there is not sufficient literature.

Additionally, there is limited data on the growth or career path and professionalization

potential of research ethics administrators in Africa, although one can assume the expansion of the position in Africa, is a result of the demanding committee workload (Kasule *et al*. 2016:13; Mokgatla, IJsselmuiden, Wassenaar & Kasule 2018:347). This assumption is supported by an increase in the number of international collaborative research studies, and an increase in complex bio-medical research involving human participants, which have increased the workload of RECs and required research ethics to be strengthened (Silaigwana & Wassenaar 2015:170; Mokgatla *et al*. 2018:341; Kasule *et al*. 2016:13; Moodley & Myer 2007:2; Davies, 2020:1). Furthermore, administrators vary greatly in background training and have, as a group, until recently, attracted little capacity building or research attention (Mokgatla *et al*. 2018:347). Administrators also vary depending on capacity as indicated by the MARC project which states that only 72% of the RECs in Africa have administrators separate from the chairperson (Mokgatla *et al*. 2018:344).

According to Kasule *et al*. (2016:13), principal functions performed by administrators in the United States include activities such as routine management of REC activities, maintaining and disseminating REC documentation, interacting with researchers and playing a key role in managing the review process and schedule. The only documented study on African research ethics administrators' roles, responsibilities and potentials was conducted among 27 African research ethics administrators (Kasule *et al*. 2016:14–18). This study found that the majority of the respondents had received ethics training, however, the study did not delve deeper into the source, content or duration of the training they had received, this suggests a gap in knowledge. The study by Kasule *et al.* had limitations, due to the use of purposeful sampling of RECs that were well established, with relatively greater experience, although they were under-resourced and had higher workloads. This sampling method may have affected the representativeness of the sample and the findings cannot be generalised to the entire population of REC administrators. Kasule *et al.* acknowledge that asking mainly closed-ended questions limited the amount of detail received in the responses. The current study is different from that of Kasule *et al.*, as the researcher endeavoured, among other objectives of the study, to discover the source and type of training received. Furthermore, this study included administrators from RECs who are both well and under-resourced, and who had low and high workloads, and a great deal of and little experience were sampled; an adequate number of open-ended questions were asked. The current study will, therefore, contribute to the body of knowledge, without duplicating previous research.

According to IJsselmuiden, Marais, Wassenaar and Mokgatla-Moipolai (2012:77), capacity building focuses on (a) training, (b) standard operating procedures, (c) infrastructural

upgrades and (d) administrative systems, but could also focus on (e) harmonising procedures and (f) improving information sharing. Therefore, capacity development provides the necessary tools and support, so that people are able to fulfil certain tasks better. The current study will design a framework that will capacitate research ethics administrators better, by focusing on abovementioned aspects of capacity development.

This study hopefully contributes to required support for the research community, by optimising RECs and improving the ethical review experience and processes through better capacitation of administrators. The overall goal of the study is to conduct a critical analysis of the status of administrators' roles, responsibilities, training requirements and needs, with the intention to develop a capacity development framework to capacitate administrators and, furthermore, contribute to the limited body of knowledge on this topic.

The aim of the study was to design a capacity development framework for research ethics administrators. The study hoped to discover ways in which administrators can be supported. The research question of this study is,

What capacity development framework can be used to better capacitate research ethics administrators?

The objectives of the study are:

i. *To establish the existing global capacity development initiatives for research ethics administrators using literature from 2014 to current (Scoping Review);*
ii. *To determine the current responsibilities, training requirements and needs of research ethics administrators within the South African context (Questionnaire);*
iii. *To establish the views of research ethics experts about the draft framework for capacity development of research ethics administrators (Delphi Survey) and;*
iv. *Arising from i,ii,iii, above, design a capacity development framework for research ethics administrators.*

The researcher applied a descriptive quantitative research design. The methodology entailed a scoping review, a survey questionnaire completed by research ethics administrators from various institutions, and a Delphi survey with current and former REC chairpersons, vice and acting chairpersons, and experts in ethics.

1.2 BACKGROUND TO THE RESEARCH PROBLEM

The increase in research activity in developing or low and middle-income countries necessitates sound ethical review structures and functioning of the RECs (Mokgatla *et al*. 2018:341). RECs are established to help protect human participants by conducting ethical reviews (Silaigwana & Wassenaar 2015:169) of research protocols/proposals– which remains their primary duty (Moodley & Myer 2007:5). To ensure that RECs operate optimally, the support structures of RECs, composed of administrators, need to be adequately capacitated, and their roles and responsibilities must be described clearly and fully, as they are effective contributors to the ethics review process and key role players in ensuring that REC goals are met, quality ethical reviews are conducted in a timely fashion, and that RECs' responses are communicated effectively and timeously (Kasule *et al*. 2016:13). By capacitating administrators, it is possible to improve the quality and efficiency of the ethics review process (Kasule *et al*. 2016:14).

The Commission on Health Research for Development (COHRED) report states that

> "*strengthening research capacity in developing countries is one of the most powerful, cost-effective, and sustainable means of advancing health and development*" (Franzen, Chandler & Lang 2017:1-2; Sombié, Aidam & Montorzi 2017:89).

Accordingly, the administrative role should be earmarked, across Africa and in its sub-regions, for harmonisation through the provision of specific capacity-building and the creation of a formal career path, by defining the role and availing appropriate rewards to recruit and retain administrators (Kasule *et al*. 2016:18).

1.2.1 The history and evolution of research ethics committees

RECs, which are known as Institutional Review Boards (IRBs) in the United States, were established when the requirement for ethics review gained momentum in the early 1960s; the United States proceeded to establish a system of IRBs (Silaigwana & Wassenaar 2019:107). The requirement and establishment of IRBs was a response to ethical research violations, such as those committed by American researchers in the Tuskegee syphilis study in 1932, in which poor African American men were enrolled, and which had devastating consequences. IRBs also addressed the unethical conduct of Nazi researchers in concentration camps. These violations led to the establishment of the Nuremberg Code in 1947 (Nuremberg Code, 1947) and, in 1974, a national commission to ensure the protection

of human subjects of biomedical and behavioural research, in a continued effort to protect research participants (Silaigwana & Wassenaar 2019:107).

Later, the Declaration of Helsinki, which is regarded as the most important set of guidelines about research on human participants, was adopted by the World Medical Association's 18th General Assembly in 1964 (Malik & Foster 2016:184). The Nuremberg Code, CIOMS and Declaration of Helsinki were established to protect research participants (Kerrison & Pollock 2005:488; Silaigwana & Wassenaar, 2015:169), though the Declaration of Helsinki is the living document that is updated regularly (Malik &Foster 2016:184). In 1975, the World Medical Association's amendment to the Declaration of Helsinki advocated for the establishment of research ethics committees, and it is according to this amendment that each health authority in the world was, consequently, been required to create research ethics committees (Kerrison & Pollock 2005:487).

In the United States, IRBs are mandated by the National Research Act of 1974 and Title 45 Code of Federal Regulations Part 46 (Office for Human Research Protections, 2018) – also known as the Common Rule (Silaigwana & Wassenaar 2019:107). Other establishments, such as the Council for International Organizations of Medical Sciences (CIOMS), which was founded in 1949, advance public health through guidance on health research, including ethics, medical product development and safety (CIOMS, 2019). After its CIOMS/World Health Organization collaboration, the United States government set up the International Ethical Guidelines for Biomedical Research Involving Human Subjects, which submitted the Belmont Report in 1979. It emphasises three basic ethical principles: respect for persons (individuals should be treated as autonomous agents), beneficence (research should maximise possible benefits and minimise possible harms), and justice (the benefits and risks of research must be distributed fairly) (Belmont Report 1979; Silaigwana & Wassenaar 2019:107). Furthermore, the CIOMS guidelines acknowledge the vital role of research ethics administrators in facilitating the ethics review process and in assisting with the safeguarding of the dignity, rights, safety and well-being of current and potential research participants (Kasule *et al*. 2016:13–14).

Nonetheless, with all the aforementioned guidelines, a systematic review of IRBs in the United States found that there was inconsistency in the structures, processes, and outcomes of IRBs (Silaigwana & Wassenaar 2015:170). The focus on administrators in this study will provide more knowledge and possibly more consistency on some aspects of the structures and processes of IRBs/RECs, such as that of operational guidance for RECs, which has

received little attention in previous literature (Kasule *et al*. 2016:13).

1.2.1.1 *Establishment of research ethics committees in Africa: South Africa*

The establishment of IRBs in the United Stated stimulated momentum to do the same in Africa, firstly, for collaborative research, to meet the requirement of obtaining ethics approval both in the host country and the sponsor country (Silaigwana & Wassenaar 2015:171; Mokgatla *et al*. 2018:341; Silaigwana & Wassenaar, 2019:107) and, secondly, for research conducted in Africa because of lower costs, lower risk of litigation and less stringent ethical reviews in Africa than that for research in the Global North (Moodley & Myer 2007:2; Moodley, Kabanda, Soldaat, Kleinsmidt, Obasa & Kling, 2020:1). The measures were also introduced to ensure that research on human participants adheres to ethics protocols and processes that are comparable to international best practice.

This REC establishment in African countries is evidenced by South Africa's establishment of the oldest REC in Africa, in 1966, at the University of Witwatersrand (Moodley & Myer 2007:1; Silaigwana & Wassenaar 2019:107; Cleaton-Jones, P. & Vorster, M., 2008), Zimbabwe's establishment of a Medical Research Council in 1974, and Malawi's establishment of the National Health Sciences Research Committee in 1988 (Silaigwana & Wassenaar 2015:171).

In South Africa, like in other countries such as Kenya and Nigeria, the National Health Act (NHA) mandates all health research conducted in the country to be reviewed and approved by a registered REC (Silaigwana & Wassenaar 2015:169–170). Furthermore, the NHA issued two official research ethics guidance documents (2004 and 2015) for SA RECs, that replaced several SAMRC guidance documents that RECs used before 2004. In South Africa, all RECs need to be registered with the National Health Research Ethics Council of South Africa (NHREC) (Department of Health 2015:40; Essack & Wassenaar 2018:240; Silaigwana & Wassenaar 2019:107; Strugo 2007:4). The NHREC is established by the Minister of Health (NHREC 2019) as a statutory body under the National Health Act, No. 61 of 2003 (South African Government 2003; Moodley & Myer 2007:2; Essack & Wassenaar 2018:240; Silaigwana & Wassenaar 2019:107). The NHREC, together with the South African Department of Health, sets guidelines, norms and standards for the functioning of local RECs. It also adjudicates complaints about the functioning of RECs and refers matters concerning violations of ethical or professional rules to the relevant health professional council (Moodley & Myer 2007:2). Furthermore, RECs audit, provide RECs with registration

and essentially oversee the functioning and operations of all 45 (and increasing) registered RECs that involve humans and animals in South Africa (Essack & Wassenaar 2018:240; Silaigwana & Wassenaar 2019:108; NHREC 2019). Moreover, the NHREC helps with capacity building in RECs, to ensure they function optimally to ensure there is as little harm or no harm to participants, researchers and institutions involved in research (NHREC 2017).

1.2.2 Research ethics committee capacity development efforts in Africa

There is a global increase in health research – more than ever before (Ali, Hyder & Kass 2012:55). A recent study found that clinical research in Africa increased during the past few decades (Kasule *et al*. 2016:13; Mokgatla *et al*. 2018:341) in response, largely, to the serious burden of disease, including the HIV epidemic (Kasule *et al*. 2016:13). Ethics experts have noted with great concern how this increase in biomedical research on human participants has not been met with a corresponding increase in REC capacity development in the Global South (also referred to as developing countries (Silaigwana & Wassenaar 2015:170), which needs to keep pace with the increase in research (Essack & Wassenaar 2018:243). This is evidenced by few studies that evaluate African RECs, which is concerning, as such studies and the information they provide would help guide ethical reviews and enhance capacity development programmes (Silaigwana & Wassenaar 2015:170). Literature on capacity development of research ethics administrators has had few empirical research studies which have focused on efforts in South Africa, (Kasule, et al., 2016; Ndebele et al., 2014). Studies that are more recent, however, suggest that there is positive traction, with an increase in research initiatives to identify current REC capacity in Africa, stimulated by an urgent need for continued capacity development in order to meet the needs created by increased research (Mokgatla *et al*. 2018:341). The review of capacity and ethics oversight of RECs in Africa and other countries in the Global South must be increased, to support the increased responsibilities of RECs. There is a persistent need for resolute efforts by various stakeholders to support capacity development and enhancement of African RECs (Silaigwana & Wassenaar 2015:169–170).

According to Silaigwana and Wassenaar (2015:169), evidence from data on some African RECs suggests that challenges that debilitate the effective functioning of RECs include lack of membership diversity, scarcity of resources, insufficient training of members, inadequate capacity to review and monitor studies, and lack of national ethics guidelines and accreditation. These challenges corroborate findings of a study on four countries in West Africa (Guinea-Bissau, Liberia, Sierra Leone & Mali), which revealed that not all ethics

committee members had received training (Sombié *et al*. 2017:94). Another study conducted in 12 African countries identified inadequate funding and lack of training as the biggest challenges experienced by most RECs (Silaigwana & Wassenaar 2015:172). Furthermore, the majority of RECs report that a lack of initial training for new members is a challenge, and that more ongoing (continuous) training was necessary (Silaigwana & Wassenaar 2015:172; Mokgatla *et al*. 2018:345), specifically on risk-benefit assessment and on minimising pressure by sponsors (Silaigwana & Wassenaar 2015:172). Thus, the need for both initial and ongoing REC member training is clear (Essack & Wassenaar 2018:243; Mokgatla *et al*. 2018:347). One can suppose that the more training REC members receive, the more research ethics administrator training will be needed, as administrators help support both RECs and their members.

The current training REC members receive includes short courses on ethics review, relevant degree qualifications, and other types of formal training (Mokgatla *et al*. 2018:345), such as Good Clinical Practice (GCP) training (Moodley & Myer 2007:3), which provides guidance for reviewing clinical research. With the advent of multicentre studies involving different countries, a uniform GCP was necessary, which led to the development of the International Conference on Harmonisation – GCP, in 1996. The South African version of the GCP guideline was published by the Department of Health for the first time in the year 2006 (Moodley & Myer 2007:2) and at the time of this study, a revised third edition was published (Department of Health 2020). In addition to the aforementioned training, further ethics training is provided to members face-to-face or online through the online training course, Training and Resources in Research Ethics Evaluation (TRREE), which provides basic training on the ethics of health research involving humans, at no cost (TRREE 2019; Essack & Wassenaar 2018:243) with a specific TRREE module covering RSA (which is of some relevance to REC administrators).

Evidently, numerous efforts have been made and are being made to provide REC members with various training and capacity development opportunities, while limited effort has been made to provide administrators with the same/similar opportunities, which presents a harmonisation gap within RECs. This fact is corroborated by Kasule *et al*. (2016:13), who note that officials who manage REC operations and implementers of the review administration in Africa lack a clear focus regarding understanding their roles and potential, nor have they received specifically tailored capacity development and input. The only documented effort in Africa is the first COHRED meeting of African Administrators of Research Ethics Committees (AARECs), which was convened in Botswana in 2011 (Kasule

et al. 2016:14). Administrators at this meeting called for greater support for REC administrator capacity development, development of a process to encourage their formal recognition through an African accreditation system, and supportive efforts to harmonise ethics review systems in Africa. However, to date, these calls, particularly those of capacity development, have not been actioned.

Presently, countries in the Global North, such as Japan and the United States, have the greatest number of researchers per 1 000 workforce (Heitor, Horta & Mendonça 2014). However, countries in the Global South should cultivate an environment that also encourages an increase in research output per 1000 workforce. Additional training through capacity-enhancing programmes, and financial support from external funders, national governments and regional stakeholders, could enhance African RECs' capacity further (Silaigwana & Wassenaar 2015:180–181), as few African research institutions allocate adequate funding to capacitate their RECs (Kasule *et al*. 2016:13). This reported lack of financial support/ funding of most RECs inadvertently affects the financial stability of most administrators (Kasule *et al*. 2016:17). It is, thus, imperative that studies such as the current one are conducted to continue providing knowledge on supporting RECs, specifically by capacitating their administrative capacity.

1.2.2.1 *Capacity development of South African research ethics committees*

In contrast to the findings of Mokgatla *et al*. (2018:341) and Ndebele et al. (2014:24), which report that clinical research in Africa has increased during the past few decades and an upsurge of international collaborative research, two studies that examined the workload and applications of South African RECs between 2003 and 2007 found that clinical trials had decreased by 16%, and general research applications had increased by 26% (Silaigwana & Wassenaar 2015:179). RECs in South Africa review between two and 30 applications per meeting (Moodley & Myer 2007:3). An increase in research applications markedly increases REC workload (Silaigwana & Wassenaar 2015:179; Kasule *et al*. 2016:13; Mokgatla *et al*. 2018:341) and provides evidence of a workload increase for South African institutional RECs over the past decade (Silaigwana & Wassenaar 2015:170). This increase confirms the need for capacity development in RECs (Essack & Wassenaar 2018:243), as most RECs have inadequate membership numbers, but an overwhelming review workload (ARESA 2019). Adequate support and capacity development may alleviate the pressure on RECs, thus, enabling members to fulfil their duties effectively.

Most African RECs vary in terms of REC status, accreditation, and adherence to ethics guidelines, though South Africa remains the most well-established (Silaigwana & Wassenaar 2015:181) and has well-organised RECs (Moodley & Myer 2007:1). Additionally, according to Cleaton-Jones and Wassenaar (2010, cited by Silaigwana & Wassenaar 2015:181), South Africa has an effective review system, which might even exceed IRB oversight standards in the United States, due to the requirement that all health research must be approved by a registered REC, the long history of institutional ethics review in the country, and ethics capacity building through the United States National Institutes of Health (NIH) Fogarty International Centre's sponsored initiatives, such as a) International Research Ethics Network of Southern Africa (IRENSA), established in 2000, b) South African Research Ethics Training Initiative (SARETI), established in 2003, and c) Advancing Research Ethics Training in Southern Africa (ARESA), established in 2010. More recently, other role players, such as the European and Developing Countries Clinical Trials Partnership (EDCTP) (EDCTP 2019), WHO/UNAIDS (UNAIDS 2000), Family Health International, and the United States' NIH Clinical Center for Bioethics, have made significant efforts to achieve this goal, with an estimated total investment, in research ethics capacity development in Africa alone, exceeding USD19 million between 2002 and 2013 (Mokgatla *et al*. 2018:341). Furthermore, this investment has not only assisted existing RECs with training, but has also established new RECs in African countries without functional RECs. However, none of these generous efforts and support have been towards the development of administrators (Kasule *et al*. 2016:13), which remains severely lacking.

The NHREC's 2017 audit report findings on 24 South African RECs found that REC composition was inadequate and lacked important details in the terms of reference; furthermore, there was a *shortage of administrative support* and a lack of capacity development (NHREC 2018). There was also a high turnover of REC members over a three-year cycle (NHREC 2018), which may be due to the workload, lack of compensation, or lack of support. In reference to NHREC's response to a question posed at the 2017 annual NHREC meeting, on how to support the South African REC community, the council advised the research ethics community to share necessary resources and create a database that includes all online training resources, for benefit-sharing purposes, while associations, such as the Southern African Research and Innovation Management Association (SARIMA) can play a role in supporting administrators (NHREC, 2017:21), though it has not provided training platforms thus far. Consequently, a gap still presents in this regard. In 2011, SARIMA and Tshwane University of Technology held a joint workshop targeting new research ethics administrators from academic institutions and national science councils in

the southern African region (Kasule *et al*. 2016:14); in spite of this initiative, there is no known record of these efforts having continued in South Africa, as far as could be ascertained.

1.3 RESEARCH ETHICS COMMITTEES' ADMINISTRATIVE SUPPORT

According to Kasule *et al*. (2016:13), principal functions performed by administrators in the United States include, but are not limited to, routine management of REC activities, ensuring availability of ethics guidance documents (ethics policy, research agenda, standard operating procedures, & legislation), maintaining and disseminating REC documentation, providing advice, ensuring compliance, monitoring and arranging for training of REC members, ensuring quality improvement of reviews, handling allegations of research misconduct and unacceptable research practices, and dealing with complaints (i.e., matters related to public responsibility in medicine & research), interacting with researchers and REC members and playing a key role in managing the review process and schedule. Most of these tasks are similar to those performed by administrators in South Africa, such as maintaining REC documentation, monitoring compliance and performing administrative tasks as required by the REC. However, few administrators have undergone adequate training, or have access to effective electronic management systems or digital tracking that could assist them to manage their heavy, complex workload (Kasule *et al*. 2016:13, 17).

Regarding workload and pressure, statistics show that a majority of African RECs still review hardcopy submissions, and have monthly meetings (Kasule *et al*. 2016:15; Mokgatla et al. 2018:344), while requiring applications to be submitted less than a month before review meetings (Mokgatla et al. 2018:344). Furthermore, administrators experience challenges in terms of good REC operational procedures, clinical trials information systems and follow-up, inviting external reviewers, rapid turnover and review, and feedback for researchers and REC members (Kasule *et al*. 2016:14, 18). Other RECs may also have few trained and independent personnel who can even serve in committees (Milford, Wassenaar and Slack, 2006:1). Some of these challenges, as noted by the aforementioned authors, are efficiency, quality, consistency, distinct application of relevant regulations and ethics guidelines, and management of diverse aspects of the ethics review process, and may be a result of ineffective and under-resourced REC administration.

Although some RECs in the world have chairpersons that double as both chairpersons and administrators, according to the MARC (Mapping African Research Ethics Capacity) project's

findings on African REC membership and staff, there has been improvement in this regard (Mokgatla *et al*. 2018:344). The MARC project is a platform and tool on COHRED's Health Research Web (HRWeb), which was established to map health research oversight and regulatory activities in Africa, and can be used by RECs and key stakeholders in health research in Africa to identify capacity constraints and development needs (Mokgatla *et al*. 2018:341; MARC 2019). The MARC project indicates that 72% of the RECs in Africa have administrators separate from the chairperson, 38% have a full-time administrator, 47% have a part-time administrator, and 15% of RECs reported that they did not have an administrator (Mokgatla *et al*. 2018:344). Most South African RECs have an office space dedicated to review activities and at least one full-time staff member (Silaigwana & Wassenaar, 2015:171), which reflects tremendous growth in South African REC administration capacity, although there is a lack in the development aspect.

The roles of a REC are that of chairperson (including vice chairperson & allocated acting chairperson in the absence of both), member, lay member and community member. The roles of lay and community members, according to Moodley and Myer (2007:5–6), are different in the sense that lay members are those who have no scientific/medical background, and may include lawyers, priests, theologians and ethicists, who usually have a higher level of education than community members, while community members are non-professional and non-scientific members who represent the community being researched, and possibly share the same language and culture as that community. Furthermore, the author of this current study has included administrators as the support structure of REC and they are not members of the committee, as has been illustrated in Figure 1.1.

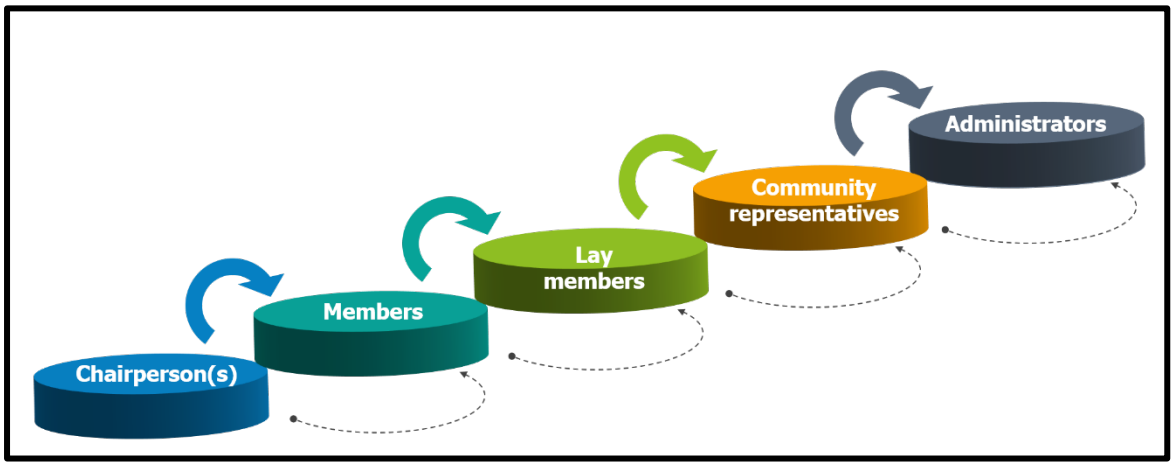


Figure 1.1: REC composition (compiled by the researcher, Mulondo, 2019)

Considering the abovementioned REC history, it is evident that research ethics

administrators need to be better capacitated if they are to be prepared for the fast-growing and changing world of research and ethics. Capacitating reviewing members of the ethics committee without capacitating its administrative support would, therefore, only lead to unbalanced growth.

1.4 PROBLEM STATEMENT

The problem that was addressed by this study is the absence of a standard capacity development framework for research ethics administrators. Although there have been numerous efforts to capacitate RECs and their members, there is limited research and limited attention on capacitating the REC support system, that is the administrators (Mokgatla *et al*. 2018:347). Furthermore, there are, as far as could be ascertained, limited data on this position in Africa (Mokgatla *et al*. 2018:347). This shortcoming, therefore, supports the need for this study.

A literature search on EBSCOhost electronic database (Academic Search Ultimate, Africa-Wide Information, APA PsycArticles, APA PsycInfo, CAB Abstracts, CINAHL with Full Text, eBook Collection (EBSCOhost), Education Source, E-Journals, ERIC, Health Source: Nursing/Academic Edition, OpenDissertations, Teacher Reference Center, Kovsiecat, KovsieScholar, MasterFILE Reference eBook Collection, MEDLINE with Full Text, APA PsycBooks) using the following two search strategies between the years 2000-2021: *TI ("research ethic* commit*" OR "institution* review board*") AND (administrat* OR secretariat* OR coordinator*) and ("research ethic* commit*" OR "institution* review board*") AND (administrat* OR secretariat* OR coordinator*) AND (capacity build* OR capacity Develop*) and on Google Scholar search engine was conducted*. The language preference was limited and set to English. A total of 92 publications were identified from these two databases. From the total number of publications identified, 22 studies were then synthesised after duplicates were removed, with only two publications that referred directly to REC administrators, while four solicited research ethics administrators' opinions/perceptions on other topics. A NEXUS search, undertaken with the assistance of a librarian, was also conducted to ascertain the uniqueness of this study. This search populated five studies, of which none were similar to the current study.

The problem identified is the increase in human research which is overwhelming RECs who need support from REC administrators. The problem is further expounded by the fact that REC administrators are not capacitated to do their work. There is currently no clear guidance

of administrators' responsibilities yet there is an increase in research. There is a real need for administrators to be capacitated so they can effectively assist RECs. If this problem is not addressed, RECs may end up being overwhelmed and not be able to effectively protect participants' rights.

1.5 RESEARCH QUESTION

The following research question was posed to address the research problem:

What capacity development framework can be used to better capacitate research ethics administrators?

1.6 AIM OF STUDY

The aim of the study was to design a capacity development framework for research ethics administrators.

1.7 OBJECTIVES OF THE STUDY

The objectives of the study were as follows:

i. To establish the existing global capacity development initiatives for research ethics administrators using literature from 2014 to current (Scoping Review);
ii. To determine the current responsibilities, training requirements and needs of research ethics administrators within the South African context. (EvaSys questionnaire)
iii. To establish the views of research ethics experts about the draft framework for capacity development of research ethics administrators (Delphi Survey)
iv. Arising from i,ii,iii, above, design a capacity development framework for research ethics administrators.

By pursuing the four objectives above, a capacity development framework for research ethics administrators was proposed, comprising aspects such as what the role involves, and the responsibility and training requirements of the role, in order to ensure an adequately equipped administrator with the necessary knowledge and skills to be a productive, skilled contributor to a REC.

1.8 THE RATIONALE AND OVERALL GOAL OF THE STUDY

This study can hopefully serve as a model and framework for supporting the research community, by optimising RECs, and improving the ethical review experience and quality of processes through better capacitating research ethics administrators. The overall goal of the study was to conduct a critical analysis of the current status of research ethics administrators' role, responsibilities, training requirements and needs, with the intention to develop a capacity development framework for research ethics administrators and to contribute to the limited body of knowledge in this regard.

1.9 RESEARCH DESIGN AND METHODOLOGY

Methodology is the strategy or plan of action that links methods to outcomes, and which governs our choice and use of methods and includes the processes for studying knowledge (Creswell 2003:5–6). Therefore, the methodology involves an overall approach to executing the research.

The following sections provides more information on the selected research design and methodology.

1.9.1 Research design

A research design guides a researcher and helps inform the research question, data collection, and data analysis process (Cooper & Schindler 2011:139; Creswell 2014:66; De Vos, Strydom, Fouché & Delport 2011:309). It is a type of inquiry into research approaches (quantitative, qualitative & mixed methods), which seeks to provide a researcher with direction (Creswell 2014:12). For selecting a research design, Creswell (2003:21) suggests that a researcher considers the research problem, the personal experiences of the researcher and the audience(s) for whom the report will be written. Doing so is important, as the research design ultimately provides the foundation for data interpretation.

There are four types of quantitative research/study designs, namely descriptive, correlational, quasi-experimental and experimental. The researcher selected the descriptive cross-sectional survey research design for this study, as it aims to describe the current status of a phenomenon – capacity development of research ethics administrators. The Delphi survey technique was also used to validate the capacity development framework.

1.9.2 Research approach

There are three different types of research approaches, namely quantitative, qualitative and mixed methods (McCusker & Gunaydin 2015:2). These three approaches are the most commonly applied, with the qualitative research design being the oldest of the three, a quantitative research only appearing in the last three to four decades, and the mixed method still in a developing stage (Creswell 2003:3).

For the purposes of this study, the researcher selected a quantitative research approach, as it enabled the researcher to gain insight from numerous research ethics administrators on their role and responsibilities. The number of responses was important, as the researcher sought to gain information from as many administrators as possible, so that it would be possible to generalise the study findings.

Furthermore, using a quantitative approach enabled the researcher to use different data collection methods in an effort to investigate the specific chosen sample of research ethics administrators. The researcher, first a) Conducted a scoping review, then b) Distributed a questionnaire for completion by research ethics administrators, then c) Triangulated findings from methods a and b, and d) Conducted a Delphi survey with a number of ethics experts.

1.9.3 Theoretical perspective

A theoretical perspective is the philosophical stance that lies behind the selected methodology, such as positivism, post positivism, interpretivism or critical theory (Creswell 2003:4). The postpositivist approach originates from 19th century writers such as Comte, Mill, Durkheim, Newton and Locke, and it challenges the traditional notion of the absolute truth of knowledge when studying behaviours and actions of human beings (Creswell 2003:7).

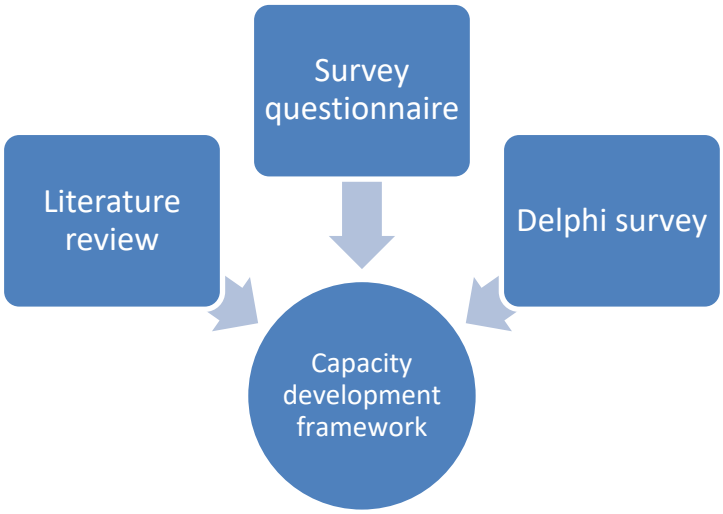
Postpositivism is sometimes also called quantitative research (Pope & Mays 2006:5), or a positivist or postpositivist approach (Creswell 2003:6). This perspective was suitable for this study, as the researcher selected a quantitative research approach- See Flowchart 1. Furthermore, according to Pope and Mays (2006:5), quantitative research is often seen as a structural or positivist approach.

The researcher, therefore, applied the postpositivist theoretical perspective, which is reductionist, as it seeks to reduce and test ideas, such as variables that establish hypotheses and research questions (Creswell 2003:6). It is important to note that researchers do not prove hypotheses, instead, they indicate a failure to reject the hypothesis (Creswell, 2003:7).

1.9.4 Research paradigm

Paradigms are knowledge claims that a researcher starts with in a project, which include certain assumptions on how and what they will learn during inquiry (Creswell 2003:6; De Vos *et al*. 2011:309). This can also be regarded as the 'worldview' the researcher seeks to follow in the study, which relates to matters such as ontology, epistemology and methodology (Botma, Greeff, Mulaudzi & Wright 2015:287; Creswell 2003:6). A *worldview* is "a basic set of beliefs that guide actions" (Creswell 2013:18; Guba 1990:17). Ontology refers to what knowledge is, while epistemology relates to how we know this knowledge (Creswell 2003:6). Therefore, a paradigm, essentially, guides the researcher on what and how to study, and how to interpret the findings (Kivunga & Kuyine 2017:26).

Epistemology affects how a researcher unearths knowledge in whatever context is being investigated (Kivunga & Kuyine 2017:27). This study was informed and guided by the epistemology paradigm, as knowledge was collected from participants (Botma *et al*. 2015:44) in relation to research ethics administrators' capacity development; this was done through conducting a scoping review, administering an online EvaSys-based questionnaire, and conducting a Delphi survey- See Flowchart 1.



Flowchart 1: Research Methodology

1.10 DESCRIPTION OF THE METHODS

The choice of research method is usually informed by how the researcher wants to study or assess that social world, while some researchers rely on the theoretical perspective to provide them with a framework for thinking about the social world (Pope & Mays 2006:2). However, in the field of health, the choice of research method is usually a result of a specific problem or issue, and not necessarily due to the theoretical perspective (Pope & Mays, 2006:3), as evidenced by the choice of research methods for this study.
For this quantitative study, the researcher used a scoping review, a questionnaire and a Delphi survey as data collection methods. These data collection methods will be expounded on further in the following sections.

1.10.1 Scoping review

The aim of a scoping review is to synthesise research evidence, map broad topics and situate the selected topic in literature, and create a foundation based on existing, related knowledge (Pham, Rajić, Greig, Sargeant, Papadopoulos & McEwen 2014:1). The scoping review enables the researcher to learn from other scholars' findings in studies. A researcher should consider existing literature before undertaking research, as it enables a researcher to locate the proposed study in an existing body of knowledge, even if the study is of a complex nature.

This study employed the Arksey and O'Malley scoping review framework (Mogaka, Tsoka-Gwegweni, Mupara & Mashamba-Thompson 2017:3). This approach was applied by, firstly, conducting a literature search on EBSCOhost electronic database (Academic Search Ultimate, Africa-Wide Information, APA PsycArticles, APA PsycInfo, CAB Abstracts, CINAHL with Full Text, eBook Collection (EBSCOhost), Education Source, E-Journals, ERIC, Health Source: Nursing/Academic Edition, OpenDissertations, Teacher Reference Center, Kovsiecat, KovsieScholar, MasterFILE Reference eBook Collection, MEDLINE with Full Text, APA PsycBooks) using the following two search strategies between the years 2000-2021: *TI ("research ethic* commit*" OR "institution* review board*") AND (administrat* OR secretariat* OR coordinator*) and ("research ethic* commit*" OR "institution* review board*") AND (administrat* OR secretariat* OR coordinator*) AND (capacity build* OR capacity Develop*) and on Google Scholar search engine*. Secondly, a NEXUS search was conducted with the assistance of a librarian. Relevant studies were identified, reviewed and analysed, with the aim of determining the scope of the current study topic in literature.

The scoping review provided the necessary background and context for the stated problem. It also formed the basis and rationale for the administration of the questionnaire, and provided content for the final development of the capacity development framework for research ethics administrators, through the expert consensus reached in the Delphi survey.

1.10.2 Survey questionnaire

In quantitative research, the strategies of inquiry include experiments and surveys. For this descriptive study, the researcher selected a survey as one of the data collection methods. According to Belisario, Jamsek, Huckvale, O'Donoghue, Morrison and Car (2015:3), survey questionnaires can either be self-administered or interview administered. According to Belisario *et al.* (2015:3), self-administered survey questionnaires are usually preferred, as they allow for a wide geographic coverage of a target population and are less resource-intensive to administer. Furthermore, the availability of electronic self-administered survey questionnaires has made it much easier and faster to collect data (Belisario *et al.* 2015:4).

An online self-administered survey questionnaire was selected for this study as it enabled the researcher to enrich the study with quantified data, and to reach out to as many participants who satisfied the inclusion criteria as possible. This method was especially suited for this study, as it gave the researcher an opportunity to gather data from the maximum number of research ethics administrators at South African RECs, with limited constraints, which must usually be considered with other data collection methods.

Although a survey questionnaire can be distributed to respondents personally, or through the post, the researcher opted to use the electronic option provided by the survey software EvaSys. As stated above, the electronic option enabled the researcher to collect data much wider and faster.

1.10.2.1 *Target population*

A target population is a group of individuals who have and share certain characteristics or traits of interest (Cooper & Schindler 2011:370; De Vos *et al*. 2011:14; Plowright 2011:36), that the researcher would like to learn the meaning of and that relates to a phenomenon or issue (Creswell 2014:175; Neuman 1997:203). The target population for the survey questionnaire of this study was administrators at RECs of various institutions in South Africa.

1.10.2.2 *Description of sample and size*

Sampling methods are divided into two main classes, namely probability and non-probability sampling. Probability sampling involves the random selection of a sample from a population, while non-probability sampling selects subjects who are available from the selected group.

The researcher selected the non-probability sampling method and, specifically, purposive sampling, as members of a particular group were purposefully sought after because they could provide information on the specific topic (Keeney, Hasson & McKenna 2011:48; Brink, Van der Walt & Van Rensburg 2012:133). Furthermore, total population sampling was the type of purposive sampling technique since all REC administrators were included in the sample. The selected study participants were able to represent the interests of the larger population from which the sample was selected (Brink *et al*. 2012:132; De Vos *et al.* 2011:223; Punch 2014:11).

The sample size was the total number of research ethics administrators at South African RECs. This particular sample of participants was selected for the survey because they work with REC administration and would, therefore, be able to provide knowledgeable responses to the questions that were posed in the survey questionnaire. According to the NHREC list of registered RECs in South Africa, there were 62 RECs in South Africa at the time. The population size of this part of the data collection was, therefore all were invited to participate in the study and no sampling was done.

1.10.2.3 *Pilot study*

A pilot study, which is a smaller version of the main/bigger study (Botma *et al*. 2015:275), was conducted to ensure that the questions in the survey questionnaire were clear, understandable and well structured. The pilot study also helped to determine the time needed to complete the survey questionnaire.

To do the pilot, an electronic self-administered questionnaire (cf. Appendix D) was sent to two research ethics administrators who had agreed to be part of the pilot study. It was sent via the electronic system, EvaSys. The feedback on the pilot study assisted the researcher to amend the survey questionnaire where it was deemed necessary. As there were no changes to the methodology, the pilot study respondents' data were included in the final

study.

1.10.2.4 *Data gathering*

According to Creswell (2003:3), procedures and techniques of data collection, analysis and writing make up what is called *methods*. These techniques include, but are not limited to, questionnaires, interviews and focus groups (Creswell 2003:5). In this study, the data were collected by means of a self-administered electronic survey questionnaire (Appendix D). A survey may include cross-sectional and/or longitudinal studies that use questionnaires or structured interviews for data collection (Creswell 2003:14). The questionnaire of this study was completed anonymously, in an effort to encourage information sharing of views and openness from the respondents (Keeney *et al.* 2011:11). The researcher designed the survey questionnaire after conducting the scoping review therefore the questionnaire was developed from relevant literature. This questionnaire comprised mostly of closed-ended questions, as most surveys that form part of a quantitative research approach do (Creswell 2003:19).

Respondents were invited to participate via email (cf. Appendix B). Their contact details were freely available from NHREC, which provided contact details of all registered RECs on the NHREC website. The invitation to participate contained all the information the potential respondents needed to know before deciding whether to participate. If potential participants agreed to participate in the study, they were sent the information document, in which, by completing the questionnaire, they provided implied consent (cf. Appendix C).

1.10.2.5 *Data analysis*

A quantitative research approach enables a researcher to measure the relationship between variables objectively (Creswell 2014:36). Quantitative research collects data on predetermined instruments that yield statistical data (Creswell 2003:18). The researcher made use of STATA© software Version 12 (StataCorp 2011) to analyse this data with assistance from the supervisors. The data were analysed using descriptive statistics, such as frequencies and percentages, with corresponding 95% confidence intervals (95% CI). The figures and tables that were generated were used by the researcher during the interpretation of results.

1.10.2.6 *Data interpretation*

Quantitative results are numerical and usually generalisable (Creswell 2003:14; Leedy & Ormrod 2001:102). After data analysis, the researcher made use of figures and tables to communicate the interpretation of the findings.

The five types of variables in quantitative research are primary, independent, dependent, extraneous moderator and mediator variables. The researcher focused on the independent variable, as it can be manipulated and changed by the researcher. Furthermore, it affects and determines the values of dependent variables. The values of the variables were measured categorically, using numerical ordering.

1.10.3 Delphi survey

A Delphi survey is a formal consensus-development method that aims to reach group consensus by expert respondents on a specific topic. It achieves this consensus through multiple stages of survey or questionnaire processes (Keeney *et al*. 2011:3), which seeks to validate findings from surveys, focus groups or interviews (Green 2014:2). Muhammad (2007:1) defines a Delphi survey as

> "*a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem*".

In educational settings, this method can assist in forming guidelines and standards, and may even help to predict trends (Green 2014:1).

For the current study, the Delphi survey was selected to help achieve consensus or agreement by having a group of experts assist in validating a capacity development framework for research ethics administrators. These experts validated data collected by the researcher in the scoping review and questionnaire.

1.10.3.1 *Target population*

The target population for the Delphi survey was current and former chairpersons, vice and acting chairpersons, and ethics experts, such as deputy vice chancellors for research.

1.10.3.2 *Description of sample and size*

For selecting Delphi survey participants, Keeney *et al.* (2011:8) recommend the following criteria:

> "*knowledge and practical experience with the issue under investigation, capacity and willingness to contribute, assurance that sufficient time will be dedicated to the Delphi survey, good written communication skills and experts' skills and knowledge*".

The participants of the Delphi survey included current and former vice and acting REC chairpersons, and ethics experts such as deputy vice chancellors for research. This particular sample was selected for the Delphi survey because members worked closely with research ethics administrators and were experts regarding most processes of the RECs. They were, therefore, suitable participants for helping authenticate the designed capacity development framework for research ethics administrators.

A group of about 10 experts is recommended for a Delphi survey (Habibi, Sarafrazi & Izadyar 2014:12), as a larger group would elicit so many opinions that it might be difficult to manage (Keeney *et al.* 2011:48). The researcher planned to recruit more than 10 current and former vice and acting chairpersons, and ethics experts such as deputy vice chancellors for research, for the Delphi survey, to build in leeway in the case of participants withdrawing during the Delphi process.

1.10.3.3 *Data gathering*

The data were collected by means of a Delphi survey (cf. Appendix G), which was designed by the researcher after she had administered a questionnaire that was completed by research ethics administrators. The Delphi survey was developed and distributed to Delphi survey participants electronically via the EvaSys system.

The researcher planned to use a minimum of two rounds of the survey, until consensus was reached. In Delphi surveys, two rounds are recommended as a minimum (McMillan, King & Tully 2016:658). The researcher set the value of consensus at the recommended rate ratio – a standard of 70%, though it could be between 51 and 80%, which the researcher accepted (Avella 2016:305; Giannarou & Zervas 2014:65). In preparing for a Delphi survey, researchers are advised to consider the time that should pass between the round – a minimum of 30 days – and to decide at the start of study when consensus will be considered to have been reached (McMillan *et al*. 2016:658). The time between rounds

may, furthermore, be affected by the time it takes to consolidate the findings and to create the questionnaire for the next round. The researcher followed up responses fortnightly. After consolidating feedback on a round, that information was used to design questionnaires for the next round, until the predetermined consensus rate was reached.
The self-administered Delphi questionnaire with content statements (Keeney *et al.* 2011:10) was sent to respondents, and they were required to respond on a three-point Likert scale (Essential=3, Desirable=2 or Not Essential=1). In the second round, participants were required to re-rate the statements on which consensus had not been reached in the first round, and which were summarised. Furthermore, the respondents were provided with their individual ratings, as well as the group consensus rating, so that they could amend their individual rating, if so desired. Feedback from the second round was used to validate the capacity development framework for research ethics administrators.

Each participant was assured of confidentiality, but not anonymity. Although the participants did not know each other, they were known to the researcher. Participants received a recruitment letter that invited them to participate via email (cf. Appendix E), and they were assured that confidentiality would be maintained, to encourage openness in their responses. Their contact details had been obtained from freely accessible NHREC information regarding all registered RECs, as provided on the NHREC website, from the websites of academic institutions, and through expert referrals. The invitation contained all the information the potential participant needed before agreeing to participate, such as the information document and consent form (cf. Appendix F). If the potential participants agreed to participate in the study, they were asked to indicate consent by ticking the consent tick-box before proceeding with the questionnaire.

1.10.3.4 *Data analysis*

Data from the Delphi survey was analysed by the researcher, with the assistance of the researcher's supervisors, in order to interpret the data that had been collected (Marshall & Rossman 2011:207). Due to the Delphi survey comprising multiple rounds, the researcher had to repeatedly analyse the data in order to draft the next round's questionnaire.

There are four types of scales of measurement, namely nominal, ordinal, interval and ratio scales. The researcher made use of an ordinal scale, which ranks data from lowest to highest and, furthermore, provides information on where data lies in relation to other data. This was done because the researcher sought to find the best and most suitable way to

capacitate research ethics administrators. Responses from each statement were collated to determine which statement received the closest ratings, and to determine if consensus by respondents in each category of statements had been achieved on the Likert scale (Essential, Desirable or Not Essential).

1.11 QUALITY ASSURANCE

Standards of validity and reliability are important in quantitative research (Creswell 2003:8) and are central to scientific measurements (Neuman 1997:138). The criteria relating to the evaluation of quality will be discussed in the next sections.

1.11.1 Validity

According to Neuman (1997:141), validity refers to "*how well the conceptual ideas and operational definitions mesh with each other*". Validity is, therefore, the extent to which the test measure is applicable to what is intended to be measured by the study (Punch 2014:239). Essentially, validity indicates how accurate the results are or whether the results measure what they were intended to measure.

Internal validity refers to the setting of the instrument, while ignoring all other influencing factors, whereas external validity focuses on the influence the tool has on external factors and replication (Siegmund, Siegmund & Apel 2015:1). Therefore, internal validity means the results are trustworthy and reliable, as it relates to the true causal relationship in a studied population; however, it does not make results more generalisable. In turn, external validity refers to how well the causal relationship can be generalised to other populations (Vaeth 2019:27).

The validity of this study was ensured by conducting a thorough scoping review before designing the questionnaire and Delphi questionnaire and, furthermore, conducting a pilot study before distributing the final questionnaire to the participants.

1.11.2 Reliability

Reliability requires ensuring that the data that is measured is dependable (Cooper & Schinder 2011:283), and refers, essentially, to the consistency of the measurement, or the

extent to which the research instrument will produce the same results under the same conditions. Neuman (1997:138) reports that similar results should be obtained each time the variables are measured.

The researcher ensured that the data were reliable by recording a trail for the methodology, every aspect of the data collection, and data analysis, to ensure that other researchers can duplicate the study and reach the same conclusion.

1.12 ETHICAL CONSIDERATIONS

The researcher took reasonable precautions to ensure that no harm was caused to any participants and, furthermore, ensured that participants' rights were respected throughout the study. Participation was voluntary, and each participant had the right to withdraw from the study at any time. Any collected data was kept in a password-protected computer. The ethical considerations applied to this study will be discussed in the sections below.

1.12.1 Approval

Approval for the research project was obtained from the Health Sciences Research Ethics Committee (HSREC) of the University of the Free State (UFS), as well as the vice rector, Research at the UFS through the UFS Gatekeepers Approval (cf. Appendix A). As no patients were involved in this study, obtaining approval from the provincial health department was not necessary. Furthermore, as participants and institutions were anonymised, ethics approval from other institutions was not required, although reciprocal approval was obtained, depending on each institution and REC.

1.12.2 Informed consent

A short overview of the study and its purpose were provided to the participants in a participant information document, which contained a clear, understandable explanation of what was required of them; consent was implied by completion of the questionnaire (cf. Appendix C) or participation in the Delphi survey (cf. Appendix F). It was essential to obtain informed consent, as human beings were involved (Burns & Grove 2009:193), so as to protect them against exploitation. Participants were encouraged to ask questions for clarification, to ensure they participated voluntarily and confirmed that they understand what they were agreeing to, so that they could provide informed consent.

Furthermore, participants were made aware that no incentives or financial gain would be offered, thus, limiting the possibility of coercion and increasing the chances of voluntary participation. Participants also had the right to withdraw from the study at any time without fear of consequence. In case participants needed further clarity, or access to the published findings of the study, the contact details of the researcher, supervisors and UFS HSREC were provided in the participant information document. Finally, participants were notified that results would be published and shared at relevant academic and research conferences.

1.12.3 Right to confidentiality

All information was managed in a strictly professional and confidential manner. Each participant in this study was assured of confidentiality, so as to free participants from fear of private information being shared without permission. As consent was implied by completion of the questionnaire, participants' names did not appear on the consent documents. The researcher ensured confidentiality by not sharing any of the participants' names nor institution names during data analysis, nor in the published study findings.

1.13 SCOPE OF THE STUDY

This study was executed in the fields of HPE and Community Health. The study lies in the domain of research ethics.

1.14 VALUE, SIGNIFICANCE AND CONTRIBUTION OF THE STUDY

It is important that the value, significance, and contribution of a study are communicated prior to a study commencing. The researcher will provide this information in next sections.

1.14.1 Value

Research on capacity development of research ethics administrators is limited, and the value of this study was to hopefully contribute knowledge in that regard. This study, ensures that RECs are equipped with sufficient knowledge to enable them to capacitate and support their administrators, with the ultimate benefit of hopefully improving the quality of REC processes and increasing the confidence of the research community in the REC.

1.14.2 Significance

Few institutions in South Africa are producing doctoral students who study research ethics. The significance of this research will hopefully be its contribution to increasing the number of doctoral students who specialise in research ethics. Furthermore, the proposed study will contribute significantly to the introduction and eventual implementation of a structured REC capacity development framework for administrators, with the eventual likelihood of REC administration being professionalised.

1.14.3 Contribution

The findings of this research will hopefully contribute knowledge that could assist institutions to improve the capacitation of research ethics administrators, by presenting a structured framework, thereby enabling research ethics administrators to support the research community better. When the REC is adequately supported, it frees RECs to fulfil their duties of ensuring that ethical studies are conducted within their institutions and/or jurisdiction, thereby providing better support to the research community as a whole. In addition, capacitation of the REC administrators will enhance the efficiency of the REC functioning. According to Abbott & Grady (2011:15), "Efficiency is achieving a desired outcome with a minimum expenditure of time, effort, and resources."

1.15 SCHEMATIC OVERVIEW OF THE STUDY

Preliminary literature review
Protocol development
Evaluation Committee Approval
UFS Ethics Committee Approval
Reciprocal Ethics Committees Approvals
Gatekeeper Permission from the Vice Rector Research (host institution)
Scoping review
Pilot study
Survey questionnaire
Data analysis and interpretation
Delphi survey
Data analysis and interpretation
Discussion of the results
Finalisation of the thesis
Submission of the thesis

Figure 1.2: A schematic overview of the study

1.16 LAYOUT OF THESIS

This study is interdisciplinary and was conducted in the fields of Health Professions Education (HPE) and Community Health. HPE and Community Health programmes not only advocate for good educators and clinicians, but for professionals who are engaged with their communities and capable of conducting research that is ethical, that leads to better supervision of students, and produces ethical outputs. The HPE programme, specifically, accomplishes this by regularly collaborating with health professionals on research that advances their divisions/departments (University of the Free State, 2019).

The policy for Masters and Doctoral degrees which states that a doctoral thesis usually has 70 000- 100 000 words or three inter-related publishable articles was followed (UFS 2015:5-6. For this study, the researcher opted for the publishable article option, and thus 3 articles have been included in this thesis. One article has been published, and the remaining two

are currently under review. The thesis includes 6 chapters of which each addressed different aspects of the study.

The arrangement of the thesis is as follows:
In this chapter, **Chapter 1, the Orientation to study** has been provided. This includes the introduction to the study, background, research question, aim and objectives of study. The research design and methodology of this study has been addressed comprehensively in this chapter as this thesis does not include separate literature review and methodology chapters.

Chapters 2-4 of this study include the results of the study which have been addressed in article-format. Each article was presented in accordance with the specific journal submission guidelines of the selected journal. Each article has been presented in this study as it was submitted to the journal and therefore includes its own reference style as prescribed by journal and relevant reference list. These references are also included in the final reference list of this thesis in the reference style prescribed by the Division Health Science Education, Faculty of Health Sciences, UFS. The promoter and co-promoters are listed as co-authors of the three articles.

Chapter 2, which is the first article titled **Capacity development of research ethics administrators: Scoping review**, addressed the first objective of this study. A scoping review was conducted to establish the existing global capacity development initiatives for research ethics administrators using literature from 2014 to current. The article was prepared according to the journal submission guidelines of *The Journal of Empirical Research on Human Research Ethics* and was submitted for review in June 2021.

Chapter 3, which is the second article titled **A survey to determine the capacity development needs of research ethics committee administrators in South Africa**, addressed the second objective of the study. A questionnaire was distributed to research ethics committee administrators to determine the current responsibilities, training requirements and needs of research ethics administrators within the South African context. The article was prepared according to the journal submission guidelines of *The Journal of Empirical Research on Human Research Ethics*. The article was **accepted for publication** in October 2021.

Chapter 4, which is the third and final article titled **A Delphi survey to reach consensus**

on a capacity development framework for research ethics committee administrators, addressed the fourth objective of the study. A delphi survey was distributed to research ethics *to establish the views of research ethics experts about the draft framework for capacity development of research ethics administrators*. The article was prepared according to the journal submission guidelines of *The Journal of Public Administration* and **accepted for publication** in January 2022.

To address the third objective, results arising from chapters 2-4 were used to inform the design of the capacity development framework for research ethics administrators.

Chapter 5, which is the **contribution and significance of the study**, integrates the findings from the three articles to address the contribution the study has made. This chapter shows how this study is among the few if any, in South Africa to produce new knowledge about capacity development of research ethics administrators.

Chapter 6, which is the **conclusions and recommendations of the study**, re-discusses each of the objectives and provides details of how each was addressed. Recommendations are also provided for consideration by future researchers.

CHAPTER 2

ARTICLE 1: DESCRIPTION AND DISCUSSION OF THE FINDINGS OF THE SCOPING REVIEW

This chapter takes the form of an article that was prepared according to the journal submission guidelines (cf. Appendix H) of the *Journal of Empirical Research on Human Research Ethics (JERHRE)* and submitted to the journal for review in June 2021.

Capacity development of research ethics administrators: Scoping review

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Abstract

Capacity development of research ethics committees is hugely limited to members and not enough on administrators. This study sought to map the global capacity development efforts of research ethics administrators. A scoping review was conducted. The literature search yielded 92 potentially relevant records while further screening yielded 22 studies. The 22 studies were extracted and synthesised from which two studies spoke directly on administrators' capacity development, while the remaining 20 focused on the capacity development of committees or of committee members. The two studies which spoke directly on administrators showed that there have been two capacity development efforts of administrators in Africa, namely the African Conference for Administrators of Research Ethics Committees and the West African Bioethics Training Program.

Keywords: capacity development, research ethics committee, administrator, bioethics, Africa

Introduction

In 2020, South Africa was recorded as having increased from the previous year's population census of 58.7 million to 59.62 million (Stats SA, 2020) which amounts to 0.76% of the world's population (United Nations Population Fund, 2020). The top four leading causes of death in South Africa are HIV, Tuberculosis, Influenza and Pneumonia (Stats SA, 2020). These leading causes of mortality have led to a growth in the number of international collaborative research, an upsurge of biomedical research involving human participants in Sub-Saharan Africa (Ndebele et al., 2014) and an increase in complex research protocols in developing countries, (Omosa-Manyonyi et al., 2014). The further growth in biomedical technologies has, in the negative, brought about rise to ethical dilemmas (Gefenas & Lukaseviciene, 2017) which has equally led to an increased workload for research ethics committees (RECs), while in the positive, it has helped strengthen Research Ethics Committees (RECs) through capacity development programmes (Kasule et al., 2016; Mokgatla et al., 2018; Moodley & Myer, 2007; Silaigwana & Wassenaar, 2015).

Capacity development has multiple and has differing definitions (Franzen et al., 2017). According to Rajeshwari et al., (2020) "a central goal of capacity development is transforming participants into autonomous agents," which is accomplished by assuming that existing capacities require strengthening. Another definition shows capacity development as "a locally driven change process through which individuals, organisations and institutions obtain, strengthen, maintain and adapt their capacities to set and achieve their own development objectives over time and learn from their efforts," (Hagelsteen & Burke, 2016). Capacity development and staff development might be similar. Steinert (2014) concurs that the definitions might be interchangeable as capacity development is generally the process by which individuals and organisations improve, while staff development predominantly focuses on improving focus areas, for example research, teaching effectiveness or administration. While the definitions of capacity development and staff development might somewhat be similar, the researchers have chosen to conceptualise the definition of capacity development for this study as *the process by which individuals and organizations expand knowledge to complete tasks competently*.

According to IJsselmuiden et al., (2012) there is an urgent need for ongoing capacity and resource development in Africa as a result of the slow pace of capacity development due to the lack of resources. However, according to Silaigwana and Wassenaar (2015) there has been a substantial increase in ethics capacity building in Africa since 2005. Furthermore, there have been several initiatives which have contributed significantly to capacity development of health research in sub-Saharan Africa, including those supported by the

World Health Organization (WHO)[i], Tropical Disease Research (TDR)[ii], the Swedish International Development Agency (SIDA) and Department for Research Cooperation (SAREC)[iii], the Bill & Melinda Gates Foundation[iv], the International Clinical Epidemiology Network (INCLEN)[v], (Halstead et al., 1991) the Fogarty International Center of the US National Institutes of Health [vi](NIH) and the Wellcome Trust[vii] (IJsselmuiden et al., 2012). Even with the increase in REC workload and abovementioned efforts and initiatives towards ethics capacity development, a recent study conducted in a South African business faculty REC still laments the meagre existing administrative structures (Davies, 2020).

The role of research ethics administrators has been well-documented in countries in the global north, yet there is not enough information on its growth, potential, professional and career trajectory in the global south; specifically, in Africa (Bankert & Amdur, 2006; Kasule et al., 2016; Mokgatla et al., 2018). This is evidenced by capacity development efforts in the global north such as that of the United States-based association called Public Responsibility in Medicine and Research (PRIM&R) for all Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committee (IACUC) research ethics professionals and administrators. This association offers two streams of formal qualification in certified IRB professional (CIP) and certified professional in IACUC administration (CPIA), which all ethics professionals and administrators are required to complete as a minimum requirement (Public Responsibility in Medicine and Research, 2020a; 2020b). Whilst there may be some semblance of criteria in PRIM&R for ethics capacity development, these criteria are not often contextually relevant to some African settings (Kasule et al., 2016) due to the geographic location, affordability, policies and systems, which states that their applicants are professionals who are "highly qualified to discharge their duties pursuant to United States rules and regulations…" which is therefore not relevant to settings outside of the United States. The eligibility criteria show that candidates must either have some Bachelor's degree training or 2 to 4 years' experience in research ethics, (Public Responsibility in Medicine and Research, 2020a; 2020b) further necessitating the need for the establishment of Bachelor's degree training in research ethics administration to allow for better vertical articulation. A similar training program called the Collaborative Institutional Training Initiative (CITI Program) is a certification organization which offers different courses for those working in ethics such as IRBs and IACUCs (Collaborative Institutional Training Initiative, 2021).

Professionals are usually registered to an accreditation body however, there are no professional associations, such as PRIM&R and CITI Program, to accredit research ethics administrators in countries such as South Africa, although the Southern African Research and Innovation Management Association (SARIMA) has so far driven a professionalisation

initiative to accredit and recognise research management administrators and managers (SARIMA, 2020). This, however, is not specifically within research ethics nor research ethics administration. One major capacity development effort for research ethics administrators in South Africa was the 2011 workshop hosted in collaboration between SARIMA and Tshwane University of Technology, which targeted incoming research ethics administrators from academic institutions and national science councils in the Southern Africa region (Kasule et al., 2016). Unfortunately, the researchers of this study could not find any signs that this workshop ever continued after this initial point. Furthermore, "Institutions such as the Steve Biko Centre for BioEthics (University of Witwatersrand, 2021), the University of KwaZulu Natal through the South African Research Ethics Training Initiative (SARETI, 2020) and the University of Stellenbosch through Advancing Research Ethics in Southern Africa (ARESA, 2021) offer research ethics formal training such as short courses, postgraduate diplomas, masters and doctoral degrees (NIH Fogarty International Center, 2020), none of which specifically cater for research ethics administrators", (Mulondo et al., 2021:2).

Although research ethics administrators' role may be administrative, in developed countries such as the United States where their duties have been well-documented, their actual tasks exceed those of just simple administrative work to complex, managerial tasks such as preparing for audits, liaising with clinical trial regulatory authorities, collaborating with other institutions and providing research ethics training; all of which require training, further attention and a concentrated effort towards their capacity development (Kasule et al., 2016).

Research objectives

Capacity development of some RECs in low- and middle-income countries (LMICs), which includes most African countries, seems to be of significant interest to the 'world' of research and capacity development while information such as their structure, composition and availability of secretariat (also known as administrators or coordinators) is often lacking, leading to difficulty in giving an accurate view of capacity building measures (Gefenas & Lukaseviciene, 2017). However, Mapping African Research Committees (MARC), which is an interactive map of RECs and their capacity to review (Council on Health Research for Development, n.d.) has been beneficial in closing some of the gap in the scarcity of information. Mokgatla et al. (2018) shared that some of the 19 African RECs not registered on MARC's Research Ethics Web[viii] are regarded as either politically unstable - where ethical health research might not be a priority, have their research conducted without REC review, (Mokgatla et al., 2018; Moodley & Myer, 2007) or are countries which do not use the English

language as their official language (Mokgatla et al., 2018). More studies, such as the current, are therefore necessary to further investigate the capacity development efforts of RECs and particularly, that of their administrators.

The aim of this study is to review the capacity development efforts of research ethics administrators with the following objectives: 1) synthesise existing knowledge on what is published about the capacity development of research ethics administrators; 2) identify the main stakeholders in the capacity development of research ethics administrators; and 3) identify the applicability of research ethics administrators' capacity development efforts.

To achieve these objectives, the methodology provided in the section below was applied.

Method

This study deployed a scoping review methodology, which enabled the researchers to explore existing literature and locate the research topic in the existing body of knowledge. A scoping review aims to synthesise research evidence, map available literature in the field of interest, and summarise the results of the extracted evidence, and is usually employed when a particular topic has not received extensive research attention (Pham et al., 2014; Mogaka, Tsoka-Gwegweni, Mupara, & Mashamba-Thompson, 2017). It enables the researcher to learn from other scholars' findings on studies which might not have previously received extensive review. According to Pham et al. (2014), the difference between a scoping review and a systematic review is that, "the purpose of a scoping review is to map the body of literature on a topic area whereas the purpose of a systematic review is to sum up the best available research on a specific question". As the current study is a preface to a larger study, it was necessary to, first, employ the scoping review to map the existing literature, instead of employing the systematic review.

This study employed the methodological framework for scoping review of Arksey and O'Malley (2005). This was achieved by, firstly, identifying the objectives to be addressed. Secondly, the relevant literature was identified through conducting a NEXUS search,[x] as well as a literature search on EBSCOhost electronic database (Academic Search Ultimate, Africa-Wide Information, APA PsycArticles, APA PsycInfo, CAB Abstracts, CINAHL with Full Text, eBook Collection (EBSCOhost), Education Source, E-Journals, ERIC, Health Source: Nursing/Academic Edition, OpenDissertations, Teacher Reference Center, Kovsiecat, KovsieScholar, MasterFILE Reference eBook Collection, MEDLINE with Full Text, APA PsycBooks) and Google Scholar search engine. In addition to the selected databases being relevant for the Global South, they are extensive enough to encompass the broader globe. Thirdly, literature sources were selected for the synthesis and, finally, the findings were

recorded and reported.

Inclusion and exclusion criteria

The language preference for this study was set at English (Ewusie et al., 2020; Mogaka et al., 2017). All non-English language literature was excluded due to the lack of access to translation resources. Although studies which were non-English but had English abstracts available, were included. Date restrictions were set at 2000 to 2021 to demonstrate the recent and current developments in this research area.

All study designs (quantitative, qualitative and mixed methods) and all literature (such as empirical research studies to scoping and systematic reviews) which covers the capacity development of research ethics administrators was included.

Research in LMICs whose conclusions and discussions could be transferable to African settings were also included for comparative purposes. Perspectives from all stakeholders, whether they were viewpoints shared by research ethics administrators or other interested parties, (Departments of Health, WHO, funders, RECs) were included.

Reference lists were also examined in search of more literature to limit the possibility that a study could be omitted from the synthesis.

Identification of relevant studies

Key search words and terms

Search words were identified which were used in the library and relevant literature search. Some of the key terms have secondary terms, such as *research ethics committee,* which is also referred to as *institutional review board*, capacity *development* is also referred to as *building*. Primary and secondary key search words were therefore used. The local tertiary institution librarian assisted in finalising the key search words, search strategy and in obtaining relevant study literature which were not readily/easily accessible to the researchers. Relevant literature was then identified, reviewed and analysed with the aim of locating the scope of the current study topic in literature.

Databases

The databases searched include the following:

Academic databases: EBSCOhost[ix] (Academic Search Ultimate, Africa-Wide Information,

APA PsycArticles, APA PsycInfo, CAB Abstracts, CINAHL with Full Text, eBook Collection (EBSCOhost), Education Source, E-Journals, ERIC, Health Source: Nursing/Academic Edition, OpenDissertations, Teacher Reference Center, Kovsiecat, KovsieScholar, MasterFILE Reference eBook Collection, MEDLINE with Full Text, APA PsycBooks).
Search engine: Google Scholar[x].

NEXUS search assisted in ascertaining the originality of this study among ongoing registered studies, such as theses and dissertations. All literature included in this study was also reference list scanned and searched for other relevant literature to ensure no study was excluded from the synthesis.

Search strategy

The databases included in this study are varied and allowed for access of diverse disciplines. Boolean operators ('and/or') were used in the literature search. The search strategy for this study was *research ethics committee [also known as institutional review board* or *research ethics committee administrator(s)]* AND *administrators (also known as secretariat or coordinators)* AND *capacity development (capacity building)*.

Study selection (screening)

A two-stage screening process was employed to assess the relevance of the literature identified. The first stage was evaluating the literature studies' titles and abstracts. The studies were grouped according to the following labels: *Include* (title and abstract relevant); *Exclude* (title and abstract do not correlate); and *Uncertain* (title and abstract might somewhat speak on the subject matter). In stage two, studies which fell within the *uncertain* category had their full text and content reviewed by the authors against the inclusion criteria until the studies fell within either the *include* or *exclude* categories.

Studies which fell within the *include* group were included in the literature synthesis and had their full text reviewed by the researchers. After every five studies reviewed, the authors communicated to ensure consistency with the research objectives. A kappa score of 80% or 0.8 agreement was set among the authors' findings, which agrees with Levac et al. (2010)'s framework that authors should engage and resolve inconsistencies regularly.

Risk of bias (quality) assessment of individual literature studies

The quality of the literature was checked to ensure clear study designs (methodological quality assessment).

Charting the evidence (data extraction)

Relevant publications were listed in the data extraction sheet according to six areas, namely the capacity development training name and year offered, location, host or funder (stakeholder), focus, author and applicability.

RESULTS

The NEXUS search yielded 5 records of which none were similar to the current study. Literature searches conducted on EBSCohost and Google Scholar electronic databases and search engine yielded 87 potentially relevant literature studies. The 87 studies from EBSCohost were then screened for duplication and after the first stage of the two-stage screening process, 50 studies were yielded. In the initial figures, 11 studies were initially in *Include*, 5 studies were in *Exclude* and 34 were in *Uncertain*. The second stage yielded 22 relevant literature studies. The researchers indicate the screening process in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram in Figure 1.

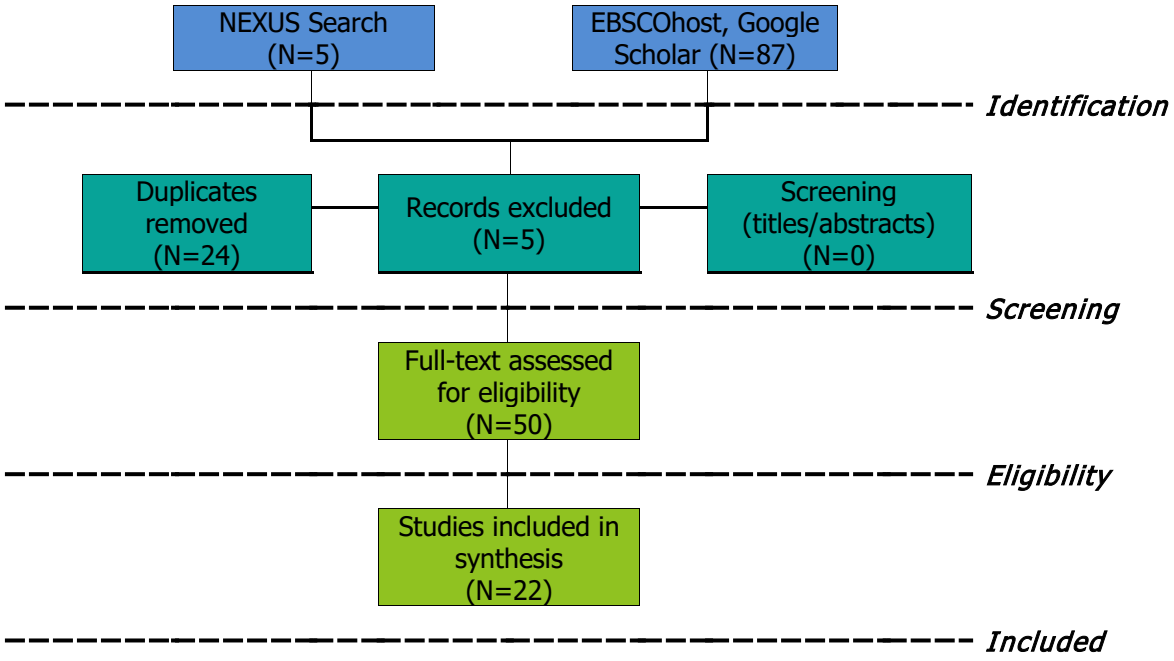

Figure 1: PRISMA flow diagram

Of the 22 relevant literature studies analyzed, eight were quantitative (Franzen et al., 2017; Jaoko et al., 2016; Kasule et al., 2016; Mokgatla et al., 2018; Van Rensburg et al., 2017; Yakubu et al., 2017; Moodley, et al.,2020; Milford, et al., 2006), six were qualitative (Agunloye et al., 2014; Frantz et al., 2019; Henrikson et al., 2019; ILoghalu, 2018;

Woodward-Kron et al., 2016; Davies, 2020), three were mixed method (Hyder et al., 2019; Ndebele et al., 2014; Omosa-Manyonyi et al., 2014), while the remaining five studies were analysis and reports on the topic (Gefenas & Lukaseviciene, 2017; Relias Media, 2018; Reston & Poliquit, 2020; Morton, et al., 2013; Choko, et al., 2020; Howard, et al., 2010). The two literature studies ,which focused on capacity development of research ethics administrators, were empirical research studies that used quantitative and mixed-method research (Kasule, et al., 2016; Ndebele et al., 2014), the single literature study that conducted a needs analysis on IRB administrators in the United States followed qualitative approach (Henrikson et al., 2019), while the literature study that established a new REC in the United States and therefore capacitated new administrators shared the findings through a report (Howard, et al., 2010).

Collating, summarising and reporting the data

One study focused on the capacity development efforts of REC members (Omosa-Manyonyi et al., 2014), and one focused on establishing a REC and therefore capacity development of the entire REC structure (Howard, et al., 2010), while only two focused on capacity development efforts of research ethics administrators (Kasule et al., 2016; Ndebele et al., 2014), and one study in the United States conducteda needs analysis of IRB administrators in genomics research (Henrikson et al, 2019). While few studies reported on capacity development efforts of RECs in general, five studies either reported on the mapping of RECs, (Mokgatla et al., 2018), performed assessments (Jaoko et al., 2016), wrote analysis and reports (Gefenas & Lukaseviciene, 2017; Morton, et al., 2013; Choko, et al., 2020; Howard, et al., 2010) or surveyed RECs (Agunloye et al., 2; 014; Yakubu et al., 2017) in Africa/LMICs, to determine what capacity development efforts would be needed.

Capacity development of research ethics administrators

The two studies which focused on capacity development of research ethics administrators (Kasule et al., 2016; Ndebele et al., 2014) showed that capacity development took place in the years 2011-2016 in Botswana and Nigeria, which are all based in Africa. The funding for these studies on capacity development of research ethics administrators were from the global north, namely from United States National Institutes of Health (US NIH) and European and Developing Countries Clinical Trials Partnership (EDCTP), while the study on needs analysis of research ethics administrators in the United States was funded by the US NIH.

Capacity development of research ethics committee members

The one study on the capacity development of REC members reports that training took place in Kenya, Africa from 2012 to 2013 (Omosa-Manyonyi et al., 2014). The study was funded from the Global North, by the Global Health Research Initiative (GHRI) of Canada. The one study on the establishment of a REC and therefore capacity development of the entire REC structure reports that the training program was in the United States, 2005 (Howard, et al., 2010). This study was funded from the Global North, by the National Center on Minority Health and Health Disparities Grants.

The rest of the studies focused on different aspects of a REC research, such as digital/health research (Hyder et al., 2019), health/hospital administrators (ILoghalu, 2018), tribally-based IRBs (Morton, et al., 2013), ethics in randomized clinical trials (Choko, et al., 2020), clinical ethics committees (Moodley, et al.,2020), REC resources (Milford, et al., 2006), review outcomes of a social science REC (Davies, 2020), novice researchers (Van Rensburg et al., 2017), research capacity (Reston & Poliquit, 2020), faculty development (Frantz et al., 2019) and perceptions of research ethics administrators on a particular topic (Woodward-Kron et al., 2016). These studies were therefore not relevant to RECs, REC members or research ethics administrators. Table 1 gives a summary of the global capacity development efforts of research ethics administrators.

Table 1. Summary of the global capacity development efforts for research ethics administrators

Author [Reference]	Focus	Type of study	Training name, year offered	Country	Funder (stakeholder)
Hyder et al., 2019	Digital health research	Mixed method	No training (case study)	LMICs (Bangladesh, Tanzania and Uganda)	Bloomberg Data for Health Initiative
ILoghalu, 2018	Healthcare administrators	Qualitative	No training	Phoenix, United States	Unknown
Frantz et al., 2019	Health professions educators	Qualitative	African faculty development programme	South Africa	National Research Foundation, South Africa
Franzen, Chandler, Lang, 2017	Health research	Quantitative	No training (systematic review), 2000–2013	LMICs	Bill and Melinda Gates Foundation
Van Rensburg et al., 2017	Novice researchers	Quantitative	Novice researcher programme for nurse educators, from 2010	South Africa	Not provided
Henrikson et al., 2019	Research ethics administrators	Qualitative	No training (needs analysis), 2018	United States	US NIH, Office of the Director
Kasule et al., 2016	Research ethics administrators	Quantitative	AAREC, 2011	Botswana, Africa	EDCTP
Ndebele et al., 2014	Research ethics administrators	Mixed method	WABTP, 2004–2016	Nigeria	US NIH Fogarty – FIC
Woodward-Kron et al., 2016	Research ethics administrators	Qualitative	No training (research ethics administrators' perceptions)	Melbourne, Australia	Melbourne Networked Society Institute
Agunloye et al., 2014	RECs	Qualitative	No training	Nigeria	International Development Research Centre
Gefenas & Lukaseviciene, 2017	RECs	Report	No training (special report)	LMICs	Not provided
Jaoko, et al., 2016	RECs	Quantitative	No training (assessing tool)	Nairobi, Kenya,	Fogarty International, NIH
Mokgatla et al., 2018	RECs	Quantitative	No training (mapping)	All African countries	EDCTP
Yakubu et al., 2017	RECs	Quantitative	No training (survey)	Nigeria	NIH/Fogarty International
Omosa-Manyonyi et al., 2014	REC members	Mixed method	Workshops, 2012–2013	Kenya, Nairobi	Global Health Research Initiative of Canada
Reston, Poliquit, 2020	Statisticians in academia	Report	Outcome-based statistical capacity development programme, 2016	Philippines	Commission on Higher Education, Philippines government
Moodley, et al.,2020	Clinical ethics committees	Quantitative	No training	African countries	Centre for Medical Ethics and Law
Morton, et al., 2013	Tribally-based IRB	Report	No training	American Indian/Alaska	Not provided

				Native (AIAN) communities	
Choko, et al., 2020	Ethics in randomized clinical trial	Analysis	No training	LMIC's	Global Forum for Bioethics in Health Research and Canadian Institute of Health Research grant
Milford, et al., 2006	REC resources	Quantitative	No training	African countries	UNAIDS/WHO HIV Vaccine Initiative (HVI) and the African AIDS Vaccine Programme (AAV)
Davies, 2020	Review outcomes of a Social science REC	Qualitative Content Analysis	No training	South Africa	Not provided
Howard, et al., 2010	Establish an IRB	Report	No training	USA	the National Center on

Notes: AAREC: African Conference for Administrators of Research Ethics Committees; EDCTP: European and Developing Countries Clinical Trials Partnership; FIC: Fogarty International Center; LMIC: low- and middle-income country; NIH: National Institutes of Health; REC: research ethics committee; US NIH: United States National Institutes of Health; WABTP: West African Bioethics Training Program

Discussion

The synthesised literature studies were diverse in methodology and study designs. Methodological screening was employed to ensure the quality of the study and to ascertain the different methodologies employed. It was, however, evident that more empirical research studies, such as qualitative research, needed to be conducted with research ethics administrators to further understand their capacity development needs.

The capacity development of research ethics administrators is a new phenomenon, which may explain the minimal research conducted on this topic in recent years. The studies analysed in this scoping review raised the necessity of capacity development of research ethics administrators as this group of staff is not just an extension but a significant role and position of a REC.

Objective 1: Identified capacity development of research ethics administrators

The PRIM&R association was noted as offering certification and short courses in the United States compliance regulations for research ethics administrators (Kasule et al., 2016). Its location and target group only caters to the United States and is therefore not applicable to settings outside the United States.

The literature revealed that research ethics administrators were capacitated either

through workshops, such as the African Conference for Administrators of Research Ethics Committees (AAREC) in 2011, or trainings such as the West African Bioethics Training Program (WABTP) offered in West Africa between 2004-2016 (Kasule et al., 2016; Ndebele et al., 2014). The AAREC conference in 2011 appears to have been the first and last conference of its type with no similar conference targeting African research ethics administrators since.

Since 2020, SARIMA and EthiXpert (ethixpert.org.za) have started hosting workshops for research ethics administrators. This brings excitement as it continues the conversations on this group of professionals.

Objective 2: Main stakeholders in research ethics administrators' capacity development

Most of the training for capacity development of research ethics administrators was from international funders, such as the EDCTP in Europe and the NIH Fogarty funded research ethics program, US NIH in America. The trainings were thus mostly funded by the global north (Kasule et al., 2016; Ndebele et al., 2014). The amount of growing research in the global south, especially in Sub-Saharan Africa, must be matched with local funding to promote capacity development of research ethics administrators and ensure sustainability of capacity development initiatives.

Objective 3: Applicability of capacity development efforts

The capacity development programmes on research ethics administrators were hosted in Africa (Kasule et al., 2016; Ndebele et al., 2014). The trainings are therefore applicable to most African settings. However, these were very limited and took place more than five years ago. There is a need to increase capacity development of research ethics administrators, especially with formal qualifications within the African continent. This is to ensure that research ethics administrators are properly qualified and skilled to be able to respond to the increasing need for ethical review of research being conducted in the African continent or global south. Although there were no initiatives in African settings, most were authored by African authors.

Conclusion

The study found very little research on capacity development of research ethics

administrators. The studies on research ethics administrators were mainly funded by organisations in the global north, such as EDCTP and US NIH. The few studies on research ethics administrator capacity development were conducted in Africa and are therefore applicable in most African settings.

More empirical studies and research need to be conducted on this topic to allow for more discourse around capacity development of research ethics administrators. Further research is needed on what level/ sort of training research ethics administrators need to fulfil their tasks and what platforms they can join to be able to network with administrators from other institutions. With the capacity development of research ethics administrators, there is an opportunity for a more efficiently-run REC.

Findings from this scoping review study may encourage future studies, which might lead to a framework for guiding ethics practice relevant for South Africa, Africa and global south in general, as well as the implementation of the capacitation of administrators in other comparative settings. While the globe's ethics committees continue to be inundated with submissions of multi-site studies on HIV-AIDS (Kasule et al., 2016) and recently, Covid-19, administrators also need comparable capacitation that REC reviewers receive.

Best practices

Capacity development of research ethics administrators may be an emerging focus and as a result may be imbedded in efforts to capacitate the entire research ethics committee. We therefore recommend separate training and capacitating efforts for research ethics administrators as the focus should be different and more targeted. This is recommended for all research institutions as well as research ethics committees.

Research agenda

It would be beneficial to conduct more research targeted at research ethics administrators in some of the LMICs. Empirical research in these geographical areas appears limited. The more the focus reaches developing countries, the more the research agenda progresses in the desired direction. Furthermore, it appears that more research and information-sharing platforms need to be made available including further research to determine whether institutional research office directors are aware of the training needs of REC/IRD administrators. It would also be necessary to explore whether training needs of REC administrative staff differ depending on the seniority/responsibilities of each REC administrator.

Educational implications

We recommend that research institutions and research ethics committees not only focus their capacitating efforts on research ethics committee members, but that they also offer training to the administrators. This may include funding such administrators to attend offsite trainings and provide them with the opportunity to benchmark from other institutions.

Notes

[i] The World Health Organization (WHO) is the directing and coordinating authority on international health within the United Nations system (https://www.who.int/).
[ii] Tropical Disease Research (TDR) is the Special Programme for Research and Training in Tropical Diseases which is a global programme of scientific collaboration that helps facilitate, support and (https://www.who.int/tdr/about/en/).
[iii] Swedish International Development Agency (SIDA) is a government agency working on behalf of the Swedish government with the mission to reduce poverty in the world while Sida's Department for Research Cooperation, SAREC is responsible for support to research (https://www.sida.se/en/about-sida).
[iv] A non-profit founded by Bill and Melinda Gates which seeks to improve the quality of life for all individuals (https://www.gatesfoundation.org/).
[v] The International Clinical Epidemiology Network (INCLEN) aims to strengthen the research capacity of medical schools in the developing world through the development of Clinical Epidemiology Units.[15]
[vi] The Fogarty International Center (FIC) aims to support and facilitate global health research conducted by U.S. and international investigators and is dedicated to advancing the mission of National Institutes of Health (NIH) (https://www.fic.nih.gov/About/Pages/default.aspx).
[vii] The Wellcome Trust is an independent global charitable foundation which aims to improve the health for everyone (https://wellcome.org/).
[viii] Council on Health Research for Development's (COHRED) Research Ethics web is used by RECs and key stakeholders in health research in Africa to share knowledge in health research ethics (https://www.cohred.org).
[ix] Global Online reference system used by most libraries in the world as a literature search engine.
[x] Freely accessible web literature search engines.

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CHAPTER 3

ARTICLE 2: DESCRIPTION AND DISCUSSION OF THE FINDINGS OF THE SURVEY QUESTIONNAIRE

This article was prepared according to the journal submission guidelines (cf. Appendix H) of the *Journal of Empirical Research on Human Research Ethics (JERHRE)* and **accepted for publication** (cf. Appendix O) in October 2021.

A survey to determine the capacity development needs of research ethics committee administrators in South Africa

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ABSTRACT

Background: Most capacity development efforts in research ethics committees focus on committee members and little on ethics administrators. Increasing studies mandate the focus on administrators' capacity development needs to enable adequate and effective committee support. This study investigated current responsibilities, training requirements and administrator role needs.

Methods: An online cross-sectional survey was conducted among administrators from 62 National Health Research Ethics Council-registered ethics committees in South Africa.

Results: In total, 36 administrators completed the questionnaire and results show that, in addition to administration, they perform managerial, review process and guidance-advisory tasks. Nearly 49% indicated only having received informal research ethics-related training not targeted formal training with 81% of the informal training being through workshops.

Conclusion: Ethics administrators' responsibilities have evolved to complex tasks requiring targeted capacity development efforts.

Keywords: Capacity development, research ethics committee, administrator, bioethics, South Africa

INTRODUCTION

Research Ethics committees (RECs) are an integral part of the research community, and these need clear governance structures for research ethics review with a clear mandate and well-defined roles and responsibilities for their members (Nabyonga-Orem, Asamani, & Makanga, 2021). Research ethics administrators are a key part of the governance structure that enables the REC to conduct timely good quality ethics reviews. However, Kasule, Wassenaar, IJsselmuiden, and Mokgatla (2016) highlighted that professionals who manage the operations of RECs and provide the administration services still do not understand their roles and potentials in terms of receiving occupation-specific capacity building inputs in Africa.

The authors further indicated that there is little knowledge on the roles and responsibilities, including the professional identity and career trajectory of research ethics administrators in Africa (Kasule et al., 2016). This is further complicated by the increase in the burden of disease that requires contextualized evidence to generate local solutions and contextual factors which need continual adaptation of health research systems (Nabyonga-Orem et al., 2021) and initiatives with complex scientific research designs. At the turn of the year 2000, the low- and middle-income countries (LMICs), mainly in Africa, as characterized by the World Bank classification- accounted for 92% of the world's disease burden (Franzen, Chandler, & Lang, 2017; Mokgatla, IJsselmuiden, Wassenaar, & Kasule, 2018). This has increased the amount of health research proposals and their complexity in response to increase in disease burden such as HIV/AIDS. This increase in research proposals has overwhelmed RECs in Africa (Kasule et al., 2016), with 92% of the committees who participated in a study on the capacities and needs of ethics research committees (ERCs) in Africa cited the need for training mostly in clinical trial designs (Nyika, Kilama, Chilengi, Tangwa, Tindana, Ndebele, & Ikingura, 2009).

In Southern Africa, although no capacitation of research ethics administrators exists, the Southern African Research and Innovation Management Association (SARIMA) has a professionalisation initiative to accredit research management administrators, managers and research ethics administrators in countries such as South Africa (SARIMA, 2020). Globally, the United States-based association called Public Responsibility in Medicine and Research (PRIM&R) for all Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committee (IACUC) research ethics professionals and administrators has been instrumental in capacitating research ethics administrators. They offer all research ethics administrators and professionals two streams of formal qualification in certified IRB professional (CIP) and certified professional in IACUC administration (CPIA), which is a

minimum requirement before taking up their responsibilities (Public Responsibility in Medicine and Research, 2020a; 2020b).

The disease burden in LMICs has led to the rise of health research and in the growth of biomedical technologies which in turn have led to the increase in ethical dilemmas (Gefenas & Lukaseviciene, 2017). Notwithstanding the dilemmas caused, health research in LMICs is necessary to combat global health challenges (Franzen et al., 2017). A study by Franzen et al. (2017), however, shows that although there has been a steady increase in the capacity development efforts in health research, the increase has not been enough compared to the increase in the burden of diseases. The same study highlighted that these capacity development efforts include workshops, research projects, centers of excellence, North–South partnerships and networks. Although efforts in health research capacity development may be on a steady increase, it appears training in health research ethics, particularly at graduate level, is limited (Ndebele, Wassenaar, Benatar, Fleischer, Kruger, Adebamowo, Kass, Hyder, & Meslin, 2014). Therefore, health research capacity development efforts should be able to include all role players, such as health researchers, REC members and administrators.

At the time of the abovementioned study, no institution in South Africa had implemented undergraduate-level research ethics capacity training for research ethics administrators. The authors further highlighted that there is still no institution offering undergraduate-level research ethics capacity training for research ethics administrators in South Africa. However, in terms of graduate-level training, institutions such as the Steve Biko Centre for BioEthics (University of Witwatersrand, 2021), the University of KwaZulu Natal through the South African Research Ethics Training Initiative (SARETI, 2020)[i] and the University of Stellenbosch through Advancing Research Ethics in Southern Africa (ARESA, 2021)[ii] offer formal training such as short courses, postgraduate diplomas, masters and doctoral degrees (NIH Fogarty International Center, 2020), none of which specifically cater for research ethics administrators (Table 1). Although the existing RSA REC training programmes, while not aiming specifically at REC administrators, do not exclude REC administrators from applying and completing the training.

Table 1. Post-graduate research ethics training in South Africa

Post-graduate research ethics training in South Africa	
University of Stellenbosch (Centre for Medical Ethics and Law, Faculty of Medicine and Health Sciences) and University of North Carolina (Center for Bioethics) - ARESA	ARESA Postgraduate Diploma in Health Research Ethics. ARESA Bioethics Leadership program: PhD (clinical and research ethics).
University of KwaZulu-Natal, (South African Research Ethics Training Initiative - SARETI)	SARETI Master of Social Sciences (MSocSc) in Health Research Ethics. PhD in Research Ethics.
University of Witwatersrand: Steve Biko Centre for BioEthics	Short course = Research Ethics: Conducting Research Responsibly
TRREE Online Course	Module that is dedicated to South African (DoH, 2004) research ethics guidance

Research ethics administrators handle the administrative aspects of the ethical process and ensure timely and high-quality reviews (EthiXpert, 2020). Their tasks exceed those of just simple administrative tasks to running operations, performing an intermediary and enabling role between researchers and research ethics committees (RECs), managerial tasks (i.e. preparing for audits, liaising with clinical regulatory authorities, providing research ethics training) which they perform with little training, (Kasule, Wassenaar, IJsselmuiden, & Mokgatla, 2016). EthiXpert (2020), documented evidence shows that this position remains ambiguous and unrecognized which leaves administrators to operate without a designated position and thus they fulfil unclearly defined tasks with no specialized training and career path. The rise in South African RECs' ethics submissions requires proper capacitation (Davies, 2020) for this group of professionals. According to Franzen et al. (2017) and IJsselmuiden, Marais, Wassenaar, and Mokgatla-Moipolai (2012), research stakeholders and RECs need to be knowledgeable, aware of and promote further participation in capacity development. It is thus vital to capacitate all REC stakeholders involved in research ethics, including research ethics administrators. Therefore, this study aimed to determine the current responsibilities, training received, and capacity development needs of the research ethics administrator role with a focus on the local situation of REC capacity development. This will facilitate continuous conversations on capacity development of research ethics administrators and the results would be beneficial to all stakeholders interested in the efficient functioning of RECs.

METHODS

The current research focuses particularly on research ethics administrators from South African National Health Research Ethics Council (NHREC)-registered RECs, which includes both human and animal RECs, as the understanding is that all research is judged according to the same ethical guidelines (Davies, 2020; Department of Health, South Africa, 2015). All health research conducted in South Africa is reviewed by a REC regulated by NHREC (Davies, 2020). In South Africa, the National Health Research Ethics Council (NHREC) oversees both the human and animal RECs within the parameters of the same ethical guidelines.

The study was deployed using the descriptive cross-sectional survey research design where data were collected from research ethics administrators through an online, self-administered questionnaire. According to Marcano Belisario et al. (2015), self-administered questionnaires are usually preferred as they allow researchers a wider geographic exposure of the target population and usually have less resource-usage and constraints. The questionnaires were completed by participants over a period of 5 months in 2020 in order to allow participants to complete the questionnaires at their own free time. The objectives of the study were to determine the current responsibilities and training of research ethics administrators as well as to identify their capacity development needs focusing on the local situation of REC capacity development. The questionnaire to assess responsibilities, the requirements and needs of research ethics administrators was developed from relevant literature and as far as could be established no validated questionnaires were available.

Inclusion and exclusion criteria

All participants (research ethics administrators) from a South African NHREC-registered REC were eligible to participate in the study. All genders and races could participate in the study. Furthermore, all years of service in the research ethics administrator role were eligible for recruitment. Length of existence of the REC was not a limiting factor for recruitment.

All South African non-NHREC-registered research ethics administrators were not eligible to participate in this study.

Data collection

Data were collected using a self-administered online questionnaire for five months in 2020. The survey included categories such as demographics, the structure and function of their

REC, their role and training needs as research ethics administrators, and opinion about their role. An email with the link to the survey was sent to the participants who completed a 35-item questionnaire online which included the following questions for background information and training received.

- Is your REC institutional (i.e. academic), governmental or private?
- How long have you been in this job?
- What is your educational background?
- What is your highest educational level of study?
- Are you working part/full-time in this position?
- Have you received any research-ethics related training?
- Was informal research ethics-related training: seminar, workshop and/or online? For any online research ethics-related training received, please specify*. (select all that apply) [Training and Resources in Research Ethics Evaluation (TRREE)., Good Clinical Practice (GCP)]*.

The following questions were used to assess the capacity development needs.

- Please indicate the managerial tasks that you require training to better fulfil your job duties *(you may select multiple options)*,
- Please indicate from the list the guidance and advisory tasks you require training to better fulfil your job duties *(you may select multiple options)*,
- Please indicate the administration of review process tasks you require training to better fulfil your job duties *(you may select multiple options)* and
- Do you have a digital research information management/tracking system?

Once ethics approval had been obtained from each REC, participants were then invited to participate via email with each administrator's REC contact details freely accessible from the NHREC website. If participants could not be reached through the NHREC contact details, each REC was emailed the study information document which included a link to the questionnaire and consenting research ethics administrators could then complete the questionnaire anonymously.

A total of 15 RECs were excluded from the study. The researcher could not get hold of three of them after several attempts. Six RECs were excluded as one institution (with three RECs) was only reviewing internal Covid-19 related research studies during the Covid-19 outbreak, two RECs did not have research ethics administrators as they had retired/resigned and one

institution required the addition of their personnel as co-researcher in this study before access to potential participants, which the researchers of this study could not grant. Five RECs (with two institutions having two RECs each) could not grant approval due to Covid-19 pressure, which in some cases resulted in quorum not being reached. One REC did not grant ethics approval (Figure 1).

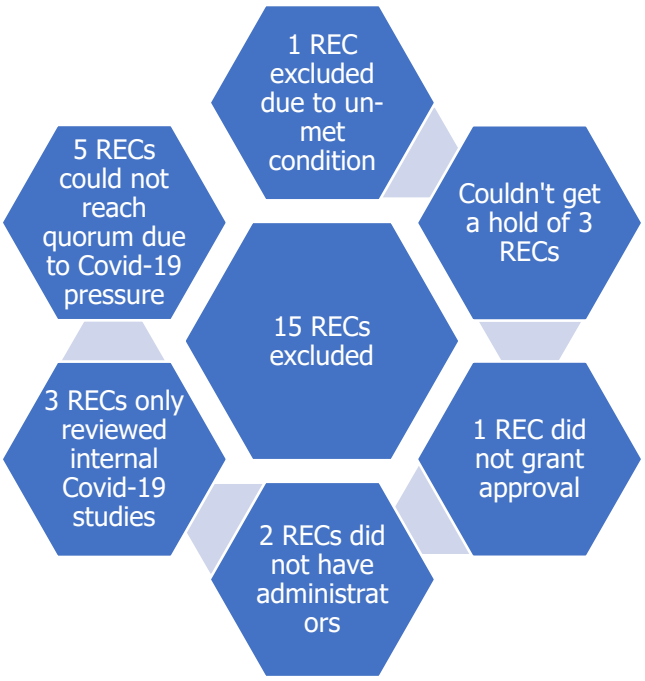


Figure 1. Research ethics committees excluded from study

Data analysis

Data were analyzed using descriptive statistics such as frequencies and percentages with corresponding 95% confidence intervals (95% CI). Received training was also presented graphically. Any association between number of years worked in the same position and training received was measured using a chi-squared test with significance level being 10%. All the data were analyzed using STATA© software Version 12 (StataCorp, 2011).

Pilot study

Due to the very small sample size for this study, only two participants were invited from two NHREC-registered RECs (one from a human REC and one from an animal REC) to participate in the pilot study on 05 June 2020. The participants communicated that the questionnaire was easy to follow and felt it had addressed all the questions they would have expected in such a study. The questionnaire was therefore accepted as final and sent

out to the main study participants. The responses of the two participants were also included in the main study.

Ethical consideration

Reciprocal, expedited and/or gatekeepers' ethics approval was obtained from each of the invited RECs before any of the research ethics administrators were approached.
Participants were provided with an information document that re-directed them to the researchers should they have any questions. The questionnaire was anonymous and therefore each participant was notified that by completing the questionnaire, they gave implied consent.

RESULTS

The researcher approached 62 RECs which are located within 38 institutions in South Africa. Some institutions have between two to four NHREC-registered RECs within an institution. Of the 62 RECs approached, 47 granted reciprocal ethics approval and 36 participants from 45 of the 47 RECs that granted approval took part in the study, which is an 80% response rate. The potential participants from the 2 remaining RECs that granted approval declined to participate.

Research ethics administrators: Background information and training received

Background information and training received for the participants is shown in Table 2. In total 36 participants responded to the online survey with approximately 66.7% REC being institutional. Nearly 63.9% had worked in REC administration position for more than five years and about 62.9% had a Bachelor's degree or higher. They further indicated that these degrees had to do with ethics, although none specifically catered to research ethics administrators. Nearly 48.6% of research ethics administrators indicated that they had received informal research ethics-related training. Thirty-two participants were employed in REC administration position on a full-time basis. Approximately 82.9% of the participants received some form of research ethics training either formal or informal or both and 17.1% of the participants did not receive any form of research ethics training. Only one-third of the participants received some training on Good clinical practice (GCP) and 70.4% had some training on TRREE. Majority (80.8%) of informal training was through a workshop and 69.2% were trained online. Of the 18 participants who were trained online, 88.9% was

trained on TRREE modules whereas only 8 (44.4%) of the 18 were trained specifically on GCP.

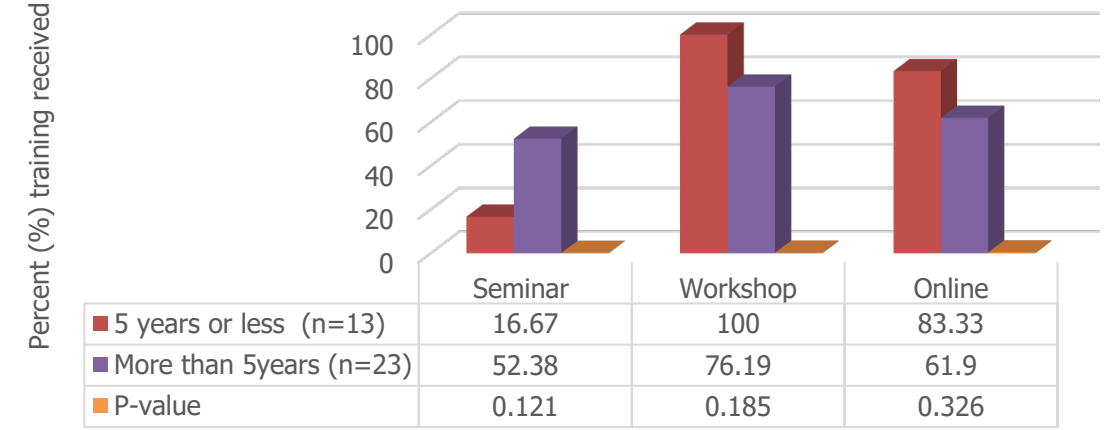
Table 2. Background information of the participants and training received

Variable Name	Category	Number (n)	Percent (%)
Is your REC institutional (n = 36)			
	Institutional	24	66.67
	Governmental	10	27.78
	Private	2	5.56
How long have you been in this job position (n = 36)			
	5 years and below	13	36.11
	More than 5 years	23	63.89
What is your highest educational level of study (n = 35)			
	Below Bachelor's	13	37.14
	Bachelor's degree and higher	22	62.86
Are you working fulltime/part time in this position (n = 36)			
	Part time	4	11.11
	Full time	32	88.89
Have you received any research Ethics related training (n = 35)			
	Yes, formal	3	8.57
	Yes, informal	17	48.57
	Yes, both formal and informal	9	25.71
	No training	6	17.14
Where you Trained in Good Clinical Practice (n = 27)			
	No	18	66.67
	Yes	9	33.33
Was informal research Ethics related training seminar/ workshop or online (n = 26)			
	Seminar	12	46.15
	Workshop	21	80.77
	Online	18	69.23
For any online research Ethics related training please specify (select all that applies) (n = 18)			
	Training and resources in Research Ethics Evaluation	16	88.89
	Good Clinical Practice	8	44.44

Comparison of training received and number of years worked in the same position as research ethics administrator

A comparison of informal training received and number of years worked in the same position is presented in Figure 2. More than half of the participants who worked for more than five

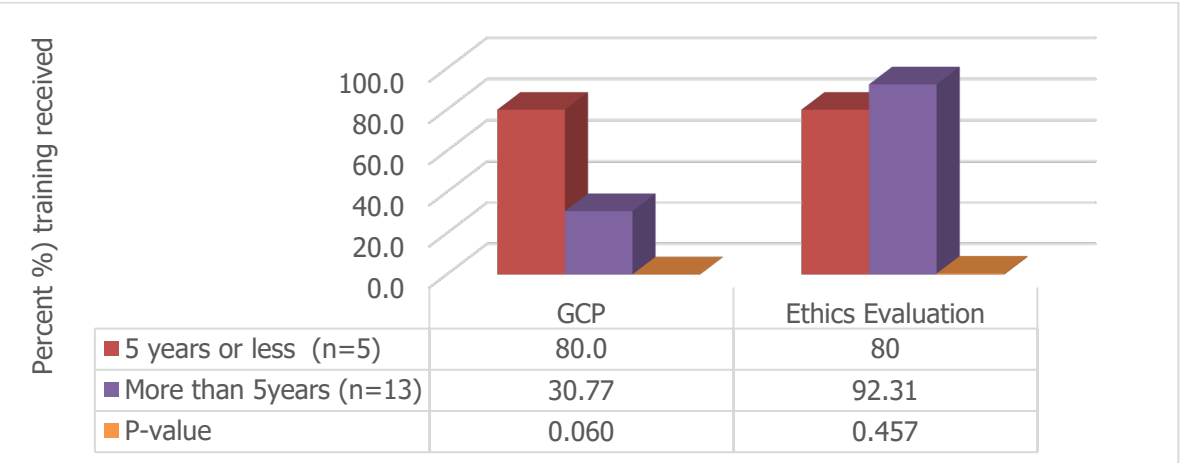
years received training through seminars (training that is more presenter-based with minimal engagement from the audience). All the participants who worked for five years or less received training through workshops (training that has its basis on the engagement and participation of the audience) and approximately 83.3% received online training. None of the informal training received was statistically significantly associated with number of years worked in the same position as research ethics administrator.



	Seminar	Workshop	Online
5 years or less (n=13)	16.67	100	83.33
More than 5years (n=23)	52.38	76.19	61.9
P-value	0.121	0.185	0.326

Figure 2. Comparison of informal training received by number of years worked in the same position

A comparison of online training received and number of years worked in the same position as research ethics administrator is presented in Figure 3. Eighty percent of the participants who worked for five years or less received training in GCP and this was statistically significantly (p=0.060) associated with number of years in the same position as research ethics administrator. Approximately 92.3% of those who worked for more than five years received training on resources in TRREE. This was not statistically significantly (p=0.457) associated with number of years worked in the same position as research ethics administrator**.**



	GCP	Ethics Evaluation
5 years or less (n=5)	80.0	80
More than 5years (n=13)	30.77	92.31
P-value	0.060	0.457

Figure 3. Comparison of online training received by number of years worked in the same position as research ethics administrator

Capacity development needs

The capacity development needs of the administrators were assessed in terms of training requirements on managerial tasks, review process tasks, guidance-advisory tasks and the needs of administrator role.

Research ethics administrators: Training requirements (needs)

The percentages of training needs on managerial tasks performed by research ethics administrators ranged between 22.2% and 58.3%. Nearly 58.3% indicated the need for more training to be better able to organize for audits, while 55.6% needed training to monitor ongoing research. About 47.2% needed training on how to handle complaints or to ensure compliance (Table 3).

Table 3. Training needs on managerial tasks performed by research ethics administrators

Managerial Tasks	**Frequencies**	**Percentages (%) n=36**	**95% CI**
Organize for audits	21	58.33	41.41; 75.25
Monitor ongoing research	20	55.56	38.50; 72.61
Handle complaints	17	47.22	30.09; 64.35
Ensure compliance	17	47.22	30.09; 64.35
Handle allegations of research misconduct & unacceptable research practices	16	44.44	27.39; 61.50
Write reports (annual, progress, etc…)	15	41.67	24.75; 58.58
Management of REC activities	15	41.67	24.75; 58.58
Maintain public relations such as marketing and communication to foster good relations with research community	14	38.89	22.16; 55.62
Report to institution about REC performance	13	36.11	19.63; 52.59
Lobbying and advocacy	11	30.56	14.75; 46.36
Manage REC secretariat	10	27.78	12.41; 43.15
Evaluate REC activities & members	10	27.78	12.41; 43.15
Disseminate research results in workshops, seminars or conferences	10	27.78	12.41; 43.15
Renew federal-wide assurance registration	10	27.78	12.41; 43.15
Serve as REC chairperson	8	22.22	7.96; 36.49

Under the review process tasks research ethics administrators performed, 47% of participants indicated the need for training in the review process of research information management systems, while 44% indicated they needed training to ensure quality

improvement of reviews. The proportion of participants who indicated the need for training on the review process ranges from 22.2% to 47.2% (Table 4).

Table 4. Training needs on review process tasks performed by research ethics administrators

Review process Tasks	Frequencies	Percentages (%) n=36	95% CI
Management of research information management systems	17	47.22	30.09; 64.35
Ensure quality improvement of reviews	16	44.44	27.39; 61.50
Screen applications for completeness	14	38.89	22.16; 55.62
Recruitment of REC members	14	38.89	22.16; 55.62
Provide technical expertise in research oversight	14	38.89	22.16; 55.62
Determine type of review for each application	13	36.11	19.63; 52.59
Guide researchers on application process	12	33.33	17.16; 49.51
Receive Serious Adverse Events (SAEs) and allocate for review	12	33.33	17.16; 49.51
Communicate REC decisions	10	27.78	12.41; 43.15
Prepare for REC meetings	10	27.78	12.41; 43.15
Clerical tasks restricted to receiving and dispatching correspondence and maintaining files (archiving)	8	22.22	7.96; 36.49
Ensure confidentiality of submitted documents	8	22.22	7.96; 36.49
Set up ad hoc meetings	8	22.22	7.96; 36.49

Under the guidance-advisory tasks research ethics administrators performed, 53% indicated they needed more training in drafting REC guidance documents, while 47% wanted training on how to collaborate with other institutions. The training needs for guidance-advisory tasks ranges from 22.2% to 50.0% (Table 5).

Table 5. Training needs on guidance-advisory tasks performed by research ethics administrators

Guidance Advisory Tasks	Frequencies	Percentages (%) n=36	95% CI
Draft REC guidance documents [ethics policy, Standard operating procedures (SOPS), legislation]	18	50.00	32.84; 67.16
Collaborate with other institutions	16	44.44	27.39; 61.50
Liaise with drug regulatory for clinical trials	15	41.67	24.75; 58.58
Establish partnerships	15	41.67	24.75; 58.58
Provide research ethics training	14	38.89	22.16; 55.62
Draft REC meeting agenda and minutes	14	38.89	22.16; 55.62
Provide background information relating to research such as technical, scientific, or research design information	13	36.11	19.63; 52.59
Draft annual REC meeting schedule	12	33.33	17.16; 49.51
Monitor and arrange REC member training	11	30.56	14.75; 46.36
Serve as REC member	8	22.22	7.96; 36.49

Needs of the research ethics administrator role

The major role of the research ethics administrator is to manage research information for the committee. However, only 42% of the research ethics administrators indicated that they had no digital research information management/tracking system. The experts regarded MS Excel and email as digital information management systems although it did not fit literature's definition of a digital REC/IRB information management system which is developed as a means to accumulate, manage, share and utilize various distributed applications and information used (Lee, Lee, Park, Lee, Kim, & Lee, 2006).

DISCUSSION

Current responsibilities of research ethics administrators include managerial, review process and guidance-advisory tasks. Administrators in this study revealed that they perform managerial tasks which exceed their expected administrative role, and indicated a need for more training regarding managerial, review process and guidance advisory tasks. The managerial tasks administrators perform support findings by Kasule et al. (2016) in which they state that administrators' tasks exceed those of just simple administration in Africa. Kasule et al. (2016) found that at least 88% of the 24 respondents were performing managerial tasks, such as reporting to the institution about REC performance. Administrators continue to perform tasks that exceed their training and the extracted results of this study indicated that administrators need training in these managerial tasks, which is an important function as RECs are to ensure that ongoing research projects continue to be monitored to ensure there are no ethical violations.

Under the review process tasks, 47.2% of research ethics administrators indicated that they require more training on the management of research ethics management systems and on how to ensure quality improvement of reviews (44.4%). The administrators' request for capacity development supports Kasule et al. (2016)'s stance that most administrators perform their tasks with very little training. With all the international standards that local RECs need to comply with, it is imperative that reviews are up to standard. Davies (2020)'s study in South Africa supports this as it is indicated that this group of professionals will require further training, due to the rise of research studies and in turn that of research ethics review. Furthermore, to be able to handle all the multi-site studies, it is important that research ethics administrators can have access to digital management systems to ensure the easy and efficient running of RECs. Not only must they have access but they

also require training in digital research information management systems from their institutions to be able to manage these systems. This supports the direction in which the world of the fourth industrial revolution (4IR) is taking.

With guidance-advisory tasks, administrators (50%) indicated a need for training in drafting guidance documents, such as standard operating procedures (SOPs), and on how to collaborate (44.44%) with other institutions. The need to collaborate with other institutions allows for information sharing opportunities such as the Network in Community of Practice[iii] hosted periodically in South Africa. The results of this study as well as other interested research stakeholders thus continue to promote participation in capacity development efforts (Franzen et al., 2017; IJsselmuiden et al., 2012) of research ethics administrators. Overall, the results indicate that administrators performed managerial tasks, review process and guidance-advisory tasks, and some felt inadequate in some tasks and needed further training.

The findings of this study revealed that although within the same country, some RECs refer to their research ethics administrators differently. Ranging from REC secretariat and REC professional, with some institutions having staff at various levels that are linked to the ethics committee's administration in some capacity. Furthermore, it is evident that administrators have been working in an environment for an extended period with inadequate training to fulfill their duties. Although some have qualifications higher than Bachelor's degrees, it is imperative that the training be research-ethics-specific for proper capacitation. Although most are highly educated, they still need specific training.

Study limitations

The Covid-19 pandemic presented a limitation to the study as some institutions had stopped processing research ethics applications to focus on their internal research studies while in some cases RECs and research ethics administrators did not have internet access while working from home due to the lockdown measures implemented in South Africa. Other institutions were inundated with numerous Covid-19 study applications and were thus not able to timeously review applications that were not related to Covid-19, as they did not have enough reviewers. Still, some could not review the applications due to not reaching quorum in their committee meetings as most of their reviewers are clinicians that were mainly serving in the health facilities. Some RECs were non-responsive, possibly due to Covid-19 lockdown restrictions or limited staff. The researchers continued to send follow-ups and made phone calls with each non-responsive REC for a maximum of three follow-ups. In most cases, the researchers were finally successful in receiving response except for

three RECs which could finally not be reached. Due to the Covid-19 pandemic, qualitative research was not considered which would have greatly strengthened the study design. However, further study regarding the roles and targeted training of research ethics administrators will be needed, especially when the pandemic is over.

CONCLUSION

This study is among the few if any, in South Africa to produce new knowledge about capacity development of research ethics administrators. The study showed that research ethics administrators' current responsibilities exceed those of just simple administrative tasks, but instead have evolved with the changing world of health research and research ethics. Research ethics administrators are performing duties that range from managerial to advisory tasks while their role has yet to be professionalized and proper capacity development for them implemented.

Most research ethics administrators have differing qualifications ranging from certificates, diplomas, degrees to more advanced postgraduate qualifications such as Master's degrees. However, there is yet to be a consensus on what the minimum qualification requirement is for the role.

A majority of the research ethics administrators stated the need for capacity development initiatives so that they are better positioned to fulfil their job. These initiatives need to focus on managerial, review process and advisory responsibilities of research ethics administrators. The training should include training on the management of research ethics management systems, how to ensure quality improvement of reviews, drafting guidance documents, such as SOPs, and on how to collaborate with other institutions. This also puts them in a better position to handle international studies if all personnel within the REC are properly and optimally trained for their job.

There is a need to harmonize the research ethics administrator title and perhaps research ethics administration hierarchy and career path.

Best Practices

REC administrators screen applications and distribute according to the expertise of each member. This is to ensure that the appropriate reviewer is able to review the relevant application. Furthermore, they stay abreast of all submitted applications to ensure there is

regular monitoring. This assists them in following up with researchers for any outstanding documentation.

Research Agenda

Future studies could also include other countries in the region and beyond to explore best practices, challenges, and opportunities for building the capacity of research ethics administrators. In addition, it would be beneficial to have research ethics experts included in similar future studies to be able to provide their expert opinions on what they believe would be the best course of action in capacitating research ethics administrators.
In-depth interviews or focus groups (qualitative study) are recommended for future studies to provide more detail from research ethics administrators. A qualitative study will allow for probing questions to be asked to understand how to better capacitate them. This was limited in this study due to the work-from-home strategy which was implemented in most countries and subsequently institutions due to the Covid-19 pandemic.

Educational Implications

We recommend that research institutions and ethics committees offer skills training to research ethics administrators to allow them to better fulfill their responsibilities. Furthermore, they must have a degree before proceeding with the profession.

Chapter 4 will be discussing the results of the delphi survey conducted among research ethics experts.

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[ii] A capacity development programme established to develop a leadership program in Bioethics in Southern Africa (ARESA website, 2020).
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CHAPTER 4

ARTICLE 3: DESCRIPTION AND DISCUSSION OF THE RESULTS AND FINDINGS OF THE DELPHI SURVEY: FINAL FRAMEWORK

This article was prepared according to the journal submission guidelines (cf. Appendix J) for the *Journal of Public Administration* and **accepted for publication** in January 2022.

A Delphi survey to reach consensus on a capacity development framework for research ethics committee administrators

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Abstract

Introduction: Little research has been done on research ethics committee administrators' capacity development, leading to a lack of uniform requirements for this role, and few training opportunities. The role may be related to administration, but it is integral to the smooth running of a research ethics committee. This study proposed and validated a capacity development framework for research ethics administrators in South Africa using a Delphi survey with ethics experts to reach consensus.

Methods: The Delphi method was applied among research ethics experts from South Africa and abroad through an anonymous online questionnaire.

Results: In total, 23 experts were approached to participate in the study, with 12 and 13 experts responding and participating in the two Delphi rounds, respectively. The results of the second round showed that 67% of the experts confirmed that administrators require basic, entry-level training at the level of a Bachelor's degree to be able to fulfil their duties. Nearly 83% of the experts confirmed 'REC administrator' as the appropriate title for this profession.

Conclusion: Research ethics administrators need to be capacitated in various ways, comparable to the training received by committee members, so that they are better placed to operate in and respond to the rapidly developing world of research ethics review. A capacity development framework was designed focusing on the following aspects: training, standard operating procedures, infrastructural upgrades, administrative systems, harmonising procedures and improving information sharing in order to better capacitate administrators.

Keywords: capacity development, research ethics, ethics administrator, bioethics, southern Africa

Introduction

The 8th Global Summit of National Bioethics Committees Advisory Bodies, in 2010,[i] identified the need for low- and middle-income countries (LMICs)[ii] to establish additional ethics committees in Africa and Asia as a global priority (Gefenas & Lukaseviciene, 2017). This summit now runs bi-annually and is supported by the secretariat of the World Health Organization (Gefenas & Lukaseviciene, 2017). Research ethics committee (REC) members have expressed a need for ethical guidelines that are more suitable to the local African context, as the guidelines of other countries may be difficult to either interpret or apply in the local context (Silaigwana & Wassenaar, 2015). There is evidence of improvement, as the 2016 summit experienced an increase in participation by delegates from LMICs, and provided opportunities for networking (Gefenas & Lukaseviciene, 2017). According to IJsselmuiden et al. (2012), there is still limited capacity in African RECs for monitoring health research, and that monitoring requires adequate resources and expertise. The lack of capacity also means that there is not enough capacity to monitor ongoing studies (Silaigwana & Wassenaar, 2015). Although initiatives to establish RECs are numerous, few studies have referred directly to capacitating research ethics administrators who support these committees.

In the United States, the Institutional Review Board (IRB) is regarded as the ethics regulatory oversight body (Henrikson et al., 2019). According to Kasule et al. (2016:13),

some of the principal functions performed by REC administrators in the United States include, but are not limited to, routine management of REC activities, ensuring availability of ethics guidance documents (ethics policy, research agenda, standard operating procedures, and legislation), maintaining and disseminating REC documentation, providing advice, ensuring compliance, monitoring of and arranging for training of REC members, ensuring quality improvement of reviews, handling allegations of research misconduct and unacceptable research practices, and dealing with complaints (i.e., matters related to public responsibility in medicine and research). In addition, REC administrators interact with researchers and REC members and are key to managing the review process and schedule.

The tasks performed by research ethics administrators in the United States do appear to be more than just simple administrative tasks. However, according to Kasule et al. (2016), research ethics administrators' roles are not defined, few administrators have undergone the necessary training, and few have access to the required electronic management systems.

Due to the globalisation of research, there has been an increase in research involving humans in LMICs (Davies, 2020). This has required a significant increase in capacity

development of RECs in LMICs, although there is limited information on the problems they face, their structure and composition (Gefenas & Lukaseviciene, 2017). Furthermore, there is a lack of information on the secretariat, possibly due to lack of resources, which leads to difficulties in providing an accurate view or securing capacitation measures (Gefenas & Lukaseviciene, 2017).

To date, there is no known capacity development framework for research ethics administrators in LMICs, specifically in South Africa, even though South Africa has some of the most advanced research ethics committees in Africa. These REC administrators' capacitation gap needs to be closed to enable stakeholders to understand the challenges RECs face, to offer assistance (Gefenas & Lukaseviciene, 2017) and thus offer better support to ethics committees.

Research objective

The aim of this study was to propose and validate a capacity development framework for research ethics administrators in South Africa using a Delphi survey with ethics experts.

The objectives of the study were to

1. Propose a capacity development framework for research ethics administrators in South Africa;
2. Validate the proposed capacity development framework for research ethics administrators in South Africa;
3. Finalise the capacity development framework for research ethics administrators in South Africa.

Methods

This study used a delphi survey design. Data were collected from research ethics experts serving on research ethics committees. These included current and former REC chairpersons, vice and acting chairpersons and deputy vice chancellors responsible for research, through an online, self-administered questionnaire. Self-administered questionnaires usually have fewer resource usage constraints and enable researchers to achieve a wider geographic reach (Belisario et al., 2015). The Delphi survey rounds were completed by participants over seven months, from October 2020 to April 2021.

Inclusion and exclusion criteria

The inclusion criteria for participation in the Delphi survey were that the research ethics experts needed to be either current or former REC chairpersons, vice and acting chairpersons, or deputy vice chancellors for research. People of all races, genders, ages, type of NHREC-registered (animal and human) ethics committees and any years of service in the expert role were eligible for recruitment and participation. The research ethics experts could be from South Africa or countries abroad.

The exclusion criterion was ethics experts who did not meet the inclusion criteria and had no background in research ethics.

Data collection

Once ethics approval had been obtained, participants were invited to participate via email. Research ethics experts were reached through either their research offices or RECs, and were then emailed the study information document, which included a link to the questionnaire for consideration. Data were collected from October 2020 to April 2021. Participants could complete the questionnaire anonymously. Data collection was achieved through two survey rounds. Results from the first round were used to present the data for consideration by the experts in the second round. The free-text responses from Round 1 also helped to provide clarity, and these responses were added as new statements in Round 2.

The researchers set the value of consensus at the recommended rate ratio – a standard of 70%, though it could be between 51 and 80%, which the researchers could also accept (Avella 2016; Giannarou & Zervas 2014). As responses were given by selecting options from a 3-point Likert scale, in cases where a statement was agreed upon by the majority, although less than 51%, that statement was considered as final. Furthermore, in cases where there was a tie in the experts' responses, the statements were presented again in the next round, until consensus was reached among a majority of experts. If there was consensus in the first round, then in the second round the statements from the same experts were indicated as 'Not Applicable'. In the 3-point likert scale, a tie means that experts' responses accumulated to the same value for two/more points in the scale, while consensus means that there was a clear agreement of one point in the likert scale.

Data analysis

Data were analysed after each round of the Delphi survey. Responses to each statement were collated to determine which statements received the highest rating (which indicated consensus) in each category of statements. Data were analysed using frequencies and percentages. All the data were analysed using STATA© software Version 12 (StataCorp, 2011).

Ethical considerations

Ethics approval was obtained from the host institution, the University of Free State (UFS-HSD2020/0432/3006) to proceed with the study. Reciprocal, expedited and/or gatekeeper ethics approvals were then sought and obtained from each REC before participant recruitment.

Participants were provided with an information document and advised that, should they have any questions, they could approach the researchers for clarity. The online questionnaire was completed anonymously and, therefore, participants were not known to either the researchers or each other. They could, therefore, provide implied consent by ticking the first page of the online questionnaire before proceeding to complete the rest of the questionnaire.

Survey development

The 30 statements in the survey that participants were requested to rank had been developed by the researchers based on the relevant literature and after analysis of the results of a scoping review and the findings of a survey that had been conducted among the REC administrators (Mulondo et al., 2021) prior to the Delphi survey. Furthermore, the researchers relied on the participants' expertise, as research ethics experts.

Expert panel recruitment

According to Habibi et al. (2014), a group of about 10 experts is recommended for a Delphi survey. However, another study recommends a minimum of 12 participants as the recommended number of Delphi participants (Vogel et al., 2019). A small group of participants is easier to manage than a large one, as it is likely to elicit fewer diverging opinions, which may be difficult to manage (Keeney et al., 2011). Overall, 23 research ethics

experts from South Africa and abroad were invited to take part in the Delphi survey. The invited participants were REC chairpersons or executive members of research and/or research ethics organisations. Of the 23 experts approached during both rounds, 12 experts completed the first round, and 13 experts completed the second round.

Results

Of the 23 recruited experts, 12 responded and participated in the first round of the survey (52% response rate); while 13 participated in the second round of the survey (57% response rate). In the first round of the Delphi survey, 12 research ethics experts completed the questionnaire by rating 30 statements and background information. In the second round, 13 research ethics experts completed the survey and rated three statements about which consensus had not been reached in the first round as well as the background information on the type of training (specifically on informal and Bachelor's degree training). Participants in Round 1 recommended an additional statement (i.e. producing time frame reports) under the review process tasks which was added to the survey and rated in Round 2, thus, increasing the total number of statements to be rated in Round 2, to four (Figure 1).

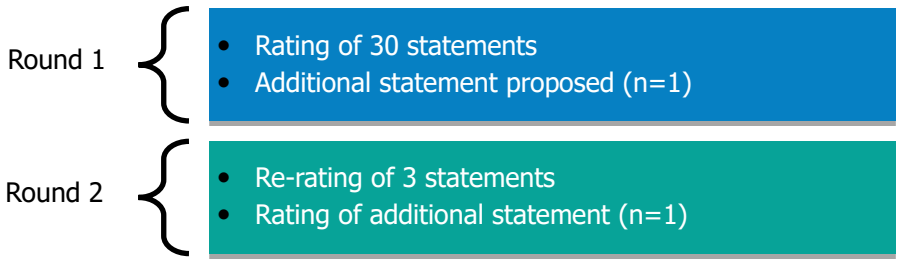

Figure 1. Two rounds of the Delphi survey

The recommendations provided by the administrators reported in the prior survey (Mulondo et al., 2021) were considered for the proposed capacity development framework. In addition, the recommended areas of development suggested in the literature (IJsselmuiden et al., 2012) were used to construct the statements ranked by the experts in the Delphi survey. The statements of the survey covered the following aspects regarding capacity development, (a) training, (b) standard operating procedures (c) infrastructural upgrades, and (d) administrative systems, but could also, focus on (e) harmonizing procedures, and (f) improving information sharing (IJsselmuiden et al., 2012). These aspects are put together and are shown in the proposed capacity development framework (Figure 2).

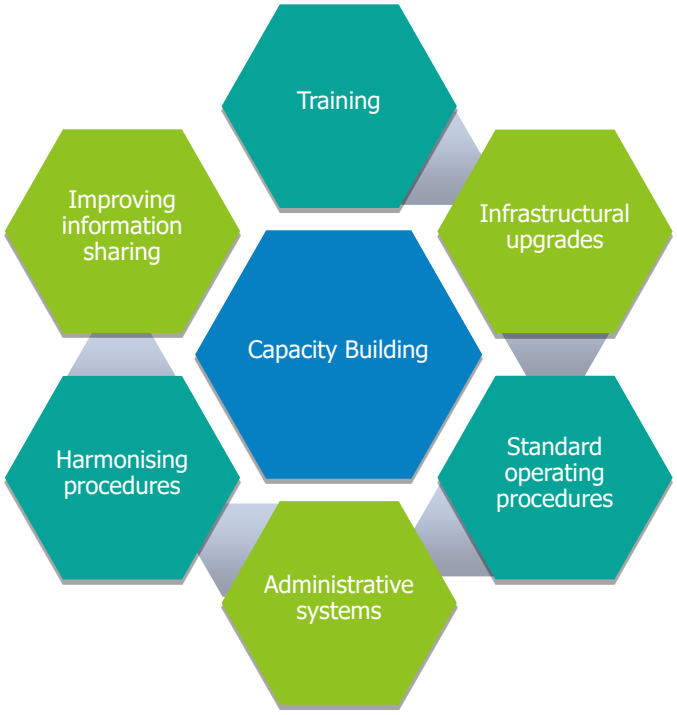

Figure 2. Proposed capacity development framework for REC administrators

Table 1 presents the demographic profile of the research ethics experts who participated in the first and second rounds. Of those who participated in first round, 73% were male and 27% were female, this may indicate that research experts who were willing to participate in the study were males. while, in the second round the gender difference were similar (46% vs 54%) for males and female, respectively. Regarding years of experience in research ethics, 50% indicated being in the role for less than nine years, while the other 50% had been in the role 10 years or longer for first and second rounds of the survey, respectively (Table 1).

Table 1. Demographic characteristics of Delphi survey participants

Characteristic		Round 1 (N=12)	Round 2 (N=13)
Gender	Male	72.7%	46.2%
	Female	27.3%	53.8%
Specialty	REC chair	91.7%	76.9%
	Other	8.3%	23.1%
Years of experience	0–4 years	0	16.7%
	5–9 years	50.0%	33.3%
	>10 years	50.0%	50.0%

The statements were grouped into three domains in line with what was identified during the first survey and the results are presented elsewhere (Mulondo et al., 2021). In the first round of the Delphi survey, the participants could not reach consensus on two of the

guidance advisory tasks and one of the review process tasks, with consensus being reached on only 80% and 91.7% of the tasks, respectively. After Round 1, one more statement was generated and added onto Round 2 for experts to reach consensus on. In Round 2, the experts managed to reach consensus on all four of the statements including the newly generated statement from Round 1. The summary of grouped statements by domain are presented in Table 2.

Table 2: Summary of grouped statements by domain

Domains	Number of statements		Statements on which consensus was reached	
	Round 1	Round 2	Round 1	Round 2
Managerial tasks	8	N/A	100% (8)	N/A
Guidance advisory tasks	10	2	80% (8)	100% (2)
Review process tasks (the two statements in Round 2 included the additional statement generated in Round 1)	12	2	91.7% (11)	100% (2)

The recommended information regarding type of training, infrastructure (upgrades) support and administrative systems, harmonising procedures and areas for improving information sharing are presented in Table 3.

Recommended training: The consensus on Bachelors' degree was reached in Round 2. When indicating what basic, entry-level training research ethics administrators need to perform their duties, 67% of research ethics experts recommended that research ethics administrators needed to have a Bachelor's degree.

Recommended infrastructure (upgrades) support and administrative systems: Regarding administrative systems and infrastructure support, such as review process tracking systems, that administrators need to fulfil their daily tasks, almost half of the research ethics experts (46%) recommended that an ethics management system be used to manage information, while a few participants recommended other systems.

Recommended harmonising procedures and appropriate title: When asked to suggest the title to use for research ethics administrators, 83% of the participants indicated that REC administrator was the appropriate term for this group of professionals.

Recommended improvement of information sharing: The results indicate that 50% of the participants recommended the National Health Research Ethics Council (NHREC), while the other 50% recommended the Southern African Research and Innovation Management Association (SARIMA) community of practice as appropriate information-sharing or networking platforms.

Table 3. General background recommended by the experts

Recommendation	Round 1 (n=12)	Round 2 (n=13)
Type of training		
Informal	41.7%	16.7%
Certificate	0	N/A
Diploma	0	N/A
Postgraduate diploma	16.7%	N/A
Bachelor's Degree	41.7%	66.7%
Other	0	16.7%
Infrastructure (upgrades) support and administrative systems		
Ethics Management System (EMS)	45.5%	N/A
Research Information Management System (RIMS)	18.2%	N/A
Infonetica	0	N/A
Research for Health and Innovation Organiser (RHInnO)	9.1%	N/A
Fluid Review	0	N/A
Research Information Gateway (RIG)	9.1%	N/A
Submittable (Information System)	0	N/A
Microsoft Excel	0	N/A
Other	18.1	N/A
Harmonising procedures		
REC Administrator	83.3%	N/A
REC Professional	0	N/A
REC Coordinator	8.3%	N/A
REC Officer	8.4%	N/A
REC Manager	0	N/A
Other	0	N/A
Areas for improving information sharing		
NHREC	50%	N/A
SARIMA	50%	N/A
Other	0	N/A

Recommended standard operating procedure: All participants indicated that drafting the REC meeting agenda and minutes was an essential task that administrators needed to fulfil. Additionally, 92% indicated that managing research information management systems, as well as screening applications for completeness, were equally essential tasks. Conversely, 58% of research ethics experts indicated that providing background information relating to research, such as technical or research design information, as well as monitoring and arranging REC member training, were not essential tasks of research ethics administrators. The figures in bold indicate the majority number of respondents after the survey was completed. The responses to statements included in the Delphi Survey are shared in Table 4.

Table 4. Responses to statements included in the Delphi survey

Preferred training	Round 1 (n=12)			Round 2 (n=13)		
	Not essential	Desirable	Essential	Not essential	Desirable	Essential
Managerial tasks						
Organising for audits	8.3%	25%	**66.7%**	N/A	N/A	N/A
Monitoring ongoing research	16.7%	25%	**58.3%**	N/A	N/A	N/A
Ensuring compliance to guidelines	8.3%	33.3%	**58.3%**	N/A	N/A	N/A
Handling complaints	25%	**41.7%**	33.3%	N/A	N/A	N/A
Writing reports	8.3%	41.7%	**50.0%**	N/A	N/A	N/A
Managing REC activities	0	16.7%	**83.3%**	N/A	N/A	N/A
Maintaining public relations	16.7%	16.7%	**66.7%**	N/A	N/A	N/A
Lobbying and advocacy	33.3%	**41.7%**	25%	N/A	N/A	N/A
Guidance advisory tasks						
Developing modules or courses	33.3%	**41.7%**	25%	N/A	N/A	N/A
Obtaining external funding for REC	**50.0%**	41.7%	8.3%	N/A	N/A	N/A
Drafting REC guidance documents	25%	33.3%	**41.7%**	N/A	N/A	N/A
Collaborating with other institutions	33.3%	**50.0%**	16.7%	N/A	N/A	N/A
Liaising with regulatory authorities	33.3%	33.3%	33.3%	**46.2%**	15.4%	38.5%
Providing research ethics training	**58.3%**	16.7%	25%	N/A	N/A	N/A
Providing background information	**58.3%**	25%	16.7%	N/A	N/A	N/A
Monitoring REC member training	**0**	16.7%	**83.3%**	N/A	N/A	N/A
Billing applicants	16.7%	41.7%	41.7%	23.1%	30.8%	**46.2%**
Updating institution's website	8.3%	8.3%	**83.3%**	N/A	N/A	N/A
Review process tasks						
Recruiting new members	**50.0%**	33.3%	16.7%	N/A	N/A	N/A
Managing information systems	**0**	8.3%	**91.7%**	N/A	N/A	N/A
Ensuring quality of reviews	18.2%	18.2%	**63.6%**	N/A	N/A	N/A
Screening applications	8.3%	0	**91.7%**	N/A	N/A	N/A
Ensuring quality review feedback	8.3%	16.7%	**75.0%**	N/A	N/A	N/A
Providing technical advice	8.3%	25.0%	**66.7%**	N/A	N/A	N/A
Determining type of review	16.7%	8.3%	**75.0%**	N/A	N/A	N/A
Allocating applications for review	25.0%	8.3%	**66.7%**	N/A	N/A	N/A

Preferred training	Round 1 (n=12)			Round 2 (n=13)		
	Not essential	Desirable	Essential	Not essential	Desirable	Essential
Drafting REC meeting agenda	0	0	**100%**	N/A	N/A	N/A
Drafting REC meeting schedules	0	0	**100%**	N/A	N/A	N/A
Designing ethics application form	16.7%	41.7%	41.7%	7.7%	23.1%	**69.2%**
Producing time frame reports (additional statement)	N/A	N/A	N/A	0	7.7%	**92.3%**

The final recommendations from the experts indicated above was utilised to finalize the capacity development Framework especially the area around training.

Capacity Development Framework

The capacity development framework which was validated through the experts' recommendations and finalized in this study is presented in Figure 3. The same six aspects as reflected in the proposed capacity framework were confirmed by the expects. These aspects were similar to what was proposed by IJsselmuiden et al. (2012). The experts further recommended a Bachelor's degree as the entry requirement for the research ethics administrator profession as part of their training requirement. This has been factored in the framework. Two domains (Infrastructural upgrades and administrative systems) were considered to be serving the same purpose in this study, irrespective of recommendations made by IJsselmuiden et al. (2012), and we propose that they can be merged. These two domains were regarded as representing the information management systems that administrators would need to use.

The experts recommended the Ethics Management System, this recommendation is optional depending on the needs of an institution or ethics committee. The experts indicated that drafting REC meeting agendas, minutes etc., were essential tasks that administrators need to fulfil as part of Standard operating procedure. In order to harmonise the procedure by which administrators are known, experts recommended 'REC administrator' as the appropriate title for this group of professionals. In South Africa, for the purpose of information sharing and networking, NHREC and SARIMA are recommended as appropriate avenues for administrators to consider for networking purposes (see Figure 3).

The experts recommended focus areas depicted in Figure 3 were reflected based on IJsselmuiden et al. (2012)'s proposed capacity building focus areas which are namely, training, standard operating procedures, infrastructural upgrades, and administrative

systems, harmonising procedures and improving information sharing. These were considered important aspects for the final REC administrators' capacity development framework (see Figure 3) with a proposed recommendation to merge infrastructural upgrades and administrative systems.

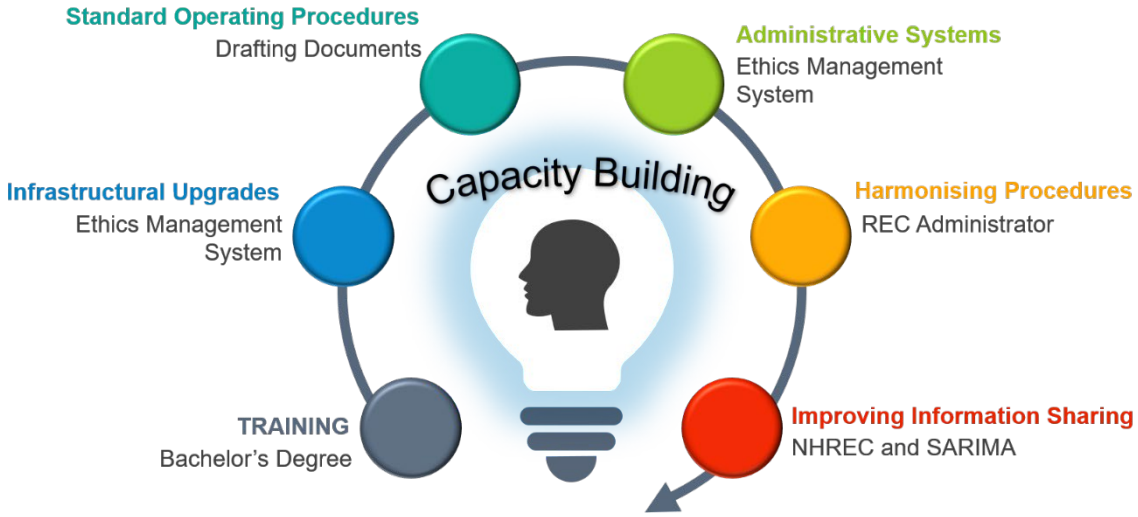

Figure 3: Capacity development framework (Adapted from IJsselmuiden *et al.* 2012)

Discussion

This study generated hopefully useful findings for the research ethics community, as it is the only research known to the best knowledge of the researchers that focuses on designing a capacity development framework for research ethics administrators in South Africa, and most of the African continent. Most capacity development initiatives in South Africa are directed at research ethics committee members who are involved with the actual review process, and not REC administrators (Mokgatla et al., 2018).

In the findings of this study, participants recommended that REC administrators need to possess basic, entry-level training equivalent to a Bachelor's degree before they take up the position. This is in line with the standards in the United States Public Responsibility in Medicine and Research (PRIM&R), which offers two streams of formal qualifications, one for certified IRB professionals (CIP), and the other for certified professional in IACUC administration (CPIA), one of which all ethics professionals and administrators are required to complete as a minimum requirement (Public Responsibility in Medicine and Research, 2020). The eligibility criteria for these streams are that candidates must either have some Bachelor's degree training, or two to four years' experience in research ethics. This reveals the need for the establishment of Bachelor's degree training in research ethics

administration in South Africa and the African continent, to enable development of REC administrators career paths. The establishment of Bachelor's degree training contribute to administrators' training, as it was reported that most administrators perform their tasks with no relevant training (Kasule et al., 2016). Currently, any B-degree is recommended as background, and then offer a postgraduate research ethics diploma for entrants wishing to train as REC administrators.

Infrastructural support and administrative systems are vital for administrators to fulfil their responsibilities. It is imperative that administrators can keep up with the fast-paced world of research and, consequently, that of research ethics too include the use of electronic management system of the review process, as opposed to paper-based or manual systems.

The experts who participated in this study concluded that the "REC administrator" is the appropriate title of this group of professionals. The conversation on the harmonization of this title was also suggested by EthiXpert, 2020 in an effort to harmonize this group of professionals' title within research ethics committees.

NHREC and SARIMA are recommended as appropriate avenues for administrators to consider for networking purposes. NHREC recommended that associations, such as SARIMA can play a role in supporting administrators (NHREC, 2017). In South Africa the suggested platforms are not necessarily appropriate places for networking, they however can serve this purpose until appropriate networking structures are established.

Strengths and weaknesses

To the researchers' knowledge, this is the first study in South Africa to focus on capacity development of research ethics administrators. The study was also able to develop a capacity development framework for research ethics administrators.

A limitation was the effect of Covid-19 lockdown restrictions during the time of the study, the researchers were unable to gain access to some of the RECs.

Conclusion

The experts reached consensus on all statements that were presented to them. Based on the results, administrators who work for RECs should be regarded as REC administrators. Standardising their title will enable harmonisation across institutions or RECs. Results, furthermore, indicate that it is imperative for REC administrators to have a certain level of basic understanding of their work, and therefore basic, entry-level training at a Bachelor's degree level is recommended.

In structuring training for this group of professionals, access to an ethics management system is required. Training of administrators should include training on drafting REC meeting agendas and minutes, managing research information management systems, and screening research ethics applications. Research ethics experts recommended that administrators utilise the NHREC and SARIMA for information sharing. It is, therefore, evident that there is a clear career trajectory for this group of professionals. Succeeding in the career path will require the buy-in of all stakeholders involved in assisting these professionals to reach their fullest potential.

Recommendations

According to Kasule et al. (2016), no systematic assessment of ethics review fees has, to date, been conducted in Africa. Findings from this study may, therefore, aid in motivating future research studies to focus on this topic, as it could help to determine the resources necessary to capacitate REC administrators properly. A lack of funding may be a contributing factor to the lack of capacitation of REC administrators, as current training does not usually focus on good operational procedures (Kasule et al., 2016).

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There were no research study sponsors.

Ethical Statement: Ethics approval was obtained from the host institution, University of the Free State (UFS-HSD2020/0432/3006). A short overview of the study and its purpose were provided to the participants in a participant information document, which contained a clear, understandable explanation of what was required of them; consent was implied by completion of the anonymous online questionnaire.

Chapter 5 will discuss the contribution and significance of the study.

Notes

[i]A biennial event, which has been held since 1996 in conjunction with the World Congress of the International Association of Bioethics.
[ii]For the 2021 fiscal year, countries in the region of Europe and central Asia are regarded as low-middle-income countries.

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CHAPTER 5

CONTRIBUTION AND SIGNIFICANCE OF THE STUDY

5.1 INTRODUCTION

Although research ethics administrators are a vital and integral part of any research ethics committee, capacity development efforts that focus on these professionals have been insufficient. This means that these professionals do not have career-building opportunities and career paths, and the role and its duties have not been professionalised.

The scoping review which was discussed in chapter 2 found that capacity development of research ethics committees is limited to members and not enough on administrators. This was established from a literature search which yielded 92 potentially relevant records while further screening yielded 22 studies. Only two studies spoke directly on administrators' capacity development, and they showed that there have been two capacity development efforts of administrators in Africa, namely the African Conference for Administrators of Research Ethics Committees and the West African Bioethics Training Program.

The survey questionnaire whose findings were discussed in chapter 3 also found that most capacity development efforts in research ethics committees focus on committee members and little on ethics administrators. The online cross-sectional survey was conducted among administrators from 62 National Health Research Ethics Council-registered ethics committees in South Africa. The findings from 36 administrators showed that nearly 49% indicated only having received informal research ethics-related training not targeted formal training towards their current duties which have become complex.

The delphi survey whose findings were discussed in chapter 4 proposed and validated a capacity development framework for research ethics administrators in South Africa with 23 ethics experts to reach consensus. The findings revealed that little research had been done on research ethics committee administrators' capacity development, which had led to a lack of uniform requirements for the role. The results of the second round showed that 67% of the experts confirmed that administrators require basic, entry-level training at the level of a Bachelor's degree to be able to fulfil their duties. Furthermore, nearly 83% of the experts

confirmed 'REC administrator' as the appropriate title for this profession.

5.2 CONTRIBUTION AND SIGNIFICANCE OF THE STUDY

As interdisciplinary research, this study makes a significant and original contribution to the frontiers of the fields of HPE and Community Health. The originality of the study is demonstrated in various ways. Firstly, the focus was on a neglected population, that of research ethics administrators. They provide support to research ethics reviewers and chairs, though their role has always been side-lined. Secondly, the study also focussed on capacity development of research ethics administrators. The study revealed that, currently, there is no formal qualification that specifically addresses the developmental needs of this population within the research ethics community. The currently available capacity development opportunities for research ethics administrators are ad hoc informal training events in the form of short learning programmes or workshops. In addition, these training opportunities focus mainly on REC members, and are intended to strengthen their ethical review skills, and not specifically designed for research ethics administrators. Some research ethics administrators have formal qualifications that are not relevant to the research ethics administration responsibilities. Thirdly, given the gap in knowledge within the research ethics community, the study did not only focus on the health sciences field or health research ethics, but was extended to include all research ethics administrators. Lastly, the findings of the research have applicability not only in South Africa, but for the African continent as a whole, and elsewhere in the Global South, given that only the United States has a capacity development framework for research ethics administrators. Therefore, the research findings may be used to enhance and propel capacity development efforts of research ethics administrators in southern Africa.

Significant findings of the study include identifying the defined needs, roles and responsibilities of research ethics administrators. These were confirmed by both research ethics administrators and research ethics experts.

These findings led to the design of the proposed *Capacity Development Framework for Research Ethics Administrators,* which will be described in the next section. The findings of the study reveal that, as part of this Capacity Development Framework for Research Ethics Administrators, a formal, long-term qualification (a Bachelor's degree) is required. This framework has important implications for the future and career path of research ethics administrators, suggesting that they would no longer be regarded merely as secretaries, but as professionals. This is significant for HPE in that, while the curriculum exists for other

health sciences professionals, there is now a need to develop curriculum specifically for research ethics administrators. This is not only needed in the health sciences field, but for research ethics administrators in general. In the United States curriculum, and elsewhere, including in the Global South and Africa, a formal qualification is needed. Hence, a framework that could guide curriculum and programme design and development for research ethics administrators is proposed. The findings, furthermore, highlight the need for administrators to be capacitated in ways comparable to training received by research ethics committee members, so that they are better placed to match the fast-growing world of research ethics review and health research.

This research contributes knowledge to the conversation on the capacity development of research ethics administrators globally. Through the development of the framework, the study highlights opportunities to be explored in future research, which would enable researchers to answer these questions: 1) Should the proposed Bachelor's degree be discipline specific or general? 2) What type of curriculum should be developed? 3) Should there be a vertical articulation of qualifications to Honours or a postgraduate diploma, Master's and doctoral levels? 4) If these higher-level qualifications are required, what roles and career path will be available to these professionals?

5.3 FORMULATION OF THE FRAMEWORK

The three interrelated articles that were presented in Chapters 2 to 4 of this thesis enabled the researcher to answer the research question of this study. The answers to the research question and the conclusions reached guided the construction of a capacity development framework to assist with capacitation of research ethics administrators. The framework will set the tone for the capacitation of research ethics administrators who work in research ethics committees.

Capacity building focuses on training, standard operating procedures, infrastructural upgrades, and administrative systems, but could also, furthermore, focus on harmonising procedures and improving information sharing (IJsselmuiden *et al.* 2012:77). In this study, aspects of infrastructural upgrades and administrative systems were merged and addressed as one aspect, as their focus is similar. The framework that was designed focuses on and addresses the abovementioned aspects of capacity development. This chapter presents the final product of the research (cf. Figure 5.1).

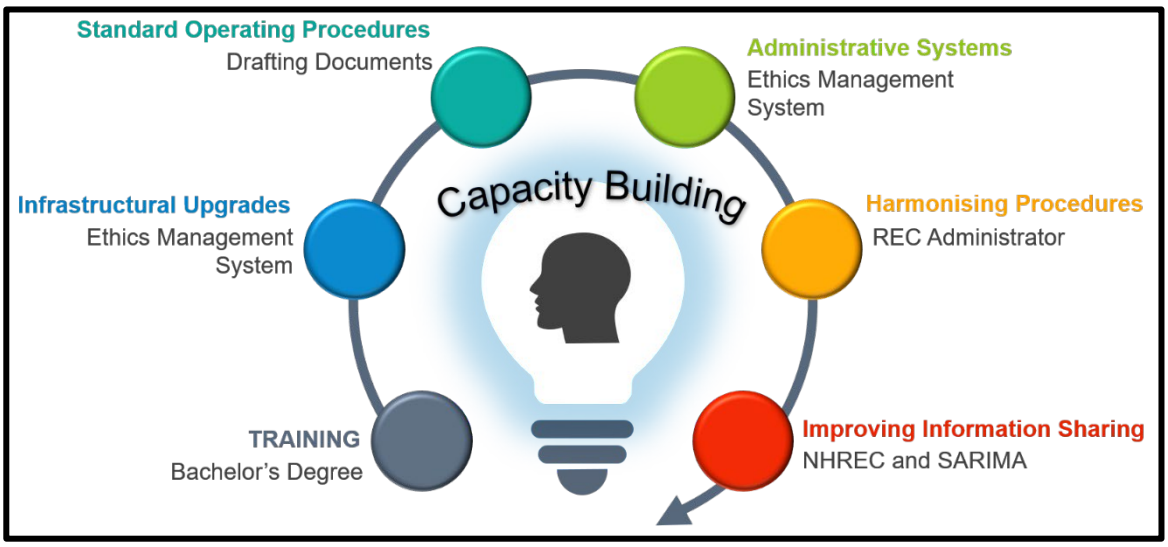

Figure 5.1: Capacity development framework for research ethics administrators

The aspects of capacity development that were listed in Section 5.1 were utilised, as no published capacity development effort for research ethics administrators was found by the scoping review. The following aspects and domains should be taken into consideration when implementing the capacity development framework for research ethics administrators:

5.3.1 Training

It is imperative that research ethics administrators have a basic level of knowledge, namely a Bachelor's degree. This guideline will assist recruiters and human resources officers to know at which level they need to shortlist, as potential REC administrators who have undergone that basic level of training are likely to be better able to grasp the complexities of the job.

5.3.2 Infrastructural upgrades and administrative systems

Although information management systems vary, depending on specific needs of an institution and research committee, the majority of the research ethics experts in this study recommended using the Ethics Management System. Competency in this skill is particularly important as, according to Kasule *et al.* (2016:13,17), few administrators have undergone adequate training or have access to efficient electronic management systems or digital tracking to assist with their complex responsibilities.

5.3.3 Standard operating procedures

All (100%) the research ethics experts indicated that drafting REC meeting agendas and minutes was an essential task that administrators need to fulfil. Additionally, 92% indicated that managing research information management systems and screening applications for completeness were equally essential tasks. Conversely, 58% of research ethics experts stated that providing background information relating to research, such as technical or research design information, and monitoring and arranging REC member training, were not essential tasks for research ethics administrators to fulfil. It is, therefore, vital that RECs refrain from inundating research ethics administrators with tasks that are beyond their scope.

5.3.4 Harmonising procedures

Furthermore, it is important to harmonise the title by which research ethics administrators are known. Some conversations lean towards using titles such as research ethics committee professionals or administrators (EthiXpert, 2020). Some RECs do have chairpersons who serve as both chairpersons and administrators, according to the MARC (Mapping African Research Ethics Capacity) project's findings on African REC membership and staff, although there has since been improvement in the differentiation of these tasks (Mokgatla *et al*. 2018:344). Furthermore, there have been instances where REC chairpersons have been referred to as research ethics administrators, although, in this study, the title was clear: administrator refers to the professional who is performing secretarial tasks in a REC. The experts who participated in this study concluded that the title "REC administrator" (henceforth referred to as such) is the appropriate title of this group of professionals.

5.3.5 Information sharing

In an effort to capacitate REC administrators and ensure they have opportunities to network, NHREC and SARIMA are recommended as appropriate avenues for administrators to consider for networking purposes. Even though it was clear that these are not the appropriate places for networking, they are likely to provide suitable networking opportunities until dedicated networking structures are established.

5.4 DISSEMINATION OF THE RESULTS

The results of this study will be disseminated by publication in peer-reviewed journals. Findings of this study will, furthermore, be presented at academic conferences related to research ethics, health education, community health and public health.

This chapter presented the proposed framework for capacity development of REC administrators and identified the various aspects that need to be considered when designing a curriculum for the development of REC administrators.

Chapter 6 will discuss the conclusions and recommendations from the study.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

The purpose of this study was to develop a capacity development framework for research ethics administrators in South Africa. The framework was designed to assist research ethics committees to capacitate their administrators, so that administrators could fulfil their responsibilities better.

As research has become more complex, it has become important for officials in every sphere of the research ethics committee to be fully capacitated and able to fulfil their tasks competently. Furthermore, international and multi-site studies necessitate proper development of each team member, so that they can handle these complex studies.

This final chapter provides concluding thoughts, the limitations of the study and recommendations.

6.2 CONCLUSIONS

Four objectives were set in order to achieve the aim of the study and answer the research question of this study:

What capacity development framework can be used to better capacitate research ethics administrators?

The conclusions related to these objectives will be presented in the following sections.

6.2.1 Research objective 1

The first research objective was,

To establish the existing global capacity development initiatives for research ethics administrators using literature from 2014 to current. *(Scoping review)*

A scoping review was conducted to address the first objective of the study. The review results were presented in Article 1, which was presented in Chapter 2 of this thesis, titled *Capacity development of research ethics administrators: Scoping review* (cf. Chapter 2).

The results show that there have been few research studies conducted on capacitation of REC administrators. The two studies (Kasule et al., 2016; Ndebele et al., 2014) that focused on capacity development of REC administrators revealed that capacity development efforts that have taken place in Africa were mostly funded by the Global North. The studies report that administrators were capacitated through informal methods, such as conferences or short learning programmes.

The scoping review concluded that there is a need for more empirical studies on this topic. It is evident that there is a need for more capacity development efforts aimed at REC administrators, particularly efforts that are suitable for the African setting.

6.2.2 Research objective 2

The second research objective was,

> *To determine the current responsibilities, training requirements and needs of research ethics administrators within the South African context.*
>
> *(EvaSys questionnaire)*

A self-administered online questionnaire was administered through EvaSys, and completed by administrators at RECs in South Africa, to address the second objective of this study. The questionnaire results were presented in Article 2 (cf. Chapter 3) of this thesis, titled *A survey to determine the capacity development needs of research ethics committee administrators in South Africa* (cf. Chapter 3).

The results indicate that administrators performed managerial, review process and guidance/advisory tasks, about which they felt inadequate and unable to fulfil certain tasks. Managerial tasks included organising for audits, with 60% indicating that they needed more training for them to be able to perform these tasks better.

The results of the questionnaire are that research ethics administrators are performing duties that range from managerial to expert tasks, while their role has yet to be

professionalised, and proper capacity development for them is yet to be implemented. Nearly 49% reported having received only informal research-ethics-related training, and not targeted, formal training – 81% of the informal training they had received was through workshops.

6.2.3 Research objective 3

The third research objective was,

> *To establish the views of research ethics experts about the draft framework for capacity development of research ethics administrators (Delphi Survey)*

A self-administered Delphi survey was designed in EvaSys and distributed to research ethics experts in South Africa and abroad to address the fourth objective of this study. The Delphi survey results were presented in Article 3 of this thesis, titled *A Delphi survey to reach consensus on a capacity development framework for research ethics committee administrators* (cf. Chapter 4).

Firstly, the results showed that administrators who serve in research ethics committees should be regarded as REC administrators, in an effort to harmonise the title. Secondly, REC administrators should have a basic level of understanding of the work, and basic entry-level training or qualification at Bachelor's degree level. Thirdly, in structuring training for this group of professionals, the Ethics Management System is an appropriate information management system to consider using. Fourthly, the training should include training in drafting REC meeting agendas and minutes, managing research information management systems, as well as in screening research ethics applications. Finally, REC administrators should refer to NHREC and SARIMA for information sharing and networking.

In summary, the findings of this study contribute to the conversation on the capacity development of REC administrators. Kasule *et al.* (2016:16) assert that there is potential to develop a locally relevant training programme for people involved in research ethics administration in sub-Saharan Africa. The framework provided in this study can add to conversations that are necessary and which could lead to change. Additionally, the results of this study could, therefore, continue to propel capacity development efforts of administrators, and their career path.

6.2.3.1 *Research objective 4*

The fourth research objective states,

> *Arising from the first 3 objectives, design a capacity development framework for research ethics administrators*

The researcher triangulated findings of the scoping review (cf. Article 1) and the self-administered online questionnaire (cf. Article 2). This was done to provide the researchers with an opportunity to draft an online Delphi survey that could respond to the fourth objective of this study.

The researcher analysed the results from the scoping review and the online questionnaire and, after discussing it with the supervisors, was able to draft the Delphi survey questionnaire. The Delphi survey was the final step before drafting the framework to capacitate REC administrators.

6.3 LIMITATIONS

The scoping review methodology provided the researcher with an opportunity to analyse a variety of studies. The EBSCOhost database and Google Scholar search engine provided a wide and varied range of articles from different database sources globally. However, the language preference was limited to English, which meant that there was no opportunity to synthesise studies published in other languages. Furthermore, the abbreviations IRB, ERC, REB and REC were not used and this could be a limitation of the search strategy.

The lack of prior studies in this topic resulted in a few literature studies provided which could have augmented the bibliography. The literature review in this study is therefore biased towards REC members and not administrators as there is not sufficient literature. The study could have benefited from prior research studies on the topic.

The lack of exploration of information on major topics which would make part of a curriculum has been added a limitation as this would require further investigation.

The Covid-19 pandemic presented a further limitation to the study, as some institutions had stopped processing research ethics applications while they focused on internal research

studies. Other RECs had limited internet access, which was exacerbated by staff having to work remotely. The researchers repeatedly attempted to contact RECs to ensure as many RECs as possible were included in the study. Furthermore, due to the Covid-19 pandemic, qualitative research was not considered which would have greatly strengthened the study design.

Finally, no actual reliability test (such as Cronbach's Alpha) was conducted in the pilot study which also presents as a limitation in this study.

6.4 RECOMMENDATIONS

For health professions education: This study proposed and designed a *Capacity Development Framework for REC Administrators*. It is recommended that a curriculum based on this framework is developed for a Bachelor's degree qualification. It is, furthermore, recommended that programmes for postgraduate degrees are developed. This would enable a vertical articulation of the qualification and ensure a successful career path.

For research: Further research into the roles and targeted training of research ethics administrators will be needed once the pandemic is over. This will enable more RECs and REC administrators to be recruited and included in a similar study. This study did not focus on the resources needed to develop the capacity of REC administrators. Future research should focus on this aspect, as it could help determine the resources necessary to properly capacitate REC administrators. It is not known if a lack of funds is a contributing factor to the shortcomings of capacitation for REC administrators.

For community health: As health research affects people directly and indirectly, it is essential that REC administrators are better capacitated, and that they are able to serve the lay public community adequately. REC administrators are the direct liaison and contact between the REC and researchers/community; thus, it is recommended that they receive the necessary research ethics training.

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APPENDICES

Appendix A: Letter to faculty management and vice rector: Research and Internationalisation, to request permission to execute the study [RIMS: UFS authorities approval]

Appendix B: Letter of request for participants to take part in the survey questionnaire (recruitment letter)

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Appendix D: Research instrument for survey questionnaire (EvaSys questionnaire)

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Appendix A:

Letter to faculty management and Vice-Rector: Research and Internationalisation, to request permission to execute the study [RIMS: UFS authorities approval]

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

LETTER TO UFS AUTHORITIES: RIMS GATEKEEPERS APPLICATION

Dear Prof C Witthun (Vice-Rector: Research)

My name is Mutshidzi Abigail Mulondo. I am a research ethics administrator at the Health Sciences Research Ethics Committee (HSREC), University of the Free State and a registered PhD candidate enrolled in the Health Professions Education program.

I hereby request approval to conduct a study which entails designing a capacity development framework for research ethics administrators. The results of this study will hopefully assist in providing necessary tools and support to REC administrators, which is currently limited.
The study will involve an electronic survey questionnaire which should not take longer than 60min and Delphi Survey. Participation in this study is voluntary and confidentiality guaranteed. Participants will have the option to withdraw at any time.

Should you have any more questions about my study please do not hesitate to email me on mulondoma@ufs.ac.za/ tshidzi.gail@gmail.com or call on 084 866 2553/051 401 7795.

Sincerely,

Mutshidzi Abigail Mulondo
HPE PhD Candidate

205 Nelson Mandela Drive/Rylaan, Park West/Parkwes, Bloemfontein 9301, South Africa/Suid-Afrika
P.O. Box/Posbus 339, Bloemfontein 9300, South Africa/Suid-Afrika, T: +27(0)51 401 9111, www.ufs.ac.za

Appendix B:

Letter of request for participants to take part in the survey questionnaire (recruitment letter)

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

RECRUITMENT LETTER: QUESTIONNAIRE

Dear *Research Ethics Committee*

I am doing research and would like to request your participation in this study

DATE

August 2020

TITLE OF THE RESEARCH PROJECT

Research ethics administrators: A capacity development framework.

PRINCIPLE INVESTIGATOR / RESEARCHER(S) NAME(S) AND CONTACT NUMBER(S):

Ms Mutshidzi Abigail Mulondo *2008017011* *084 866 2553/ 051 401 7795*

FACULTY AND DEPARTMENT:

Faculty of the Health Sciences
Health Sciences Education

STUDYLEADER(S) NAME AND CONTACT NUMBER:

Prof Joyce Tsoka-Gwegweni (UFS staff member)
051 401 7961

Prof Puleng LenkaBula (UFS staff member)
051 401 3735

WHAT IS THE AIM / PURPOSE OF THE STUDY?

The aim of the study is to design a capacity development framework for research ethics administrators. I am conducting a study which entails designing a capacity development framework for research ethics administrators. The results of this study will attempt to assist in providing necessary tools and support to research ethics administrators, which is currently limited.

WHO IS DOING THE RESEARCH?

My name is Mutshidzi Abigail Mulondo. I am a Research Ethics Committee (REC) administrator at the Health Sciences Research Ethics Committee (HSREC), University of the Free State and a registered PhD candidate enrolled in the Health Professions Education program.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received approval from the Research Ethics Committee of UFS. A copy of the approval letter can be obtained from the researcher.

Approval number: *UFS-HSM2020/0432*

WHY ARE YOU INVITED TO TAKE PART IN THIS RESEARCH PROJECT?

As an administrator/coordinator in a REC, I believe your expertise will be of immense value to this study. I obtained your contact details from the NHREC list of registered REC's in South Africa which is freely available on their website. I will endeavor to recruit administrators from all 64 NHREC registered South African RECs situated within 41 institutions.

WHAT IS THE NATURE OF PARTICIPATION IN THIS STUDY?

This study will involve an electronic survey questionnaire which should not take longer than 60min. You will be expected to share information about support tools you know of and some that you use to be better equipped at fulfilling your role.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

The capacity development framework that will be developed from this study will assist research ethics administrators by improving the administrative process through providing and directing administrators to supportive tools in their career. Furthermore, the results of this study will assist future researchers in developing a training program and/or professionalizing this administrative role, both of which are beyond the scope of this study.

WHAT IS THE POTENTIAL RISKS TAKING PART IN THIS STUDY?

There are no foreseen risks from participating in this study. However, during the course of the study should you feel uncomfortable, you are free to withdraw participation. You are also welcome to ask any questions of clarity during the interview.

WILL THE INFORMATION BE KEPT CONFIDENTIAL?

All information will be managed in a strictly professional and confidential manner. Private information will not be shared without your permission. Furthermore, your name and institution will not be shared in the findings of this study, your name will not be recorded anywhere and no one will be able to connect you to the answers you give. Confidentiality will further be assured by ensuring that the electronic response is exclusively accessible to the researcher and researcher's supervisors and not made available to any third parties. Your answers may be reviewed by people responsible for making sure that research is done properly, including the UFS Biostatistics department and members of the Research Ethics Committee. Otherwise, records that identify you will be available only to people working on the study. Furthermore, your answers will be given a fictitious code number and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

HOW WILL THE INFORMATION BE STORED AND ULTIMATELY DESTROYED?

Once the research is completed, all collected electronic data will be stored on a password protected computer, archived for future research or academic purposes and destroyed after 5 years. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable.

WILL THERE BE PAYMENT OR ANY INCENTIVES FOR PARTICPATING IN THIS STUDY?

There are no costs incurred to participate in this study nor will you be paid to participate.

HOW WILL THE INSTITUTION / ORGANISATION / COMPANY BE INFORMED OF THE FINDINGS / RESULTS OF THE STUDY?

If you would like to be informed of the final research findings, please contact Ms. Mutshidzi Abigail Mulondo on 084 866 2553/051 401 7795 or email tshidzi.gail@gmail.com/ mulondoma@ufs.ac.za. The findings are accessible for 5 years. Should you require any further information or want to contact the researcher about any aspect of this study or have concerns about the way in which the research has been conducted, you may contact the researcher or Health Sciences Research Ethics Committee, UFS.

Yours sincerely

Ms Mutshidzi Abigail Mulondo

_____

Appendix C:

Information document for survey questionnaire (participant information document with implied consent)

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

RESEARCH STUDY INFORMATION LEAFLET AND CONSENT FORM

DATE

August 2020

TITLE OF THE RESEARCH PROJECT

Research ethics administrators: A capacity development framework.

PRINCIPLE INVESTIGATOR / RESEARCHER(S) NAME(S) AND CONTACT NUMBER(S):

Ms Mutshidzi Abigail Mulondo 2008017011 084 866 2553/ 051 401 7795

FACULTY AND DEPARTMENT:

Faculty of the Health Sciences
Health Sciences Education

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Prof Puleng LenkaBula (UFS staff member)
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WHO IS DOING THE RESEARCH?

My name is Mutshidzi Abigail Mulondo. I am a Research Ethics Committee (REC) administrator at the Health Sciences Research Ethics Committee (HSREC), University of the Free State and a registered PhD candidate enrolled in the Health Professions Education program.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received approval from the Research Ethics Committee of UFS. A copy of the approval letter can be obtained from the researcher.

Approval number: *UFS-HSD2020/0432*

WHY ARE YOU INVITED TO TAKE PART IN THIS RESEARCH PROJECT?

As an administrator/coordinator in a REC, I believe your expertise will be of immense value to this study. I obtained your contact details from the NHREC list of registered REC's in South Africa which is

freely available on their website. I will endeavor to recruit administrators from all 64 NHREC registered South African RECs situated in approximately 41 institutions.

WHAT IS THE NATURE OF PARTICIPATION IN THIS STUDY?

This study will involve an electronic survey questionnaire which should not take longer than 60min. You will be expected to share information about support tools you know of and some that you use to be better equipped at fulfilling your role.

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The capacity development framework that will be developed from this study will assist research ethics administrators by improving the administrative process through providing and directing administrators to supportive tools in their career. Furthermore, the results of this study will assist future researchers in developing a training program and/or professionalizing this administrative role, both of which are beyond the scope of this study.

WHAT IS THE POTENTIAL RISKS TAKING PART IN THIS STUDY?

There are no foreseen risks from participating in this study. However, during the course of the study should you feel uncomfortable, you are free to withdraw participation. You are also welcome to ask any questions of clarity during the interview.

WILL THE INFORMATION BE KEPT CONFIDENTIAL?

All information will be managed in a strictly professional and confidential manner. Private information will not be shared without your permission. Furthermore, your name and institution will not be shared in the findings of this study, your name will not be recorded anywhere and no one will be able to connect you to the answers you give. Confidentiality will further be assured by ensuring that the electronic response is exclusively accessible to the researcher and researcher's supervisors and not made available to any third parties. Your answers may be reviewed by people responsible for making sure that research is done properly, including the UFS Biostatistics department and members of the Research Ethics Committee. Otherwise, records that identify you will be available only to people working on the study. Furthermore, your answers will be given a fictitious code number and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

HOW WILL THE INFORMATION BE STORED AND ULTIMATELY DESTROYED?

Once the research is completed, all collected electronic data will be stored on a password protected computer, archived for future research or academic purposes and destroyed after 5 years. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable.

WILL THERE BE PAYMENT OR ANY INCENTIVES FOR PARTICPATING IN THIS STUDY?

There are no costs incurred to participate in this study nor will you be paid to participate.

HOW WILL YOU BE INFORMED OF THE FINDINGS / RESULTS OF THE STUDY?

If you would like to be informed of the final research findings, please contact Ms. Mutshidzi Abigail Mulondo on 084 866 2553/051 401 7795 or email tshidzi.gail@gmail.com. Should you require any further information, have questions about any aspect of this study or have concerns about the way in which the research has been conducted, you may contact the researcher and/or Health Sciences Research Ethics Committee on ethicsfhs@ufs.ac.za or 051 401 7794/5.

Thank you for taking time to read this information sheet and for participating in this study.

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

CONSENT TO PARTICIPATE IN THIS STUDY

I, _____ (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or have had explained to me) and understood the study as explained in the information sheet. I have had sufficient opportunity to ask questions and am prepared to participate in the study. I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable). I am aware that the findings of this study will be anonymously processed into a research report, journal publications and/or conference proceedings.

I have received a signed copy of the informed consent agreement.

Full Name of Participant: _____

Signature of Participant: _____ Date: _____

Full Name(s) of Researcher(s): _____

Signature of Researcher: _____ Date: _____

Appendix D:

Research instrument for survey questionnaire (EvaSys questionnaire)

DRAFT

EvaSys | A CAPACITY DEVELOPMENT FRAMEWORK FOR HEALTH RESEARCH ETHICS COMMITTEE ADMINISTRATORS | Electric Paper

Mark as shown: ☐ ☒ ☐ ☐ ☐ Please use a ball-point pen or a thin felt tip. This form will be processed automatically.

Correction: ☐ ■ ☐ ☒ ☐ Please follow the examples shown on the left hand side to help optimize the reading results.

1. INTRODUCTORY QUESTIONS

1.1 Is your REC institutional (i.e. academic), governmental or private?
☐ Institutional ☐ Governmental ☐ Private

1.2 How long have you been in this job position?
☐ Less than a year ☐ 1 to 2 years ☐ 3 to 4 years ☐ 5 years ☐ More than 5 years

1.3 What is your educational background?

1.4 What is your highest educational level of study?
☐ PhD ☐ Masters degree ☐ Hon degree ☐ B degree ☐ PGDip ☐ Matric ☐ Other *(please complete Q1.5)*

1.5 For 'Other' in Q1.4, please specify.

1.6 Are you working part/full time in this position?
☐ Part time ☐ Full time

2. TRAINING REQUIREMENTS
Training requirements:

2.1 Have you received any **research ethics-related** training?
☐ Yes, formal *(please answer Q2.2 and 2.3)* ☐ Yes, informal *(please answer Q2.4 to 2.7)* ☐ Yes, both formal and informal *(please answer Q2.2 to 2.7)*
☐ No training *(please go to next tab)*

FORMAL TRAINING

2.2 For formal **in-house** (i.e. from your institution) training, please list **all research ethics-related** certificates, diplomas and/or degrees received.

2.3 For formal **out-house** (i.e. from another institution) training, please list **all research ethics-related** certificates, diplomas and/or degrees received.

INFORMAL TRAINING

2.4 Was informal **research ethics-related** training: seminar, workshop and/or online? *(Select all that apply)*
☐ Seminar ☐ Workshop ☐ Online *(please also complete Q2.6 and Q2.7)*

2.5 Please specify any **other** research ethics-related training(s) **media** not listed above.

2.6 For any **online** research ethics-related training received in Q2.4, please specify. *(Select all that apply)*
☐ Training and Resources in Research Ethics Evaluation (TRREE) ☐ Good Clinical Practice (GCP)

DRAFT

2. TRAINING REQUIREMENTS
Training requirements: [Continue]

2.7 For any **other online** research ethics-related training in Q2.6, please specify.

3. TRAINING, STANDARD OPERATING PROCEDURES
Role's perceptions, responsibilities and training needs:

3.1 Please indicate from the list the **managerial tasks** that you require training to better fulfil your job duties. *(You may select multiple options)*

- ☐ Report to institution about REC performance
- ☐ Write reports (annual, progress, etc.)
- ☐ Manage REC secretariat
- ☐ Evaluate REC activities and members
- ☐ Handle complaints
- ☐ Handle allegations of research misconduct and unacceptable research practices
- ☐ Disseminate research results in workshops, seminars or conferences
- ☐ Organise for audits
- ☐ Monitor ongoing research
- ☐ Ensure compliance
- ☐ Renew federal-wide assurance registration
- ☐ Serve as REC Chairperson
- ☐ Maintain public relations such as marketing and communication to foster good relations with research community
- ☐ Lobbying and advocacy
- ☐ Management of REC activities
- ☐ Other *(please complete Q3.2)*

3.2 For 'Other' in Q3.1, please specify any other **managerial tasks** you fulfil, that are not listed above, which you require training or support in.

3.3 Please indicate from the list the **guidance and advisory tasks** you require training to better fulfil your job duties. *(You may select multiple options)*

- ☐ Draft REC guidance documents (ethics policy, SOPs, legislation)
- ☐ Liase with drug regulatory authorities for clinical trials
- ☐ Establish partnerships
- ☐ Collaborate with other institutions
- ☐ Provide background information relating to research such as technical, scientific, or research design information
- ☐ Provide Research Ethics training
- ☐ Serve as REC member
- ☐ Draft REC meeting agenda and minutes
- ☐ Monitor and arrange REC member training
- ☐ Draft annual REC meeting schedule
- ☐ Other *(please complete Q3.4)*

3.4 For 'Other' in Q3.3, please specify any other **guidance and advisory tasks** you fulfil, that are not listed above, which you require training or support in.

3.5 Please indicate from the list the **administration of review process tasks** you require training to better fulfil your job duties. *(You may select multiple options)*

- ☐ Recruitment of REC members
- ☐ Provide technical expertise in research oversight
- ☐ Clerical tasks restricted to receiving and dispatching correspondence and maintaining files (archiving)
- ☐ Management of research information management systems
- ☐ Ensure quality improvement of reviews
- ☐ Determine type of review for each application
- ☐ Screen applications for completeness
- ☐ Guide researchers on application process
- ☐ Communicate REC decisions
- ☐ Prepare for REC meetings
- ☐ Receive SAEs and allocate for review
- ☐ Ensure confidentiality of submitted documents
- ☐ Set up adhoc meetings
- ☐ Other *(please complete Q3.6)*

3. TRAINING, STANDARD OPERATING PROCEDURES
Role's perceptions, responsibilities and training needs: [Continue]

3.6 For 'Other' in Q3.5, please specify any other **administration of review process tasks** you fulfil, that are not listed above, which you require more training or support in

3.7 Please indicate any tasks, which do not fit the abovementioned categories, that you require more training or support to better fulfil your duties.

4. INFRASTRUCTURAL UPGRADES, ADMINISTRATIVE SYSTEMS
Infrastructural Support:

4.1 How many other administrators do you work with?

4.2 Do you have a digital research information management / tracking system? ☐ Yes *(please complete Q4.3)* ☐ No *(please complete Q4.5)*

4.3 For 'Yes', please specify system(s). *(Select all that apply)*

☐ Research Information Management System (RIMS) ☐ Infonetica ☐ Ethics Management System

☐ Other *(please complete Q4.4)*

4.4 For 'Other' in Q4.3, please specify.

4.5 For 'No', please specify what research information management / tracking system you make use of.

5. HARMONISING PROCEDURES

5.1 What is your current job title?

5.2 Does the job title accurately describe your duties? ☐ Yes ☐ No

5.3 Please specify reason for response of 'No' in Q5.2.

5.4 Please specify what job title would adequately describe your duties.

5.5 What would you consider as an adequate entry minimum requirement into this position?

6. INFORMATION SHARING
Networking or Collaboration:

6.1 Do you have any opportunities to network or collaborate with other administrators? ☐ Yes *(please complete Q6.2)* ☐ No

6. INFORMATION SHARING
Networking or Collaboration: [Continue]

6.2 Please specify which opportunities.

6.3 Do you have any information sharing platforms with other administrators? ☐ Yes *(please complete Q6.4)* ☐ No

6.4 Please specify which information sharing platforms.

Appendix E:

Letter of request for participants to take part in Delphi survey (recruitment letter)

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

RECRUITMENT LETTER

INVITATION TO PARTICIPATE IN A DELPHI SURVEY

TITLE: RESEARCH ETHICS ADMINISTRATORS: A CAPACITY DEVELOPMENT FRAMEWORK

Dear Research Ethics Expert,

My name is Mutshidzi Abigail Mulondo. I am a Research Ethics Committee (REC) coordinator at the Health Sciences Research Ethics Committee (HSREC), University of the Free State and a registered PhD candidate enrolled in the Health Professions Education program.

I am conducting a study which entails designing a capacity development framework for research ethics administrators. The results of this study will hopefully assist in providing necessary tools and support to research ethics administrators, which is currently limited. As a research ethics expert, I believe your expertise will be of immense value to this study.

I would therefore like to invite you to participate in this study as a Delphi Survey expert participant. This will involve two or more rounds of the survey which should not take longer than 60min per round. Participation in this study is voluntary and confidentiality guaranteed. Should you agree to participate, please note that you will have the option to withdraw at any time.

If you are willing to participate, please respond to this invitation by responding to my email on mulondoma@ufs.ac.za/ tshidzi.gail@gmail.com or send me a message/WhatsApp on 084 866 2553 and indicate your name and contact details to allow me to make further arrangements.

Sincerely,

Mutshidzi Abigail Mulondo

_____

205 Nelson Mandela Drive/Rylaan, Park West/Parkwes, Bloemfontein 9301, South Africa/Suid-Afrika
P.O. Box/Posbus 339, Bloemfontein 9300, South Africa/Suid-Afrika, T: +27(0)51 401 9111, www.ufs.ac.za

Appendix F:

Letter to obtain consent from participants to take part in the Delphi survey (information document and consent form)

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

RESEARCH STUDY INFORMATION LEAFLET AND CONSENT FORM: DELPHI SURVEY

DATE

August 2020

TITLE OF THE RESEARCH PROJECT

Research ethics administrators: A capacity development framework.

PRINCIPLE INVESTIGATOR / RESEARCHER(S) NAME(S) AND CONTACT NUMBER(S):

Ms Mutshidzi Abigail Mulondo 2008017011 084 866 2553/ 051 401 7795

FACULTY AND DEPARTMENT:

Faculty of the Health Sciences
Health Sciences Education

STUDYLEADER(S) NAME AND CONTACT NUMBER:

Prof Joyce Tsoka-Gwegweni (UFS staff member)
051 401 7961

Prof Puleng LenkaBula (UFS staff member)
051 401 3735

WHAT IS THE AIM / PURPOSE OF THE STUDY?

The aim of the study is to design a capacity development framework for research ethics administrators. I am conducting a study which entails designing a capacity development framework for research ethics administrators. The results of this study will hopefully assist in providing necessary tools and support to research ethics administrators, which is currently limited.

WHO IS DOING THE RESEARCH?

My name is Mutshidzi Abigail Mulondo. I am a Research Ethics Committee (REC) administrator at the Health Sciences Research Ethics Committee (HSREC), University of the Free State and a registered PhD candidate enrolled in the Health Professions Education program.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received approval from the Research Ethics Committee of UFS. A copy of the approval letter can be obtained from the researcher.

Approval number: *UFS-HSD2020/0432*

WHY ARE YOU INVITED TO TAKE PART IN THIS RESEARCH PROJECT?

As a research ethics expert, I believe your expertise will be of immense value to this study. I obtained your contact details from either the NHREC list of registered REC's in South Africa which is freely available on their website or through expert referral. I will endeavor to recruit at least 15 research ethics experts to participate in this Delphi survey.

WHAT IS THE NATURE OF PARTICIPATION IN THIS STUDY?

This study will involve an electronic Delphi survey questionnaire which should not take longer than 60min per round. I estimate a minimum of 2 rounds but might continue until we reach 70% consensus from the participants. You will be expected to share information about support tools you know of and those which serve to better equip research ethics administrators at fulfilling their role.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

The capacity development framework that will be developed from this study will assist research ethics administrators by improving the administrative process through providing and directing administrators to supportive tools in their career. Furthermore, the results of this study will assist future researchers in developing a training program and/or professionalizing this administrative role, both of which are beyond the scope of this study.

WHAT IS THE POTENTIAL RISKS TAKING PART IN THIS STUDY?

There are no foreseen risks from participating in this study. However, during the course of the study should you feel uncomfortable, you are free to withdraw participation. You are also welcome to ask any questions of clarity during the survey.

WILL THE INFORMATION BE KEPT CONFIDENTIAL?

All information will be managed in a strictly professional and confidential manner. Private information will not be shared without your permission. Furthermore, your name and institution will not be shared in the findings of this study, your name will not be recorded anywhere and no one will be able to connect you to the answers you give. Confidentiality will further be assured by ensuring that the electronic response is exclusively accessible to the researcher and researcher's supervisors and not made available to any third parties. Your answers may be reviewed by people responsible for making sure that research is done properly, including the UFS Biostatistics department and members of the Research Ethics Committee. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records. Furthermore, your answers will be given a fictitious code number and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

HOW WILL THE INFORMATION BE STORED AND ULTIMATELY DESTROYED?

Once the research is completed, all collected electronic data will be stored on a password protected computer, archived for future research or academic purposes and destroyed after 5 years. Future use of the stored data will be subject to further Research Ethics Review and approval if applicable.

WILL THERE BE PAYMENT OR ANY INCENTIVES FOR PARTICPATING IN THIS STUDY?

There are no costs incurred to participate in this study nor will you be paid to participate.

HOW WILL YOU BE INFORMED OF THE FINDINGS / RESULTS OF THE STUDY?

If you would like to be informed of the final research findings, please contact Ms. Mutshidzi Abigail Mulondo on 084 866 2553/051 401 7795 or email tshidzi.gail@gmail.com/ mulondoma@ufs.ac.za. Should you require any further information, have questions about any aspect of this study or have concerns about the way in which the research has been conducted, you may also contact the researcher and/or Health Sciences Research Ethics Committee, UFS on ethicsfhs@ufs.ac.za or 051 401 7794/5.

Thank you for taking time to read this information sheet and for participating in this study.

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS UV

CONSENT TO PARTICIPATE IN THIS STUDY

I, _____ (participant name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or have had explained to me) and understood the study as explained in the information sheet. I have had sufficient opportunity to ask questions and am prepared to participate in the study. I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable). I am aware that the findings of this study will be anonymously processed into a research report, journal publications and/or conference proceedings.

I have received a signed copy of the informed consent agreement.

Full Name of Participant: _____

Signature of Participant: _____ Date: _____

Full Name(s) of Researcher(s): _____

Signature of Researcher: _____ Date: _____

Appendix G:

Research instrument for Delphi survey (Delphi questionnaire)

DRAFT

EvaSys	ONLINE DELPHI QUESTIONNAIRE FOR HEALTH RESEARCH ETHICS EXPERTS	Electric Paper

Mark as shown: ☐☒☐☐☐ Please use a ball-point pen or a thin felt tip. This form will be processed automatically.

Correction: ☐■☐☒☐ Please follow the examples shown on the left hand side to help optimize the reading results.

1. CONSENT

1.1 Please indicate whether you are willing to complete this questionnaire.

NOTE: by selecting '**Yes**', you provide implied consent. The questionnaire will then be activated.

☐ Yes, I am willing and understand that completing the questionnaire implies consent.

☐ No, I am not willing to complete the questionnaire.

2. INTRODUCTORY QUESTIONS

Please tick appropriate box.

2.1 Gender

☐ Male ☐ Female ☐ Other

2.2	Health Research Ethics speciality (Please indicate one):	☐ Research Ethics Committee (REC) chair (current, vice, acting, former)	☐ Executive (Manager, DVC, director, etc)	☐ Other *(please complete Q2.3)*

2.3 For 'Other' in Q2.2, please specify.

2.4	Years of experience in Health Research Ethics?	☐ 0-4	☐ 5-9	☐ 10 or more

3. HARMONISING PROCEDURES

3.1	Please indicate what **title** you suggest as appropriate for personnel performing administrative tasks in a REC. Please select one title.	☐ REC Administrator	☐ REC Professional	☐ REC Coordinator
		☐ REC Officer	☐ REC Manager	☐ Other *(please complete 3.2)*

3.2 For 'Other' in Q3.1, please specify.

4. BASIC TRAINING REQUIREMENTS FOR ADMINISTRATORS

4.1	Please indicate what **basic entry level training** personnel performing administrative tasks in a REC require before taking up a job in a REC. Please select one:	☐ Informal training (workshop, seminar, etc)	☐ Certificate or short course (3-6 months)	☐ Diploma
		☐ Postgraduate Diploma	☐ Degree	

5. INFRASTRUCTURE SUPPORT AND ADMINISTRATIVE SYSTEMS

DRAFT

5. INFRASTRUCTURE SUPPORT AND ADMINISTRATIVE SYSTEMS [Continue]

5.1 Please indicate in your expert opinion on what **research management information / tracking system** you recommend for personnel performing administrative tasks in a REC. Please select one.

- ☐ Ethics management system
- ☐ Research Information Management system (RIMS)
- ☐ Infonetica
- ☐ RHInnO Ethics
- ☐ Fluid review by Survey monkey
- ☐ Research Information Gateway Converis (RIG)
- ☐ Submittable - Submission management system
- ☐ Microsoft Excel

5.2 Please indicate any other suggestions for research information management / tracking systems not listed above:

6. INFORMATION SHARING (NETWORKING, COLLABORATION)

6.1 Please indicate what **information sharing / networking platforms** you recommend for personnel performing administrative tasks in a REC.

- ☐ National Health Research Ethics Council (NHREC)
- ☐ SARIMA - Community of practice

6.2 Please indicate any other suggestions for information sharing / networking not listed above:

7. STANDARD OPERATING PROCEDURES

Please refer to Likert scale below when responding to questions below:

Question A: Please rate each of the **management tasks** that personnel performing administrative tasks within a REC require training in to best fulfil their job.

		Not essential	Desirable	Essential
7.1	Organising audits	☐	☐	☐
7.2	Monitoring ongoing research	☐	☐	☐
7.3	Ensuring compliance to guidelines	☐	☐	☐
7.4	Handling complaints, allegations of research conduct and unacceptable research practices	☐	☐	☐
7.5	Writing REC performance reports (annual, progress, etc) to institution	☐	☐	☐
7.6	Management of REC activities	☐	☐	☐
7.7	Maintaining public relations to foster good relations with research community, such as marketing and communication	☐	☐	☐
7.8	Lobbying and advocacy	☐	☐	☐
7.9	Developing modules or courses for research ethics training for research community and REC members	☐	☐	☐
7.10	Getting external funding for REC and administrative resources	☐	☐	☐

7. STANDARD OPERATING PROCEDURES [Continue]

Questions B: Please rate each of the **guidance and advisory tasks** that personnel performing administrative tasks require training in to best fulfil their job.

		Not essential	Desirable	Essential
7.11	Drafting REC guidance documents (ethics policy, SOPs, legislation)	☐	☐	☐
7.12	Collaborating with other institutions and establishing partnerships	☐	☐	☐
7.13	Liaising with drug regulatory authorities for clinical trials	☐	☐	☐
7.14	Providing research ethics training	☐	☐	☐
7.15	Providing background information relating to research such as technical or research design information	☐	☐	☐
7.16	Monitoring and arranging REC member training	☐	☐	☐
7.17	Billing of applicants	☐	☐	☐
7.18	Updating institution's website with new information to keep research community updated	☐	☐	☐
7.19	Recruiting new REC members	☐	☐	☐

Question C: Please rate each of the **administrative tasks** that personnel performing administrative tasks require training in to best fulfil their job.

		Not essential	Desirable	Essential
7.20	Managing research information management systems	☐	☐	☐
7.21	Ensuring quality improvement of reviews	☐	☐	☐
7.22	Screening applications for completeness	☐	☐	☐
7.23	Ensuring quality review feedback / correspondence	☐	☐	☐
7.24	Providing technical advice in research systems / submissions	☐	☐	☐
7.25	Determining type of review for each application	☐	☐	☐
7.26	Allocating applications for review	☐	☐	☐
7.27	Drafting REC meeting agenda and minutes	☐	☐	☐
7.28	Drafting annual REC meeting schedule	☐	☐	☐
7.29	Design ethics application form	☐	☐	☐

7.30 Please indicate additional tasks not listed above you suggest REC administrators would need training in:

Appendix H:

Author guidelines: *Journal of Empirical Research on Human Research Ethics (JERHRE)*

Manuscript Preparation

The following summary of the parts of manuscripts is too brief and generic to handle all issues concerning manuscripts appropriate for submission to JERHRE. Prospective authors are encouraged to refer to previously published JERHRE articles to find relevant examples.

Your **cover letter** should contain the following:

- A statement about all submissions and previous reports that might be regarded as redundant publication of the same or similar work. Copies of such possibly redundant material should be sent to the editor at the time the manuscript is submitted.
- A statement that the manuscript has been read and approved by all authors, that the requirements for authorship (see above) have been met, and that each author believes that the manuscript represents honest work.
- Verification that the treatment of human subjects was in accord with ethical standards and other requirements, as set forth in the country in which the research was conducted.
- A copy of the permission granted to reproduce or adapt any copyrighted material from another source or a notice that permissions are pending.
- Nomination of reviewers: Prospective authors are invited to nominate one of their three peer reviewers. Your nominee is to be someone whose special expertise is in your area, who has no conflict of interests with the role of reviewer of your manuscript, and whose critical comments you would greatly appreciate. Please provide one or more nominees, along with the email address and a very brief statement about each.
- A statement about whether any of the authors have an actual or perceived conflict of interest.

Abstract. The abstract of your article is its most important paragraph. It is used by readers to decide whether to read the article, and by information services to index and retrieve articles. The abstract must reflect the content of the article accurately. It must be non-evaluative (report, rather than evaluate, what is in the text), readable and vigorous, using verbs rather than noun equivalents and active rather than passive voice. Abstracts of empirical studies should describe (a) the problem, in a sentence, if possible, (b) the research subjects, (c) the research method, (d) the findings, and (e) the conclusion. An abstract for a review article should describe (a) the topic, (b) the purpose and scope of the article, (c) the main sources used, and (d) conclusions. Succinct, accurate, informative and clear abstracts increase the audience and retrievability of an article. Please see "Help Readers Find Your Article" on the SAGE Author Gateway for more information on writing an abstract optimized for search engines. Abstracts should not exceed 120 words.

Title Page. The title page should contain:

1. A concise title of the article containing information that makes electronic retrieval both sensitive and specific.
2. Authors' names and institutional affiliations in the following format: John Doe[1] and Mary Smith[2] [1]University of California, San Diego (USA); [2]Harvard University (USA)
3. Disclaimers, if any.
4. Corresponding author's name, mailing address, telephone and fax numbers, and email address. Email addresses of all authors.
5. Source(s) of support.
6. Running head no more than 40 characters long.
7. Word counts of the text only, excluding abstract, acknowledgements, and references.
8. The number of figures and tables that belong with the manuscript. (Note: figures and tables must be submitted as separate documents, rather than embedded in the manuscript.)
9. A list of three to nine key words.

Introduction. The body of a manuscript should open with the title of the article, but not the byline, since the manuscript will be "blind" reviewed. The introduction should answer the following questions in one or two paragraphs, giving the reader an overview of what was done and why:

1. What problem is addressed and why is the problem important? What are its practical implications for understanding or solving ethical problems in human research? Bear in mind JERHRE's diverse readership: investigators, ethics committee staff and members, students, research administrators, and policymakers. Your writing should be lively, perhaps with examples or vignettes of the problem designed to capture the interest and imagination of any of JERHRE's readers.
2. How does the hypothesis or research design relate to the problem?
3. What are the theoretical implications of the research and how does it relate to previous work in the area? How does it relate to research policy or practice?
4. What theoretical propositions are tested?

Develop the background by discussing relevant literature. Discuss and cite only works pertinent to the specific issue, emphasizing pertinent findings, relevant methodological issues, and major conclusions. Refer the reader to general surveys or overviews of the topic if they are available.

Method. This section describes in detail how the study was conducted and enables the reader to evaluate the appropriateness of the methodology, and the reliability and validity of the results. This section should be written in accord with the requirements of your scientific society or the discipline within which your research was conducted.

Results. This section summarizes the data collected and the data-analytic treatment used, and should be sufficiently detailed to justify the conclusions. Authors should employ the reporting standards of their scientific discipline. Report all results, including those that run counter to expectations. Statistical presentations should include descriptive statistics such as per-cell sample size, means or medians, and standard deviations or ranges, using parametric or nonparametric measures appropriate to the characteristics of your data. Statistical data should include the magnitude of observed effects and confidence intervals, so that the reader can judge the practical significance of the findings for purposes of ethical decision making. Qualitative data may be presented in a wide variety of ways; authors should not hesitate to consult with the editor concerning the most effective ways to do so and the formats that are feasible.

The electronic version of JERHRE is hosted on the SAGE Journals platform which provides extensive multimedia capabilities for presenting results and other details of the research, as well as hosting a variety of data sources and replication code.

Discussion. Open the Discussion section with a clear statement of the support or nonsupport of your hypotheses. Interpret any similarities or differences between your results and the work of others. As you interpret the implications of your findings, bear in mind the applied nature of JERHRE; investigators, ethics committee members and policy makers will want to know how you have increased understanding of the problem and what insight your study provides into practical solutions to ethical issues.

In addition to the usual parts of a manuscript (title page, abstract, introduction, method, results, and discussion) and before the reference section, brief additional sections should appear, as follows:

Best Practices is a thoughtful, practical set of recommendations based on your findings. Typically this will include recommendations in relation to one or more specific cultures and contexts or whatever other variables seem relevant. These recommendations should include discussion of limits of generalizability of your findings. Think of "Best Practices" as your recommendations to the relevant stakeholders in the human-research enterprise, based on your paper.

Research Agenda is a discussion of useful kinds of additional research on aspects of your topic. In some cases, "Research Agenda" should be a nuanced discussion of exactly what needs to be investigated and why such investigation would be an important way to advance the field. In other cases, the agenda is simpler and more obvious than this, and would require little or no discussion. Think of "Research Agenda" as your recommendation to other investigators of important specific research on your general topic that they might usefully pursue. In many cases, it is also useful to treat the research agenda as an invitation to others elsewhere to join you in a Collaboratory. Be prepared to share your raw data (with identifiers removed) with others who wish to extend the research to other contexts or cultures and publish a comparison of their data with

yours; depending on wishes of the collaborators and the degree to which each contributes to the research, collaboratories may result in a joint publication.

Educational Implications is a discussion of how key concepts from your article may be taught effectively to relevant audiences. In most cases, the audiences are investigators, ethics committee members and staff, and students at various stages of their training; in other cases audiences are other stakeholders such as the media and general public, research participants, and policy makers.

Acknowledgements is a paragraph that may include the source of funding, thanks to persons or organizations who helped with the research, disclosure of any relationships that might be perceived as a conflict of interest, and any disclaimer required by your employer, for example, stating that the paper does not necessarily reflect the views of the organization.

Author Note is a brief paragraph telling readers where they may direct correspondence. It includes only the corresponding author's name, mailing address, email address, and phone and fax numbers.

Authors' Biographical Sketches. Because JERHRE's authors and readership cut across many professional and scientific boundaries, readers will be interested to know who the authors are and why they are credible. Hence, appearing at the end of each article is a brief, three-sentence statement that connects the author with the general or specific topic of the paper, stating the author's current role, main research interests, and the author's role in the research that is reported. This brief biographical statement should not discuss general credentials or educational background, but rather the author's specific experience as it relates to your paper. Multi-authored articles should contain a biographical sketch about each author and conclude with a statement of the role of that author in the work reported. Each author thus certifies responsibility for that aspect of the article. The order of authorship on the byline should be a joint decision of the co- authors; where the order is alphabetical, that should be stated here. Individuals who played a minor role in the development of the article, perhaps contributing ideas but not seminal theory or methodology, should be thanked in the Acknowledgements, not treated as an author. For further guidance on the criteria for authorship, see the 6th edition of the APA Publication Manual or, see II.A.1 (pp. 2-3) of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

In keeping with requirements of the Publication Manual of the American Psychological Association, the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, and the Council of Science Editors, all authors must have read and approved the final manuscript and believe that it represents honest work. Understand the right of the editor to respond to allegations of scientific misconduct by authors.

End Notes. JERHRE employs endnotes thus: 1 (small superscripted numerals) rather than footnotes. The end notes are placed in the manuscript just before the Reference section. Endnotes are for additional information that is too limited for an appendix or supplementary online document. Please use endnotes sparingly, if at all.

References. Employ 6th edition APA style. All citations in the manuscript must have a corresponding reference; there should be no references to sources that are not cited in the manuscript.

Appendix I: Author guidelines: Journal of Public Administration

Editorial Policy and Manuscript Specifications

1. The Journal of Public Administration is a quarterly scholarly publication issued on behalf of the South African Association of Public Administration and Management (SAAPAM).
2. The purpose of the Journal is to further the understanding of the science and praxis of governance by publishing articles of interest to practitioners and scholars in English.
3. The Journal publishes peer-reviewed articles, review articles, case studies, exemplar profiles, viewpoints and research results from practitioners of all grades and professions, academics and other specialists on the broad spectrum of governance concerns regarding local, provincial, national, and international affairs.
4. All manuscripts are circulated anonymously to specialist referees for evaluation. Reports from referees may be made available to authors but the names of the referees will be withheld. On the basis of the referees' reports, content and other deficiencies, the Editor reserves the right to make minor alterations or to reject any manuscript.
5. Copyright of articles published in the Journal vests in SAAPAM and may not be published or reproduced in any form without the prior consent of the Chief Editor.
6. Warning: Infringement of copyright exposes offenders to criminal proceedings that could result in civil actions and/or a fine/imprisonment and a criminal record. Therefore, authors are advised to acknowledge the origin of any content in an article or other contribution obtained from another source.
7. Reprints of articles can be obtained from the Editor on the payment of a prescribed fee.
8. Opinions expressed in the Journal are, however, those of the individual authors, and are not necessarily subscribed to by the Editor, Editorial Committee or the Editorial Board.
9. Authors are required to pay a fee of R650-00 per page for any article or research results printed in the Journal. Payment is due on receiving confirmation from the Editor that a contribution is to be published in a particular issue of the Journal. Authors should consult their respective faculties or employer to establish the responsibility for the payment. An article will only be published once payment has been received. Payment should be made directly to the Journal of Public Administration, but proof of payment must also be submitted to the Editor or the Executive Director of SAAPAM to avoid any possible delay in the publication of a contribution. Journal of Public Administration
• Volume 51 • Number 3 • September 2016 10.

Except in special cases where prior permission has been obtained, articles should not exceed 8 000 words. Prospective contributors are specifically requested to ensure that the language and technical aspects of their contributions are of a high standard. Manuscripts, typed in 1.5 line spacing, 12pt Times New Roman should be emailed to the Editor. Each manuscript should be accompanied by an English abstract of up to 200 words. Since manuscripts are circulated anonymously for evaluation, the name and affiliation of the author(s) should appear on a separate page. If the manuscript is accepted, a computer disk with the text, preferably in MS Word or WordPerfect must be sent to the Editor, unless the Chief Editor grants special permission in some exceptional instances. 11. All manuscripts must be accompanied by a covering letter in which the author(s) state(s) that the manuscript has not been submitted or will not be submitted or published or is not being published elsewhere in any form unless rejected by the Editor of the Journal of Public Administration.

Appendix J:

Language Editing Certificate

Declaration

16 August 2021

PO Box 4
Otjiwarongo
Namibia
+264 813359120
hettie.human@gmail.com

Student: Mutshidzi Abigail Mulondo

Thesis: Research Ethics Administrators: A Capacity Development Framework

I confirm that I edited the document, checked that the reference list contains the references cited, and recommended changes to the text.

MA Language Practice

Hettie Human
WRITER | EDITOR | TRANSLATOR | INTERPRETER

+264 813 359 120 | hettie.human@gmail.com

Appendix K:

Turn-it-in Report

Research Ethics Administrators: A capacity development framework

ORIGINALITY REPORT

10%	8%	4%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	slidelegend.com Internet Source	<1%
2	ir.mu.ac.ke:8080 Internet Source	<1%
3	Submitted to Westmont College Student Paper	<1%
4	nrl.northumbria.ac.uk Internet Source	<1%
5	Lianne Keiller, Champion Nyoni, Chantel van Wyk. "Online Faculty Development in low- and middle-income countries for Health Professions Educators: A rapid realist review", Research Square Platform LLC, 2021 Publication	<1%
6	sajp.org.za Internet Source	<1%
7	www.pamelavcarmichael.com Internet Source	<1%

Appendix L:

Proof of Submission: Article 1

Submission Confirmation

Thank you for your submission

Submitted to
Journal of Empirical Research on Human Research Ethics

Manuscript ID
JERHRE-21-0044

Title
Capacity Development of Research Ethics Administrators Globally: Scoping Review

Authors
Mulondo, Mutshidzi
Tsoka-Gwegweni, Joyce
LenkaBula, Puleng
Chikobvu, Perpetual

Date Submitted
28-Jun-2021

Appendix M:

Proof of Submission: Article 2

Submission Confirmation

Print

Thank you for your submission

Submitted to
Journal of Empirical Research on Human Research Ethics

Manuscript ID
JERHRE-21-0056

Title
A survey to determine the capacity development needs of research ethics committee administrators in South Africa

Authors
Mulondo, Mutshidzi
Tsoka-Gwegweni, Joyce
LenkaBula, Puleng
Chikobvu, Perpetual

Date Submitted
13-Jul-2021

Appendix N:

Proof of Submission: Article 3

Tshwane University of Technology, College Road South, Soshanguve 0152

Tel: 012 382 9769

Cell:

Postal Address

Private Bag x 14257 Hatfield 0028

Email: saapam@tut.ac.za

REG No.:039-162-NPO

22 Oct 2021

Dear Mutshidzi Abigail,

ACKNOWLEDGEMENT OF AN ARTICLE

We acknowledge receipt of your article/s titled ***A Delphi survey to reach consensus on a capacity development framework for research ethics committee administrators*** for possible publication in the Journal of Public Administration.

The article reference number is JOPA-2021-1423.

Your article will follow the normal triple blind peer-review process, and the results will be communicated to you once the process has been completed. The process normally takes a minimum of 6 weeks. For future reference, please use the reference number allocated.

Yours Faithfully

John N Molepo

SAAPAM

Appendix O:

Article 2 journal publication approval letter

Decision Letter (JERHRE-21-0056.R2)

From: wassenaar@ukzn.ac.za

To: tshidzi.gail@gmail.com, mulondoma@ufs.ac.za

CC:

Subject: Journal of Empirical Research on Human Research Ethics - Decision on Manuscript ID JERHRE-21-0056.R2

Body: 07-Oct-2021

Dear Ms. Mulondo,

It is a pleasure to accept your manuscript entitled "A survey to determine the capacity development needs of research ethics committee administrators in South Africa" in its current form for publication in Journal of Empirical Research on Human Research Ethics. Please note that the article will undergo further final minor editorial changes and edits so please check that you are happy with these when you receive the proofs to review in due course.

Thank you for your contribution. On behalf of the Editors of Journal of Empirical Research on Human Research Ethics, we look forward to your continued contributions to the Journal.

Sincerely,
Dr. Douglas Wassenaar
Editor in Chief, Journal of Empirical Research on Human Research Ethics
wassenaar@ukzn.ac.za

Reviewer(s)' Comments to Author:

Associate Editor(s)' Comments to Author:

Associate Editor: Ndebele, Paul
Comments to the Author:
(There are no comments.)

Date Sent: 07-Oct-2021

Appendix P:

Article 3 journal publication approval letter

College Road South
Soshanguve South
0152

Tel.: (012) 382 9769
Fax: (012) 382 9042
Cell: 076 750 2300
E-mail: SAAPAM@tut.ac.za
Web: www.saapam.co.za

Private Bag x 14257
Hatfield
0028
039-162-NPO

18 January 2022

Dear Mulondo Mutshidzi Abigail
University of Free State

PROVISIONAL LETTER OF ACCEPTANCE

This is to inform you that your paper titled: **A Delphi survey to reach consensus on a capacity development framework for research ethics committee administrators** which was submitted to us for possible publication in the Journal of Public Administration has been assessed and accepted to be published in the Volume 56 Number 4, December 2021.

The editor is satisfied that the corrections recommended by the reviewers have been satisfactorily effected. Your paper will therefore be included in the December 2021, Volume 56 Number 4 of the journal subject to the payment of the stipulated publication fee.

Note: This acceptance letter is not a guarantee that the paper will be published. If payment is to be made on behalf of an author, we require a letter from such an institution, on its letterhead, guaranteeing that they will make the said payment on behalf of the author.

Kind regards,

Dr John N Molepo
SAAPAM Executive Director