



**Is the Ethics Review Process Prepared for Digital
Autonomy?**

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26th March 2024

DECLARATION

I, Brenda Adhiambo Otero declare that:

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ABSTRACT

The ethics review process is of primacy in ensuring research is ethical and the protection and rights of participants are maintained. Internationally, review ethics committees (RECs) are run independently and have different ethics review methods that they use. However, very little is known about what methods are used in the ethics review process, and the challenges and successes around adopting digital platforms for ethics review (DPER). The current study aimed to address this gap by inquiring whether the ethics review process in Kenya is ready for digital autonomy.

A qualitative approach was adopted in this study, including six in-depth interviews with REC members and two focus group discussions with researchers. The in-depth interviews and focus group discussions entailed two sub-groups: one group included participants who mainly use traditional methods (paper and email) and the other group included participants who mainly used DPER. These transcripts were analysed using thematic analysis, informed by Braun and Clarke's (2013) six-step approach.

While generalisability is not assumed, the findings suggest that the ethics review process will only be ready for digital autonomy when all the challenges highlighted are dealt with and infrastructure is reinforced to support it. These findings imply that digital autonomy in the ethics review process is best effected when all research stakeholders are involved in the deployment, creation, and implementation stage, where institutions offer support and privacy, and security is upheld in all these technologies. Recommendations are made in practice for all research stakeholders, inclusive of RECs, researchers, and DPER deployers and developers. Recommendations are also made for future research developments on how to make the research ethics review process ready for digital autonomy.

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LIST OF ABBREVIATIONS

BREC – Biomedical research ethics committee

DPER – Digital platform for ethics review

FGD – Focus group discussion

IDI – In-depth interview

NACOSTI – National Commission for Science, Technology, and Innovation

NMT – Nuremberg Military Tribunal

PI – Principal investigator

RECs – Research ethics committees

SU-ISERC – Strathmore University Institutional Scientific and Ethics Review Committee

UKZN – University of KwaZulu-Natal

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CHAPTER 1: BACKGROUND AND INTRODUCTION

1.1 Background of the Study

Research ethics committees (RECs) play a fundamental role in ensuring the ethical implementation of research, prioritising the rights of those participating in the research and of those who may be directly and indirectly affected by the research (Council for International Organisations of Medical Sciences [CIOMS] Working Group, 2021; Gelling, 1999; Grady, 2015; Page & Nyeboer, 2017; Shore et al., 2011; Singh & Wassenaar, 2016; United Nations Educational, Scientific and Cultural Organisation [UNESCO], 2005; World Health Organization [WHO], 2009). While there has been a strong interest in developing strategies to prevent direct and indirect harms, and to provide researchers with mechanisms to do so, less research has been focused on how the REC application process can be strengthened to facilitate a smoother or more favourable experience for researchers (Abbott & Grady, 2011; Nicholls et al., 2015; Turner, 2004). Little is also known about how researchers and those who are involved in the REC processes experience these processes and what their recommendations are to create a better system (Ralefala et al., 2016). The current study aimed to address this gap by exploring researchers' and other research ethics stakeholders' (REC members and Administrators) perspectives on the use of digital platforms in the ethics review process. It further considers the merits and demerits of transitioning from traditional methods (paper and email) to using digital platforms for ethics review (DPER) and the factors that promote their use.

The role of RECs lies in the protection of participants and ensuring the social value of the research (Guillemin et al., 2012). This major responsibility entails reviewing research proposals while being influenced by standard operating procedures, ethical guidelines, and institutional decisions based on committee member values (Schuppli & Fraser, 2007). In addition, RECs are responsible for the research participants' welfare, safety, dignity, and rights (CIOMS Working Group, 2021). The committee also holds the right to monitor ongoing studies and amendments, and the researchers to report any severe adverse effects of the study (Silaigwana & Wassenaar, 2015). When research is completed, the final reports of the study should also be looked at by the RECs (World Medical Association [WMA], 2013).

Over the last two decades, RECs have primarily relied on traditional methods (i.e., email and paper) to operationalise the ethics review process (Biggs & Marchesi, 2013). Although a long-standing and widely used approach to ethics reviews, the traditional approaches have been

associated with various challenges; these include continued delays in turnaround times, lack of a streamlined process, missing documents due to poor storage, unintentional mishandling, and sending of wrong documents to different principal investigators (PIs) and reviewers, among others (Larson et al., 2004; Straight, 2009; Whitney et al., 2008).

Most RECs in Africa are reported to rely mostly on the use of traditional methods in the ethics review process (Mokgatla & Wassenaar, 2012; Nyika et al., 2009). This use of traditional methods brings its fair share of challenges, as suggested above. The use of traditional methods leads to incomplete forms, manual errors (Detlor & Wilson, 2015), incorrect applications, missing physical forms, and a lack of data verification functionalities (Egan-Lee et al., 2010; Mbabe et al., 2021). Extended turnaround times or unprecedented long delays with the use of traditional methods were also reported (Mbabe, 2021; Mokgatla et al., 2017; Wang et al., 2021). In addition, the email system, just like paper, does not provide status-tracking of reviews and verifications by research stakeholders, compared to DPER (Mokgatla & Wassenaar, 2012; Mbabe, 2021). It was also reported that researchers lose interest in the intended research, due to the long delays associated with using traditional methods in the ethics review process (Mbabe, 2021). Therefore, in this regard, traditional approaches do not seem to synchronise with the current progressions in technology and more can be done to strengthen and revolutionise the process.

This is where digital autonomy interposes. Digital autonomy is the ability of an institution or a body to have full and independent control of its information technology and data, even if the platform or application being used is from an external service or service provider (Asmar et al., 2020). Pertaining to the ethics review process, the concept of digital autonomy in this study is defined as the exclusive utilisation of, and/or control over, technology-driven environments, particularly in the realm of online and digital platforms utilised for the ethics review process. These platforms may encompass a variety of digital media, including web-based and cloud-based applications, as well as virtual meeting spaces such as Zoom or Google Meet, to be used in the ethics review process. In these settings, research stakeholders engage with digital content and services pertinent to the submission, review, and decision-making aspects of the ethics review on these online applications/platforms. Consequently, the term ‘digital platforms for ethics review’ (DPER) is introduced to collectively describe these **online tools**, which play a pivotal role in evaluating and enhancing the operational effectiveness of the ethics review process, thereby facilitating the platform's transition towards digital autonomy. This, therefore,

excludes paper-based and email methods which may slow down the operational effectiveness of the ethics review process. Furthermore, in this study, the ethics review process is defined as the comprehensive workflow encompassing the involvement of all stakeholders, including researchers, administrative staff, and the REC. This involves the development and submission of applications, as well as the iterative exchange of these applications among stakeholders, to refine the application until it is ideally considered prepared for approval (Page & Nyeboer, 2017).

Since the inception of the REC in the 1970s, concern that RECs may not be able to function effectively due to challenges in the ethics review process has troubled many researchers, due to the changing research environment (Christian et al., 2002; Gold & Dewa, 2005). Of paramount disquiet is whether the ethics review process can master a system/model where there is less use of the traditional paper- or email-based submission. This leads to the greatest potential solution: the adoption of digital methods in the ethics review process. Thus, these concerns have given rise to the need for digital autonomy in the entire ethical review process.

Before and into the computer age, a REC would use traditional methods; that is, they began by using paper, then transitioned from paper to email as tools to run the research ethics review process. In this study, traditional methods are characterized by the reliance on paper documents and email communications to facilitate the ethics review process. Biggs and Marchesi (2013) report how an Australian REC migrated from paper to email, deeming it effective and efficient over time. The review process is commonly divided into five steps: the submission, the screening, the reviewing, the decision-making, and the approval (Page & Nyeboer, 2017). Each of these steps would be represented by heaps of paper and/or a string of emails to and from the REC secretariat to the reviewers and then the principal investigator (PI).

There have been efforts to go digital or use technology in some RECs. In their study, Biggs, and Marchesi (2013) assessed an Australian REC, which aimed to rebuild the research ethics review process. There was an introduction to the use of email, data storage devices, and a small amount of paper for members who chose to review that way. The study goes further to illustrate how the use of email and storage devices led to new low-risk ethical reviews, an increase in lead reviewers, enhanced efficiency, and shorter turnaround times. There was also an improvement in communication between the research stakeholders, giving the REC

effectiveness in the ethical review process (Biggs & Marchesi, 2013).

To establish the significant demand for digital autonomy, research must not only validate the efficiency of the review process but also demonstrate that all stakeholders involved in the ethics process value the contribution of digital autonomy. The primary purpose of this study is to see if there is evidence of the use of DPER in Kenyan RECs, and whether our ethics review process is prepared for digital autonomy. In addition, this research study will use this basis and go further, using a qualitative method study to look at the experiences and perspectives in the use of DPER.

While the value of digitalisation in various sectors has received increasing attention, questions arise about whether the ethics review process is ready for digital autonomy. In other words, is the ethics review process ready to solely use DPER moving forward? This current study aimed to address this question, by exploring researchers' and REC members' perspectives and anticipated experiences of digital autonomy in the ethics review process, focusing on the Kenyan context.

1.2 The History of RECs: Time Machine into the Ultimate Development of RECs

The Doctor's Trial unveiled the atrocities done by different researchers to vulnerable groups of people (prisoners and detainees) in the name of research. After the Second World War, the researchers responsible for these horrendous acts were detained and a trial was called. The trial, with the help of Andrew Ivy, led to a draft of the Nuremberg Military Trial guidelines in April 1947 (Ghooi, 2011; Velyne & Huster, 2009).

Even with the Nuremberg Code in place, from the aftermath of World War II to the 1950s, a new tragedy occurred, namely the Thalidomide tragedy (Lenz, 1988). The drug, which was used for treating morning sickness, was given to pregnant women; however, neither they nor pregnant animals were part of the experimentally tested groups (Botting & Botting, 2015; Kim & Scialli, 2011). It soon became apparent that the drug was causing abnormalities and limb malformations to all fetuses of women who used it. In turn, these events brought about the 1962 Kefauver-Harris Amendments to the 1938 Food, Drug, and Cosmetic Act of the USA, which demanded that any new drug should go through a series of trials to ensure that it is effective and safe and that research participants give informed consent. This later gave rise

to the Declaration of Helsinki, which was revised to the latest version in 2013, to establish how research should be carried out (WMA, 2013).

It was not until 1974 that research ethics committees were formed. This was after clinical violations continued to escalate in the research community, for example, the Tuskegee Syphilis study which had been going on from 1932 to 1972; this was where 400 African American men were denied treatment, even after a suitable treatment had been discovered. They were also denied informed consent and coerced into the studies (Spelley & Busse, 2021; White, 2000). This prompted the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, which was formed through the National Research Act of the USA (CIOMS Working Group, 2021). This was the first institutional review board. The commission was mandated to recognise the basic ethics principles that govern the conduct of biomedical and behavioural research. It also developed guidelines for research involving human participants; hence, the Belmont Report was created in April 1979 (Rice, 2008). This was built with the Nuremberg Code and Declaration of Helsinki as a foundation and provided the basis that ethics review committees would be formed to look at any research study (Miracle, 2016). However, it was not until recently that different bioethicists and RECs inaugurated the use of the Emanuel et al. benchmarks as the ‘ethical guide’ for reviewing different research proposals (Emanuel et al., 2004).

1.3 The Ethics Review Scene in Kenya

Currently, many RECs operate under the mandate of tertiary institutions. This includes universities, hospitals, teaching universities’ hospitals, and research institutions. In Kenya, RECs are accredited by the National Commission for Science, Technology, and Innovation (NACOSTI) to review certain disciplines in research. They also ensure membership and compliance within the different RECs in the country. However, it is not clear how many RECs use digital platforms and/or traditional methods to run their processes.

In 2015, the Research for Health Innovation Organiser (RHInnO), a cloud-based ethics review platform, introduced a digital platform for ethics review (DPER) system for RECs in research in Africa. Kenya is one of the eight African countries out of 25 where RECs use the DPER system. Strathmore University in Kenya, Pharma Ethics, and Uganda Virus Research Institute were among the first institutions to adopt this DPER system. This in turn created efficiency and reduced turnaround times due to the adoption of these systems (Kombe et al.,

2019). This corroborates earlier research which estimated that the DPER system can reduce the turnaround time of the ethics review process by approximately 56% (Mokgatla et al., 2017). Still, while the adoption of such digital platforms is a step in the right direction, given the fast-paced evolution of the digital age, further research is necessary to understand how digital autonomy can be promoted in a way that is effective and efficient, and with insights from research stakeholders on how it can be made possible.

1.4 Study Rationale and Problem Statement

The ethics review process is thought of by some individuals as a proverbial black box (Page & Nyeboer, 2017). Over the years, studies have focused on streamlining the review process (Biggs & Marchesi, 2013). In many spaces, the ethics review process has continued to be handled in traditional ways; that is, with the use of paper and emails as the ways different ethics review committees review proposals. Digital autonomy is the ability of an institution or a body to have full control of its information technology and data, even if the platform or application being used is from an external service and service provider (*Digital Autonomy*, 2022). This digital process starts with the submission of the protocol by the principal investigator, followed by the triage process by the administrator, then moving to the reviewing process and the dispatch of the ethics approval letter.

Biggs and Marchesi (2013) further indicated that the use of an online and partly paper submission of the ethics review process would reduce turnaround time and effort by the principal investigator. In addition, more independent researchers will want to take part in research, as the administrative processes may cost less (Walanj, 2014). The use of emails in today's ethical review process has helped greatly, with some RECs making email use mandatory (Biggs & Marchesi, 2013). However, there still seem to be delays in the reviewing process and more can be done to make the ethics review process efficient through the establishment of digital autonomy.

Consequentially, this study is relevant because it will help explain the perceptions of the effectiveness and uptake of a digital ethics review process, using a digital/online platform. It will also contribute to the growing recognition of the benefit of solely using digital platforms in the ethics review process. Similarly, it will form a basis for a digital guide or framework for how RECs can approach the use of digital autonomy for the ethical review process. Moreover, the insights gleaned from the study will generate and support discussions aimed

at addressing any potential obstacles or ethical considerations that may arise in integrating different ethics review methods used in ethics review. The findings may also inform the creation of a digital guide or framework of ethics to be used by all digital ethics review approaches. Finally, the findings from this study will form a basis for further academic discourse.

As previously mentioned, the ethics review process has been described as a “proverbial black box” (Page & Nyeboer, 2017, p. 2), with poor stakeholder engagement (Nicholls et al., 2015; Turner, 2004); clearly, the process is poorly understood. A need therefore existed to explore the digital and non-digital processes as a comprehensive workflow design to understand the impacts, perceptions, and uptake of automated DPER systems (Oder & Pittman, 2015). Studies (Biggs & Marchesi, 2013; Mrisho & Essack, 2021) have illustrated that using digital methods for the ethics review process cuts unnecessary costs like transport, while printing is eliminated. In turn, all stakeholders involved can access the review process collaboratively (Mrisho & Essack, 2021). However, there may be potential challenges around the uptake, experiences, and perceptions of having the ethics review process go digital. Few studies exist in this area of work, but they suggest that any form of integration of technology improves the review process.

Given the paucity of research, this study provided insights into the research ethics review stakeholders’ perceptions on the effectiveness and uptake of a digital ethics review process, solely using a digital/online platform. Recommendations have been made to improve REC efficiency through a digital/electronic system, which would reduce any chances of a gap in the ethics review process (Wassenaar & Slack, 2016). However, even with evidence of using DPER platforms like RHInnO Ethics to improve the efficiency and quality of reviews, full adoption of DPER continues to be slow (Kombe et al., 2019). A retrospective analysis proved that accelerated adoption of the use of a DPER would rely on a reasonable subscription fee, adaptability to the platform, and data protection (Ngongo et al., 2019).

Thus, the overarching research questions relate to readiness for the use of digital platforms in the ethics review process, starting with Kenya as the sounding board. Unpacking this broad question leads to the following specific questions:

- i. What are the gaps in exploring researchers’ and other research ethics stakeholders’

perspectives on the use of digital platforms?

ii. What do the REC stakeholders recognise or opine as the merits and demerits of moving from traditional methods to a digital autonomous ethics review process?

iii. What factors facilitate the use of traditional methods or digital autonomous ethics review?

1.5 Study Aims

The overall aim of this study was to explore researchers' and other research ethics stakeholders' experiences and perspectives towards DPER.

1.5.1 Study Objectives

- i. To explore researchers' and other research ethics stakeholder perspectives on the use of digital platforms.
- ii. To explore the perceived merits and demerits of moving from traditional methods to a digital autonomous ethics review process (techno-ethics).
- iii. To identify participants' recommendations on the factors that facilitate or hinder the use of digital platforms for ethics review (DPER).

1.6 Thesis Structure

This thesis takes the following form:

Chapter 1 – Introduction: This chapter has laid out the background of the study, as well as the study's aims and objectives.

Chapter 2 – Literature Review: This chapter extensively reviews relevant literature through a systematic review of the available literature on the use of digital platforms in the ethics review process. It goes further to apply thematic analysis to the eligible articles and discusses them according to the outcome of the themes emerging from the analysis.

Chapter 3 – Research Methodology: This chapter outlines how the research was conducted, detailing data collection and analysis techniques, as well as steps taken to try and attain an extent of reliability, validity, and rigour. Additionally, it highlights the study's limitations and offers a concise reflection on the researchers', REC members', and secretariat's experiences, and perspectives concerning the use of digital platforms for ethics review (DPER) and traditional methods (email and paper).

Chapter 4 – Research Findings: This chapter presents the primary results of the research, highlighting significant themes, sub-themes, and the creation of a coding framework. These insights expound the experiences and perspectives of researchers, REC members, and the secretariat in the use of different ethics review methods. It goes further to share findings on the merits and demerits of these methods and factors that encourage their use.

Chapter 5 – Discussion, Implications and Conclusion: This chapter positions the primary findings within the context of the existing literature. Moreover, it formulates conclusions aligned with the core objectives of the study, examining how the identified insights from the findings align with suggestions from existing literature. It outlines implications for enhancing the need to understand whether the ethics review process is ready for digital autonomy in practice and research, while also providing a conclusion.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

While ethics review is a cornerstone of ethical research practice (Nicholls et al., 2015), there is a paucity of studies that focus on the use of technology in the ethics review process and whether the process is ready for its adoption. This is indicative in the very few studies that were found to be eligible in the current systematic review. With the increase in research workload in Africa, emerging and innovative review solutions are found to assist in the efficiency of the process. However, it is not known whether there is proper infrastructure, policy, and regulation to ensure digital autonomy in the ethics review process. Therefore, employing a rigorous approach to the literature in this thesis, a systematic review of the literature was conducted to further provide a comprehensive understanding of digital autonomy as a concept in the ethics review process.

This chapter delves into the literature to examine the readiness of the ethics review process for digital autonomy. It begins with a meticulous systematic review aimed at identifying existing literature on digital autonomy within the ethics review framework. The chapter then outlines the systematic methodology employed and provides a detailed thematic analysis of the findings from the six articles included in the review. Finally, it concludes with reflections on the outcomes of the themes that emerged and a discussion of the limitations of the review.

2.2 The Systematic Review

A systematic review combines data from multiple studies into one overall summary (Petticrew & Roberts, 2006). Its purpose is to provide a comprehensive review of all existing primary research for a particular research question (Clarke, 2011; Tawfik et al., 2019).

The value of the systematic review was to:

1. **Establish a foundation:** Systematic reviews contribute to a deeper understanding of previous research hence a well-structured literature review sets up proper groundwork (Booth et al., 2016). Torraco (2005) discusses the value of consolidated literature reviews in synthesising research findings and establishing a firm foundation for new studies. Especially in this current study where literature on digital autonomy in the ethics review process is scarce.

2. **Identifying gaps:** Both traditional and systematic literature can help identify gaps in the current body of knowledge, guiding future research directions (Jesson et al., 2011). Through the systematic review, gaps and opportunities are identified in the existing literature. Including this in the current literature review section highlights these gaps and shows how the current research addresses them, justifying the need for the study.
3. **Demonstrating rigor:** The systematic review is a rigorous method of synthesising research, involving systematic search strategies, selection criteria, and appraisal of studies (Gough et al., 2017). By including it in the literature review section, it demonstrates the thoroughness of my approach to understanding the existing body of work, enhancing the credibility of the current research.
4. **Comparing methods and findings:** A systematic review allows for a detailed comparison of the methods and findings of previous research, which can offer new insights or validate existing knowledge (Petticrew & Roberts, 2008). Including this analysis in the literature review section offers an understanding of how my research fits into the larger conversation.
5. **Facilitating reader understanding:** Hart (2018) discusses that systematic reviews can make research findings more accessible and impactful for readers by providing a clear context.

In the current study, a systematic review was conducted to identify studies that describe the role and/or value of digital autonomy in the ethics review process. This meant exploring the literature on the use of digital platforms in the ethics review process. To do this, a comprehensive and unbiased search of existing literature was conducted in selected databases using search terms that signify ‘digital autonomy’ within ‘the ethics review process’. This was then followed by a structured approach to identify, evaluate, and synthesise all relevant studies. In the next section, the review approach will be outlined, followed by a synthesis of the review results.

2.2.1 Review Approach

To conduct the systematic review, three databases were consulted: EBSCOhost, ProQuest, and Google Scholar. EBSCOhost and ProQuest are aggregator databases, which means they

compile and provide access to diverse and comprehensive information (i.e., journals, databases) that is crucial for studies, systematic reviews, and staying current in a field of study. These two databases were thus preferred for the systematic review, as they provided a diverse range of sources, interdisciplinary coverage, as well as theses and dissertations, and peer-reviewed articles, which might have been excluded in other databases. Google Scholar was also used as a database, given its extensive reach and open accessibility to scholarly literature despite its non-traditional form as an aggregator database; this offered a broader look at the literature to be looked at, considering the novelty of the study.

To map out the literature that describes the role of ‘digital autonomy’ in the ‘ethics review process’, certain keywords needed to be identified. The keywords fit into the definition of digital autonomy in the ethics process, which is described as the sole use and management of online platforms and tools, specifically to conduct ethics reviews and decision-making concerning them. It involves having complete authority over technological resources in the context of the ethics review process.

Each search term had the aspect of ‘digital or online’, meaning the use of technology was included, and for it to be the use of technology in the context of the ethics review process, the keywords ‘ethics review’ or ‘review’ were added to come up with the six search terms. Given the definition of digital autonomy, these keywords were operationalised in the search through the following keywords:

- a) “online ethics review”
- b) “ethics review platform”
- c) “electronic ethics review”
- d) “automated review platform”
- e) “ethics review software”
- f) “ethics review system”

The search strings for EBSCOhost and ProQuest were “online ethics review” OR “ethics review platform” OR “electronic ethics review” OR “automated review platform” OR “ethics review software” OR “ethics review system”. The various articles were located by employing the search terms. Searches in both EBSCOhost and ProQuest were conducted simultaneously. For Google Scholar, the approach was operationalised differently given that it functions

differently. In Google Scholar, each search term was input in the advanced search option, with the additional limit that reads “with all the words” regarding the search terms. Thus, searches on Google Scholar were executed individually for each term. The time parameters of the search were January 2013 to December 2022, which accumulates to ten years. The findings are documented in Figure 2.

During the identification phase, the inclusion criteria across the databases were the following:

- a. Articles must mention at least one of the keywords in the full paper.
- b. Articles must be published in the English language.
- c. Articles must be available in full text.
- d. Articles must be peer-reviewed.

During the screening and eligibility phases, the following exclusion criteria were applied:

- a. Articles were excluded when they did not focus on the use of online and/or digital platforms in the ethics review process.

2.2.2 Review Processes

The three databases and the initial results are shown in the flow diagram in Figure 1. EBSCOhost web produced 32 articles, ProQuest produced 73, and Google Scholar produced 198 articles for analysis, after all duplicates were removed and articles excluded accordingly. This resulted in a total of 303 articles which were later screened and read for eligibility.

The Prisma flow chart of the review is provided in Figure 2, as shown; following the first search, the databases collectively identified 303 articles that used the keywords. These articles were saved and subsequently reviewed using strict criteria (i.e., excluded if they did not focus on the use of online and/or digital platforms in the ethics review process). The second screening was done, and 78 duplicates were removed. The 225 remaining articles were read and the reasons for exclusion were the following:

1. While the articles didn't delve into examining the ethics review process via DPER, one suggested simplifying it through a collaborative platform as a conclusion of the study.
2. Many articles offered insights on improving RECs' performance, by highlighting ways

to enhance the ethics review process, its efficiency, and roles through training, capacity building and monitoring their performance, but did not directly focus on digital autonomy in these processes.

3. Some articles discussed bioethics topics that were unrelated to digital autonomy in the ethics review process.
4. Others were entirely irrelevant to the study, resulting in their exclusion.

Only six articles were eligible for further in-depth analysis. The six (n=6) articles are summarised in Table 1, detailing the title of the article, the authors, and the focus of their studies as it aligns with digital autonomy in the ethics review process. The articles were further uploaded onto the ATLAS.ti application for a thematic analysis.

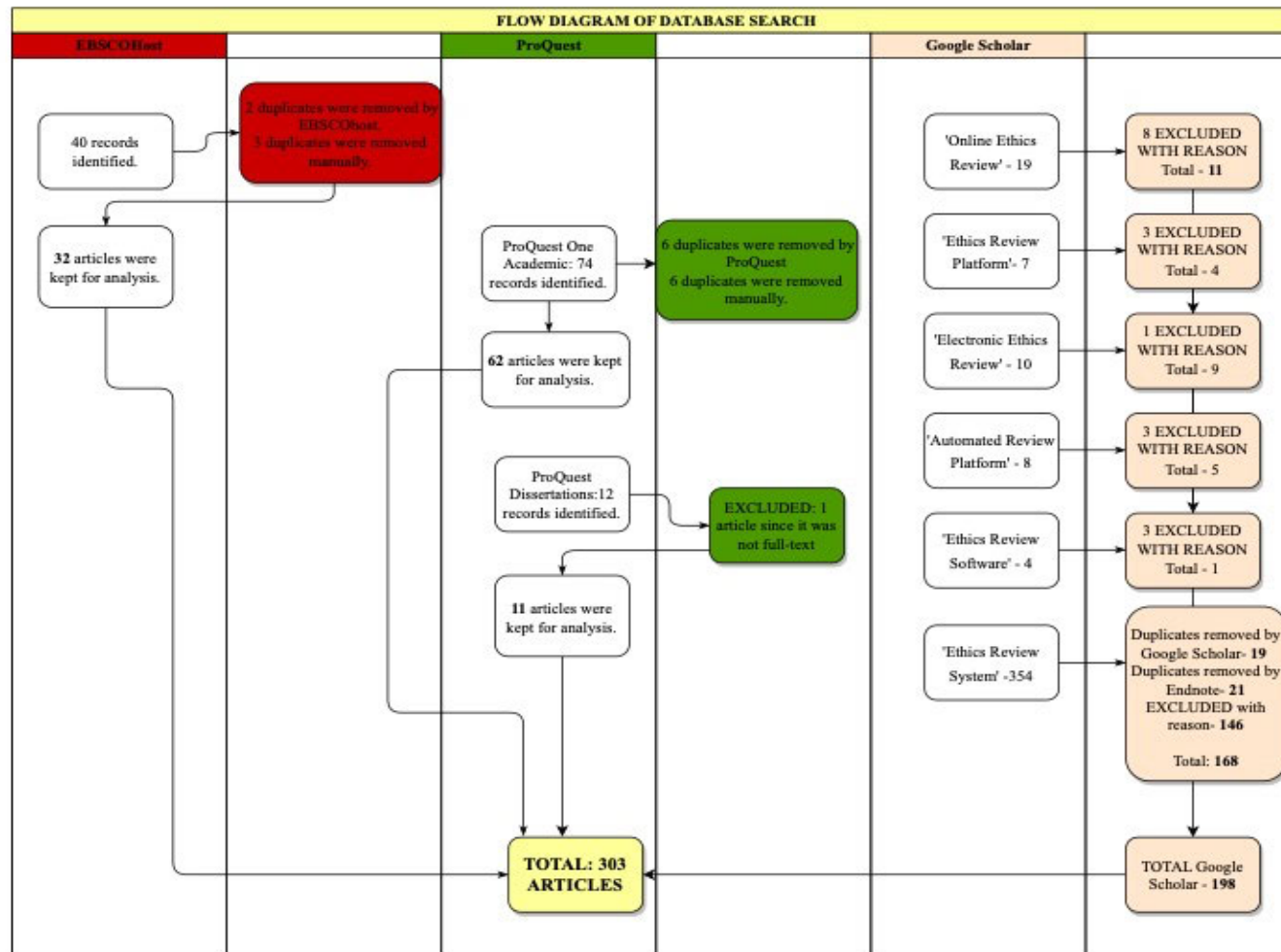


Figure 1: Flow Diagram of Database Search

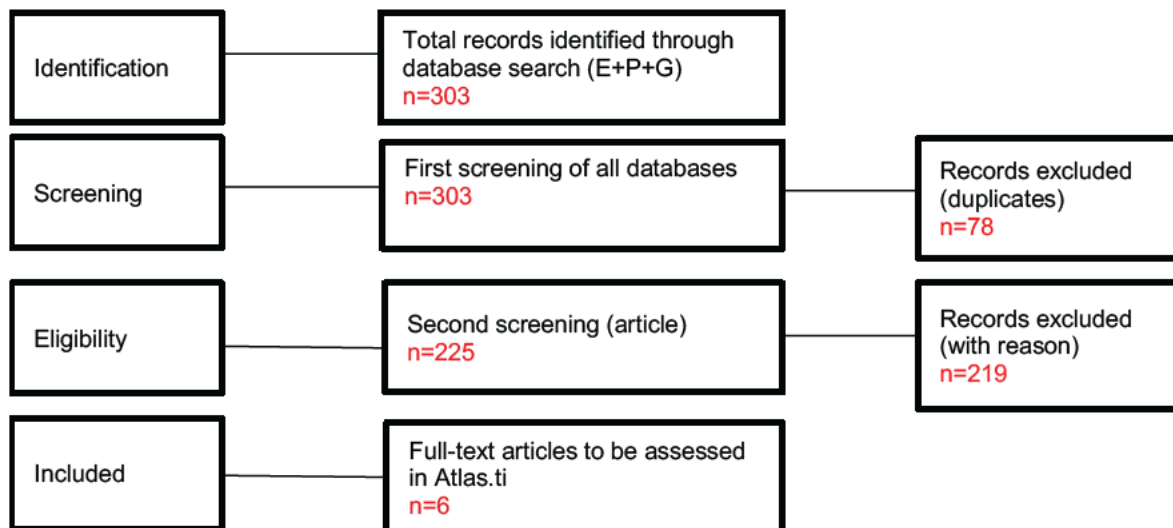


Figure 2: PRISMA Diagram to Screen Articles

Table 1: Summary of Eligible Articles

Title	Author (s)	Focus of Study
1. A workflow system for managing ethical clearance in research work (2021).	Wanga Mbabe, Olasupo Ajayi, Antoine Bagula, Louise Leenen and Natasha Schoeman	Automating the ethical clearance approval process and develop a workflow system to reduce challenges of traditional methods.
2. Developing quality and efficiency of IRB review under HRPP at a leading hospital in central southern China: A descriptive analysis of the first three years (2021).	Xiaomin Wang, Jessica Hahne, Lun Li, Kaveh Khoshnood, Guoping Yang, Hong Yuan, and Xing Liu	Description of the IRB, including protocols submitted and the review process itself using an online platform.
3. Enhancing the efficiency and quality of African research ethics review processes through an automated review platform (2017).	Boitumelo Mokgatla, Prince Bahati and Carel IJsselmuiden	Evaluation of an automated review platform since its roll-out. Evaluation of the technological needs of RECs in Africa.
4. Ethics governance outside the box: Reimagining blockchain as a policy tool to facilitate single ethics review and data sharing for the 'omics' sciences (2018).	Vaso Rahimzadeh	The use of distributed ledger technologies to facilitate single institutional ethics review of multisite collaborative studies. The ethical, legal, and social implications of applying such technologies to ethics review.
5. The satisfaction and use of Research Ethics Board information systems in Canada (2015).	Brian Detlor and Michael J. Wilson	To poll research ethics personnel on the use and satisfaction of research ethics board web systems and gain insight on the factors that influence their implementation and success.
6. Supporting ethical web research: A new research ethics review (2015).	Anne Bowser and Janice Y. Tsai	Creation of a research ethics framework and a research ethics submission system within Microsoft Research or web-based research.

Table 2: Thematic Analysis Summary

Code groups	Number of articles contributing n=6	Number of transcript quotations/excerpts assigned
Successes (What are the favourable results of using digital platforms?)	6	16
Challenges (Difficulties while using different ethics review methods.)	3	9
Recommendations (How best to leverage the use of digital platforms.)	4	8
Focus (What the study focuses on.)	6	8

2.2.3 Review Results and Discussion

The primary foci of the studies included in this paper were directed toward the use of digital platforms in the ethics review process. The patterns that emerged were directed towards challenges, successes, and recommendations related to the use of digital platforms. Table 2 shows the different patterns and themes that emerged from the thematic analysis done on the six (n=6) articles.

2.2.3.1 Challenges of Using Ethics Review Methods

The articles presented challenges associated with using digital and/or traditional approaches. However, given the focus of these studies (i.e., on the value of DPER), studies focused more on the challenges associated with traditional approaches than those associated with digital platforms. Challenges associated with traditional approaches centred on the use of email in correspondence in the ethics review process, where it does not offer advanced opportunities for monitoring or tracking (Mbabe et al., 2021). Other challenges mentioned included long delays, lost applications, and loss of research interest when using traditional methods. The approval processes were reported to take a long time when using traditional methods, which caused a ripple effect with researchers losing interest in their research and funders also pulling out of

projects (Mbabe et al., 2021; Mokgatla et al., 2017). As a result of these challenges, a DPER prototype was developed to mitigate them (Mbabe et al., 2021).

Challenges associated with digital approaches were only described in two studies, which considered the development of DPER that only looked at web research (research done from social media) and no other forms of research and was biased towards practices of Microsoft Research (Bowser, & Tsai, 2015). This study highlighted that, while creating a prototype for a DPER, they decided against the use of already existing platforms since they are expensive and time-consuming to implement (Bowser, & Tsai, 2015). Usability issues were also reported by users, where using the prototype of the digital platform may not have been user-friendly (Bowser, & Tsai, 2015). Similarly, research by Mbabe et al. (2021) reported there were also challenges encountered with the DPER software during the prototype deployment, including issues such as inaccurate data entry in certain fields, fonts that were difficult to read, suboptimal colour selections, inadequate mobile phone compatibility, and a notification system that was implemented ineffectively.

2.2.3.2 Successes with Using Digital Platforms

Successes with using digital platforms were described in all the studies, as illustrated in Table 2. Potential success is described in the use of blockchain technology to ensure confidentiality, privacy, and control by RECs of the DPER, as outlined by Rahmizadeh (2018). This article also described that, if the technology is embedded in DPER, it will allow for an auditable ethics review process. Research by Taherdoost (2022) suggests that the decentralized architecture of blockchain technology means that data is distributed across multiple locations, significantly reducing the risk of manipulation, fraud, or centralized control. This level of decentralization is particularly beneficial for DPER, offering a transparent and verifiable system for logging decisions, modifications, and updates related to ethics submissions and evaluations. Blockchain's capability to provide an unalterable record ensures every action is logged and traceable, promoting a sense of responsibility among all involved parties. This framework not only enhances the integrity of the review process but also supports a transparent, accountable culture within the ethics review ecosystem (Taherdoost, 2022). Qualitative research done on a test for a DPER showed that turnaround time was reduced, communication between stakeholders was improved, and human errors of data input were reduced (Mbabe et al., 2021).

Across most analysed studies, decreased turnaround time was reported with the adoption of

DPER. This coincides with existing literature reports, where the turnaround time reduced significantly, from 23 days to around 15 days, when a DPER was introduced (Wang et al., 2021). According to the research (Mokgatla, 2017), there was reduced review time, and a survey done by REC personnel showed that the long, unprecedented, review time was reduced while using DPER. Another report from research stakeholders from South Africa describes the creation of a prototype DPER that was hoped to reduce the ethics review turnaround time (Mbabe et al., 2021). Similarly, in this study, the researcher included research stakeholders on their experience using DPER.

In addition, Mbabe et al. (2021) introduced a prototype at the University of the Western Cape which digitised the entire ethics review process end to end and ensured users' feedback on the DPER and areas that require debugging and customisation. The use of blockchain technology in DPER would also conceptually improve efficiency and transparency, translating to quicker turnaround times (Rahimzadeh, 2018). Despite this finding, most of the studies do not focus on all research stakeholders' perspectives, inclusive of REC members, secretariat, and researchers. The current study targets these stakeholders by exploring their perspectives on the use of digital platforms in the ethics review process.

To evaluate the impact of the deployment of a DPER and to evaluate the technological needs of the REC in eight African countries, a study by Mokgatla et al. (2017) showed that respondents reported improved communication among research stakeholders, which was also reported by Mbabe et al. (2021). Aside from that, there was reduced workload (Mokgatla et al., 2017) and increased confidentiality and security (Mokgatla et al., 2017; Rahimzadeh, 2018). Another favourable finding reported from the literature was that a digital platform can be designed to calculate the risks of a research study, which determines the type of review; this in turn reduces administrative delay in the ethics review process (Bowser & Tsai, 2015).

Furthermore, the systematic review also reported that the use of DPER minimises human error when collecting key information since it is already automated on a digital platform (Detlor & Wilson, 2015; Mbabe, 2021). Another minimisation reported is concerning administrative costs. Budgetary constraints among research stakeholders are a challenge faced by most RECs in Africa (Milford et al., 2006; Ikingura et al., 2008; Ndebele, Blanchard-Horan et al., 2014). Findings from the articles revealed that the use of DPER reduces operational costs for most RECs (Mokgatla et al., 2017)

2.2.3.3 Recommendations for Using Digital Platforms

Three articles offered recommendations for using digital platforms. For Detlor and Wilson (2015), knowing the context of the number of research proposals for review is important for knowing what the platform needs to be; it is also important to consider the stakeholders' feedback to improve user satisfaction. Deltor and Wilson (2015) go further to report that one size does not fit all; the development of DPER should be dependent on the needs of the research stakeholders.

As a recommendation, Rahimzadeh's (2018) research offered the concept of embedding blockchain technology, where individual RECs could secure all their data. The RECs would then control their records, how they were accessed, and by whom, to keep track of and audit the ethics review process, thereby providing data security, ownership, and confidentiality.

There is a high cost of subscribing to already existing platforms or third parties. The study by Bowser and Tsai recommended against existing platforms because they were expensive and time-consuming to implement (Bowser, & Tsai, 2015). This meant that the REC could create its own customisable DPER that fits its contexts and needs, borrowing from an already existing journal platform.

Additionally, in qualitative research by Mokgatla et al. (2017), a respondent recommends that there should be a standard DPER for all RECs to use to harmonise the ethics review process; the respondent also said there was a need to enhance efficiencies in ethics review infrastructure in Africa. To ensure institutional support, it was recommended that providing decision-makers with empirical evidence of different literature and reports on how DPERs are faring can help implement DPERs in different contexts (Detlor & Wilson, 2015).

Despite the studies giving insight into the success and challenges of the DPER, there are relevant gaps, seeing that there was no inclusion of those using these technologies. Furthermore, there is a need for researchers to build more on research regarding the use of technology in the ethics review process. With the articles analysed, there is a clear potential for DPER. The goal moving forward is to explore whether the ethics review process is ready for digital autonomy.

2.2.4 Systematic Review Summary

To sum up, the articles showed that DPER plays a vital role in research, recognising the importance of streamlining the process for everyone involved as shown in Figure 3. To adapt the ethics review process for digital independence, it is essential to delve into and learn from the various stakeholders’ perspectives and experiences. The systematic review indicates a significant lack of research in this area, evident in the finding that only six articles were identified. As will be shown later in this thesis, the current study bridges this research gap by investigating the experiences and insights of research stakeholders, including RECs and secretariats, in utilising various methods of ethics review.

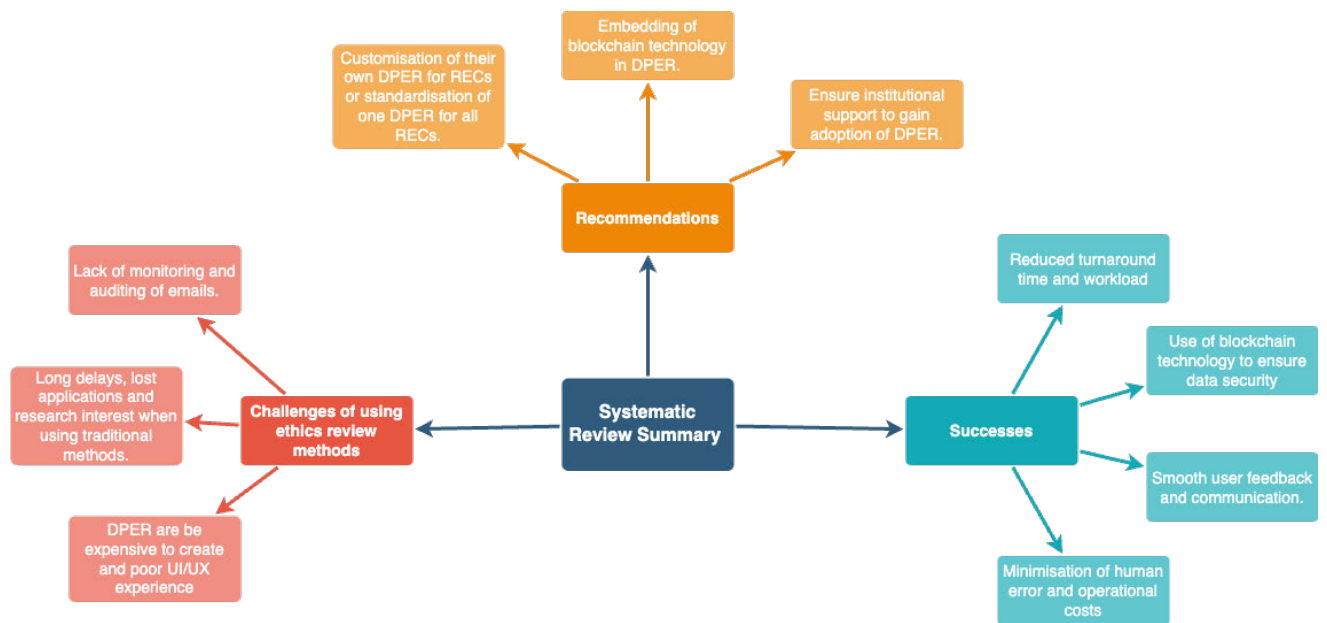


Figure 3: Systematic Review Summary

2.2.5 Limitations of Systematic Review

The results of the systematic review must be interpreted within the context of the limitations of the study. The sampling frame was limited to a specific number of databases. As such, some articles, (e.g., some articles about digital autonomy in the ethics review process), may be missing based on the limits and boundaries of the included databases.

Excluding grey literature was also seen as a limitation. This is because this type of literature often contains data not available in commercially published literature, serving as a vital platform for sharing studies with null or negative results that might not be published otherwise (Paez, 2017). Including this type of literature can help decrease publication bias, enhance the completeness and promptness of reviews, and contribute to a more accurate representation of the evidence available (Paez, 2017). As a corrective measure for this limitation, it is advised that future systematic reviews incorporate grey literature.

Another limitation concerns the keywords used. Although efforts were made to select appropriate keywords, the effectiveness of the search might have been restricted because there is no established term for 'digital platforms for ethics review' (DPER) in research ethics. To address this, keywords closely related to the concept of DPER were included, as inferred from its definition. The significant number of articles identified through this method suggests that this strategy is useful in a diverse field like the application of technology in research ethics review. A recommendation emerging from this limitation is that there needs to be a common keyword(s) to indicate digital platforms in the ethics review process. This study gives the options of DPER, digital platforms, and digital autonomy to refer to the sole use of the digital platforms. In addition, the search approach focused only on publications in English. This could have skewed the findings in favour of countries where English is the primary language for publishing and an incomplete overview of evidence (Morrison et al., 2012). This might explain the higher number of articles from specific countries or regions.

The systematic review was time and resource intensive which was a limitation to this current study (Gough et al., 2017).

In conclusion, the systematic review was intended to map existing literature on whether the ethics review process is ready for digital autonomy. The primary purpose of the systematic review was to identify the nature and extent of current research on digital autonomy in the ethics review process. In addition, it intended to identify research gaps, clarify key concepts, and inform further research.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlines the research approaches adopted, the techniques applied for data collection, and the data analysis. It provides the rationale for the chosen methods and details the steps taken to try and attain the study's integrity and trustworthiness. Additionally, ethical aspects considered throughout the study will be detailed.

Methodological Framework: Social Constructionism

In recognising the participants' perspectives of different operational processes for ethics review the researcher was prompted to identify a theoretical framework that would accommodate and unpack the experiences which are constructed through social processes and interactions. The social constructionism framework by Berger and Luckmann (1991) was thus adopted as it is concerned with lived experiences that are not inherently fixed but constructed through our social interaction with people, spaces, and structures in the world (Berger & Luckmann, 1991). Social constructionism recognizes the existence of an objective reality but focuses on how knowledge about this reality is formed and comprehended (Andrews, 2012). In applying this theoretical framework, the researcher thus acknowledges that the participants' interpretations and experiences of the world are subjective and varied.

Berger and Luckmann (1991) state that to maintain, modify and construct subjective reality, 'conversation' is the most important means. Therefore, in keeping with the framework, in-depth interviews and focus group discussions were conducted with participants. Pertaining to language and communication in this current study, the framework supported the qualitative design. Burr (1995) comments that within this framework, language transmits thoughts, feelings, and concepts into the way the world is experienced. This current study heavily relied on this aspect of language as a tool for participants to express their views and for the researcher to understand their experiences in the current ethics review methods.

In addition, this theory views knowledge as constructed as opposed to created (Andrews, 2012). Knowledge is viewed as co-constructed by the interactions of individuals within a society (Schwandt, 2003). The IDIs and FGDs drew directly from this where these forums provided interactive spaces where the researcher and participants engaged in discussions contributing to the co-construction of knowledge related to digital autonomy in the ethics review process.

The social constructionist views further states that there is not a single, objective truth but multiple realities based on an individual's experiences and interpretations (Hammersley 1992, 2006). This current study's identification of this framework allowed for the exploration of diverse perspectives by the participants. This showed how different individuals from different settings and environments shared similarities and differences in understanding of whether the ethics review process was ready for digital autonomy.

Furthermore, this theoretical framework appreciates that the perspective of the researcher may also influence the research process (reflexivity) (Hammersley 1992, 2006; Andrews, 2012). The use of IDIs and FGDs in this current study, were flexible methods used that enabled the researcher to reflect on her own role in the data collection process, based on the participants' responses and reflections.

3.2 Research Design

A qualitative design was adopted in this study. Qualitative research seeks to answer research questions on the 'what' or 'how' of processes or experiences (Silverman, 2017). It is aimed to address questions in understanding the research participants' concepts, knowledge, opinions, or experiences (Fossey et al., 2002). A qualitative research design helps to describe and explain people's practices, activities, and interactions, and the social contexts of a process (Strauss & Corbin, 1990).

In the current study, qualitative research was appropriate given the researcher's interest in the digitisation of the ethics review process and the aims of gathering in-depth insights into the research problem and generating new perspectives. This was because the study needed to draw on different experiences of the uptake of different ethics review methods. This study fits perfectly into the use of the qualitative research design. It aimed to allow access to the perspectives and experiences of REC stakeholders to understand the effectiveness of the ethics review process using digital platforms for ethics review (DPER) or traditional methods. This design could provide deep, contextual, and narrative-based understandings, which are crucial in exploring ethical considerations and human-centred issues in the use of digital platforms or lack thereof for ethical review (DPER). These insights are pivotal in developing comprehensive strategies, policies, and ethical guidelines on the potential use of DPER in the digital age.

3.3 Participants and Recruitment Procedures

A purposive-convenience (Bryman, 2016) sampling approach was followed in this study. This utilised a targeted, non-random sampling approach to incorporate cases rich in information (Starks & Trinidad, 2007; Blanche et al., 2006).

Purposive sampling is aimed at selecting the appropriate research participants to provide information to answer the research questions in a specific research environment, using established criteria (Fossey et al., 2002; Liamputtong & Ezzy, 1999). Consequently, the study explored research ethics review stakeholders' perceptions on the effectiveness and uptake of a digital ethics review process and traditional methods. In addition to purposive sampling, the researcher also used convenience sampling. Convenience sampling is a type of non-probability or non-random sampling where research participants, who meet certain practical criteria (Dörnyei, 2007; Etikan, 2016; Kothari, 2004) and are easily accessible (Given, 2008), are included in the study. The researcher used purposive sampling by reaching out to her networks. The sample is thus convenient, as the researcher drew from her established networks to recruit potential participants.

The sample included two participant groups: REC members (including secretariats) and researchers. Apart from geographical proximity and accessibility, the following inclusion criteria applied to these respective groups:

REC members' recruitment

- REC members who serve in RECs within Nairobi and its environs.
- REC members with at least two years' experience of serving as either a secretariat or member of a REC.
- REC members who met the criteria and were willing to participate in the study.

Researchers' recruitment

- Researchers who reside and work in Nairobi and its environs.
- Researchers who have submitted at least one study to a REC for ethical approval within the last three years.
- Researchers who met the criteria and were willing to participate in the study.

Exclusion criteria

- Participants were excluded if the above criteria were not met.

3.3.2 Recruitment Procedures

Participants were selected based on their experience either working in research ethics committees (RECs) or having submitted applications to a REC, aligning directly with the research objectives (purposive sampling). Additionally, the selection leveraged the researcher's existing professional networks (convenience sampling).

Engagement with potential participants was primarily conducted within the researcher's professional circles in Nairobi's research community, utilising emails, and phone calls to invite voluntary participation in focus group discussions (FGDs) and in-depth interviews (IDIs). A screening process was implemented to verify that participants met the specific inclusion and exclusion criteria of the study. All potential participants were provided with a consent form, ensuring they were fully informed about the study's objectives, procedures, and their role before giving their informed consent.

3.3.3 Participants

After finalising the recruitment, 18 participants consented to join the study. The participants recruited in the IDIs and FGDs constituted different individuals. Table 3 illustrates the breakdown of the IDIs: four were REC members and two served as REC secretariats. The study thus encompassed six stakeholders from the REC, which included either a REC member or a secretariat; these stakeholders were engaged in individual in-depth interviews. Participants fell into two categories: those employing the digital platform for ethics review (DPER) and those who used traditional methods like email and paper submissions. Two focus group discussions (FGDs) were also conducted, consisting of twelve participants in total who were primarily researchers and some who served in RECs. Half of these FGD participants utilised traditional methods, while the remaining half had adopted digital techniques. Some of the participants recruited as researchers also serve as reviewers in their respective RECs.

Table 3: IDI Participants

Participant ID	Age	Institution Type They Represent	Role in the ERC/REC	Ethics Review Method Used
Interviewee 1_23	35	Research institution SERC (public institution)	member	Digital/Email/Paper *Transition
Interviewee 2_23	50	University ISERC (public institution)	member	Email and Paper
Interviewee 3_23	36	Hospital-University SERC (public institution)	secretariat	Email and Paper
Interviewee 4_23	30	Research institution SERC (private institution)	secretariat	Email and Paper
Interviewee 5_23	42	University SERC (private institution)	member	Digital and Email *Transition
Interviewee 6_23	74	Hospital-university SERC (private institution)	member	Digital and Email *Transition

3.4 Data Collection

Individual in-depth interviews (IDIs) and focus group discussions (FGDs) were used to collect the data presented in this study. Interviews and focus group discussions with the participants are usual modes of qualitative data sampling research (Fossey et al., 2002). This study used these two approaches, and all interview sessions were audio-recorded.

3.4.1 In-depth Interviews

Primary data were collected through in-depth one-on-one interviews with REC members and/or secretariats. A study by Fossey et al. (2002) asserts that interview guides contain a list of questions that guide a conversation to get in-depth information, making the interview flexible and conversational. The study took a semi-structured interview approach. The approach focuses on predetermined open-ended questions which allow for more questions to come up in the conversation with the participant (DiCicco-Bloom & Crabtree, 2006). Semi-structured

interviews allow for follow-ups and are intended to elicit specific ideas, views, and opinions that will privilege the participant's knowledge (Creswell & Creswell, 2017; Fossey et al., 2002; Kothari, 2004). This kind of interview allows the PI to delve into social, personal, and procedural matters (DiCicco-Bloom & Crabtree, 2006) in the ethics review process. Individual interviews were most fitting for this group because this allowed the researcher to delve deeply into the participant's experiences, perceptions, and opinions. The individual interviews uncovered rich, detailed narratives and complex thought processes concerning the ethics review process. (Fontana & Frey, 2000; Kvale & Brinkmann, 2009).

The interviews focused on the use of traditional and DPER methods, including the methods used by the participant, as well as their experiences and perspectives of each method, depending on the category they fell under (see Table 3). Additionally, questions also tried to delve into different uptakes of these two methods, if there are any ethical concerns with using DPER, and factors that led to the use of each method. The idea for the broad questions was to allow the PI to elicit more conversation and knowledge related to the research questions.

All interview sessions were recorded or audio-taped in real-time, with the six research participants' permission, which was voluntary (see Section 3.6.4 for ethical considerations). The sound recordings were transcribed verbatim in English.

3.4.2 Focus Group Discussions

FGDs were most appropriate for this group of researchers, some of whom also serve as members of ethics committees. This is because it allowed the researcher to explore participants' ranging opinions and perspectives in one setting, which stimulated participants to reconsider and refine their views; this led to richer and more developed insights into the ethics review process. (Gundumogula, 2020; Leung & Savithiri, 2009; Nyumba, 2018).

Researchers have a voice in the ethics review process since they form the stakeholders and the ones who carry out the research. They initiate the ethics review process by submitting a proposal for review (Page & Nyeboer, 2017). However, for most researchers, the process of ethics review, especially the activities occurring in ethics committee meetings, is often compared to a mysterious black box, as described by De Vries and Forsberg (2002) and Fitzgerald and Yule (2006), where very little is known by researchers on what occurs and very little is obtained from them. There is very little reported on the views and perceptions of REC members and even less

evidence on the perceptions of researchers in the ethics review process (Guillemin et al., 2012; Ralefala et al., 2018).

Facilitated discussion groups explore a research issue through a group interaction of people (Fossey et al., 2002; Liamputtong & Ezzy, 1999), who have some form of similarity in context (Krueger & Casey, 2004). Focus group discussions allow the PI to get a wider range of research knowledge (DiCicco-Bloom & Crabtree, 2006). Two separate focus group discussions comprised recruited researchers. There were six in each group, divided according to those who used digital platforms for ethics review (DPER) and those who used traditional methods.

The focus group discussion took a multiple-category design (Krueger & Casey, 2004). Krueger and Casey (2004) show that this design allows the researcher to compare two groups, like in this study: those researchers using or experienced in using traditional methods and those who use DPER. The purpose of a focus group discussion is to generate a discussion or debate about the perceptions, views, and opinions behind a certain topic (Nyumba et al., 2018). The aim was to obtain different perceptions of the uptake or effectiveness of different methods used by the researchers in the ethics review process.

The focus group interview guide contained open-ended questions and probes for the researcher to pose for the group to discuss the specific question within the topic. Focus groups help give a better understanding of the topic of interest (Krueger & Casey, 2004). According to Krueger and Casey (2004) in a focus group, the setting is designed to be more reflective of real-life situations, allowing participants to interact and influence one another in ways that are typical of their everyday environments. This approach was used to get a better understanding of the researchers' perceptions of the different methods.

Two focus group discussions were conducted with researchers (some of whom serve as REC members), which were categorised into two groups, which included six who used digital methods and six who used traditional methods (email and paper). The FGDs took place online on the Google Teams application and were recorded, with the researchers' permission. The transcripts from Teams were later transcribed verbatim by Teams and edited by the researcher.

3.5 Data Analysis

The dataset used for this analysis includes eight transcripts: six from the individual in-depth

interviews and two from the two FGDs. These transcripts were analysed using thematic analysis (Clarke & Braun, 2017), which was the preferred guide for analysis by the researcher with the help of the Atlas.ti application. This kind of analysis is used to identify and unpack trends of themes/meanings in the qualitative data (Clarke & Braun, 2017; Fossey et al., 2002). Thematic analysis of qualitative data can be used to analyse large or small sample sizes or large interview studies (Cedervall & Åberg, 2010; Friedman, 2008). Fundamentally, most qualitative techniques, like interviews, FGDs, and qualitative surveys, can be analysed using thematic analysis (Braun & Clarke, 2013). The six-step approach described below was used to analyse the data (Braun & Clarke, 2006; Maguire & Delahunt, 2014):

Step 1: Re-reading participant interviews and focus group transcripts:

During this phase, the researcher began noting down observations, identifying potential codes, and highlighting notable quotes. This process enabled the researcher to gain a deeper understanding of the data's nuances. Reviewing each transcript facilitated answering the primary concern of discerning whether the ethics review process was prepared for digital autonomy.

Step 2: Organising emerging codes into different sets depending on the research questions:

Sections of the text were labelled with specific codes, as suggested by Boyatzis (1998), referenced in Braun & Clarke (2006). This coding was driven by the primary objectives of the study, using Atlas.ti. Extracts were identified based on the different experiences and perspectives that appeared in the transcripts. The labelling of the text was done semantically, closely mirroring the language used by the study participants (Sandelowski, 2000).

Step 3: Themes clustering:

In this step, the researcher started by conceptualising potential connections between codes, as described by Green et al. (2007). The codes were evaluated to determine if they could be grouped into logical clusters (Green et al., 2007). For instance, the codes 'recommendations for adopting digital platforms' and 'reasons for adopting digital platforms' were grouped, as both seemed to address the factors that enhance the use of digital platforms.

Step 4: Review and sorting of codes into different levels of sub-themes:

The data were reviewed and sorted to come up with the main theme. This led to making a coding framework (see Appendix 5) As detailed in the preceding chapter, this framework

consisted of five themes:

Theme 1: Participants' current ethics review processes.

Theme 2: Participants' perspectives on digital autonomy.

Theme 3: Participants' experiences of digital platforms.

Theme 4: Traditional methods versus digital methods (DPER).

Theme 5: Participants' recommendations on how digital autonomy can be promoted in the ethics review process.

Step 5: Writing themes using the coding framework and thematic map:

Each theme was clearly described, based on Braun & Clarke (2006). The narrative showed the main idea of each theme, as mentioned by Braun & Clarke (2006). These narratives explained the experiences and perspectives concerning using different methods in the ethics review process. They also explained whether the ethics review process was ready for digital autonomy. The best examples supported each theme. The extracts and quotes were used to show why each theme was important to the study (see Chapter 4).

3.6 Trustworthiness of the Data

In addition to employing a well-recognised and respected analysis approach, the trustworthiness of the study's findings is further illustrated through the following criteria:

3.6.1 Credibility

To ensure the credibility of the information, the researcher made sure that all participants were engaged throughout the research study. This was to ensure that the data collected addressed the intended research questions. Shenton (2004) states that credibility in research is meant to give confidence that the researcher has reported the accurate phenomena of the research findings. The use of in-depth interviews and focus group discussions as different methods (triangulation) compensate for their demerits as data collection methods and exploits their respective benefits (Lincoln & Guba, 1985; Mishel, 1991; Shenton, 2004). The researcher managed group dynamics in the FGDs and probed effectively in the IDIs. Throughout the study, the researcher ensured continual self-analysis and reflection on personal biases and how they may affect the research. The researcher also utilised ATLAS.ti, a qualitative data analysis software that allowed for a systematic and transparent data analysis.

3.6.2 Transferability

Transferability is safeguarded where the findings and conclusions provided are used in the participants' contexts. This is done by using purposive sampling to ensure results can be generalised or transferred to other contexts (Forero et al., 2018). The researcher facilitated this by providing detailed descriptions of the participants' research context and processes. In addition, she included direct quotes from participants and specific examples in the findings (see Chapter 4), which would later help relate findings in future research to understand the effectiveness or lack thereof of traditional or DPER methods. The participants were able to share their experiences within their context, while sharing their practices, perceptions, and original findings reported (Korstjens & Moser, 2018).

3.6.3 Dependability and Confirmability

To maintain dependability and confirmability, the researcher consistently applied comprehensive codes which had been developed step-by-step, ensuring the stability of the findings, if replicated. Regular coding comparisons and discussions between the student and supervisor guaranteed systematic data coverage. These also confirmed that themes were both centralised and distinct. Additionally, revisiting previously coded transcripts verified the ongoing applicability of codes (Braun & Clarke, 2006; Green et al., 2007).

The researcher documented and tabulated each step of the thematic analysis. The research study steps and findings are richly reported and have an audit trail (Korstjens & Moser, 2018), to ensure future researchers can build on or explore further the research findings (Shenton, 2004). The researcher's supervisor, in conjunction with the researcher, consistently checked whether the thematic analysis process was in line with the research design. With the supervisor's guidance, all interpretations of the data were grounded in the data and not based on the personal viewpoints of the researcher. The findings of the study to be reported are a true reflection of the research participants' views and perceptions, not the researcher's (Shenton, 2004). The method of triangulation (Korstjens & Moser, 2018) was used to avoid bias by the researcher.

3.7 Ethical Implications

The researcher received all ethical approvals and research permits necessary for data collection (see Appendix 1 - 4). Data were collected in Nairobi and its environs in Kenya. Using the Emmanuel et al. framework (Emmanuel et al., 2004), as required when conducting

behavioural research with research participants, all the ethical considerations were observed as described below.

Collaborative Partnership/Community Participation

Before undertaking the research, the researcher had a conversation with the participants concerning the reasons for the study and why it was important for the research community.

Social Value

Even though the benefits will be indirect, the findings will be shared with all stakeholders through public engagements, seminars, or publications.

Scientific Validity

The researcher committed to the proposed research method and design since no study amendments were made.

Fair Selection of Participants

The demographic of the study matched the research questions in that it was a purposive and convenient sampling of REC stakeholders.

Favourable Risk/Benefit Ratio

The benefits of the study might not have been direct, but they will be shared through the dissemination strategy described in the next section. There were minimal to no anticipated risks in this study, except for potential discomfort during interview sessions.

Independent Ethical Review

As mentioned in the data collection section, ethical approval was sought (see appendices). Ethical clearance through the Social and Biomedical Sciences Review Ethics Committee (BREC) from the University of KwaZulu-Natal, two ethics approvals from a REC in Kenya, and a research permit from the National Council of Science, Technology, and Innovation (NACOSTI) were obtained. The Data Protection Act (2019) of Kenya ensured the protection and confidentiality of the transfer of personal data outside Kenya.

Adequate Informed Consent

Participation in the study was voluntary and the participants did not undergo undue inducement or coercion. They signed an informed consent form that allowed them to opt in or out of the study, allowing record-keeping and audio-recording of the sessions.

Ongoing Respect and Dignity

Participants were able to withdraw without any consequences. After the research was over, their data were kept confidential, and they were informed of the storage procedures. Findings may be shared in public forums or publications, and the participants will be informed of this.

3.8 Dissemination Strategy

With the findings reported in Chapter 4, the study was aimed at contributing to experiences and perspectives on the use of digital platforms in the ethics review process by different RECs. The researcher hoped that it would also inform about (potential) barriers and factors that lead RECs to go the traditional (paper and email) or digital route. Additionally, it may provide information that will help in developing a digital guide or framework from which to approach the use of DPER. This will in turn inform whether the use of DPER will result in increased efficiency of the ethics review process.

The main users of these findings may be different RECs. The findings also have the potential to be used in regulatory bodies that undertake research throughout Kenya. The study may be used to create awareness of, or sensitise stakeholders to, the use of digital platforms in the ethics review process. Additionally, the findings of this study will be made available in scholarly meetings and publications. Peer-reviewed papers may be published in open-access journals to ensure access to a wide audience. The research report will also be made available in the institutional repository. An infographic may also be shared with findings to the respective participants, once the study has been completed.

3.9 Reflexivity

The researcher recognised how their role, prior assumptions, and experiences might have influenced the data collection process in the research. Researchers should place greater emphasis on self-awareness and sensitivity, deepen their comprehension of how the self-influences the generation of knowledge, meticulously oversee how their own biases, beliefs,

and personal experiences affect their research, and ensure a balance between personal perspectives and universal principles (Berger, 2015).

In recognising the limitations associated with convenience sampling, the researcher implemented strategies to mitigate potential biases and enhance the credibility and representativeness of her findings. These include efforts to diversify the sample, which was achieved by getting participants from different organisation types, and different roles in stakeholder ethics review workflow. Combining both convenience and purposive sampling ensured key stakeholders were not overlooked reducing potential bias. This reflexivity in the methodological approach not only acknowledged the researcher's role in the research process but also underlined her commitment to rigorous, ethical, and reliable research practices.

In terms of her prior assumptions and experience, the researcher, acting as both a secretariat and reviewer in their own REC, needed to consider how their professional background, being known to the participants, might have influenced the participants' openness in sharing experiences or affected the content of their discussions. To try to address as much bias as possible, a bracketing technique was used when engaging with the participants. Bracketing is where the researcher puts aside their preconceptions, enters the research participants' environment, and uses themselves as an interpreter of the participants' experiences, knowledge, or perceptions (Gearing, 2004; Tufford & Newman, 2010). The researcher practised these measures throughout the study, with the help of her supervisor who held her accountable.

CHAPTER 4: FINDINGS

4.1 Introduction

This chapter presents the findings that emerged from the interviews and focus group discussions previously reported in Chapter 3. Similar issues emerged across the participants' narratives, thus the themes presented below include the perspectives of both the REC members and researchers. By taking this approach, the researcher acknowledges the shared narratives across the two groups; however, where needed, group-specific perspectives are noted.

The following themes will be discussed:

Theme 1: Participants' current ethics review processes.

Theme 2: Participants' perspectives on digital autonomy.

Theme 3: Participants' experiences of digital platforms.

Theme 4: Traditional methods versus digital methods (DPER).

Theme 5: Participants' recommendations on how digital autonomy can be promoted in the ethics review process.

Theme 1 presents findings concerning participants' thoughts on using either traditional or digital platforms in the ethics review process (*Participants' current ethics review processes*). Theme 2 delves into participants' feelings and insights towards the adoption of traditional methods or digital platforms in the ethics review process (*Participants' perspectives about digital autonomy*). Theme 3 details how the ethics review process is carried out within specific institutions (*Participants' experiences of digital platforms*). Theme 4 explores differences in the use of both methods (*Traditional methods versus digital methods (DPER)*). Lastly, theme 5 identifies factors that promote the use of either traditional or digital approaches in the ethics review process (*Participants' recommendations on how digital autonomy can be promoted in the ethics review process*).

For each theme, extracts were used to illustrate the participants' responses. Following Groenewald and Bhana's (2015) example, the following transcription conventions were used: Square brackets "[]" enclose additional material inserted into the text for clarification. Ellipsis points "(...)" show when the participant's thoughts have trailed off. Uppercase letters are used

to show emphasis. A full stop in parentheses “(.)” represents a pause in speech, and “[...]” shows a break in the extract.

4.2 Themes

4.2.1 Theme 1: Participants’ Current Ethics Review Processes

Participants were asked to describe the ethics review processes that they were currently using, either as a REC member or when applying as a researcher, at the time of the interview (see Table 4).

Table 4: Ethics Review Methods Used by Participants

Participant ID	Ethics Review Method Used
In-depth interviews (IDI)	
[P1, IDI]	Digital/Email/Paper *Transition
[P2, IDI]	Email and Paper
[P3, IDI]	Email Paper
[P4, IDI]	Email and Paper
[P5, IDI]	Digital and Email *Transition
[P6, IDI]	Digital and Email *Transition
Focus Group Discussions (FGD)	
[PX, FGD 1]	Digital
[PX, FGD 2]	Traditional

Findings revealed that participants used a combination of review approaches, including paper-based, email, and digital platforms. For example:

“We have three different systems. I can say we have a parallel, it is not even parallel, we have three different systems. Shipment of biological samples – those are purely paper. Paper-based. The new protocol is submitted through a system called [platform name]. The other applications, apart from the new, like the amendment, continuing

review reports, notifications, deviations, and close-outs, are submitted through email. So those are three.” [P1, IDI]

“When COVID came, a lot of people were working from home. So, we decided to use emails to share with people whom we cannot access physically; if yes, we will use Google Drive. Just make sure at least to capture the details of the proposal number. And then see along the process at some point to call the researcher or the student to share some copy through email. The same now is shared with our reviewer on Google Drive.” [P3, IDI]

“So, my experience with these platforms is that one, some are better than others and, two, it takes up minutes, it takes a minute to get used to it [...]. You’re doing both email and the platform. So, we’re always from getting to a place where we are comfortable. I know the PIs are excited about it [the digital platform]. I’m looking forward to the time as a reviewer, I will be as excited so that we can meet that goal of a quick turnaround.” [P5, FGD1]

“Initially, they’ll do this through, of course, email submissions. These email submissions come in and go to the respective board review members. But then again, until recently, of course, a lot of things now coming in and now, slowly but surely, moving to other digital spaces to minimise the issues of online submission. And now having these, these now done through our platform that [organisation name] has provision for the ethics and Scientific Review Committee. So, we are slowly but surely now going towards moving away from email submissions.” [P5, IDI]

Participants talked about paper-based approaches, a common co-occurrence when using traditional methods, where they had to gather several copies of the proposal, physically visit the REC, and acquire physical signatures:

“You are required to first gather all the documents and do several, like for (...). I’ll speak from experience from the institution and what we require [is] to have three separate copies of the proposal. With several sheets of paper before you even get to the proposal, like the signatures collected from everyone and the approvals on the site where you’re going to collect the data and so it’s three different copies that go to the

ERC. It's a physical visit to the office and you sign some signature books that you've submitted." [P2, FGD2]

"... it must go through the centre first before it goes to the specific ERC, and we are required to do the paper submission. We also do two copies as well. And we are required to go there physically, and you know, for the copies, you can imagine a submission package having the protocol, having the investigator's brochure, having the site-specific addendum, all those documents you must print them in two copies each and take them there physically." [P3, FGD2]

"I applied for ethical approval from [institution name] so the process is on my side. I can say it wasn't a very good experience 'cause first, we must, I mean the procedure is to download some forms from the [institution name] website. Then you fill those forms physically; after you fill the forms, you must submit the forms physically to [institution name]. First, you must take those to Graduate School. So, you also need to, I mean, print copies, at least four copies of your proposal, with the additional forms." [P4, FGD2]

4.2.4 Theme 2: Participants' Perspectives on Digital Autonomy

The use of digital platforms comes with its share of issues and concerns. To capture this, participants were asked to recount their perspectives on their use of digital platforms. This theme further illustrates their mistrust and any ethical issues that arose or might arise while using digital platforms.

4.2.4.1 Mistrust and Ethical Issues on the Uptake of Digital Platforms

In both data sets, when asked about ethical concerns about DPER, mistrust and issues around techno-ethics (which denotes a broad range of ethical issues revolving around technology, in this case relating to the use of DPER), were reported. Participants' narratives reported on data privacy, confidentiality, cybersecurity, and data ownership rights. The following quotes noted this:

"You know, systems can be hacked, systems can be ... not like paper; when you lock it in your room, no one else can get it. Unless your room is broken into. But for digital platforms, you cannot say you've locked it, because it can be hacked." [P1, IDI]

“You know, for traditional methods, unless you have someone’s hard copy of the research proposal, there’s no way you can share someone’s intellectual property, just like that. So, with digital, you know, it’s now so easy to share. You can share this with people who are not part of the team. That is a concern to most people. Issues of confidentiality, you know, having access to their documents, how are we able to contain that? Indeed, it’s only the reviewers who will have access to it and such.” [P3, IDI]

“Of course, cybersecurity is one of the key things coming in and people can easily walk in tomorrow, you do it, and out tomorrow, out there you find information all over... For example [name], has a certain idea and [name] being sharp the way she is, runs with this information. Before you realise [it], you find that information out there; already that article has been, researched and published. And you ask yourself, huh? Or someone goes and uses it for fundraising, you get [it]?” [P5, IDI]

“I remember an institution that had a problem with their databases and all that; they were hacked. So, in such a scenario, and this is an issue that was mentioned, is there one, maybe, perhaps one platform that can be adopted in these reviews? ... But suppose hacking happens. You know that can also be a challenge and therefore, maybe, I think proper software to protect the information, at least information. See if they can be hacked and taken by people who are not supposed to get that information, you know, that kind of [can] be a serious issue to the reviewing board and so forth.” [P4, FGD1]

“How secure is my data? I’ve also received some links on the same [one] you sent your proposals, and you received some emails asking you some questions and you wonder where this has come from. Where have they gotten my information or information about PIs?” [P3, FGD2]

Participants among both data sets expressed concerns regarding the amount and protection of information shared with research ethics committees (RECs), where confidentiality and privacy of the research study documents emerged as significant concerns:

“And I understand everything about protecting and the need for confidentiality and they [RECS] need to ensure that the data that’s coming in is well protected for

whichever subject is being looked at out there because everything starts from the protocol that's being submitted.” [P4, IDI]

“We give too much information for review; we give you a whole protocol. All the questionnaires, all the documents, everything, and then you are left wondering. How? How secure? How safe? Is somebody else going to take your protocol and, you know, do a study out of it? We don't have that. Like, we are not given that surety. And that is my biggest concern.” [P6, FGD1]

“Do we have the privacy rights that are usually retained for now, as the researcher, in terms of now, I think we had the Data Protection Act rather? So of course, some of the issues addressed in that are, like, now the sharing of information or maybe people being able to acquire information online and use it for other purposes, not for the ones that you wanted them to do.” [P4, FGD2]

Data ownership and access to data in third-party digital platforms also raised concerns. It was reported that there was concern about who the researcher's and REC data belonged to, where it was, and whether it was safe:

“When it comes to digital systems. So, the first time we started, the server, the technical assistance was in [country 1]. So, they are awake, and we are asleep. We were asleep and they were awake, so it was very difficult to get real-time assistance for the system, so that didn't work very well. So, we said, can it come a bit closer? And it came a bit closer, and it moved now [country 2]. And in [country 2], at least, is just two hours different. So that's a bit better. But now we are struggling to have the server in our own country, that is Kenya. We have been asking about where our information is. We keep asking where is that information. There's a lot of information that we are giving about, what kind of research we're doing in this country, and they keep saying that we can access it. But now we haven't quite been able to access it. So, even if we want to write a report and say that in the last ten years, the last decade, or these are the types of proposals we've been receiving ... It would be difficult. [P5, FGD1]

There was a fear that it would be easy for a researcher's work to be plagiarised or sections picked out since the system is not fully confidential and trustworthy. The following quotes

illustrate this:

“The fear has always been if you send somebody a proposal by email, you’re not always too sure whether they’re not going to pick sections of it. Or some people [are], like, clever; they can see where this is going to go and then they use it for themselves and apply for other research opportunities.” [P2, IDI]

“Recently there is information that was being sought by the Commission for University Education about publications, innovations, and so forth. We happen to have a group of business students at the master’s level and all these business students have graduated just recently; they all have an innovation, a business, but they have refused [to give the information] because of previous experiences. And therefore, they have refused to share that information ... So, that becomes a major concern, and it was said – that is this platform going to expose research and researchers to the unknown and that the unknown could bring some things that we may not know even how to address.” [P4, FGD1]

“Some of these digital things people fear. In my work as a psychologist, I have found whenever I’m doing research that’s very personal, sensitive information; people fear still in the local economy to give a lot of stuff online, and you’ll see that they are also limiting or truncating their responses because of the system not being completely confidential. So, there is always the risk of being hacked or wondering whether the information will be truly used as it is indicated.” [P1, FGD2]

4.2.4.2 Benefits of the Ethics Review Methods

A common view among the participants related to both the potential and perceived benefits that they look forward to seeing with the use of digital ethics review methods for the ethics review process. For example, a participant who reported solely using the traditional methods (as their platform is being worked on) looks forward to remote working:

“The fact that you can work from anywhere. Like this office, it’s a small office and we can retain it as is but increase the workforce. THE WORKFORCE. In terms of the secretariat, whereby most of us can work from home, even if we have two desks. Yeah, but we have, like 20 of the secretariat team, but gone through the virtual way.” [P3, IDI]

Another anticipated advantage mentioned across both data sets is the management of ethics review data, which is expected to influence future policy as the world moves towards an era of big data. This includes the potential for enhanced monitoring and evaluation capabilities:

“We are moving away [...] now talking about the big data. Talking about big data evolves today to create a portal. This portal earmarks and of course can track the protocols that came in at addressing the human subjects ... Don’t you think you can shape the thinking within the country and what’s coming up and ask yourself why everybody is doing [their work in] this space and what can we do differently as a secretariat?” [P5, IDI]

“The experience has been rewarding, to say the least, because we receive a lot of applications and sometimes we have new members coming into the committee. So, I think it’s become like a database of some sort, where it can be used as a tool for learning so that people can understand more about the processes, the procedures, and the policies that guide the ethics, the ethics committee. And I think also even the specific responses, you’re able to know what exactly are you required to do in the specific processes.” [P2, FGD1]

Furthermore, participants highlighted a key benefit of digital platforms, namely their positive environmental impact. This benefit comes from reducing paper usage, which not only saves trees but also cuts costs associated with paper consumption:

“And then number 2, practically, trees. Paper – environmental. We are being told each time, REDUCE YOUR USE OF PAPER, REDUCE YOUR USE OF PAPER. So ideally and practically, it is cheaper and better to go online.” [P2, IDI]

“When you look at the environmental impacts of printing out paper, you find that using a digital platform helps us be able to be more sustainable in the long run, in terms of cost, in terms of environmental sustainability as well.” [P1, FGD1]

Participants also noted the perceived benefits of digital platforms in streamlining the ethics review process, alleviating backlogs, and reducing the workload on researchers:

“I think it will help us to streamline the process in terms of timelines... The same will apply to setting out the documents or reviewers and getting feedback. I STRONGLY BELIEVE IT WILL REALLY HELP IN TERMS OF THE TIMELINES FOR THIS ERC.”

[P3, IDI]

“It helps reduce the backlog, for most of the researchers and reviewers. All they must just [do is] create an account and upload their documents and everything else is done by the reviewers, without the researcher having to keep writing in there, going back and forth, and sending letters. I was saying that it lessens the burden on the researchers, where the researcher must keep following up and taking documents to the committee.”

[P6, FGD1]

4.2.3 Theme 3: Participants’ Experiences of Digital Platforms

In this theme, participants illustrate their experiences using digital platforms. From Table 4 above, six participants from FGD 1 used digital platforms and three from the IDIs used digital platforms. This theme reports these participants’ experiences with the different DPERs and goes further to showcase the benefits and challenges of the DPER.

4.2.3.1 Challenges of the DPER

Participants acknowledged facing challenges when integrating digital platforms with conventional methods (such as email and paper) for the ethics review process. Participants highlighted the inability of the current DPER they were using to support the transition which led them to still rely on traditional methods in addition to DPER. This perspective is reflected in the subsequent remarks:

“... We are going to, because (.) we are in the transition phase of going online, (.) all these other applications that are coming through email will eventually be processed through the system. It’s only that the system is still not able to accommodate everything. So, we are doing it in phases. So, it is a work in progress.” **[P1, IDI]**

“And then finally, in one committee, we have three different systems of dealing with applications because the online one cannot accept the other two. So, we have a system which is online. Then we have a system which is email and then we have a hard copy.

So, we have requested in one committee to have the people who developed the system come, and they did, and then we asked if we could make some changes. But they said, perhaps rightly, that we're not the only ones who are going to be using the system. So, they are now going to be putting things into a system which other ethics committees didn't require." [P5, FGD 1]

In addition to the lack of transition support by the DPER, when asked why they had a digital platform, but it was not in use, a participant responded that the system was not thoroughly thought through before being deployed and some documents would go missing:

"Some hitches. [...] The people who developed the system did not think it through. So, even before we started using it, it had challenges. And just be honest, yes. From space, from the hardware to the actual system. So, they must go back to the drawing board and just address those hitches. Before we can leave [the old systems], there's no point in starting to use it. Yeah. Only for it to crash within a month." [P3, IDI]

"But there was also (...) one of the issues that I experienced was, sometimes, the documents that were required, searching for them, that some would be missing, some would not be easily found, or some would be uploaded in a format that was not easy for the reviewer to find to locate." [P3, FGD1]

Furthermore, the DPER also came with some form of rigidity, where customisation and flexibility of the platform to fit the REC was difficult:

"I also find that the systems that come, because they were not made with the people who are going to use them, are a little bit rigid and there are certain things they cannot do. As I have said, there's one system [which] will accept resubmissions and another system will not. So, you can only submit the initial proposal for one system, and then any other application, like a protocol deviation, like a request for annual renewal, is given through email." [P5, FGD 1]

In addition, participants acknowledged the challenges that come with using digital platforms for ethics review. One was the lack of capacity and not enough training to adopt digital platforms in the ethics review process.

“So, if you’re going to go to digital space, then be prepared also to do some bit of proper training along that particular [system] and just ensure that the people are well apprised of the platform, but then again, it also comes with its technology. You also need to have a support team just geared towards solving the client-related problems, if necessary.” [P5, IDI]

“I don’t know if there were IT people or what or if they had gone through it for them, it was very easy, but generally, it did not TAKE in the first time. Even the second time. And for both platforms, we’ve had to have smaller sessions to get us on board. And I would like to (...) up till now on both platforms, I still get stuck. And I still say I can’t find this or where do I find the other?” [P5, FGD1]

The complexity of the reluctance and slow adoption of digital platforms was also reported as a challenge in the traditional method FGD 2:

“You don’t want to change. You are too used to the old way of doing things. It is not just the old guys. Some old guys will receive it by email and will give you very good comments by email and written by email. Some young guys if it is not physical – ‘I’m not bothered’. So, you can’t say whether it is the old or young or new faculty or old faculty. It varies. Some guys adopt these things quickly, [for] others it’s slow.” [P2, IDI]

“Recently we went for a brainstorming with the ERC that we work with and that was after the government’s directive to have all systems, all government systems, digitalised. And you know, we’re giving our perspective on the transition, and we could still feel, you know, some bit of reluctance even from their end, especially when it comes to the issue of letters being signed.” [P3, FGD2]

It was also reported that, if not everyone was ‘tech-savvy’ about using DPER, this may cause some form of *unfairness* and sometimes clarification within the platform may act as a guide:

“Unfairness, because assuming PIs or assuming investigators are using it on the ground. And maybe some participants of the system are unable to use it, because of the

technological know-how. So, at the end of the day, it will ... It may bring some unfairness, or we are not uniform in the way we operate – in the way we do things. Because maybe I'm better at accessing the system. Someone else is not better in accessing the system, so it will bring some form of unfairness at some point.” [P1, IDI]

“[...]the people coming up with the platform need to find means of clarifying, concepts or terms that are not familiar when submitting because we as researchers don't know what some terms mean in the platform when applying. If there are some notes beneath, those could clarify and make the process of application simple.” [P4, FGD1]

The frustration of waiting for REC feedback was also reported, as this can cause some form of frustration and anguish to the researcher:

“Today, I see that as something which can cause mental (...) I don't know (.) maybe others can be able to chip in here, but I'm saying this is something that can cause mental anguish, especially for those researchers who normally have, like, you've already submitted your proposal or protocol. You've received feedback. The feedback is not very clear or you're not in agreement with the feedback and you, you can [do] this, you do not have that (...) we have a problem now with the generation where the one thing was done quickly, just like the way the digital platform helps us get things done quickly. So, there is a lot of frustration sometimes from the person who is doing the submission and anger sometimes.” [P1, FGD1]

4.2.3.2 Successes of the DPER

A common experience reported among all participants was the reduction of turnaround time when they transitioned to using DPER:

“One of the biggest is like (.) turnaround time. And in turnaround time, we reduced turnaround time when ... when we went (.) electronic (.) 90 DAYS. 90 DAYS. But when we were doing paper. BUT NOW WHEN WE WENT AND THIS IS, REMEMBER THIS IS AVERAGE. Some move them faster than that. Some will delay a bit, a little bit, [but] on average, when we introduce the system, we reduced up to 67.” [P1, IDI]

“The turnaround, THE TURNAROUND TIME. Then I save time in terms of, I do not

have to physically move from one place to another, submitting my documents and saving on the cost of printing. As you know, the way we must print manually is, if you submit it manually, you must print the documentation. Sometimes you must look for signatures and all that, so it's time-consuming and the experience of having to do most of these things. I find it to be effective.” [P1, FGD2]

Among all data sets, participants also reported that DPER would cut costs:

“...cost saving. In as much as there's some money that you spend in accessing the system or in buying the system, it is more. It is cheaper than when you decide to go [the] paper way (.) because there are some printing costs. There are some courier services. Maybe you want to send the document, so there are some courier services. Maybe some costs of the meeting. But now, when you are virtually again, you see, that's another way of using the digital platforms. And again, you don't need to hire conference rooms, you don't need to buy people, tea, lunch, and snacks.” [P1, IDI]

“I think I find it easy. 'Cause, you just must get your documents to upload them. You don't need to print them, take transport to that place, and deliver them in person, which is also cost-effective, which is nice.” [P6, FGD1]

“... It also reduced the cost because we had several members from different parts of the country. Then the travel cost and accommodation costs were also decreased, so generally, it did make work easier.” [P3, FGD1]

Meeting attendance seemed to have improved drastically by using digital/online platforms for meetings and members seem to always attend meetings:

“A great advantage that we have witnessed is that the reviewers' attendance is high now. Because the inconveniences which would normally lead to apologies have largely been reduced; sometimes we can hold a review where, a good lady is in KwaZulu-Natal and I am in Nairobi and, say, the vice-chair is in New York. So, such a meeting would have had a problem with the agenda because of the physical absence of these people and you get so many apologies; yet when you can, when you are virtual, you can attend from any corner of the globe. So, that is one big advantage that we have seen, that the

apologies have gone down [and] the attendance has greatly increased.” [P6, ID1]

“...but never has it happened that it has led to the total postponement of a meeting, but one or two of the reviewers may be in places where the connection is poor, but that is now because, apart from using the platform, the committee will always meet, so that there is a consensus on the review from the three reviewers who will have submitted their reports to give the final verdict on the protocol.” [P3, FGD1]

In addition to attendance increase, it was also reported that communication was now more concise and faster when using digital platforms:

“...like, the responses are, they are very precise. Or rather, you know you don’t have to get so much information, because I think, for us, the digital platform has a max of this number of words. So, you get the specific information that you need and that communication, if you need communication or something that needs clarification. It’s quick and the communication is quick for you to get.” [P2, FGD1]

4.2.4 Theme 4: Digital versus Traditional

The findings presented in this section include all participants. Apart from offering insights into digital autonomy, participants also described their thoughts on the more traditional approaches (i.e., paper-based and/or email) that have historically been used in the ethics review process. These discussions often occurred with digital platforms, where the benefits and challenges associated with traditional approaches were compared to digital applications. The present research reveals that these two methods exhibit a contrast, as evidenced by participant narratives.

Participants explained that traditional methods offer distinct advantages. They noted that using paper lends an aura of authenticity and trustworthiness and that there is less risk of breach of their original contribution:

“(...) let me use the proposal, a research proposal by a student. You know, you will be sure that that student got help from the supervisors. Because they will LITERALLY have to sign and date the document. So, what will be brought to the office, you are assured, has gone through due process from the student and researchers. THAT IS a good thing.

Yeah, there is evidence that this document was signed by ink from a student under a supervisor because when it goes through the digital way, you can probably [suspect] someone else is doing that proposal for that student.” [P3, IDI]

“I feel the risk of that breach is minimal as compared to the digitalised platform.” [P4, FGD2]

As indicated below, some participants also emphasised that paper was still a form of back-up:

“Backup, so you always have a backup of some kind, which can still be done digitally ... But with a hardcopy, or even see their students, you can look at them in the eye. Yeah, you can confront them and tell them, this document doesn’t look like it’s yours. Such things?” [P3, IDI]

“What we know from archiving is that paper still stands the test of time ... So, the advantage, as I said earlier, for the traditional methods of paper and email is that they can be used where, for instance, we still have problems with access to electricity and the internet in this country.” [P1, FGD2]

“The only advantage I see with the traditional method is maybe backup because apparently, for example in our organisation, as much as you submit your submission on the digital platform, you must make hard copies for backup just in case something happens. Whether it’s hacking or the system is down, you’re able to follow your documents through the traditional way.” [P5, FGD2]

Traditional methods were reported to be easier to access and navigate than DPER, which is best represented by Participant 1 FGD2’s narrative below:

“Unlike in the past years, you know, we need to also look at infrastructural issues and the context of access, as well as the user experience, which I think somebody alluded to. So, depending on the interface of the device you have, we may have an issue of lack of information on the services and how to use them or how you can easily change the data after you submit. Therefore, that is where the traditional services come in.” [P1, FGD2]

In addition to describing these benefits, participants also presented the challenges associated with traditional methods in comparison to digital approaches. A key issue that emerged related to confidentiality and privacy when using traditional methods, where it would be easy to plagiarize someone's work and use it as your own. This is illustrated as:

“Confidentiality is a big one. Because the document can be shared. It's very easy for something on email to be forwarded to somebody else. The other one we don't like is where somebody uses your ideas, picks your sentences, words, and everything, and does a proposal himself and takes it to another funder to do something like what you are doing. Those are the concerns.” [P2, ID1]

Participants who relied on paper for the ethics review process recognised the inconvenience of needing to be physically present at the office to collect ethics review submissions. In contrast, with digital platforms, PIs can submit at any time.

“Any time, you remember, during the time we used paper, they must bring the document when you're in the office. The PI had to submit the document when I was in the office. But now, they can send the [document] wherever they are, any time.” [P1, ID1]

Narratives by participants also reported the challenge of how paper can be easily misplaced or lost. There was also an emphasis on the time it takes to retrieve documents from different digital platforms. This can be illustrated in the following quotations:

“Misplacing documents. Very crucial documents. Then, maybe the system of how the document is being organised; it's also a challenge. OK, the system of document management. Number two, it takes a lot of time, maybe in terms of document retrieval. IT TAKES A LOT OF TIME. In terms of organisation, it requires more effort to bring things in. Compared with the digital platform, cause that one you just hit the keyboard, you type what you want, but for this one, you do search things manually, so it really consumes a lot of time. Then it requires a lot of manpower. And it needs your availability. Once you are not there, especially if you are the only person who is working on that, maybe that item, if you're not there, you can't proceed. So, the work continuity with the manual thing, it's not that okay.” [P4, ID1]

“You know documents can get lost. Yes, that is the unfortunate thing. Digitally, always there’s a tracking of it. Traditional – someone can literally come and delete an email. The hardcopy can get lost, someone can go home with it, and use it to go in a matatu with it and forget the bag. You know, things happen. Someone can break into your car and still assume that it’s something valuable. So yes, those things do happen. And we lose documents. Same for comments, you can misplace them and literally won’t be able to retrieve them. Those are some challenges that you can face.” [P3, ID1]

Increased delays and turnaround times were also reported with the use of traditional methods and how the process is handled in general:

“Usually, the waiting periods are still long, still roughly around two months. You can request an expedite, but it’s still not as fast compared to the electronic. I’ve done both electronic, but not here, and this paper-based. So, it’s still not as fast as that one. I don’t know whether it’s because they’re reviewing physical copies of the booklet. Or getting the booklets to the reviewers.” [P2, FGD2]

“So, it’s cumbersome and time-consuming and then, when you get there, you wait for a while, maybe two weeks before you can be put on the agenda.” [P3, FGD2]

“You’re told to look at, I mean, a lot of letters to check where your letter is; there for me, that was quite frustrating because I couldn’t understand why it couldn’t be [there]. Maybe they don’t have like an automated platform whereby you just tell them your name and they check whether your data is out, so you must sift through a lot of letters. I mean, even way back, you find letters from 2018 or way back, and you can’t even find your letter. So, the first month, I didn’t find the letter. I was told to keep waiting. So that’s continued for three months. I decided to look for ethical approval from another institution because it was taking quite long, and I wanted to start collecting samples.” [P4, FGD2]

In addition to this, it was also reported that the use of traditional methods does not offer the opportunity to work remotely or to access the documents from anywhere, since you do not need a physical copy using DPER:

“There is a reason why my proposal took too long; [that] was that the people supposed to review the proposal were not present, they were not there at the university at the time. They’ve gone to teaching classes, but this means these people only had to have access to the physical copy of the proposal. Imagine if, I mean, we had like an electronic platform whereby regardless of where the person was, they’d still [be able to] access the proposal anywhere in the country.” [P4, FGD2]

Relatedly, it was stated by participants that, before the COVID era, they would physically carry hundreds of proposals to designated meeting locations to distribute to members for every meeting. This was very *cumbersome* for the secretariat. This was illustrated in the following quote:

“So, you can imagine every single proposal that is under review, we will have to carry and take to the physical location of the meeting. Yes, that is something that used to happen, before we went the virtual way of meetings. So that was quite cumbersome. Carrying hundreds of proposals. You bring three copies of your proposal. So, two members will be assigned, and the office will always retain one. So that one copy is what we will go with to the meetings. And remember, we probably like, right now, we are in number 500. SO, CARRYING 500 PROPOSALS.” [P3, IDI]

Although there have been efforts to shift from paper-based methods to email and Google Drive, participants observed a limited uptake of email usage. For example, a participant described scenarios where committee members persisted in giving handwritten feedback, even when electronic meeting comments were available. This produced significant frustration which is highlighted in the following excerpt:

“So, you will literally type each comment. Yes, that is what we do. WE LITERALLY TYPE. And it still happens. Don’t think that it doesn’t. Yes, we still have reviewers who handwrite. As I told you, they’re still receiving some hard copies. And so, while you are typing their comments, some of us cannot understand their handwriting. Some of them are doctors. Such poor handwriting. There we are struggling.” [P3, IDI]

Similarly, another participant recounted his frustration in capturing information provided

through paper-based submissions. His focus was on the accuracy and potential errors that can occur during capturing, in this case, data on Excel, which could require multiple personnel to review and verify the work. This sentiment is captured in the subsequent quote:

“I entered everything else, but it also is another issue, it comes with possible data entry errors you get if you only have one person doing it, chances are (...) we always say in data entry, you must have at least one or two, three. I or someone or two-three people to come in and help cross-check to ensure that what you’ve entered is a true reflection of what is it.” [P5, IDI]

One participant also reported that a benefit of traditional methods can be the precision one exercises to fill their application, unlike in DPER where people sometimes rush:

“The only advantage I would have with traditional methods such as email and paper is that perhaps people will take time to fill out the form. In my experience, sometimes an online platform may make people feel rushed, because typically, people will get online to do a couple of things and have several tabs open at the same time. There’s a probable attention or focus or concentration difference if you must fill a hard copy or paper.” [P1, FGD2]

In all, although some participants’ narratives were replete with the challenges and benefits of traditional ethics review methods, they still seem to recognise the value of DPER in addressing these challenges.

4.2.5 Theme 5: Participants’ Recommendations on How Digital Autonomy Can Be Promoted in The Ethics Review Process

As shown in the previous themes, there appears to be a strong acceptability of the use of DPER. This theme focuses on the factors that participants said are needed to promote digital autonomy in the ethics review process.

4.2.5.1 Institutional Support

It was reported by participants that digital platforms are to be adopted for the ethics review process, and institutional support is one way to enhance the use of digital platforms. It was described that it would be helpful to appoint a dedicated IT person who would help with the

digital platform:

“Giving the committee resources like an IT person or enabling a member just to allocate someone to manage the system and give that support. So that now the committee feels enabled and supported. So, for the committees that charge a small fee, that money can be used to buy better equipment for the REC and maybe also to give some small stipend for the person managing the system, so that they don’t get corrupted, as it were. Someone in the committee or an administrator who has an IT background. Why not have someone in IT who can do that back-end support for you? Help support and maintain the system and ensure that the integrity is there.” [P2, IDI]

Furthermore, it was mentioned that if the RECs got a unified platform, it would be helpful to promote the use of a digital platform through Kenya’s regulatory body:

“Or going from this ERC, if you get comments or get disappointed, you go to another ERC with the same [proposal]. So, if we have a unified system, it would be able to say this one has been reviewed in [organisation name] and somebody’s against submitting it to the University of Nairobi. Why? So, I’ll encourage NACOSTI, or I give my recommendation to NACOSTI, if they can have a unified system for all of us.” [P1, IDI]

4.2.5.2 Proper Infrastructure and Resources

Narratives by participants emphasised how the digital platforms should be developed and supported in a manner that is satisfactory to the research environment, which refers to the infrastructure needed to promote the use of DPER:

“... maybe I think proper software to protect the information, at least information. See if they can be hacked and taken by people who are not supposed to get that information, you know, that [can] kind of be a serious issue to the reviewing board and so forth.” [P4, FGD1]

It was reported that good infrastructure would mean that platforms protect participants, but also support a generation that is not openly comfortable with technology and needs to stay with the traditional method:

“So, for me, I think as we move towards technology and using the web platforms, the digital platforms and so forth, there will be also a need for the review bodies to come up with a solid infrastructure that can stand the tests of time. That is in case you want to go back to your history of online reviews. Can we trace that? And so forth. So, moving but also at the same time building an infrastructure that is good to support the kind of work that is required or about reviews and not leaving because, yes, there is a generation that is privy to this technology, but there is also a generation that is not going away soon. We also need to have consideration of what about those who still are traditional. Is there a possibility that we don’t lock out a group or a population of researchers who want to apply, maybe even to resubmit, if it is locally to submit the hard copies?” [P4, FGD1]

It was reported that, for each digital platform, user guides or chatbots to assist in the navigation of the platform are required:

“So, something like (...) a guide, even just within the page of where somebody’s doing the submissions ... We have ways of mitigating (...) know if with other platforms there’s normally a chat assistant or something like that; this chat assistant can be an AI or a person. Doesn’t matter, but sometimes the person who is going through this, it can be helpful for them to have a way of receiving that instant feedback.” [P1, FGD1]

It was reported that artificial intelligence and the pre-loaded questionnaire in the system to answer the ethical concerns of research studies are too rigid and do not focus on emerging technologies and research trends:

“But even as we migrate and transition more fully into digital, we need to ask those questions because you’ve had several respondents here, talk about some questions, the AI, the artificial intelligence, or the system being a little bit rigid and not being able to capture the various things that we are reviewing. So just this morning somebody was calling about genetic review and genetic studies and genomes and when I think about the two systems, I mean, they might not quite allow you to answer those questions because what these systems tend to do is they tend to give you questions to answer. When you answer those questions, they reckon you’ve done the review and I’m trying to recollect to see if there have been any questions in both the systems that I review with

to do the genetics, to do with AI itself, to do with data sharing. [P5, FGD 1]

In addition, there is a need to customise the platform to fit the needs of all the users:

“What we experienced was that the customisation that digital platform needed to be customised to the organisation because we used a digital platform, which was designed for general use, and then it had to be customised for our organisation and that took several months for it to reach a stage where they users were also had been trained and were using it well.” [P3, FGD1]

“I’ve known of other places where the system is bespoke, so I know in [a] university, I think of the University of Wits [Witwatersrand], in South Africa, in their university IT department, they created a system that was suitable for their needs. It costs a lot of money, but buying a system also costs a lot of money. So, that they could have something very suitable for them. It’s very fit for purpose.” [P5, FGD1]

4.2.5.3 Catalysers Enhancing Transition to Digital Platforms

Some participants were asked about any noticeable drivers that led to the use of DPER compared to traditional methods. Before its adoption, they borrowed from already existing experiences they picked from their institution in other areas other than the ethics review process. Participants remarked:

“These are not even my thoughts (.) because we did a study. We did a study that was funded by WHO, and we tried to compare efficiency before the system was introduced or before the online system was introduced ... The turnaround time was on average, because this was on average it was... [putting emphasis] 90 days. 90 days. But when we were doing paper. BUT NOW WHEN WE WENT AND THIS IS, REMEMBER, THIS IS AVERAGE [emphasis], some move them faster than that. Some will delay a bit, a little bit, on average when we introduce the system which reduced up [sic] to 67 [days].”
[P1, IDI]

Another participant noted that, while they continue to rely on paper and email, their decision to develop a platform for their institution was influenced by the insights they gained from a digital platform employed for journal submissions at conferences:

“So that we know, when we send you the form, how long it’s going to take you, you get reminders when you are late. So, the platform IS BEING DEVELOPED, but it is based on the journal. So, we are doing a modal syntax emailer and our conference, which is done (...) the papers are ... papers which are received online, distributed, reviewed online, responses sent online, and confirmation sent online.” [P2, IDI]

4.2.5.4 Adherence to the Data Protection Act When Using DPER

Participants emphasised that RECs needed to adhere to the Data Protection Act (DPA) (2019), even when adopting digital platforms, to ensure risks are mitigated when using these platforms:

“You’ve indicated a major one, which is privacy and confidentiality. You know, legally in Kenya now, we have the Data Protection Act of 2019. So, we are trying to comply with their Act. And again, it has some ethical concerns, because the system has a lot of personal information you give there, your personal information, your name, email, phone number.” [P1, IDI]

Furthermore, some participants also raised the requirement that data from the DPER should be stored in adherence to the DPA (2019). It was illustrated by this quotation:

“And also, now the requirements of the Data Protection Act, you must keep the information where you know, and it is secure. So that’s why we said (...) we thought, why not just develop a platform that we can use for ourselves? So, that’s the reason. So that we are in control. You’re not having a platform where the server is in the USA. And then people can harvest, and we don’t know what they’re picking the data from and then they run into problems with NACOSTI, THE DATA PROTECTION ACT.” [P2, IDI]

“Do we have the privacy rights that are usually retained for now, the researcher, in terms of now, I think we have the Data Protection Act rather? So of course, some of the issues addressed in that are like now the sharing of information or maybe people being able to acquire information online and use it for other purposes, not for the ones that you wanted them to do.” [P4, FGD 2]

It was also reported that the Data Protection Act now ‘*qualifies what scientists*’ and RECs have been saying to researchers all along regarding confidentiality and ethical principles.

“So, it’s not easy, because some people say: ‘You know who we are? We know good science ... you know we’ve been doing it before ... why NACOSTI?’ But we tell them, it’s the law. Similarly with the Data Protection Act, which is good for us scientists; we’ve always been complaining. So having it qualified is good. Because you, if you’ve done research before, you’ve known about confidentiality, beneficence, all those ethics. So, when the government says, comply with this, you’re like (...) already I’m complying.” [P2, IDI]

Furthermore, another participant insisted that training on data protection and how researchers’ data should be handled discreetly was essential, and that the team should be subject to a clear code of conduct.

“So, the risk that comes with such a kind of a platform, if you must go that direction, also ensure that the team that is also handing that kind of information are also in line and have been trained on the need for data protection. So, that they also come in. You’re handling this information, yes, but please, at least when it comes to issues of code of conduct: there’s a very clear code of conduct that comes with everybody who interacts with a kind of portal to ensure that information doesn’t leak.” [P5, IDI]

4.2.5.5 Readiness for Digital Autonomy

In line with the overall aim of this study, the final question that the participants were asked was whether the ethical review process was prepared for digital autonomy. This was described as the sole use of digital platforms for the ethics review process without the use of any other methods. It was reported with great emphasis that all RECs should now move to using digital platforms, due to current advancements in technology and the need to evaluate, monitor, and learn:

“It is high time! IT IS HIGH TIME. People should not be in the paper model now.” [P1, IDI]

“Yes, RECS need to move to a digital platform, and I think it’s also part of digital

learning and the fact that we are continuously advancing in technology. And the other thing is also about when you have such a database that is full of so many research studies and research protocols, you can sort of evaluate, monitor, and learn. How best can you improve the system? I have, for instance. And the aspect of just doing it by email, I think that would not be a good way to monitor, evaluate, and learn how you conduct the ethics or rather being in the ethics committee. So, I feel it's timely for research organisations to use digital tools and see how [much] better they can handle research ethics.” [P2, FGD 1]

In addition, it was reported that transition is necessary because the next generation of researchers will only know digital platforms:

“But going forward, the reason why we must move is that we are having a population that will soon be serving a population where all they're learning and their work and their communication and the interaction has been digital, so that will be what will be natural for them. So, in preparing for that group, it means that we need to move [towards] this group of the future, the near future. It's a very near future; [they] would not even be able to understand the non-digital systems. So, because of that, we must migrate, because we are migrating, but there are some people there [already]. There is a group that is coming as researchers where digital communication and work is what they know, what they use, and what is natural to them.” [P3, FGD 1]

The participants expressed their belief that, for digital autonomy to be successful, it is crucial to maintain confidentiality and safeguard the data of research studies. Additionally, they emphasised the importance of establishing infrastructure to protect researchers from vulnerability:

“I'm not sure how I'm supposed to answer that as a researcher, because I hope it gets to that point where they have digital autonomy [which] makes things easy for us as researchers. But then, they could address the issues of confidentiality, assuring researchers that whatever information they send is protected and what [P5] has said. Reviewers ask for too much information, which we are, we are bound to give even if you don't like it. So, if they could review the process so that you only give the part that touches on methodology and not the whole study. So that even if somebody else could

access it, they could not just lose use of it right away. Then I think we will be ready for digital autonomy at that point.” [P6, FGD1]

“Researchers/data scientists and other professionals need to build the infrastructure required for assessing digital ethics, before deploying them to anchor research data. Ethical standards, risks and advantages, privacy, access and usability, and data management must all be considered when selecting and implementing digital ecosystems in health research. Contemporary technologies have the potential to offer autonomy or significant benefit; nevertheless, if not well evaluated, they may increase ethics questions among the most vulnerable.” [P2, FGD1]

To ensure that research information is protected, data provided by researchers regarding their studies need to be minimal and not give too much information to the RECS, apart from those surrounding the ethics:

“I happened to do a fellowship overseas one time and I noticed that the only information you give the ethics committee is information regarding the methodology and the ethical considerations. So, you don’t give the background, you don’t give a literature review, you don’t give your conceptual framework. You just give the information that is relevant to ethics; so you might have the informed consent document, you might have a study questionnaire and so forth.” [P5, FGD1]

Participants also reported that for ethics review systems to be ready for digital autonomy, they need to be ready to protect researchers’ intellectual property and information first:

ARE WE READY FOR DIGITAL AUTONOMY? I would say no. We’re not ready for digital autonomy, but we’re going to have to do digital. Are we? Do we have to go in that direction? The answer is yes. We must go in that direction. So, for me, even when you invited me to be in this FGD and I was thinking about the questions, for me, the question is, how do we get ready for digital autonomy? ... This is why all these protocols are intellectual property. People think and write these protocols and out of these protocols one day something good is going to come, you know; with science, things do come slowly, but they do eventually come. And if we don’t get control of our information right now, somebody else can claim it, and of course, you’ve heard about

this.” [P5, FGD1]

However, other participants felt that the manual system still needs to be retained until all the challenges raised around the use of digital systems are tackled for readiness:

“I think first, there is a need to have some workshops or seminars where people should share their experiences. I am talking. I’m sharing. I’m just giving my own experiences. Another member may be having a different experience altogether. So, if we have a workshop where we are saying, what are the challenges and what are the advantages and disadvantages if we have that workshop, you will be able to identify the challenges and you use that workshop to sensitise people.” [P6, IDI]

“I would say that we are not ready, and we’ll never be quite ready. It is a continual learning process because even with these platforms, the digital world keeps changing. So, we’ll keep learning. So now we need to learn quickly. We need training of our IRBs and our researchers, so that we can at least understand what is there now.” [P3, FGD1]

“But that training will need to be continuous because these platforms and the technology keep changing, as you know, the way things used to be four years ago is very different now; issues about AI are coming and they will change many things. So, my answer is that we are not ready, but we must continue learning and continue using the platforms and know that the training will need to be continuous, because these are rapidly changing technologies.” [P3, FGD1]

“So first, I need, maybe we can, we can make this possible, because we [must] address some of the key questions or some of the key concerns that will come up transforming to know the digitalised platform, for instance, the privacy issues and concerns and in terms of now the data that we avail in the digital-based platforms.” [P2, FGD1]

Other participants reported that making it mandatory means changing the law and going hybrid would be much better. Furthermore, it should be optional for RECs to choose whether they want digital or traditional platforms. This quote illustrates this:

“And we are talking about an amendment to the Science Technology and Innovation Act and we are talking about the entry into the scene of NACOSTI, the National Council for Science Technology and Innovation, saying that you shall use a digital platform. I think it is too early for us to be able to make that into a kind of law. It should be left optional for RECs to be able to decide that, given their circumstances.” [P6, IDI]

“I think it’s prepared. Oh, from the perspective of where I stand, I feel like the digital platform is more beneficial and it has been well embraced. Especially with the fact that someone can participate in the reviews remotely without really having a physical meeting. But I think adopting hybrid systems would be better, where you have both a digital and the traditional method integrated.” [P6, FGD2]

When asked if the ethics review process is ready for digital autonomy, it was also reported by participants across data sets that readiness was enhanced by the COVID-19 pandemic. It is reported that COVID *did open their minds* to remote working and using digital platforms in the ethics review process:

“Yes, thanks to COVID-19. Initially, people are not ready for these things. But when COVID came in, people had to do it, because of social distancing and other directives from the government. So, I would say people are now ready to adopt the systems, because like, when we’re having a virtual meeting, that was not there before. [Or] it was there, but it was not used. So, we people are ready, or Kenya is ready for this.” [P1, IDI]

“And COVID taught us a bit of things initially. Remember, for you to have to attend an ethical review committee, sit and review protocols, people will meet physically in offices or boardrooms to sit and align themselves in respective spaces.” [P5, IDI]

Participants reported it would be commendable for RECs to benchmark from NACOSTI in its readiness:

“And maybe to just put it as a reference in terms of now getting the NACOSTI licence, I can say that, in comparison to now seeking ethical approval [it] is not as tedious. Because once you have all the necessary letters and everything, you need to upload to

NACOSTI; it's not as bad as now ethical approval.” [P4, FGD 2]

When asked if the ethics review process in Kenya is ready for digital autonomy, it was reported that the government and stakeholders must come together to promote access to and use of DPER:

“Yes, of course, we have enough digital experts, we do have a very progressive constitution and a government that's currently digitising everything. However, we still have many issues regarding access and user experience of digital platforms, and we are still embedded in what I would consider the most major issue, which is corruption and lack of transparency.” [P1, FGD 2]

In all the findings revealed, mixed results; however, stronger findings lean towards the adoption of and transition to DPER, with the caveat of proper support being required. In addition, the findings of the present study show that challenges cluster around ethical issues (techno-ethics) associated with using digital platforms in the ethics review process. The findings also reveal that, in comparing both methods, participants still seem to support that the ethics review process is ready for digital autonomy. In the next chapter, the findings will be discussed in more depth in the literature.

CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter will discuss, interrogate, and unpack the findings, interpreting and linking them to the broader literature towards understanding whether the ethics review process in Kenya is ready for digital autonomy; this was the aim of this study. To explore this readiness for digital autonomy, participants were asked to describe their current research ethics processes, their perspectives and experiences related to digital autonomy, their perspectives on traditional ethics processes about digital methods, and to offer recommendations on how digital autonomy can be promoted. While there are limits to the generalisability of the findings, the findings suggested that:

1. Many of the participants were already moving towards or considering moving towards digital approaches.
2. Participants generally recognised or described the value of digital autonomy in the ethics review process, in terms of:
 - a. Reasons to recommend digital autonomy.
 - b. Use of hybrid/combinations of methods.
 - c. Traditional versus digital methods.
3. Participants provided favourable insights into how digital autonomy can be promoted in the ethics review process:
 - a. They recognised challenges that need to be addressed.
 - b. They identified requirements for the adoption of DPER.

5.1.1 The Already Shifting Reality

Findings showed that most of the participants had transitioned or were in the process of transitioning to a digital approach. As indicated in the findings, out of the six RECs, three were using and/or were transitioning to DPER, while two were creating their digital platforms. This clearly shows that there is a shift in the ethical review process, where RECs are now beginning to discover the importance of using technology in the ethics review process. A study by Oder and Pittman (2015) shows the effect of computer automation systems on ethics review process efficiency.

A statistical analysis from cross-sectional surveys on REC administrators/secretariats provided data which showed that there was an increase in the percentage of protocols processed for all the RECs that used DPER (Oder & Pittman, 2015).

5.1.2 The Value of Digital Autonomy in the Ethics Review Process

5.1.2.1 Reasons to Recommend Digital Autonomy

A positive finding is that the implementation or introduction of DPER leads to the reduction of the turnaround time of the ethics review process. Processes which avoided physically having to print, transport, and email reduced the overall time taken to review a research study. Similarly, qualitative research done on a test for a DPER showed that mean turnaround time was reduced while using DPER (Detlor & Wilson, 2015; Mbabe et al., 2021; Mokgatla et al., 2017; Wang et al., 2021). In addition, streamlining allows for reduced timelines and reduces workload for the research stakeholders. This is corroborated by literature that shows that DPER allows for the streamlining, efficiency, and efficacy of the ethics review system (Detlor & Wilson, 2015; Mokgatla et al., 2017; Rahimzadeh, 2018). Similarities are seen in how the Mayo Clinic case study demonstrated the increased efficiency of RECs by implementing a new pre-award and IRB system; the system reduced the turnaround time from 37 days to 24 days, also reducing the need for resources (Smith & Gronseth, 2011).

In the findings, communication and feedback loops using DPER were reported to have improved significantly. Previously, communication, feedback loops, and status updates between RECs and research stakeholders were quite slow to almost non-existent during ethical review. Reviewers could write their comments in a handwritten form which secretariats then needed to type; this slowed down the flow of communication to the researchers. According to Mbabe et al. (2021) and Mokgatla et al. (2017), the use of DPER improved communication, status updates, and review reminder updates on the ethics review process among the research stakeholders.

Committee members generally found an improvement in meeting attendance and achieving a quorum following the introduction of meetings online. This is because members could attend from anywhere in the world, with no need to move around physically. This resonates with Hinga et al. (2022), whose research acknowledges the increase in reviewer attendance during meetings while using DPER. However, findings indicate that, in online meetings, members were not able to hold as substantive and engaged discussions on reviews as they did when

physical meetings were held. This was also a key concern cited by Hinga et al. (2022). Correspondingly, findings from this study also found that online meetings reduced the camaraderie that used to be there during online meetings.

Adoption and uptake of online applications from paper and DPER increased when COVID-19 hit the country and the world at large. Evidence from findings shows that the remote working and lack of physical contact among the RECs and researchers promoted the use of DPER, to ensure the research ethics review process proceeded. Therefore, the present study resonates with Hinga et al. (2022), who observed an accelerated shift from paper-based to DPER methods following the distribution of the COVID-19 guidance document; this also included online meetings (Hinga et al., 2022).

5.1.2.2 Use of Hybrid/Combinations of Methods

The findings revealed that most RECs were already transitioning to DPER. However, some DPERs were not ready to transition from traditional methods, some systems did not function well enough compared to others, and they were rigid and not fully customisable. This caused some RECs to use both traditional and DPER (hybrid methods) which still did not allow for digital autonomy; thus, the efficiency of the platforms was not felt, which made the transition and usability of DPER challenging.

The present study showed mixed results about digital autonomy, where the majority favoured the transition. Even though participants recounted different concerns and challenges relating to DPER, they felt that, if these issues were addressed, the ethics review process would be ready for digital autonomy. Technology continues to grow tremendously and the use of DPER is inevitable; it needs to be embraced immediately and adopted, especially for the new generation, who will be digitally adept. Some participants generally felt that hybrid methods (both traditional and DPER) should continue to be used to include those without access, and as backup and for those who do not want to embrace technology. Some participants were comfortable with the traditional methods and saw them as effective while they were using them. In addition, others felt they should be retained until all the DPER challenges are dealt with. In other findings, it was reiterated that the only way that the ethics review process can be prepared for digital autonomy is by dealing with all the challenges mentioned above and obtaining support from stakeholders.

5.1.2.3 Traditional Versus Digital Methods

The present findings showed that some participants felt that using traditional methods gave a sense of trustworthiness, authenticity, and less risk of breach, unlike DPER. This is because the researcher brings physical documents with the necessary signatures and has completed the due process. In addition, there is little to no possibility of hacking or security breaches of research documents since they are in their physical form. Some participants emphasised another benefit of traditional methods in that they offer a form of backup or archiving of records, especially where there is no internet or electricity. However, researchers' loss of interest in proceeding with the research, which was caused by long delays and lost applications, is recognised as a challenge with using traditional methods; to mitigate these challenges, a prototype digital system was introduced (Mbabe et al., 2021). This is supported by the findings, where researchers tend to lose interest, even after applying for ethics review.

Findings advocate that DPER offers monitoring, tracking, and management of data, unlike traditional methods. Having a digital platform offers the ability to audit, track, and monitor different research studies, which can be used to show trends in research and inform policy. Comprehensive oversight and auditing of the ethics approval process were reported not to be done easily when using traditional methods for the review process, especially email (Mbabe et al., 2021; Mokgatla et al., 2017; Rahimzadeh, 2018). Building on Biggs and Marchesi's (2013) research on the effectiveness evidence for using emails only, there is a need for a DPER system in ethics review.

One problem with traditional methods reported in the study is the risk of errors when manually inputting data. When personnel and researchers enter information for the collection of data manually from paper and using Excel sheets or Google Drives, this creates inevitable human data entry errors. However, these errors can be reduced using DPER, since it is already automated on a digital platform (Detlor & Wilson, 2015; Mbabe et al., 2021).

Findings show that the research ethics approval workload has increased tremendously and streamlining the ethics review process will help with any backlog and timelines when using traditional methods. Literature indicates that research has increased in regions in Africa (Glickman et al., 2009; Hyder, 2004; Nyika et al., 2009), which has been underscored in the findings and has led to an increased workload (Hyder et al., 2013; Nyika et al., 2009). The use of a DPER would help in reducing workload and administrative costs for research stakeholders.

According to Mokgatla et al. (2017), RECs using DPER reported a reduction in administrative workload and costs. Furthermore, participants reported the streamlining, efficiency, and efficacy of the ethics review system using DPER (Detlo & Wilson, 2015; Mokgatla et al., 2017; Rahimzadeh, 2018).

5.1.3 How Digital Autonomy Can Be Promoted in the Ethics Review Process

5.1.3.1 Challenges That Need to be Addressed

Rigidity in the DPER resulted in the platform review questions not being customisable to fit ongoing research; the standard inquiry prompts within the platform to be answered by committee members were outdated and excluded review questions on emerging trends in research. The use of artificial intelligence (AI) algorithms set up in the DPER did not conform to the RECs' needs. Findings thus corroborate Detlor and Wilson's (2015) opinion that 'one size does not fit all' when it comes to the adoption of DPER; regardless of the volume of protocols being submitted for ethics review, a fully-fledged, robust, and customisable DPER must be developed to ensure functionality, adequate review, transition, and focus on the needs of the research stakeholders (Detlor & Wilson, 2015). Similarly, existing platforms were decided against because they were expensive and time-consuming to implement and customise, so it would be best to develop one's own customisable DPER (Bowser & Tsai, 2015; Detlor & Wilson, 2015).

Great efforts are being made to strengthen research ethics in Africa, with substantial emphasis focused on the training of the review process for all relevant stakeholders (Ndebele, Mwaluko et al., 2014). To manage and streamline review procedures, proposal submission pathways, and operational processes, COHRED's HRWeb and MARC teams designed an information management system (IMS) called RHinnO for RECs. However, it should be noted from the present findings that these same platforms need to be customised, so they are not rigid, and so that they focus on the needs of the REC.

Ethical concerns while using DPER emerged as a common and key issue among the participants. The concerns revolved around the lack of data privacy and confidentiality, data sharing, data ownership (intellectual property), cyber-attacks, hacking, data security, and plagiarism. This was because researchers share too much of their research information, while on the other hand, RECs are unaware of where their data is stored and where the servers are when using a DPER from a different region. This resonates with Rahimzadeh (2018) on the

importance of blockchain technology in safeguarding all research data and ensuring transparency in a DPER. This resonates with this literature since blockchain technology can significantly improve the consistency and reporting quality of REC decisions in collaborative studies while promoting secure data sharing and ensuring responsible access through encryption, pseudonymisation, and so much more (Rahimzadeh, 2018). Utilising the secure and encrypted features of blockchain technology, platforms dedicated to ethics review can safeguard sensitive information against unauthorized access or leaks. This protection is critical due to the nature of confidential data often involved in the ethics review process. Additionally, blockchain technology supports the anonymisation of applicant identities without compromising the process's integrity, thus achieving a balance between the need for transparency and privacy concerns (Taherdoost, 2022).

As shown in the findings, another emerging issue was the mistrust of the uptake of digital platforms. The culture of mistrust in research can stem from historical and systemic disparities (Sankar et al., 2003). This mistrust is not just toward individuals but also toward the policies and motives of institutions when deploying any platform (Petraiki, 2016). Concerns about DPER being more secure in paper-based methods than digital could be attributed to perceptions of data privacy and security. This is evident in this current study, where researchers felt that paper-based applications offered more control over sensitive information, stemming from concerns about cyber security threats and data breaches in digital systems. This current study also raised issues of power and control among researchers where it seemed to influence these perceptions, as traditional, paper-based processes may offer a sense of direct oversight and control that DPER perceived as more vulnerable to external access, does not.

5.1.3.2 Requirements for the Adoption of DPER

From the findings, it emerged that training sessions, user guides, or assistant chatbots in using DPER were requirements in the ethics review processes. Participants found it difficult to navigate DPER systems, which made it difficult each time they reviewed or submitted their research. According to Bowser and Tsai (2015), testing and user feedback are necessary to ensure challenges faced in the system are noted and iterations done on the platform. A prototype DPER in South Africa was also employed and comments from research stakeholders were logged to iterate and improve the other versions of the DPER (Mbabe et al., 2021). This could also allow for focused training on what the users need help with when navigating the DPER.

The findings disclosed the importance of the implementation of the Kenya Data Protection Act (2019) when using any DPER. Participants explained all the perceived risks that come with using technology to manage research data, saying the RECs should ensure that they comply with the DPA (2019). The risks mentioned included privacy rights, data consent, and confidentiality of individuals' data. This compliance aligns with Sections 28-30, 33, and 35 of the Data Protection Act.

Institutional and infrastructural support was seen in the study as a major need when it came to recommending how digital autonomy can be promoted. This includes systems related to how the system is built, goodwill from the institution to purchase or build DPER, and information technology personnel, which are all needed to allow RECs to adopt DPER; without this support, it may be difficult to adopt. Rebuilding and adoption of technology requires all stakeholders to be involved, whether in transition or adoption (Biggs & Marchesi, 2013). Moreover, findings showed that there was a need for a centralised platform for all RECs that would allow harmonisation of ethics review processes. This is to ensure that different RECs are communicating with each other to be aware of which researchers applied to which REC and why they were not approved, or a certain decision was made. This resonated with literature that asserted that RECs move towards a harmonised ethics review process (Mokgatla et al., 2017; Rahimzadeh, 2018).

Findings also showed that the adoption of DPER could be promoted by borrowing from existing platforms in the institution. This resonates with literature by Bowser and Tsai (2015), which customised an existing conference system to create a DPER. This in turn reduces the cost and catalyses the adoption of DPER. The use of empirical findings to show the importance of a DPER system can also catalyse institutional support for its adoption. Findings showed that illustrating the importance of using DPER through a study or evidence-based reports from other institutions can back up the proposal to authorities to use DPER in research. To ensure institutional support, it was recommended that providing decision-makers with empirical evidence of different literature and reports on how DPERs are faring can help implement DPERs in different contexts (Detlor & Wilson, 2015).

In conclusion, Figure 4 synthesises the factors that hinder and promote digital autonomy, as expressed by the participants in the current study (see Chapter 4) and as identified through the systematic review (Chapter 2).

Factors that promote DPER adoption

Factors that hinder DPER adoption

- Lack of institutional and infrastructural support.
- Rigid DPER, poorly customised by developers.
- Lack of training.
- Reliance on hybrid methods.

- Inclusion of blockchain technology (or technology that offers data security).
- Institutional and infrastructural support.
- Customisable DPER.
- Training on DPER systems.
- Involvement of all stakeholders during deployment.
- Implementation of DPA (2019).
- Developing one's own DPER, borrowing from what exists.

Figure 4: Summary of Factors That Hinder/Promote Adoption of DPER

5.2 Study Implications

Although purposive and not generalisable, the findings of the study hold implications for practice and indicate some directions for future research on digital autonomy within the ethics review process.

5.2.1 Implications for Practice: Recommendations for institutions transition their RECs on to Digital Platforms

The main aim of this study was to explore the research ethics review stakeholders' perceptions on the effectiveness and uptake of a digital platform ethics review (DPER) process, solely using a digital platform. This was done by reporting on the knowledge, perceptions, attitudes, and practices of researchers, REC members, and secretariats relating to their experiences of using ethics review methods.

Accordingly, the first major practical contribution of the present research is that it provides much-needed empirical data on the actual ethics review methods being used, their challenges, benefits, and successes, as well as recommendations on the way forward. This is important

given that there are few to no studies that focus on this area of research. Recounting in depth the activities of researchers, REC members, and the secretariat will allow institutions, regulators, policymakers, IT experts, front-end and back-end platform developers, trainers, consultants, and others to design capacity-building initiatives (Detlor & Wilson, 2015), tools and actions based on what RECs and researchers need to be prepared for digital autonomy, how to do it, and where they are now in terms of their methods (rather than what they think they need).

For example, DPER deployers, research regulators, and policymakers could note that the platforms are being created for users who need to find them user-friendly and customisable and to cater to the research stakeholder's needs. This will allow them to redesign the DPER accordingly. Others could derive similar implications from most of our findings. Our study thus responds to the report made by Detlor and Wilson (2015), among others, who highlighted this need for the ethics review process. In this regard, the researcher believes that the research is especially timely from the literature (Glickman et al., 2009; Hyder, 2004; Nyika et al., 2009), which confirms the increase in research in Africa and which raises the need to have fewer challenges in the ethics review process.

A second important implication of the study derives from the finding on the uniqueness of the knowledge and information work carried out by DPER in the ethics review process. Findings point to the need for all research data to be owned by the appropriate RECs and researchers need to be certain that their data is safe and secure while still protecting the research participants. This could be achieved by using blockchain technology (Rahimzadeh, 2018), from DPER deployers ensuring proper policy guidelines, and by implementing the DPA (2019) concerning where the research data is stored and how secure it is, and, if stored abroad, how safe it is. Leilasadat Mirghaderi et al. (2023) described that blockchain technology can shed light on and tackle the often-encountered "zones of non-transparency" in DPER. By generating a transparent and verifiable record of actions and decisions, blockchain technology addresses the issues stemming from the lack of clarity in platform operations, the decision-making processes of algorithms, and the governance models of digital platforms. This transparency is crucial for upholding trust and integrity in the ethics review process, ensuring that every procedure aligns with the highest ethical standards.

A third implication stems from the reframing of the issue of how to ensure the ethics review

process is ready for digital autonomy. The study findings suggest that before deployment of any DPER or any form of transition, training or prototype testing should be done before uptake. Accordingly, the research findings suggest the need to ensure that all users have access to the internet, electricity, and devices that will assist in the use of DPER. In addition, RECs should restructure what they need from researchers, since they ask for excessive information.

Finally, the study provides indications to regulators such as NACOSTI and the government regarding several desirable and necessary ways to promote the use of DPER. This study's wish and intention is that its present findings may be incorporated into the existing and future capability-building frameworks when RECs are trained.

5.2.2 Implications for Future Research

The research presented here, characterised by its exploratory and interpretive approach, opens numerous possibilities for future inquiries. These opportunities lie not only in altering practices and shifting attitudes but also in the need for additional research to enhance and expand upon the research finding's novel discoveries.

Firstly, the study offers the opportunity to understand the use of different ethics review methods, as well as the practices and knowledge behind them. This includes, for example, the use of technology to enhance the ethics review process and how the IT technicians and developers can make it easier to make sure adoption is smooth sailing. One could also ask whether and to what extent it is possible to identify what is the best way to ensure the ethics review process is ready for digital autonomy and what is the best DPER to be used by RECs.

The findings report what research stakeholders need. For example, the findings discussed could also be used to generate hypotheses for further empirical research using a broader sample and qualitative research methods. Questions could include the following:

- What sections of the DPER systems offer challenges? Is it the login, submission of documents, or review section?
- Is there a data agreement between the DPER deployers of data-sharing practices and regulatory compliance for research stakeholders?
- How can institutions offer support in reclaiming and transitioning to the efficiency of DPER and owning the process through prototyping?

- Has the quality of reviews improved or reduced with the use of DPER? And to what extent?

The study could also be extended in longitudinal and comparative ways. For example, in the present study, the focus was on a small group of research stakeholders' experiences and perspectives. Further research could elaborate on this point, providing more information from all stakeholders involved from CEOs of DPER companies, IT and developers, regulators, policymakers, government, and training bodies. Further research could also take a broader approach and look at Africa to compare different DPERs and how different RECs are using them effectively and efficiently.

Furthermore, upcoming studies can draw inspiration from the research ethics activity model proposed by Page and Nyeboer (2017). This model can be adapted to develop a conceptual framework for applying it in real-world scenarios of (DPER). This proposed framework will focus on examining the significance of digital autonomy within the ethical procedure at every stage of the ethics review process.

5.3 Study Limitations

The study is not without limitations. This is a qualitative study. The study provided the participants' insights on the topic; however, this review only focused on a few Nairobi RECs and researchers and the study participants are from the researcher's close networks, which may cause the group of participants to be all rather similar and may have held similar views.

The study utilised a purposive-convenience sampling approach, due to its non-random selection process, it might have introduced potential biases. While efforts were made to minimize these biases through reflexivity and methodological strategies, it is recommended that future research consider employing a different sampling method that incorporates random selection to enhance the sampling's randomness and potentially reduce biases further.

The researcher did not draw from an exhaustive list since the researcher contacted specific participants through her networks who would take part in my study. Therefore, the findings cannot be generalised to the broader population. And future studies should focus on other sampling methods.

In the research, data saturation was achieved when no new information was observed in the data (Fusch & Ness, 2015), indicating that the collected data was sufficient to understand if the ethics review process was ready for digital autonomy. This was evidenced by the repetition of themes and the lack of new insights emerging from the participant interviews and data analysis as shown in the findings section of this thesis. This suggests that the sample size was adequate to capture the range of experiences and perspectives relevant to the participants in the current study.

CHAPTER 6: CONCLUSION

The overall aim of this study was to explore the researchers' and other research ethics stakeholders' experiences and perspectives towards DPER. The participants were thus asked about a) their perspective on DPER, b) the REC process that they were engaging with at the time of the study, and c) their thoughts on transitioning to DPER. In reflecting on this issue, the research questions were met as reflected in the following key findings:

1. Stakeholders favour digital autonomy and transitioning to DPER but are not ready.
2. Stakeholders are ready but require institutional support and training.
3. Trust needs to be built on the use of DPER to ensure that the ethics review process is ready. trust.
4. DPER should be made with the end user in mind and embed technology that ensure data privacy and confidentiality.

In conclusion, designing and piloting appropriate digital platforms for ethics review (DPER) with input from research stakeholders is a priority. It is recommended that future studies explore the extent to which all the research stakeholders involved, especially DPER deployers, can reduce the challenges of adoption and encourage digital autonomy. Research on the specific challenges associated with different DPER versions or types is also required. Furthermore, research on the role of the regulators, government, and policymakers in promoting the use of DPER is needed.

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APPENDIX I- UKZN ETHICAL APPROVAL



31 January 2023

Ms Brenda Adhiambo Otero (222125149)
School of Applied Human Sc
Pietermaritzburg

Dear Ms Otero,

Protocol reference number: BREC/00005014/2022
Project title: Is the Ethics Review Process Prepared for Digital Autonomy?
Degree Purposes: Masters

EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application.

The conditions have been met and the study is given full ethics approval and may begin as from 31 January 2023. Please ensure that any outstanding site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

Please note: Kenyan REC approval must be submitted to BREC for noting before you begin this study.

This approval is valid for one year from 31 January 2023. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on RIG on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2020) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be noted by a full Committee at its next meeting taking place on 14 March 2023.

Yours sincerely,



Prof R Bhimma
Deputy Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee
Chair: Professor D R Waasenaar
UKZN Research Ethics Office Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Email: BREC@ukzn.ac.za

Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>

Founding Campuses:  Edgewood  Howard College  Medical School  Pietermaritzburg  Westville

INSPIRING GREATNESS

APPENDIX II- AGHA KHAN UNIVERSITY ETHICAL APPROVAL



THE AGA KHAN UNIVERSITY

Faculty of Health Sciences
Medical College

Ref: 2023/ISERC-57 (v3)
September 26, 2023

Ms. Brenda Odero –Principal Investigator,
Master of Social Science in Health Research Ethics
University of KwaZulu Natal, South Africa

Dear Ms. Odero and Team,

Re: Is the Ethics Review Process Prepared for Digital Autonomy?

The Aga Khan University, Nairobi Institutional Scientific and Ethics Review Committee (ISERC), is in receipt of your protocol uploaded on Infonetica. The ISERC has reviewed and approved this project *(as per attached official stamped protocol and attachments - version Ref: 2023/ISERC-57 (v3))*. You are authorized to conduct this study from September 26, 2023. This approval is valid until September 25, 2024 and is subject to compliance with the following requirements;

1. The conduct of the study shall be governed at all times by all applicable national and international laws, rules and regulations. ISERC guidelines and Aga Khan University Hospital policies shall also apply, and you should notify the committee of any changes that may affect your research project (amendments, deviations and violations)
2. Researchers desiring to initiate research activities during COVID-19 pandemic must comply with the [COVID-19 SOPs for Research](#) as well as submit to the Research Office a [Request Form to Initiate, Reinstate or Continue Research During COVID-19 Pandemic](#).
3. **Prior** to human subjects enrolment you must obtain a research license from the [National Commission for Science, Technology and Innovation](#) (NACOSTI), *where applicable*, site approvals from the targeted external site(s) and file the copies with the RO.
4. *As applicable, prior* to export of biological specimens/data, ensure a Material Transfer Agreement (MTA)/Data Transfer Agreement (DTA), is in place as well as seek shipment authority/permit from the relevant government ministry. Copies of these approvals, should be submitted to the RO for records purpose.
5. All Serious Adverse Events and the interventions undertaken must be reported to the ISERC as soon as they occur but not later than 48 hours. The SAE shall also be reported through the AKUHN quality monitoring mechanism(s) at Client Relations Department of the Chief of Staff's Office.
6. All consent forms must be filed in the study binder and where applicable, patient hospital record.
7. Further, you must provide an interim [Progress Report Form](#) 60 days before expiration of the validity of this approval and request extension if additional time is required for study completion; **as well as submit the completed Self-Assessment Tool -Monitoring Ethical Compliance in Research**. You must advise the ISERC when this study is complete or discontinued and a final report submitted to the Research Office for record purposes.
8. The Aga Khan University Hospital management should be notified of manuscripts emanating from this work.

If you have any questions, please contact Research Office at AKUKenya.ResearchOffice@aku.edu or 020-366 2148/1136.

With best wishes,

Dr. Christopher Opio,
Chair - Institutional Scientific and Ethics Review Committee (ISERC)
[Aga Khan University, \(Kenya\)](#)
Copy: Co-Investigators

APPENDIX III- STRATHMORE UNIVERSITY ETHICAL APPROVAL



16th February 2023

Ms Odero Brenda Adhiambo,
brendafreemanodero@gmail.com

Dear Ms Odero,

RE: Is the Ethics Review Process Prepared for Digital Autonomy?


This is to inform you that SU-ISERC has reviewed and approved your above master's (University of Kwazulu-Natal) research proposal. Your application reference number is SU-ISERC1597/23. The approval period is from 16th February 2023 to 15th February 2024.

This approval is subject to compliance with the following requirements:

- i. Only approved documents including (informed consents, study instruments, and MTA) will be used
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by SU-ISERC.
- iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to SU-ISERC within 48 hours of notification
- iv. Any changes, anticipated or otherwise, that may increase the risks or affect the safety or welfare of study participants and others or affect the integrity of the research must be reported to SU-ISERC within 48 hours
- v. Clearance for the export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to the expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days of completion of the study to SU-ISERC.


Before commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology, and Innovation (NACOSTI) <https://research-portal.nacosti.go.ke/> and obtain other clearances needed.


Yours sincerely,


Dr Ben Ngoye,
Secretary; SU-ISERC

Cc: Mr Ambrose Rachier,
Chairperson; SU-ISERC


APPENDIX IV- NACOSTI PERMIT


REPUBLIC OF KENYA


**NATIONAL COMMISSION FOR
SCIENCE, TECHNOLOGY & INNOVATION**

Ref No: **782876** Date of Issue: **16/March/2023**


RESEARCH LICENSE




This is to Certify that Miss., **BRENDA ADHIAMBO ODERO** of University of KwaZulu-Natal, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: **Is the Ethics Review Process Prepared for Digital Autonomy?** for the period ending : **16/March/2024.**

License No: **NACOSTI/P/23/24235**

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APPENDIX V: INDIVIDUAL INTERVIEW GUIDE

REC Secretariat and/or REC member In-depth Interview Guide

Name of Interviewer _____

Date _____

Code name _____

Notes for the Interviewer (PI)

Note 1: For interviewer: Interview starts by salutations and greetings and self-introduction.

Note 2: Interviewer provides information about the study, its purpose, and the focus on the three sectors and assures confidentiality following the approved information sheet provided.

Note 3: Interviewer seeks consent to record the interview of REC secretariat and/or member to participate in the interview.

Note 4: Interviewer is expected to probe, seek clarifications, and engage the respondent in a lively discussion.

Broad Questions Directed to Digital REC Stakeholders to Guide the Interview

1. Can you tell me about what work you do?
2. How long have you been a member of the REC? What ethics training have you received?
3. Tell us about your REC process.
4. What are your thoughts on using a digital platform for the ethics review process?
5. Do you think it is important for RECs to move from traditional methods (paper and email) to digital platforms?
6. What do you feel has changed in the ethics process using a digital platform in your current REC compared to the traditional method?
7. What are the challenges you may face using digital platforms in the ethics review process?
8. Do you feel there's a need to have a standard digital guide for all RECs going digital?

Broad Questions Directed to Traditional (Email and Paper) REC Stakeholders to Guide the Interview

1. Can you tell me about what work you do?
2. How long have you been a member of the REC? What ethics training have you received?
3. Tell us about your REC process.
4. What are your thoughts on using a digital platform for the ethics review process?
5. Tell us about your REC process. What happens?
6. Have you heard of the digital platforms used during the ethics review process?
7. In your experience, do think it is important for traditional methods to stay?
8. Do you feel it is important for RECs to move towards a digital platform for ethics review?
9. What challenges do you face using traditional methods?
10. What do you think are the ethical issues that may arise with going digital?

11. How did your REC manage the paper process during COVID-19?

APPENDIX VI: TRADITIONAL (EMAIL AND PAPER) RESEARCHERS FOCUS DISCUSSION GROUP INTERVIEW GUIDE

Name of Interviewer _____

Date of FGD _____

Instructions

Facilitators (PI) note 1: Welcome and introduction

- Welcome participants to session by greeting them
- Thank participants for offering to participate in the study and availing themselves for the session in which their attitude, knowledge, and perceptions on using digital or traditional methods in the ethics review will be focus of discussion.
- Inform them who you are (your name as facilitator), and assistant.
- Inform participants the goal of the study and what you will be talking with them about.
- Inform participant the focus of FGD (to look at the perceptions on the effectiveness and uptake of a digital ethics review process, solely using a digital platform. Use the provided information sheet).
- Be sure that each participant understands why the FGD is organized and that each wants to participate voluntarily.
- Inform participants that they should not share any personal information in the focus group, given limitations to confidentiality

Facilitator Note 2: Consent process

- Take participants through signing of consent form or record the verbal consent if that is preferred.

Facilitators note 3: About the focus group

- Inform participants how the FGD will proceed (Inform that we will seek to learn from you positive and negative aspects).
- Point out that views of each participant are valid and valued (that we appreciate that each participant has important knowledge and experiences, needs, or perspectives that we will want to learn more about through the FGD).
- Inform participants that in the discussion, everyone is free to not agree or achieve any form of agreement, rather, the PI is gathering information so they should air their views freely.
- Inform participants that it is okay if a participant has different opinions and ideas from those of other participants in the group.

Facilitator Note 4: Logistics and ground rules

- Inform participants the duration the FGD will take (This group discussion will last no more than 90 minutes)
- Inform the group on ground rules (Everyone to participate, only one person talks at a time and pay attention to each other's ideas and opinion; no judging a members contribution to a question as right or wrong, that each contribution is valid; and that the discussion will be audio recorded to help us capture all that is said compared to handwritten notes that will be taken by investigators, and it will allow us to double check our data for accuracy.
- Ask participants to kindly not have side conversations and speak clearly to increase recording quality.
- Ask them for the duration of discussion to turn off or switch their phones to silent mode to minimize interrupting other FGD discussions.
- Ask if there are any are participants who want anything clarified or if they are ready for the discussion to get started.

Facilitator Note 5: Starting of the discussion

- If participants do not have questions and indicate readiness to get started with discussion, turn on recorder and begin the discussion. Ask your questions clearly and do not rush participants in their answers.

1. Tell us about the RECs you submit applications to for ethics approval?

Probes:

What is the process like?

How do they handle the process?

2. Tell us about your experience using the traditional methods in the ethics review process.

Probes:

What do you think have been the major impacts of using traditional methods?

3. Tell us about any challenges you may have faced using the digital platform.

Probes:

Were the challenges easily sorted out?

How long did it take to sort out the challenges?

4. Tell us if RECs need to stay or move towards a digital platform for ethics review.

Probes:

Why is migration important?

What is traditional doing that the digital process is not?

Has there been a shift in the RECs you now approach depending on the methods they use?

5. Tell us about your experience of using traditional methods as a researcher.

Probes:

What stands out most in the ethical process?

Has there been a change in how you handle your research?

6. What ethical concerns may you have regarding using digital platforms in the ethics review process?

Is the confidentiality of your study information a concern? Is plagiarism or hacking a concern?

Are there any such concerns with traditional methods?

Facilitator Note 6: Concluding the session

- Having gone over all the questions, inform participants that you have satisfactorily gone over and received rich information from them regarding the focus of the discussion
- Ask them if they have any questions or comments.
- There is no question or after responding to any question there may be, inform participants that the discussion has come to an end.
- Thank them once more for accepting to participate in the discussion and in giving their perspectives on issues.
- Stop recording and wind up.

APPENDIX V- CODING FRAMEWORK

Examples of Sample Extract/ Quotation from Transcript	Initial Code	Code level 1: Free text coding/notes	Code level 2: Emerging codes	Code 3: Theme Cluster	Code level 4 Theme Cluster: Main theme/Code family
<p><i>“We have three different systems. I can say we have a parallel, it is not even parallel, we have three different systems. Shipment of biological samples – those are purely paper. Paper-based. The new protocol is submitted through a system called [platform name]. The other applications, apart from the new, like the amendment, continuing review reports, notifications, deviations, and close-outs, are submitted through email. So those are three.” [P1, IDI]</i></p>	Ethical review methods	<ul style="list-style-type: none"> - Use of email. - Use of DPER. - Use of Google drive and Excel sheets. - Use of hybrid systems (combination of traditional and digital methods) 	<ul style="list-style-type: none"> - Ethics review methods used by different RECs. 	- Ethics review methods.	Theme 1: Participants’ current ethics review processes
<p><i>“You know, for traditional methods, unless you have someone’s hard copy of the</i></p>	Ethical Concerns	<ul style="list-style-type: none"> - Unfairness in accessing the system. 	<ul style="list-style-type: none"> - Mistrust and Ethical Issues on the Uptake 	Confirmation of ethical concerns that may arise	Theme 2: Participants’ Perspectives on Digital Autonomy

research proposal, there's no way you can share someone's intellectual property, just like that. So, with digital, you know, it's now so easy to share. You can share this with people who are not part of the team. That is a concern to most people. Issues of confidentiality, you know, having access to their documents, how are we able to contain that? Indeed, it's only the reviewers who will have access to it and such." [P3, IDI]

"When it comes to digital systems. So, the first time we started, the server, the technical assistance was in [country 1]. So, they are awake, and we are asleep. We were asleep and they were awake, so it was very difficult to get real-time assistance for the system, so that

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- Cyber-attacks and cyberbullying since some systems run adverts.
 - Forging approval signatures by supervisors
 - Hacking
 - Intellectual Property
 - Risks in data sharing
 - Lack of privacy and confidentiality
 - Data ownership.
 - Management of ethics review data.
 - Embracing of remote working.
- of Digital Platforms
- Benefits of the Ethics Review Methods
- with the use of digital platforms.

didn't work very well. So, we said, can it come a bit closer? And it came a bit closer, and it moved now [country 2]. And in [country 2], at least, is just two hours different. So that's a bit better. But now we are struggling to have the server in our own country, that is Kenya. We have been asking about where our information is. We keep asking where is that information. There's a lot of information that we are giving about, what kind of research we're doing in this country, and they keep saying that we can access it. But now we haven't quite been able to access it. So, even if we want to write a report and say that in the last ten years, the last decade, or these are the types of proposals we've been receiving ... It would be difficult.

[P5, FGD1]

“We are moving away [...] now talking about the big data. Talking about big data evolves today to create a portal. This portal earmarks and of course can track the protocols that came in at addressing the human subjects ... Don't you think you can shape the thinking within the country and what's coming up and ask yourself why everybody is doing [their work in] this space and what can we do differently as a secretariat?”

[P5,

IDI]

<p><i>“I also find that the systems that come, because they were not made with the people who are going to use them, are a little bit rigid and there are certain things they cannot do. As I have said, there's one system [which] will accept resubmissions and</i></p>	<p>Digital challenges</p>	<ul style="list-style-type: none"> - Digital platforms were not able to accommodate the transition from paper to platform straightaway. - Can be costly to develop and host. 	<ul style="list-style-type: none"> - Transitioning challenges from traditional to digital. - Successes of going digital. 	<p>Challenges of DPER Successes of the DPER</p>	<p>Theme 3: Participants' Experiences of Digital Platforms.</p>
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another system will not. So, you can only submit the initial proposal for one system, and then any other application, like a protocol deviation, like a request for annual renewal, is given through email.” [P5, FGD 1]

- Lack of capacity building in how to use the platforms.
- Lack of comradery or humanness when physical meetings when physical meetings were a thing when paper was being used.
- Not technological savvy
- Platform down-time
- Platform is not user-friendly.
- Power outage during virtual meetings
- Questions on digital platform do not allow reviewers to raise their own issues due to pre-determined questions on the platform.
- Slow adoption and uptake of digital

platforms for the ethics review process.

- The unknown use of artificial intelligence in virtual meetings and platforms
- Very short meetings and less debates when using virtual platforms during meetings.
- Lack of internet.
- Non customisable DPER
- Reduction of turnaround time using digital platform.
- Allows for remote working.
- Better quality of comments if written in a computer.

- High attendance and timely during virtual meetings.
- Management of ethics proposal reports and data.
- No reduction of quality using digital platforms when transitioning from paper.
- Reviewers can review from anywhere in the world.
- Using digital platforms makes ethics review secure.
- Easy tracking of documents and operational efficiency using digital platforms.
- Save more money using an digital platform.

<p><i>“(…) let me use the proposal, a research proposal by a student. You know, you will be sure that that student got help from the supervisors. Because they will LITERALLY have to sign and date the document. So, what will be brought to the office, you are assured, has gone through due process from the student and researchers. THAT IS a good thing. Yeah, there is evidence that this document was signed by ink from a student under a supervisor; because when it goes through the digital way, you can probably [suspect] someone else is doing that proposal for that student.”</i> [P3, IDI]</p>	<p>Comparison of traditional and digital</p>	<ul style="list-style-type: none"> - Easy to authenticate physical documents. - Less encounters of breach. - Traditional methods offer a form of back-up. - Misplacing of documents. - Inconvenience of physically bringing documents to the office. 	<ul style="list-style-type: none"> - Contrast emerging between traditional and digital methods. 	<p>Different methods under analysis.</p>	<p>Theme 4: Digital versus Traditional</p>
<p><i>“So first, I need, maybe we can, we can make this possible, because we [must] address some of the key questions or some of the key concerns that will come</i></p>	<p>Recommendations</p>	<ul style="list-style-type: none"> - A unified platform where ERCs can communicate effectively. 	<ul style="list-style-type: none"> - Institutional Support - Proper Infrastructure and Resources 	<p>Factors influencing readiness for digital autonomy.</p>	<p>Theme 5: Participants’ Recommendations on How Digital Autonomy Can Be Promoted in The Ethics Review Process.</p>

up transforming to know the digitalised platform, for instance, the privacy issues and concerns and in terms of now the data that we avail in the digital-based platforms.” [P2, FGD1]

- ERCs/RECs should now adopt an digital platform for ethics review.
 - RECs should have a uniform digital platform.
 - Using already existing to platforms to carry out coordinated submission.
 - Give options, not everyone should be mandated to use digital systems.
 - Digital platforms can only be adopted if capacity is built and there is enough infrastructure.
 - Enhancing digital platforms should be done with the end user in mind.
- Catalysers
Enhancing
Transition to
Digital
Platforms
 - Adherence to
the Data
Protection Act
When Using
DPER
 - Readiness for
Digital
Autonomy

- Digital systems should be proprietary.
- Regulatory bodies need to sensitise and encourage committees to adopt digital platforms.
- We cannot fully go digital, there needs to be some form of manual left behind.
- All manual processes should stop, and ethics review follows suit of digital platforms.

