STUDY REPORT ON THE EFFECT OF PUBLIC HEALTH EMERGENCIES ON THE RESEARCH REGULATORY SYSTEMS

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Funding

This project was part of the ACCESS Africa II project, funded by The European & Developing Countries Clinical Trials Partnership 3 (EDCTP3) Grant Project No. 101103296

Implemented By

Uganda National Council for Science and Technology (UNCST)

Ethics And Regulatory Approvals

NARC-2023-10
SS2192ES

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Preface

Science, Technology and Innovation (STI) are expected to play a critical role in advance of Uganda's socio-economic transformation alongside advancement in research and global technological advancements. The Uganda National Council for Science and Technology (UNCST) charged with regulating all aspects of science and technology plays as critical role in quality assurance of STI products and services.

Regulatory science is essential for balancing the need for innovation with the need for safety and efficacy, ultimately protecting public health and promoting global health security. The occurrence of public emergencies such as COVID-19 pandemic has unprecedented challenges on the healthcare systems, shutting down economics and greatly affecting clinical research ecosystem. While the measures may have helped to disrupt the spread of the virus, they also disrupted the conduct of research activities. The study sought to explore the effect of public health emergencies on the research regulatory system in Uganda to identify gaps, implement targeted improvement and better preparedness for future public health emergencies. Assessing the effect of public health emergencies such as the COVID-19 pandemic on the research regulatory systems in Uganda will help identify gaps to inform the development of specific guidelines for emergency research and ensure the protection of participants` rights and welfare.

I want to thank the Government of Uganda, the Science, Technology and Innovation-Office and President through the Minister, Hon Dr. Monica Musenero who has tirelessly echoed and established a guided framework for STI. We believe ventures such as these are in that dedicated direction as we move towards a qualitative leap in Uganda's economy.

Martin Patrick Ongol (PhD)
Ag. Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Acknowledgement

We extend our gratitude to the government of Uganda which has supported the initiatives of the Uganda National Council for Science and Technology through the Science, Technology and Innovation-Office of the President (STI-OP). We also thank Global Health EDCTP3 for making the activities under the study report on the effect of public health emergencies on the research regulatory systems project possible.

In a special way, we would like to extend our gratitude to the collaborating intuitions as well as the Uganda investigative team who developed a wining proposal and carried out the study whose results are embedded herein.

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List of Abbreviations

AVAREF	African Vaccines Regulatory Forum
BMC	BioMedical Central
BU	Boston University
COVID-19	CoronaVirus Disease 2019
CTSA	Clinical and Translational Science Awards
EDCTP	European and Developing Countries Clinical Trials Partnership
EUREC	European Network of Research Ethics Committees
FGDs	Focus Group Discussions
FTRPs	Fast Track Review Procedures
HSP	Human Subject Protection
HIPAA	Health Insurance Portability and Accountability Act
ICH-GCP	International Council for Harmonisation-Good Clinical Practice
IDI	In-Depth Interviews
IRB	Institutional Review Board
KII	Key Informant Interviews
NARC	National HIV/AIDS Research Committee
NDA	National Drug Authority
NRA	National Regulatory Agencies
NRIMS	National Research Information Management system
OECD	Organisation for Economic Co-operation and Development
PIR	Post-Implementation Reviews
REC	Research Ethics Committee
RTR	Rapid Turnaround Review
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SSA	Sub-Saharan Africa
UNCST	Uganda National Council for Science and Technology
UNHRO	Uganda National Health Research Organization
USA	United States of America
WHO	World Health Organization

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CHAPTER ONE: INTRODUCTION

1.0 Background

Public Health Emergencies (PHEs) are events or situations that pose significant threats to the health of communities or populations. PHE is "an occurrence or imminent threat of an illness or health condition, caused by bioterrorism, epidemic or pandemic disease, or a novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of humans [fatalities] or incidents or permanent or long-term disabilities (WHO, 2022). Nelson et al (2007) define PHEs as "any situations whose health consequences have the potential to overwhelm routine capabilities to address them due to the scale, timing or unpredictability of the situation". They can be due to various causes and can have local, national, or international implications. Understanding and preparing for these emergencies is crucial to minimizing their impact on the health and well-being of populations.

Between 2007 and 2020, the frequency of PHEs has been increasing. From the H1N1 influenza pandemic (2009), Ebola (West African outbreak (2013–2015, outbreak in the Democratic Republic of Congo 2018–2020), poliomyelitis (2014 to present), Zika (2016), and COVID-19 (2020 to present) (Wilder-Smith & Osman, 2020). Globally, approximately 362 million people are directly affected by PHEs annually resulting from natural and human-made hazards (AMREF, 2022). While the frequency and diversity of zoonotic disease outbreaks have become major public health threats, there are many other risks that need to be addressed including bioterrorism and slow-onset risks such as antimicrobial resistance (IFRC, 2021). As such, many countries are reviewing their regulatory preparedness for prevention, mitigation, and recovery activities to respond to these events. For instance, the United States has increased investment in excess of $5 billion to increase the country's ability to prepare for and respond to PHEs (Nelson *et al.*, 2007). Many low- and middle-income countries remain inadequately prepared during PHE events.

One of the thirteen core capacities identified by the International Health Regulations (IHR) for countries to effectively detect and respond to public health risks and emergencies is national "system preparedness" (WHO, 2005). During the 2009 pandemic and more recent pandemics, Ebola and COVID-19, the absence of well-functioning national regulatory systems was identified as one of the potential barriers for countries' timely receipt and deployment of medical products (WHO, 2022). The absence of robust research regulatory systems (policies, institutions, processes and tools to pursue and maintain good quality research) to address the specific challenges of PHEs remains a challenge. Moreover, the poor adoption of features such as regulatory provisions for reliance, a fast-tracking registration process, and an effective and adaptable pharmacovigilance system has further compounded the limited preparedness of developing countries to respond to these events. And yet, research regulatory systems play a crucial role in the context of regulatory preparedness for PHEs. These systems are designed to oversee and manage scientific investigations, ensuring that research activities adhere to ethical standards, safety protocols, and legal requirements.

During PHE events, research becomes a vital component in understanding, controlling, and mitigating the impact of the emergency. Whereas Africa has made great strides in promoting preparedness and resilience to these threats, including the development of policies that guide regional and national emergency interventions, the region continues to experience threats of novel and re-emerging infectious diseases (AMREF, 2023). On average, the region records one hundred outbreaks per year (Talisuna *et al.*, 2020) and there have been at least 1,910 reported incidents of disease outbreaks across Africa between 1970 and 2019 (Mboussou, *et al.*, 2019). Specifically, the East Africa region continues to face recurrent outbreaks and disasters. In the past three years alone, the region faced outbreaks of diseases including cholera, Ebola, Marburg, measles, and Rift Valley Fever. Increased regional movement of people for trade and travel between the countries presents a risk of rapid cross-border spread of diseases and other PHEs. Uganda is highly vulnerable to PHEs due to its geographic location next to the Congo Basin epidemic hot spot, placement within multiple epidemic belts, high population growth rates, and refugee influx (Kayiwa *et al.*, 2021).

In Uganda, like in many other countries, the regulatory framework for research is managed and maintained

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by Uganda National Council for Science and Technology (UNCST) which has established guidelines, standards and frameworks to ensure that research is conducted responsibly and ethically. In the context of PHEs, these regulatory systems ensure that studies conducted prioritize participant safety and adhere to ethical principles. This oversight is crucial, especially when dealing with vulnerable populations or when interventions may have immediate consequences (WHO, 2020).

Through structures like Research Ethics Committees (RECs), the National Regulatory Agencies (NRAs) in Uganda together with the UNCST ensure that research methodologies and interventions meet high safety and quality standards especially when testing new drugs, vaccines, or medical interventions in the context of a PHE. The Ministry of Health (MoH) established the National Public Health Emergency Operation Centre (PHEOC) to enhance its capacity to respond to disease outbreaks and other PHEs. Uganda has also implemented several interventions that have contributed to prevention, early detection, and effective response to PHEs (Ario *et al.*, 2023).

Whereas responding to PHEs requires decision-making in a context that is different from "business as usual", many of these countries lack adequate preparedness in terms of plans and tools for timely response. And yet, these unique events influence all phases of the research regulatory value chain. Specifically, PHEs can bring about confusion and unnecessary delays if the roles of the different actors are ill-defined; or the powers and controls (such as the ability to make or exercise emergency powers, impose quarantines, etc.) are vague. The absence of robust research regulatory systems during a PHE can have adverse effects since functional regulatory systems are particularly crucial to achieving equitable access to quality-assured and safe medical products during such events. This is because PHEs could give rise to the use of unregistered, investigational, or candidate medical products with a minimum set of quality, safety, and efficacy data. During the 2009 pandemic and more recent pandemics, Ebola and COVID-19, a lack of well-functioning national systems for regulatory approval was identified as one of the potential barriers to countries' timely receipt and deployment of medical products (WHO, 2021). The control of emergencies is a core function of Public Health systems. Certainly, natural or human made effects or emerging and re-emerging infectious diseases such as COVID-19, Ebola, Marburg, severe respiratory diseases, and hemorrhagic fevers among others constitute a public health risk that requires an urgent, coordinated, and well-organized response from governments and healthcare systems (Aristei *et al.*, 2022). Notably, the COVID-19 pandemic had the worst effects that claimed human lives and left serious challenges in the functioning of the research regulatory system (Omary *et al.*, 2020).

The global spread of SARS-CoV-2 and the thousands of deaths caused by coronavirus (COVID-19) led the World Health Organization to declare a pandemic on 12 March 2020. The world lost human lives, economic repercussions, and increased poverty during the COVID-19 pandemic (Ciotti *et al.*, 2020). The subsequent lockdowns and restrictions directly impacted the research quality assurance system across the world as compliance with ethics guidelines for research became even more critical. By March 2021, more than 4,900 studies and trials had been registered worldwide (Pundi *et al.*, 2020). The increase in the number of emerging COVID-19 research projects resulted in an overwhelming number of research project submissions to ethics and scientific committees and research regulatory bodies. Key aspects of the review of studies, like rigorousness, responsiveness, and timeliness were put to the test.

The pandemic forced many research regulatory agencies across the world to develop emergency regulatory responses in a context where the clinical picture of the virus had not been fully understood and with the lack of robust evidence based on the effectiveness of containment measures (Maciel, 2021). Funders rapidly implemented research calls, expedited review processes, hurriedly constructed methodologies, compressed research timelines, and rushed through publications. From regulatory management tools, regulatory impact assessments, stakeholder engagement and ex-post evaluation, these emergency procedures aimed to ensure robust regulatory oversight in research regulation.
During the COVID-19 pandemic, at least a quarter of the world's regulatory agencies issued COVID-19 guidance documents, expediting standard review, and approval processes (Wegner & Science, 2021). European countries put in place accelerated procedures for the evaluation and authorization of clinical trials related to the management of the pandemic covering also the Research Ethics Committee (REC) review

process (Tusino & Furfaro, 2022). The European Network of Research Ethics Committees (EUREC) issued a statement that stressed that the administrative processes for reviewing research protocols during the COVID-19 pandemic must be accelerated and simplified if these protocols are related to the treatment, prevention or diagnosis of infections caused by SARS-CoV-2. In the Netherlands, implementation of so-called 'fast-track-review-procedures' (FTRPs) enabled a swift start of urgent and relevant research (IJkema *et al.*, 2021). In Latin America, 53% of the countries issued legal or guidance documents in order to streamline ethics review and oversight of research in response to the COVID-19 pandemic (Palmero *et al.*, 2021). In Pakistan, the anticipated increase in research reviews in the wake of the COVID-19 pandemic led to the introduction of a national rapid turnaround review (RTR) system, catering specifically to the public health emergency (Shekhani *et al.*, 2021).

Across Africa, regulatory agencies and Research Ethics Committees (RECs) agreed to combine their expertise to expedite clinical trial review and approvals for new multinational preventive, diagnostic and therapeutic interventions to the COVID-19 pandemic (Bekker & Mizrahi, 2020) for example Remdesivir, innovative test kits and assays. By April 2020, member states of the African Vaccines Regulatory Forum (AVAREF) agreed to adopt measures, like the use of an online platform for joint reviews of clinical trial applications for preventive, diagnostic and therapeutic interventions related to the COVID-19 pandemic. Specific countries across Africa, reviewed their guidelines or developed new ones to respond to the research ethics issues around COVID-19 research. For instance, in Egypt, new guidelines required the RECs to come up with "out-of-the box" solutions to maintain an effective, accelerated review while at the same time practicing the ethical principles required. These included on-line conferencing, digital signatures, and the increased frequency of meetings to every other day, then every week or twice a week instead of the previous monthly schedule.

The COVID-19 pandemic in Uganda was part of the ongoing worldwide crisis The Uganda UNCST as part of its mechanism to adapt the global regulatory climate where conduct of research was on-going, developed the National Guidelines for Conduct of Research during Coronavirus Disease, 2020 to streamline conduct of research during the COVID-19 pandemic. The RECs have established systems to fast track the development and testing of effective and safe means (drugs, vaccines, tests) for the treatment, prevention, and diagnosis of COVID-19 infections. Inadvertently, the pandemic had major implications on the operational outlook of RECs and in the way they undertake their routine activities. The COVID-19 pandemic resulted in an overwhelming increase in research studies submitted to research ethics committees (RECs) which presented several ethical challenges. However, no empirical work has been undertaken to establish the effects of COVID-19 on Uganda's Research Regulatory System, and particularly on the operations of the RECs in Uganda.

1.1 Statement of the Problem

The occurrence of public emergencies such as COVID-19 pandemic have unprecedented challenges on the healthcare systems, shutting down economics and greatly affecting clinical research ecosystem. On 11th March 2020, the World Health Organization (WHO) declared Coronavirus Disease 2019 (COVID-19) as a Pandemic (WHO, 2020). In response, most countries including the Uganda government-imposed measures that slowed the transmission of COVID-19 during the pandemic (MoH, 2020). While the measures may have helped to disrupt the spread of the virus, they also disrupted the conduct of research activities.

Across the globe, concerted efforts were made to respond to the pandemic through release of information faster than any other event in research history (Hashem *et al.*, 2020), however, the search for a scientific and actionable interventions raised significant ethical complexities and challenges observed in research during the pandemic, Dothu (2020) & Marzouk *et al.* (2021). Comparably, the lockdowns and travel restrictions had a direct impact on ethical conduct of research in Uganda. A study exploring the experiences and lessons learnt by researchers in an HIV trial in Uganda, reflected on the need to adhere to local regulations, government policies as well as the ethical principles which consequently affected the overall management of the trial during the pandemic (Muwanguzi et al, 2021).

While some studies have documented the experiences and lessons learnt by researchers and study participants in research during COVID-19 pandemic, there wass paucity of data on how the COVID-19 affected the research regulatory ecosystem in Uganda. Therefore,

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this research study examined the effect of public health emergencies such as the COVID-19 pandemic on the research regulatory systems in Uganda to identify gaps and implement targeted improvement and better preparedness for future public health emergencies.

1.2 Overall Objective

The study sought to explore the effect of public health emergencies on the research regulatory system in Uganda to identify gaps, implement targeted improvement and better preparedness for future public health emergencies.

1.3 Specific Objectives

1. To examine how COVID-19 facilitated or constrained research regulation in Uganda
2. To examine the effectiveness of Uganda research policies and guidelines during the COVID-19 pandemic.
3. To describe the coping strategies of researchers, NRAs and RECs amidst the COVID-19 pandemic.

1.4 Research Questions

1. What were the facilitators and barriers to the research conduct during the COVID-19 pandemic March 2020- March 2023?
2. What was the impact of the COVID-19 on the research regulatory processes in Uganda?
3. How did the COVID-19 pandemic affect the research policies in Uganda?
4. What were coping strategies undertaken by the researchers, NRAs and RECs in the conduct of research during the COVID-19 pandemic March 2020-March 2023?

1.5 Justification of the Study

Public Health emergencies such as the COVID-19 pandemic necessitate rapid decision-making to address emerging public health or safety concerns (Raimi *et al.,* 2021). Similarly, regulatory systems need to adapt and expedite research processes to inform policy and management options during public health epidemics and emergencies (Mullard, 2020).

The impact of the COVID-19 pandemic on regulatory oversight cannot be overemphasized. A study done by Marzouk *et al.* (2021) indicated that the regulation gaps in research were worsened by the COVID-19 pandemic, especially in Sub-Saharan Africa. These findings were further supported by London *et al.* (2020) and Theresa-Burgess *et al.* (2023), where significant ethical complexities and challenges were identified. Consequently, it's imperative to understand the effect of the COVID-19 pandemic on the regulatory landscape in Uganda.

Therefore, assessing the effect of public health emergencies such as the COVID-19 pandemic on the research regulatory systems in Uganda will help identify gaps to inform the development of specific guidelines for emergency research, and ensure the protection of participants` rights and welfare.

1.6 Scope of the Study

The study took place in Gulu, Mbale, Mbarara, Bushenyi and Kampala districts. The study considered regular operations of the National Regulatory Agencies (NRAs) and accredited Research Ethics Committees during the COVID-19 pandemic (March 2020 to March 2023). COVID-19 disease as one of the PHEs led to world's regulatory agencies issuance of COVID-19 guidance documents, change of standard review, and approval processes and thus was a key point of study on the regulatory systems in Uganda.

CHAPTER TWO: LITERATURE REVIEW

2.1 The Effects of Public Health (PH) Emergencies on the Research Regulatory System

According to Zhao & Wu (2022), a public health emergency is defined as an international spread of an event that is likely to result in a disease that poses a public health risk to the world. The emergencies could be major epidemics including infectious diseases, mass illnesses caused by mysterious and unfamiliar origins, major food poisoning, or occupational hazards, as well as other events that occur unexpectedly and can cause serious damage to public health (Abeysinghe & Leopold, 2023). Such events are coordinated internationally as a response to prevention and management through research that ensures the quality and safety of the interventions. For example, during the COVID-19 and Ebola epidemics, governments and health organizations around the world collaborated to share information, conduct research, and develop vaccines and treatments. This international coordination helped prevent the further spread of the viruses and mitigating the impact on public health globally. Additionally, these efforts led to the establishment of guidelines for testing, contact tracing, and quarantine measures to manage the disease effectively.

Research on public health emergencies has expanded in terms of frequency, methodological, and disciplinary scope. Public health calamities are at most times concealed in everyday life and tend to break out during undefined time and space situations (Saxena *et al.,* 2019). When the emergencies break out, they are hazardous and can cause serious social and health harm. As the emergencies occur, they create a great impact on the prevention, control, and emergency response systems worldwide, including the research regulatory systems (Lowe *et al.*, 2022). However, there are instances where research on public health emergencies may not have expanded as expected due to a lack of expertise, lack of policies, and access to specialized knowledge. Consequently, such areas struggled to adequately prepare for and respond to public health emergencies, exacerbating the social and health harm caused by such crises.

According to Packenham *et al.* (2017), most of the public health emergency studies are characterized by their urgency of carrying out data collection as immediately as the crisis happens, with the interest of obtaining baseline data before it is lost or altered. However, it is noted that fulfilling the research regulatory requirements needs careful methodical actions to conduct clinical research during a public health emergency is a great trial, with difficult operational challenges, despite the fact that it is an area of need (Lowe *et al.*, 2022). For example, the 2014-2016 Ebola outbreak in West Africa highlighted the importance of data gathering during public health emergencies. However, logistical constraints, funding issues, and political unrest hindered research projects and clinical research.

Similarly, the research regulatory bodies across the world have experienced the most urgent challenge of having a rapid review of protocols submitted by investigators during the emergency period, which have been designed to learn more about or intervene in an emergency crisis (Yeoh & Shah, 2021). This happens because of the urgent need for the medical and public health communities to get more evidence for drafting informed decisions regarding improving outcomes for patients affected by the crisis event (Falb *et al.,* 2020). Pharmaceutical companies rush through drug approvals during crises, potentially causing side effects or ineffective treatments, despite the urgent review process.

The regulatory committees tend to experience much pressure to carry out the review process quickly so that studies can get underway to address the emergency crisis at hand; yet this is supposed to be done without any relaxations of the ethical review standards (Ford *et al.,* 2021). This kind of pressure not only comes from investigators who need approval to secure funding from the sponsors of their studies, but also from many other stakeholders including world leaders, the community, the media, and professional organizations (Tamariz *et al.,* 2021). Besides the external pressure and excessive number of studies, there are challenges experienced by the research regulatory bodies in regards to the application of the Belmont principles of respect for persons, beneficence, and justice (Tamariz *et al.*, 2021).

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During public health emergency settings, research regulatory systems encounter ethical concerns among professionals and scholars in health and humanitarian organizations, especially when it comes to debates on the lack of consensus around key ethical principles like equity, risk, beneficence and vulnerability (Archard *et al.*, 2020). Different researchers have noted differing perspectives and tensions on ethics that are based on the more social scientific and biomedical areas. During emergency settings, similar debates as above are usually magnified, especially when it comes to health research, given the nature of vulnerabilities and sensitivities related to the health research (Abeysinghe & Leppold, 2023). For example, although research regulatory systems protect certain groups like prisoners, women, children among others, they have no clear strategies on how to offer protection to the potentially vulnerable research participants who are survivors of the PH emergency event (Packenham *et al.*, 2017).

In situations where the occurrence of the PH emergency involves lockdowns and limited movements, like for the case of the COVID-19 crisis in 2020, most or all the research regulatory institutions in many regions in the world had to shut down their onsite activities, and the staff resorted to working from their homes (Ford *et al.,* 2021). This limited the workflow efficiency of these regulatory bodies, amidst the increased volumes of work and research protocols received for approval (Aarons, 2018). This limitation becomes even greater among the research regulatory bodies that have no mature electronic or web-based research submission systems; hence they get limited to work online.

Similarly, the research studies that involve human participants escalated during the COVID-19 pandemic, and this caused serious challenges to RECs all over the world to get familiarized with meeting their demands and at the same time achieve high standards of review (Sheehy *et al.*, 2021). According to the Pan American Health Organization (2021), all research projects are required to be reviewed and approved by the RECs before their implementation, as this guarantees their social and scientific values, ethical conduct, respect for participants' rights, security, and well-being. It is the REC's responsibility to conduct ethical reviews rapidly and approve research protocols that meet ethical standards after a rigorous analysis (Pan American Health Organization, 2021). However, this process was affected by the COVID-19 pandemic.

The COVID-19 pandemic resulted in unprecedented research work worldwide. For this reason, the regulation of research remained essential to ensure the safety, dignity and well-being of research participants; similarly, the RECs worldwide have experienced vast new, and composite, ethical challenges (Shee*hy et al.,* 2021). Ever since the new pandemic of COVID-19 invaded the globe, researchers began research projects to comprehend the novel virus, including its epidemiology and pathogenicity, and then discover best approaches of prevention and control (Marzouk *et al.,* 2021). Worldwide, the "Clinicaltrials.gov" has registered a total of over 4,900 studies and trials since COVID-19 pandemic started in 2019 (Marzouk *et al.,* 2021). However, the rising number of emerging studies created an overwhelming number of research project submissions to RECs, with ethical challenges on the rise (Marzouk *et al.*, 2021).

2.2 Research Regulatory System Operations

Research regulatory agencies oversee and ensure compliance with ethical, safety, and legal standards in various research activities. They put in place guidelines necessary for conducting research that involves human subjects, animals, or certain substances (International Compilation Research Standards, 2021). These agencies play a crucial role in safeguarding participants, promoting scientific integrity, and maintaining public trust in research outcomes. Examples include the FDA (Food and Drug Administration) and IRBs (Institutional Review Boards) (Hinterleitner & Knill, 2023).

The operation of research regulatory systems involves several key components that collectively contribute to a regulatory system that ensures the ethical conduct, safety, and quality of research activities (Ministry of Health - Nigeria, 2007). For example, they develop and update guidelines that outline ethical and safety standards for different types of research, ensuring compliance with legal and ethical principles (Ministry of Health - Nigeria, 2007). Also, they are responsible for reviewing researchers' study protocols that are submitted to be reviewed, which includes information on study design, participant recruitment, informed consent, and safety measures. Regulatory agencies, often through research ethics committees (RECs) or Institutional Review Boards (IRBs), assess the

ethical aspects of research to ensure that studies respect the rights and well-being of participants (Hinterleitner & Knill, 2023). Researchers need approval from regulatory bodies before initiating a study. This approval signifies that the research aligns with established standards and is ethically sound. Regulatory agencies do monitor ongoing studies to ensure continued compliance. Audits are conducted to verify that researchers adhere to approved protocols.

Researchers are typically required to report adverse events, protocol deviations, and other relevant information during the study. This transparency helps maintain the safety and integrity of the research (Cody, 2020). In fields such as pharmaceuticals, regulatory agencies continue to monitor products after they enter the market to identify and address any unforeseen issues or risks. Regulatory agencies have the authority to enforce compliance through penalties, sanctions, or, in extreme cases, halting ongoing research if significant violations are identified (Ganguli Mitra & Sethi, 2016). They also communicate important information about research findings, safety concerns, and regulatory updates to the public, fostering transparency and trust.

International guidelines stipulate that research that involves human participants requires an independent ethics committee review (Council for International & Organizations of Medical Sciences (CIOMS), 2016). As ingrained from the principles of the Declaration of Helsinki and the Belmont Report, the quest for research review and approval is required because it ensures that adequate measures are put in place to safeguard and protect research participants (World Medical Association (WMA), 2013).

As a result of the increase in the number of research studies done in many low- and middle-income countries, most of which involve human participants, led to an increase in the number of Research Ethics Committees (RECs) established in many countries (Silverman *et al.*, 2015). The committees are rooted in institutions including ministries of health, universities, research institutions, and non-governmental organizations. The RECs reviews are done in accordance with the International Council for Harmonisation-Good Clinical Practice (ICH-GCP) harmonized standard guidelines (ICH-GCP, 1996).

The role of the Research Ethics Committees (RECs) in the reviews is to determine whether the risk of the proposed study to potential participants is minimized and/or reasonable in relation to the relevance of the expected knowledge and outcomes of the study (Kass *et al.*, 2007). The committee approves, criticizes, and monitors all research activities within its competence and requires changes while considering the proposed research's institutional, legal, scientific, and social implications (Silaigwana & Wassenaar, 2019). To carry its mandate, each committee must have at least two independent reviewers, one of which is not an institution's employee or affiliate and the other not a scientist. The committee usually partners with experts/ consultants with the aim of obtaining advice in their areas of expertise on a regular basis during protocol reviews; though, it must work independently to ensure that any potential conflict of interests is not a real conflict (Sleem *et al.*, 2010).

The RECs have operational guideline documents that provide guidance on the protection of human participants. Such documents include conflict of interest and research misconduct policies as well as research protocol application manuals or guidelines to aid their prospective clients (Orimadegun, 2021). The RECs are designed mainly to provide third-party review so as to reduce conflicts of interest; to protect the welfare of research participants through attention to risks, benefits, and informed consent; and to avoid exploitation of vulnerable individuals and populations (Mokgatla-moipolai & Ijsselmuiden, 2012). The RECs operate based on the three foundational ethical principles, that is respect for persons, beneficence, and justice.

Furthermore, it was noted that during the COVID-19 crisis, most RECs in different countries across the world were affected in their operations, where the monitoring and approval of studies was mainly affected by limited human resources and financial resources, limited training of members, the lack of national regulations, lack of adequate funding, as well as lack of gold standards to be followed internationally (Eyelade *et al.*, 2012; Owusu *et al.*, 2022).

In Uganda, according to the Uganda National Council for science and TecTechnology (UNCST), out of the 24 accredited RECs in the country, most of them have mostly been reviewing observational studies (Nabukenya at al, 2023). During the COVID-19 pandemic, the observational studies reviewed by the RECs make up 45%, while clinical trials make up 19%, and the rest of the other types of research account for only 36% (Ainembabazi *et al.*, 2021). However,

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challenges similar to other low- and middle-income countries related to new emerging information and complex designs emerged in Uganda. The challenges occurred whenever the RECs were presented with protocols which stretch their expertise, for example when the members of the RECs had inadequate competences to review the research protocol(s); and this greatly affected the safety, rights and welfare of research participants (Ainembabazi *et al.*, 2021).

2.3 Challenges for Regulation of Research during Public Health Emergencies

The World Health Organization (WHO) abridged the key universal ethical standards aimed at ensuring ethical research during the PHEs. These standards were meant to be adhered to by researchers, review bodies, funders, publishers, and manufacturers during the pandemic (Almeharish *et al.*, 2020). Ethical review during the PHEs is a crucial aspect required in ensuring the safety, dignity, and well-being of research participants (Sheehy *et al.*, 2021). Despite this, the RECs faced new, and often complex, ethical considerations and logistical challenges that exerted great pressure to conduct timely and rigorous ethical reviews (Sheehy *et al.*, 2021).

Public health emergencies often demand swift research initiatives. Regulatory agencies must balance the urgency of the situation with the need to uphold ethical standards, ensuring that research is conducted safely and responsibly. Whereas, during emergencies, there may be pressure to expedite research without a thorough ethical review (Sethi, 2018). Balancing the urgency of public health needs with ethical considerations poses a challenge for regulatory bodies (Ma *et al.*, 2020). On the other side, the urgency to collect and share data quickly can heighten concerns about data security and privacy (Faust *et al.*, 2021). Regulatory agencies must ensure that data handling complies with established standards, even in crises.
Public health emergencies may strain the resources of regulatory agencies. Limited staff, funding, and infrastructure can hinder their ability to effectively review and oversee a surge in research activities. Despite the above, international collaboration becomes crucial during pandemics (World Health organization, 2018). Coordinating regulatory efforts across borders, aligning standards, and facilitating data sharing require effective communication and collaboration among regulatory agencies globally (Sethi, 2018). More still, public health emergencies are dynamic, with evolving challenges and uncertainties. Regulatory agencies must adapt their processes and guidelines in real-time to address new developments and emerging threats (Pan American Health Organization, 2022).

During PH emergencies, involving and communicating with affected communities becomes paramount. Regulatory agencies need effective strategies to engage communities, address concerns, and ensure informed consent, considering the unique challenges posed by the crisis (Ma *et al.*, 2020). Balancing the need for accelerated access to treatments or vaccines with the requirement for sufficient evidence of safety and efficacy poses a challenge. Regulatory agencies may need to issue emergency use authorizations judiciously (Faust *et al.*, 2021). Public health emergencies also often give rise to misinformation. Regulatory agencies must actively counter misinformation, ensuring that accurate information about research, treatments, and preventive measures reaches the public (World Health organization, 2018).

The use of technologies that included use of digital technologies, powered by mobile apps, artificial intelligence, among others also generated concerns and issues around privacy, and individual rights (Almeharish *et al.*, 2020). Potential subjects were contacted by email or phone to determine interest and eligibility. There was suspension of recruitment activities that involved face-to-face interactions with human subjects; and the virtual means were adopted instead, that involved use of phone calls, BioMedical (BMC) Zoom, Boston University (BU) Zoom Meetings for Health Insurance Portability and Accountability Act (HIPAA), and BU Teams among others (organization for Economic Co-operation and Development, 2020).

According to Palmero *et al.* (2021), various countries worldwide, including Africa, have been actively participating in the advancement of COVID-19 vaccines and treatments, regardless of their limited research capacity and scarce resources. Fegert *et al.* (2020) pointed out that the COVID-19 pandemic caused an overwhelming increase in research projects submitted to research ethics committees (RECs) for review and approval, which has led to many ethical challenges. These among others included a new accelerated mode of review, online meetings, balance of risks and benefits, measures to mitigate risks, co-enrolment in different studies, protection of a vulnerable COVID-19 population, accelerated decisions, online research, how to handle informed consent during the pandemic, and

justification of placebo arm among others (Fegert *et al.*, 2020; Marzouk *et al.*, 2021). In addition, the ethics review and oversight of research remained an important aspect that ensured the social value, trusted quality and transparency of knowledge gathered, as well as protection of participants (Almeharish *et al.*, 2020).

According to Lynch *et al.* (2022), research is so important in combatting COVID-19, though ethical regulations for Human Subjects Protection (HSP) positioned a challenge during pandemic. Compliance challenges associated with the RECs were identified, some linked to review and approval, informed consent, emergency research, and research involving incarcerated people (Lynch *et al.*, 2022). Whereas, Singh *et al.* (2020) identified challenges that happened during COVID-19-related legal restrictions or logistical, staffing or operational concerns, the other major research processes which were not related to COVID-19 were significantly deferred worldwide and this implied that the welfare of many participants was at risk.

As noticed by Taylor *et al.* (2021), most research activities involving in-person interactions with subjects were either delayed or stopped during the past COVID-19 pandemic, this aimed at protecting the research subjects and staff. In the same regard, during the pandemic, on-campus research was also suspended (Taylor *et al.*, 2021).

While according to Ford *et al.* (2021), in many countries like the USA, the most common and urgent challenge was rapidly reviewing protocols submitted by investigators/ researchers that were drafted focusing on learning more about COVID-19. It was noticed that many RECs strategized plans to review these received protocols related to the COVID-19 pandemic as more rapidly as possible (Ford *et al.*, 2021). From a study done online that surveyed among the REC Directors at Clinical and Translational Science Awards (CTSA) institutions, the findings highlighted that 66% of the COVID-19 protocols were reviewed across all their committees, while only 22% of them allotted the protocols to only one committee, and 10% of them created new other committees to handle and review the COVID-19 protocols (Ford *et al.*, 2021); all the strategies were done to reduce the backlogs of unreviewed protocols and maximize turn around time for approvals.

Most of the research regulatory systems experienced significant increases in modifications or amendments to the research protocols, with the aim of adding COVID-19 related data collections processes (Loucks *et al.*, 2021). This was because in most or all the protocols, COVID-19 related data was not originally considered, and then changes to the protocols was necessary so as to gather data during the unique, transient period of time during the pandemic (Sisk & Dubois, 2020). All strategies caused temporary delays in RECs operations, with longer estimated turnaround time.

2.4 Opportunities and Coping Strategies During Public Health Emergencies

During public health emergencies, research regulatory bodies got opportunities that significantly contributed to understanding, mitigating, and managing crises (Faust *et al.*, 2021). They explored new treatment methods, assessed the efficacy of existing interventions, studied transmission dynamics, and developed strategies for outbreak control. Additionally, research during these times led to advancements in diagnostic tools, vaccines, and public health policies, enhancing our preparedness for future emergencies (Pan American Health Organization, 2022).

Furthermore, the research regulatory bodies during PHEs diverted to implementing streamlined review procedures to accelerate the approval of research protocols related to public health emergencies (Guha-Sapir & Scales, 2020). This has helped in initiating studies promptly without compromising ethical considerations. Whereas, adapting regulations to the evolving nature of public health emergencies has permitted regulatory bodies to address unique challenges (Ganguli Mitra & Sethi, 2016). This flexibility has always enabled researchers to modify protocols as needed while maintaining compliance with ethical standards. Additionally, while adapting regulations to public health emergencies can address unique challenges, it may also create inconsistencies and confusion. Different regulatory bodies may interpret and implement these adaptations differently, leading to inconsistencies in the approval process.

As a result of public health emergencies, there is improvement in the development of communication channels by the research regulatory bodies, that facilitate quick and transparent information exchange., accompanied by regular updates, guidelines, and

This project has received funding from the European Union's Horizon Europe under GA No 101103296. This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

feedback that help researchers to understand evolving regulatory expectations and requirements (Guha-Sapir & Scales, 2020). Collaborative efforts are also achieved among regulatory bodies, research institutions, and other stakeholders that foster a coordinated approach, hence ensuring efficient resource allocation, but also minimizing duplication of efforts and facilitating a cohesive response to public health emergencies.

Emphasizing ethical principles remains crucial during public health emergencies (National Commission Science Technology and Innovation, 2020). The research regulatory bodies usually tend to prioritize the protection of research participants, which ensures that studies which are conducted during emergencies do adhere to ethical standards, such as informed consent and respect for autonomy (Smits *et al.*, 2023). Also, given the urgency of public health emergencies, regulatory bodies carefully assess the risks and benefits of research interventions, since balancing the need for rapid action with safety considerations is paramount in decision-making.

There is also continuous real-time monitoring of ongoing research during public health emergencies, which helps the research regulatory bodies to identify and address emerging issues promptly. This proactive approach ensures that studies remain in compliance with established protocols and regulatory standards (El-Jardali, 2023). There is also improved data sharing and transparency resulting from public health emergencies, which fosters collaboration and enables the scientific community to collectively address public health challenges. Hence regulatory bodies play a role in promoting responsible and secure data sharing practices.

Allocating resources strategically is essential during public health emergencies. The research regulatory bodies work to prioritize and support research efforts that have the greatest potential impact on understanding and mitigating emergencies (Ganguli Mitra & Sethi, 2016). After the crisis dwindles, the regulatory bodies usually conduct post-emergency evaluations that assess the effectiveness of their response strategies, which include identifying lessons learned and areas for improvement in preparation for future emergencies (Burkle, 2019). By employing these strategies, regulatory bodies aim to balance the need for urgency with ethical and safety considerations, ensuring that research conducted during public health emergencies contributes meaningfully to addressing the crisis (EU CDPC, 2018).

As a result of the PHEs especially the COVID-19 pandemic, the REC review meetings went virtual, and this led to increased participation of the REC attendance during the virtual meetings. Similarly, there were more virtual support hours to researchers, investigators, and their teams (WHO, 2020). The past pandemic also led to creation of new other committees to handle and review the COVID-19 protocols as well as conduct the research regulation processes as quickly as possible (Ford *et al.*, 2021). This was because of the long turnaround time of protocol reviews by the RECs worldwide, and this was due to the pandemic crisis. For example, BMC set up a COVID-19 research scientific review committee, to review and prioritize proposals for COVID-19 research at BMC.

According to Organisation for Economic Co-operation and Development (OECD), the effect of the pandemic also resulted into development of coping strategies among which included the use of digital technologies, powered by mobile apps, artificial intelligence, and big data, provide potential opportunities to researchers and investigators to reach out to their study subjects as well as effectively conduct the studies amidst the pandemic period (OECD, 2020). According to Bolislis *et al.* (2021), open and well streamlined communication that involved the use of virtual communication platforms and online updates through the pandemic proved useful in reaching out to the different stakeholders as well as improving the quality of regulatory systems provided.

The COVID-19 crisis has as well improved collaboration both across and between the different research regulation systems and with governments as well (Bolislis *et al.*, 2021). Many government-led partnerships and global consortia were set up to work together with the RECs to ensure that the human subjects are appropriately protected against harm caused by the research studies amidst the COVID-19 pandemic (Jones *et al.*, 2020). The collaborations aimed at bringing together efforts to build scientific knowledge and to pool resources to create solutions to the pandemic while the subjects are protected (Sheehy, 2021). The research regulatory systems worldwide obtained vast funding from different donors with an interest in conducting research while controlling the spread of COVID-19. The pandemic as well led to increased strengthening of protection of human subjects. However, a counterexample to

this could be seen in the rushed development and distribution of COVID-19 vaccines. Although the research regulatory systems received significant funding, the fast-tracked approval process raised concerns about potential long-term effects and insufficient testing on certain populations. Additionally, there were instances where vaccine trials were conducted in countries with limited healthcare infrastructure, potentially exposing vulnerable subjects to harm without adequate protection.

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CHAPTER THREE: METHODOLOGY

3.1 Research Approach

The study applied a qualitative research approach.A qualitative interview was adopted to describe the effects of Public Health Emergencies (PHEs) on the RECs, researchers, and the research regulatory agencies in Uganda. Data was collected using in-depth, focus groups and key informant guides. The qualitative approach involved a deep probe and application of subjectivity. the study generated in-depth, multi-faceted understanding of the complex situations that affected the RECs operations and research regulatory systems during public health emergencies in Uganda.

3.2 Research Design

The study applied a descriptive design. This allowed a clear description of the specific experiences faced by the regulatory agencies, researchers and RECs during the PHEs (Magilvy & Thomas, 2009). The summary of events that happened during the PHEs such as COVID-19, and Ebola were documented and described.

3.3 Study Setting

The study was conducted in Seven districts in Uganda including Gulu, Mbale, Mbarara, Bushenyi, Wakiso, Mukono and Kampala. The study participants were obtained from accredited RECs and NRAs across these districts in Uganda. The partners in the regulatory system in Uganda included the researchers, the RECs, the Uganda National Council for Science and Technology (UNCST), National Drug Authority (NDA), and Uganda National Health Research Organization (UNHRO). The list of RECs that is indicated in table 1 below was generated for inclusion in the study.

Table 1: List of Accredited RECs for Inclusion in the Study

Table 1: List of Accredited RECs for Inclusion in the Study

RESEARCH ETHICS COMMITTEES	HOST INSTITUTIONS
Uganda Virus Research Institute (UVRI-REC)	Research-Based RECs
Joint Clinical Research Centre (JCRC-REC)	
National HIV/AIDS Research Committee (NARC-REC)	
Vector Control Division Research Ethics Committee (VCD - REC)	
The AIDS Support Organization (TASO - REC)	Non-Government Organization-Based RECs
Mildmay Uganda Research & Ethics Committee (MUREC)	
Hospice Africa Uganda Research Ethics Committee (HAUREC)	
Makerere School of Medicine Research Ethics Committee (SOM -REC	Education Institution-Based RECs
Makerere School of Biomedical Sciences Research Ethics Committee (SBS-REC)	

RESEARCH ETHICS COMMITTEES	HOST INSTITUTIONS
Makerere School of Health Sciences REC	
Clarke International University Research Ethics Committee (CIU-REC)	
Mbarara University of Science and Technology (MUST-REC)	
Gulu University Research Ethics Committee (GUREC)	
Makerere School of Medicine Research Ethics Committee (SOM -REC	
Makerere School of Biomedical Sciences Research Ethics Committee (SBS - REC)	
Makerere School of Health Sciences REC	
Clarke International University Research Ethics Committee (CIU - REC)	
Kampala International University Research Ethics Committee (KIU -REC)	
Uganda Christian University Research Ethics Committee (UCI - REC)	
Bishop Stuart University Mbarara Research Ethics Committee	
Mengo Hospital Research Ethics Committee (MH -REC)	Hospital-Based RECs
Mulago Hospital Research & Ethics Committee (MHREC)	
Uganda Cancer Institute Research Ethics Committee (UCI -REC)	
Uganda National Health Laboratory Services Research Ethics Committee	
CURE Uganda Research Ethics Committee (CUREC)	
Mbale Regional Referral Hospital Research Ethics Committee (MRRH -REC)	
Lacor Hospital Research Ethics Committee (LHREC)	
St Francis Hospital Nsambya REC	
Uganda Heart Institute Research Ethics Committee (UHI-REC)	

3.4 Study Population

The study was conducted among the REC Chairpersons and REC administrators of all the UNCST accredited RECs by March 2023. The RECs' membership rosters indicated in Table 1 under section 3.3 were generated for inclusion in the study. The REC Chairpersons and researchers were the primary participants for the study. The NRAs and REC administrators were the secondary participants in the study. In addition, the researchers who conducted research between March 2020 and March 2023 during the COVID-19 and Ebola PHEs were included in the study.

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The National Regulatory Agencies (NRAs) namely, Uganda National Council for Science and Technology (UNCST), National Drug Authority (NDA), and Uganda National Health Research Organization (UNHRO) were included in the study as key informants.

3.5 Sample Size Determination

A total of 49study participants were involved in the study. These included the 15 REC Chairpersons and 10 researchers. The study interviewed at least 5 participants selected from the relevant National Regulatory Agencies (NRAs) (1) from the Uganda National Health Research Organization (UNHRO), 2 from the National Drug Authority (NDA), and 2 from (UNCST. All the REC administrators from the 29 RECs were involved in the study, which consisted of 6-12 participants per FGD. Study participants, as indicated in Table 2, were interviewed until the saturation point was reached.

Table 2: Distribution of Participants and Sample Size for the Study

Study Participants	Sample Size	Data Collection Method
REC Chairpersons and researchers	25	In-Depth interviews
REC Administrators	4 FGDs (29 REC administrators grouped 6-8 participants per FGD	Focus Group Discussions
Regulators (UNCST, NDA, UNHRO)	5	Key informant interviews

3.6 Inclusion and Exclusion Criteria

3.6. 1 Inclusion Criteria

1. REC chairpersons who held positions during the research period.
2. REC administrators who were appointed and working within the research period.
3. Researchers leading clinical trials within the research.
4. Participants who consent.

3.6.2 Exclusion Criteria

1. Participants who do not consent
2. Newly accredited RECs

3.7 Sampling Procedures

The research participants from the regulatory agencies were purposively selected for the study and interviewed until saturation as key informants. Expert purposive sampling technique was used for selecting the participants due to their expertise in understanding of the operation of the national regulatory systems. The research regulators have expertise knowledge and experiences related to the research regulation policies and guidelines at both local and international, monitoring and inspection of products, and research for quality assurance. In addition, the regulators have a mandate to understand the unique challenges and experiences faced by the RECs and researchers for possible redress at the national level. The REC administrators have expertise knowledge in the operations of the RECs and a clear understanding of the challenges and experiences of researchers during the processes for registration of the studies and these were included in the study as focus group participants. The REC Chairpersons and researchers

for the in-depth interviews were purposively selected across the various RECs as per the type of host institution for the views, experiences, and perceptions related to the operation of the REC activities and the coping strategies during the peak of the COVID-19 pandemic and lockdown. All study participants were interviewed until the saturation point was achieved.

The contact information for the study participants was extracted from the UNCST accreditation and research registration database and these were contacted via phone, and emails and invited to participate in the study. The UNCST through the Principal Investigator introduced the research assistants to the regulatory agencies, researchers, and to the Chairpersons of the accredited RECs that were involved in the study.

3.8 Data Collection Methods

3.8.1 In-depth Interviews

The in-depth interviews were conducted among the REC chairpersons and researchers. The interviews were conducted by the researcher and or the research assistants at places with quiet rooms that are convenient to both the researcher and the interviewee. The interviews were conducted in English and lasted approximately 60 minutes. The in-depth interview guide containing mainly open-ended questions, was used to collect data from the study participants. The tool addressed issues related to the research regulation operations, the implementation of the National Research Information Management System (NRIMS), and the challenges experienced during the PHEs. Relatedly, coping strategies that enabled the RECs to function during the pandemic were described. The detailed information from the participant's thoughts, insights, and experiences provided data that was analyzed to achieve the study objectives.

3.8.2 Key Informant Interviews

The key informant interviews were conducted with the representatives of the national regulators from agencies such as the Uganda National Health Research Organization (UNHRO), the National Drug Authority (NDA), and the Uganda National Council for Science and Technology (UNCST). The interviews were conducted by the researcher and or the research assistants at the respective agencies' offices. The interviews were conducted in English and lasted approximately 45-60 minutes. The key informant interview guide containing open-ended questions, was used. The issues that were addressed by the tool included the description of how the existing national policies and guidelines were utilized and supported the regulation of research during the pandemic. The coping strategies by the regulatory agencies in supporting the RECs and researchers were also described. The expert information shared through the interviews with the regulators was generated into themes that informed the study's goals and objectives.

3.8.3 Focus Group Discussions

The FGDs were conducted with the 29 REC administrators from the 29 accredited RECs that were included in the study. A workshop model was adopted for the collection of data from REC administrators. The participants were interviewed virtually through videoconferencing. The discussions were handled by at least two research assistants, one moderated the discussions while the second observed the group dynamics, body language, and social interactions. The interviews were conducted in English and lasted approximately 45-60 minutes.

A total of 4 focus group discussions were held, each consisting of at least 6-12 REC administrators. The criteria for inclusion in the FGDs was based on the type of REC host institution and the type of REC reviews. The 4 FGDs included; 1 FGD from hospital-based RECs, 1 FGD from education institution RECs, 1 FGD from RECs that majorly review social sciences and humanities, and the last from RECs that review majorly Medical and health sciences research protocols.

The focus group discussion guide containing open-ended questions was used. The issues that were addressed by the tool included, research regulation operations, the implementation of the National Research Information Management System (NRIMS), and the challenges experienced during the PHEs. The rich data and new ideas generated was emerged with the in-depth interview data before deriving logical conclusions in achieving the specific objectives of the study.

3.9 Data Collection Procedures

The researcher and or the research assistants recruited the participants and set appointments for when the interviews shall be conducted. This focused on the convenience of the participants. The interview were administered in English and recorded for purposes of enabling the participants to express themselves but also allowing the moderator to record. Permission was sought from participants to have proceedings of each interview audio recorded to ensure that all the data is captured accurately. Recordings were transcribed verbatim, and transcripts were stored in password-protected computers in preparation for analysis.

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The interviews were facilitated by two research assistants with a minimum of a bachelor's degree in a social science-related discipline, in possession of a valid certificate in Human Subject Protection (HSP) course, and have experience in conducting research interviews.

3.10 Data Analysis

Data was analyzed using the thematic analysis approach outlined by Braun and Clarke (Braun & Clarke, 2008; Vaismoradi, Turunen & Bondas, 2013). This analysis approach was chosen because it is suitable for studying people's perspectives, opinions, and experiences. First, the transcripts were read and cross-checked against the recordings, with any errors corrected. Data analysis started by reading all the transcripts repeatedly to gain familiarity with the data. Data was then read word by word, and phrases or sentences were highlighted and given shorthand labels called codes. Similar codes were aggregated to form clusters, and in the process, some codes were merged while others were discarded. Codes were then grouped to create themes. Finally, themes that have been developed were reviewed, defined, and named to provide a clear understanding of the data. The results of the study were presented using themes with illustrative quotes from the data. To ensure rigor during data analysis, two analysts independently coded the data. Discrepancies in definitions of the codes were resolved by consensus and by referring to the transcripts.

3.11 Quality Control Measures

All research assistants were trained on the protocol, study tools, and interviewing skills before the commencement of any study activity. The principal investigator supervised the study activities and met the research team bi-weekly to minimize errors and manage emerging issues. Before using the interview guides in the actual study, a pilot study was carried out first to ensure that the tools that will be used in the study are valid and reliable. 1 FGD, 5 in-depth and 2 key informant interviews were carried out during the pilot study. The pilot was carried out among the regulators, researchers, and REC chairpersons of Bugema University, Uganda Christian University, Kabale University, and Lira University RECs that were not participating in the study.

Data obtained through field note-taking was compared with the actual data collected using audio recording to make sure that there was no missing information. Backing of the data was done regularly and stored on the UNCST data server to protect it against hazards. Finally, for the entire study process, any deviations from the approved proposal were noted and reported to the REC and UNCST to promote transparency in the study process.

3.12 Ethical Considerations

Ethical and scientific approval to conduct the study was obtained from the National HIV/AIDS Research Committee, and final clearance was sought from the Uganda National Council for Science and Technology (UNCST) for registration and approval. The administrative clearances were sought from UNCST, NDA, and UNHRO before the commencement of any study activity. The UNCST, NARC, and the research team ensured that the study was conducted ethically, and in compliance with the national and international guidelines for research involving Humans as Research Participants (UNCST, 2014). According to Kathryn (2012), "Researchers have an ethical obligation to minimize the risks that research may pose to participants" (pg. 151). The purpose of the ethical considerations is to ensure that the rights and welfare of human research participants are protected during research.

Informed consent was obtained from all study participants before they were enrolled in the study. Only the approved study protocol, informed consent forms, and study tools were used when conducting the study. Personal identifiable information provided by participants was kept confidential, and measures to protect their privacy were always ensured while conducting study activities. The participants were compensated 50,000 shillings for their time, effort, and inconvenience while participating in the study activities. Participation in the study was voluntary, and participants were free to withdraw from the study at any time without being penalized.

3.13 Data Sharing Plan

Data available from the study was managed and stored by the Uganda National Council for Science and Technology (UNCST). Both the UNCST and EDCTP have ownership of the data and as such have full access to de-identified data. EDCTP has the right to use non-sensitive information relating to the study results and materials and documents received from the UNCST such as publications in paper or electronic form) for

policy, information, communication, dissemination, and publicity purposes during and after the closure of the study. This is guided by the data agreement signed by all consortium partners. All data was de-identified before sharing and dissemination to all partners. All the data will be destroyed five years after the study is completed. The findings of the study will be shared at a stakeholder meeting.

3.14 Community Engagement Plan

In the development of the proposal the Forum for Research Ethics Chairpersons (FRECU) as well as a pool of researchers were consulted. Development of the proposal included members from the FRECU. The community was engaged during the implementation of the study activities through the various communication forums i.e emails, WhatsApp groups of stakeholders and workshops. The findings will be disseminated through reports and presented to the different stakeholders at both local and international conferences and workshops. We will also prepare and submit the findings for publication in a peer-reviewed journal.

3.15 COVID-19 Mitigation plan

In conducting this study, the research team put the following measures in place to protect the research team and the study participants from contracting COVID-19. Both the research team and the research participants wore masks properly during research activities. The research assistants were provided with masks and were given extra masks to offer to any willing participant who may not have a mask. The research team ensured adequate ventilation and avoided close contact with the study participants during the study activities. Hand hygiene was emphasized by hand washing with soap and water or the use of an alcohol-based sanitizer. The research team had hand sanitizer that was used during the study activities for hand sanitization before and after writing on the study forms.

3.16 Limitations

The interviews took a lot of time due to the sensitivity of dealing with respondents' emotions about what happened during the COVID-19 pandemic and restrictions. The recall bias rose as a result of trying to remember the various experiences and operations of the RECs since March 2020. The limitations were minimized by a careful selection of the research questions, choosing an appropriate data collection method, and ensuring that the strategies to maintain rigor in the conduct and reporting of the study findings were followed. Inaddition, the researcher recruited trained research assistants who knew how to create a good rapport with participants before the interview and put emphasis on maintaining the privacy and confidentiality of the research participants.

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CHAPTER FOUR: RESULTS

4.1 Facilitators and barriers to research conduct during the COVID-19 pandemic

4.1.1 Facilitators for research conduct

Despite the challenges posed by the COVID-19 pandemic, several factors facilitated the continuation of research activities in Uganda. Key among these were the development of research guidelines, implementation of risk management plans, prioritization of urgent projects, and digital transformation. These measures helped ensure that research could be conducted while adhering to both public health regulations and ethical research standards

4.1.1.1 Development of research guidelines

One of the most significant facilitators was the establishment of research guidelines tailored to pandemic conditions.

"So, in that period, guidelines were put in place on how to implement research during, during pandemic, such a in a period like COVID-19 when it happened. Okay. So those guidelines, before I go to the implementation…" (FGD 1, REC Administrators).

"We didn't know how people are going to move between places, how people are going to interact and engage. So, the guidelines were important…" (IDI 01, REC Chairperson).

These guidelines provided clear instructions on how to conduct research safely and ethically during COVID-19. These new policies streamlined the review process and provided researchers with a structured approach to navigating pandemic-related challenges.

4.1.1.2 Implementation of risk management plans

In addition to formal guidelines, risk management plans were introduced to minimize the health and safety risks associated with conducting research during a pandemic.

"At least as a REC we did that, we encouraged the researchers to do those. I think the other time around the same time, the thing that came out was the risk mitigation. COVID-mitigation basically should be for things beyond COVID. But specifically, we used to ask that researchers include, COVID-19, risk assessment, and mitigation plan" (IDI 04, REC Chairperson),
"I think there were elements of protection, uh, procedures for protecting the researcher, but also, the population" (IDI 02, Researcher).

Researchers and ethics committees developed specific strategies to protect both research staff and study participants.

"We had to put in place risk management plans to ensure that research activities did not expose people to unnecessary danger" (FGD 2, REC Administrators).

4.1.1.3 Prioritization of urgent research projects

Another critical facilitator was the prioritization of urgent research projects, particularly those related to COVID-19.

"…the REC received, uh, a submission on a project regarding COVID-19, which required RECs to put in place quick means on how to make sure that that project is reviewed. Because it was something which required, maybe what, how can I say it? Uh, it required, uh, a quick response so that, because it was an issue of saving life, and by then the, the researchers who were linked to COVID-19 were more of saving life other than, uh, maybe other than treatment and whatever" (FGD 1, REC Administrators).

Regulatory bodies expedited the approval process for research studies that were deemed essential for understanding and combating the pandemic. By prioritizing such studies, the research community was able to generate timely data to inform public health responses.

4.1.1.4 Digital transformation

Lastly, the guidelines supported research activities to continue online, making remote research engagement possible.

"And then, you know, also thinking about how we support

researchers online, the business of going to their offices or the business of bringing hard copy, hard copies. Documents for signing and delivery and all that stopped ceased." (IDI 06, REC Chairperson).

4.1.2 Barriers to research conduct

While the introduction of COVID-19 research guidelines was meant to streamline research activities and ensure safety, they also had unintended negative effects on ongoing studies. Many researchers and institutions faced disruptions, increased operational costs, and gaps in information about the new requirements.

4.1.2.1 Disruptions to ongoing studies

One of the biggest challenges was that the guidelines disrupted already ongoing studies, forcing researchers to modify their study procedures or pause their projects altogether.

"Some people managed that, but it was, it was difficult for others. In fact, I have, um, I am a PI of a project here that, uh, had a PhD supporting PhDs. One of our PhDs actually dropped out..." (IDI 07, REC Chairperson).
This led to delays in data collection and analysis, affecting project timelines and study outcomes.

4.1.2.2 Distortion of research activities

Closely related to this disruption, research activities were distorted, with many researchers struggling to adapt to the new protocols.

"I think the REC, I know that they stopped studies during that time, and we had ongoing trials at that time, and they stopped, the National Council stopped enrolment" (IDI 10, Researcher).

Some studies had to be redesigned to comply with COVID-19 restrictions, which in some cases altered the initial research objectives. This adjustment process often led to confusion and inefficiencies in study execution.

4.1.2.3 Increased financial burden

Additionally, the new guidelines led to increased expenses for researchers, as they had to allocate additional resources for compliance.
"What I'm saying is, let me assume that my initial budget was X, but then in following the guidelines for such during COVID, the IPC measure and things like that, they would increase my budget (IDI 05, Researcher).

"But you can imagine that, and this is not the fault of the direct or the National Council, but you can imagine that this increased study costs or studies which were already running, our budgets were already set, but it was necessary under those circumstances" (IDI 11, REC Chairperson).

These costs included purchasing personal protective equipment, covering internet costs for online engagements, and adjusting budgets for new logistical needs.

4.1.2.4 Lack of clear communication

A major issue was the lack of clear communication about the guidelines, leaving many researchers unaware of what was required of them.

"So most of the times they would submit protocols without the COVID-19 risk mitigation plan. And then you had to tell them to prepare it. And then they're like, so, but what is this? Then, you have to refer them to UNCST websites, for this. So it affected, it delayed our review process at the REC level, largely because of limited awareness amongst the researchers" (IDI 02, Researcher).

Some researchers were forced to navigate the new system through trial and error, as there was no structured approach to disseminating the new requirements. This led to delays in compliance and frustration among researchers.

4.1.2.5 Technological adaptation challenges

The shift from physical to online review processes posed difficulties, especially for long-serving REC members accustomed to analogue systems. Many struggled to navigate online platforms, which slowed down decision-making.

"One of the challenges was, um, members had to review via online, and that was so challenging because it was like the first time people were used to the physical meetings, and it was somehow dragging the REC decisions" (FGD 1, REC administrators).

Limited digital literacy among some members meant constant troubleshooting and additional training.

This project has received funding from the European Union's Horizon Europe under GA No 101103296. This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

4.1.2.6 Poor internet connectivity

Unreliable internet connectivity frequently disrupted virtual meetings and increased review turnaround times.

"One of the major challenges was, you know, the internet connectivity. Uh, for some of the things really understand the quality, the quality of the internet would be poor because some old, for instance, yeah. We live in areas where, because of the infrastructure, sometimes they have poor quality of the internet. And so the interruptions, sometimes, uh, was difficult. We couldn't hear what somebody was saying and, and that, you know, sometimes the meetings would stretch longer than, then planned because, um, sometimes the internet would go off for some individuals while somebody speaking or something presenting. And so you, you had to organize another meeting to finish the ones, the protocols that were not discussed, discussed. That was one of the challenges" (IDI 19, REC Chairperson).

Many researchers and REC members struggled with weak internet infrastructure, which made it difficult to conduct online reviews efficiently. In some cases, review meetings had to be rescheduled due to unstable internet.

4.2 Impact of COVID-19 on the research regulatory process

4.2.1 Effects of COVID-19 on research policies

The COVID-19 pandemic had a profound effect on the research regulatory process in Uganda, leading to both disruptions and adaptations in the way research was conducted and reviewed. While some activities were temporarily halted, the pandemic also accelerated changes such as expedited reviews, the introduction of new guidelines, and a transition to digital processes.

4.2.1.1 Expedited reviews

In response to the urgency of the pandemic, regulatory bodies expedited reviews for COVID-19 related studies, allowing critical research to proceed faster than usual.

"I think COVID-19 taught us that it's, it's possible to review a clinical trial in a short time. Yes. And I think that is a good thing because before then you would take your time to review a clinical trial. But COVID-19 orders that it was possible to review in a short time. In a short time" (KII 02, Regulator).

This acceleration allowed for the rapid generation of evidence to guide interventions while maintaining essential ethical standards.

4.2.1.2 Shift to digital submissions

A significant shift in research processes was the transition from hard copy to online submissions and reviews. Previously, researchers were required to submit physical documents for approval, but with movement restrictions in place, the system had to adapt, allowing researchers to submit their protocols online instead of delivering hard copies. This transition aimed to reduce physical interactions while maintaining efficiency in the review process.

"Like it made us UNCST to shift now from the hard copy, uh, to the, to the online, but also in terms of uh, being, being alert. And I'm happy that that is coming up because it has made us to like to be alert that in case of the similar, similar issue or similar emergency, we need to be awake" (KII 03, Regulator).

This adaptation was particularly important in ensuring that research activities were not disrupted by movement restrictions.

4.2.1.3 Introduction of new guidelines and policies

Also, new guidelines and policies were drafted to align research activities with health and safety measures. These policies provided guidance on ethical considerations, safety measures, and remote data collection methods to ensure that studies complied with both research ethics and public health guidelines.

"And uh, it did, of course. I mean, if we are talking about, for example, the COVID-19 guidelines, you know, they had to get people, you know, facilitate them to sit and then review and come up with those guidelines" (KII 01, Regulator).

Relatedly, the standard operating procedures were revised to align with COVID-19 prevention measures. This included updates on informed consent procedures, participant interactions, and safety protocols for

fieldwork. These revisions ensured that research was conducted in a way that protected both researchers and participants from the risk of infection.

4.2.2 Impact of COVID-19 on research regulation and oversight

4.2.2.1 Temporary halts or closure of research, and delays in research approvals

One of the major setbacks was that some research activities were put on hold, as regulatory bodies and institutions struggled to adjust to the new reality.

"We were, we were supposed to do regulatory activities, which involves review of research protocols, which involves site visits, which involves review, which involve review of site or research protocols, site visits, and regulatory work. Okay. Uh, as, as a whole. As a whole. So, in that, hello? Yes, yes. Proceed. Yes. So, in, in, in that period, because, uh, uh, we had, uh, that put in place the government of Uganda put in place, um, is it guidelines to, to eliminate the spread of COVID-19. So, in that, in that period, there was, uh, sort of…but, uh, somewhere, somehow the studies were on hold. Okay. Especially those we, which had sites far away in the, in the fields, far away from the, the main sites" (FGD 1, REC administrators).

This pause affected both ongoing and new studies, as researchers waited for clarity on how to proceed under the new restrictions. Similarly, some were put on hold until researchers could adjust their methodologies to comply with the new guidelines. Unfortunately, the pandemic also forced some studies to close entirely, particularly those that required an increase in the budget due to required changes.

"…so particularly, I'll speak for my Research Ethics Committee. Yes. So, I already said the studies went down. Mm. And also, some of the studies closed, uh, because of the budgetary, you know, like already said, transport had to go up for participants. But then remember, this is a study that had been approved before the pandemic. So, they were running on that budget" (KII 01, Regulator).

The pandemic caused delays in research approvals and decision-making due to multiple factors, including quorum issues, slow online submissions, and disruptions called by illness. Some REC members contracted COVID-19, which led to temporary halts in review activities.

4.2.2.2 Increased workload for RECs

With research activities surging during the pandemic, REC members faced a sharp increase in the volume of protocols to review. This was made worse by the shift to online reviews, which lengthened the review process and required additional administrative support. "The other challenge was to do with, uh, resource constraints. You know, because of the overwhelming workload, very many people are bringing in protocols or proposals, covid related, and even the numbers were so high. So, in one way or the other, the overwhelming workload also is related with something to do with resource" (FGD 2, REC administrators).

Furthermore, REC members had to balance their official duties with personal responsibilities, as many were working from home.

"So, you know, an environment where you are in a virtual meeting, you're at home with families, how small children running around like that, that was also one of the challenges" (FGD 2, REC administrators).

4.2.2.3 Limited oversight due to movement restrictions

The restrictions on movement and in-person interactions affected monitoring of ongoing research studies. RECs struggled to ensure compliance with ethical guidelines since traditional site visits were not feasible.

"…we're not sure whether our researchers would adhere to this risk mitigation strategies that they were submitting. You know, it's another thing to submit, but even us we could not verify that what they have submitted is what we are doing. So, I think that was a challenge to ensure that the PIs were adhering to the mitigation plan, although they had submitted. So, it was a difficult time" (IDI 19, REC Chairperson).

This created gaps in oversight, raising concerns about research integrity. Some researchers resisted the online review process, expressing concerns about the legal validity of decisions made virtually.

"There are some who are resistant to the idea of all the time meeting online. We are saying, yeah, but we need to be in the same room. We need to be together, can we postpone this until the lockdown is over?" (IDI 07, REC Chairperson).

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4.2.2.4 Financial burdens

The pandemic introduced new financial burdens for both researchers and REC members. Researchers had to cover additional costs such as data, virtual meeting subscriptions, personal protective equipment, and COVID-19 safety measures.

For some, the costs associated with joint review meetings escalated beyond budgeted amounts, making compliance difficult.

"Imagine if you don't have funding, you can't organize a joint review, but you know previously you could send your protocol to the REC" (IDI 19, REC Chairperson).

Students and independent researchers, in particular, struggled to afford the additional expenses required to meet new guidelines.
4.3 Effectiveness of Uganda's research policies and guidelines during COVID-19

4.3.1 How COVID-19 research guidelines supported research

Despite the challenges brought by COVID-19, the research guidelines introduced during the pandemic played a crucial role in ensuring that research activities continued smoothly. These guidelines enhanced collaboration, facilitated joint protocol reviews, helped standardize research methods, and provided a framework for research operations.

4.3.1.1 Enhanced collaboration between researchers and regulators

One of the major benefits of these guidelines was that they enhanced collaboration between researchers and regulators, creating a more structured approach to research oversight.

"The other things, what the guide guidance I've done, uh, I think it the guidance enhanced collaboration. Collaboration between researchers and, uh, so that researchers may not look at us only as, again, regulators who may be trying to find faults, but as people who could advise, because now, we also pass in, now UNCST advises like this, what would that kind of thing be? So, you say, oh, the possible contents of this are here. So, I think it also created the kind of possible friendship and possible collaboration that in other words, troubleshooting all of us together" (IDI 08, Researcher).

4.3.1.2 Facilitated joint reviews of protocols

Another key advantage was that the guidelines facilitated joint reviews of protocols, allowing different regulatory bodies to work together in evaluating research proposals.

"During the pandemic. What I know is that all for the COVID-19 related studies were supposed to be at least jointly reviewed by the different, stages like in the RECs and National Council and NDA, if there were IPUs required. So, this required, I mean, this kind of brought all the regulators together to review the protocol to together in one sitting. Uh, so that the different concerns will be addressed those by the REC or National Council, NDA, so by the time the researcher comes back, at least everything is being addressed because the usual processes that someone goes to the REC, of course, they may get comments there. Then once they have respond to them satisfactorily, they go to national council, but National Council, so may notice some other things that need to be addressed, which have to come back to the investigator and go back to a REC still before they come back to national council or even a national or a National Drug Authority. They may also realize that the other things which have to go back to the investigator, so they joint I review process, which was used mostly during the COVID-19 pandemic" (IDI 17, Researcher).

The joint review helped researchers to receive comprehensive feedback at once, rather than navigating separately regulatory processes at different stages. The guidelines also enabled RECs to continue with their activities despite the restrictions, providing clear directives on how research could proceed.

"…allow people to continue conducting research…but also it facilitated the operations of the REC because at my institution, people, the REC members were able to continue meeting to discuss protocols actually and facilitated the review of protocols in spite of the fact that people were not meeting physically at the time" (IDI 22, REC Chairperson).

4.3.1.3 Provided clear guidance for protocol amendments

Additionally, the guidelines provided clarity on necessary amendments to ongoing studies to align them with COVID-19 protocols.

"…during that period, we had many studies undergo amendments. Yeah. Because during that period, the Uganda National Council Science and Technology had sort of halted research activities for some time. as they were working with these guidelines and try to, trying to see the situation and how best to, to work with it, but also not to let research activities take place. Yeah. So, for the consent, what I can say is during that period, we had many researchers coming into amend to, uh, to, for example, follow up participants virtually using phone mainly, I think phone calls. And for some of the new studies, we had them now come in with, um, innovative ways of, of the consenting" (KII 01, Regulator).

This helped standardize and unify research procedures and expectations across institutions.

4.3.1.4 Standardized research review processes

Moreover, the policies and guidelines made it easier for RECs to operate during that time, giving them clear directions on how to handle research approvals and oversight under pandemic conditions.
"So, all researchers had to make sure they align with the policy. For me personally, I took it very positive. Because it didn't add any delays. It wasn't delay, like it wasn't hard. You just need to declare how you're going to protect" (IDI 13, REC Chairperson).

By providing a framework to guide research activities, the guidelines ensured that all research adhered to ethical and safety standards and the researchers adhered to the guidelines.

4.4 Coping strategies of researchers, NRAs, and RECs during COVID-19

4.4.1 Coping strategies by NRAs

During the COVID-19 pandemic, National Regulatory Authorities (NRAs) implemented several coping strategies to ensure that research oversight continued despite movement restrictions and public health risks. These strategies focused on establishment guidelines, enforcing COVID-19 protocols, leveraging online platforms, and limiting in-person office interactions.

4.4.1.1 Developed SOP guidelines

One of the key strategies was the establishment of guidelines to regulate research and ensure continuity of oversight during the pandemic.

"And then there are some like guideline which were created like by National Council guidelines to deal with COVID-19" (FGD 2, REC administrators).

These guidelines helped researchers navigate the regulatory environment under pandemic-related restrictions, ensuring that ethical standards were upheld despite the challenges.

4.4.1.2 Enforced COVID-19 guidelines to minimize risk

NRAs also followed COVID-19 guidelines to minimize the risk of infection among their staff and researchers. This involved strict adherence to social distancing, hand hygiene, and use of personal protective equipment:
". If I am supposed to handle paperwork, I have to sanitize, sanitize the paper. Like everything becomes messy. So, by the time we went to online, we just had to cope up because we cannot stop. It's continuous kind of work every day" (FGD 2, REC administrators).

4.4.1.3 Maintaining essential on-site operations

However, the required physical work was also handled by a skeleton staff. To minimize the spread of COVID-19, NRAs restricted some people from coming to the office, prioritizing remote work for non-essential staff while allowing only critical personnel to access office spaces. This helped to maintain essential operations while safeguarding the health of regulatory staff.

4.4.1.4 Conducted joint online reviews

Still, to adapt to movement restrictions, NRAs shifted to online meeting and reviews, allowing research ethics committees and regulatory authorities to continue evaluating research protocols virtually. This approach reduced physical interactions while maintaining oversight of ongoing and new research studies.

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4.4.1.5 Provision of data support for remote work

In response to the high cost of internet data and remote work challenges, the NDA provided data to its members to facilitate online research review processes.

"NDA provided us with moderns that we could use at home. Okay. Yeah. So, they would provide us with data every month" (KII 02, Regulator).

4.4.2 Coping strategies by RECs

During the COVID-19 pandemic, RECs had to adapt their operations to ensure that research oversight continued despite movement restrictions and health risks. Various strategies were implemented to maintain research review processes while minimizing disruptions. These strategies focused on adopting new monitoring approaches, leveraging technology, ensuring compliance with guidelines, and facilitating movement for key personnel.

4.4.2.1 Adopted passive monitoring

One of the primary adaptations was the adoption of passive monitoring to oversee research activities remotely. Instead of conducting physical site visits, RECs relied on progress reports from researchers to track study progress.
"And also, we had some difficulty with monitoring research. You know, we keep going face to face, going to monitor research. Yes. Because people are a bit fearful of where you are going, you know, particularly in the community in some places. So, some of the monitoring, monitoring, we did it also online" (FGD 1, REC administrators).
This strategy allowed RECs to maintain oversight without increasing the risk of COVID-19 transmission.

4.4.2.2 Engaged in online research reviews

To further facilitate research oversight, RECs engaged with researchers online instead of conducting site visits.
"That's how now what most reviews were in held online using either Zoom or team. So, the concept of team, team meetings or zoom meetings. Became the, the normality of reviews because the, there was, uh, a plan on, uh, on members meeting" (FGD 1, REC administrator).

Additionally, RECs reviewed research protocols online, ensuring that research approval processes continued despite restrictions.

Also, RECs accommodated both online and offline processes. This helped to ensure that those who faced technical challenges could still participate. At the same time, REC offices gazetted two days a week to stamp documents, allowing essential paperwork to be processed in an organized manner.

Collaboration and networking among RECs, as well as joint reviews by NRAs and UNCST, were essential in streamlining processes during the pandemic.

"We worked closely with other RECs and regulatory bodies to harmonize decisions and improve efficiency" (FGD 2, REC administrators).

Technology played a crucial role in sustaining REC operations. To ensure smooth adaptation, REC members were trained on how to use online platforms for research review. Additionally, some RECs provided data for their members to support online activities, reducing the financial burden of working remotely. To further optimize online engagement, meetings were organized during peak hours when most members were available.

4.4.2.3 Processed movement permits for REC administrators

To address movement restrictions, RECs processed movement permits for REC administrators, enabling them to perform critical tasks that required physical presence.

"During the pandemic, the movement for record administrators was a bit difficult. For example, for me, one time the police stopped me, where are you going? Yet they were calling me to go and stamp documents so, it was hard, but our institution processed for us the movement permit. And we were able to move freely, and the policemen would not stop us" (FGD 1, REC administrator).

Meanwhile, site visits were restricted to emergency studies only, minimizing unnecessary exposure.
"Site visits were only conducted for emergency studies to ensure compliance while reducing health risks" (FGD 1, REC administrators).

This accommodated both online and offline processes. This helped to ensure that those who faced technical challenges could still participate. At the same time, REC offices gazetted two days a week to stamp documents, allowing essential paperwork to be processed in an organized manner.

4.4.3 Coping strategies by researchers

During the COVID-19 pandemic, researchers had to adapt their methods to comply with movement restrictions, minimize health risks, and ensure that their studies continued without major disruptions. To mitigate these challenges, researchers implemented online consenting processes, transitioned to online protocol submissions and presentations, and made budgetary adjustments to accommodate new research-related costs.

4.4.3.1 Transitioned to online consent and protocol submission

One of the key adaptations was the use of online consenting to enrol participants in studies remotely. Since physical interactions were limited due to social distancing guidelines, researchers had to shift from traditional in-person consenting to digital methods.

"…actually, that is when people invented in were requesting for waivers of consent. People started the electronic consenting only the different kind of consenting that they would work with that did not involve for personally in person meeting" (FGD 2, Administrators).

This ensured that ethical standards were upheld while minimizing the risk of COVID-19 transmission.

Another major adjustment was the submission and presentation of research protocols online. Instead of delivering hard copies of research proposals to ethics committees, researchers uploaded their protocols onto digital platforms and defended their proposals in virtual meetings. This helped reduce administrative bottlenecks and allowed the review process to proceed despite movement restrictions.

4.4.3.2 Adjusted research budgets to cover COVID-19 related costs

Additionally, researchers had to adjust their budgets to accommodate the unforeseen costs associated with the pandemic, such as internet expenses, personal protective equipment, and logistical changes in study implementation.

4.5 Experiences with the NRIMS

4.5.1 Benefits of NRIMS

The NRIMS transformed the research regulatory process by digitising submissions, reviews, and approvals. Many users appreciated its role in improving communication, streamlining collaboration, and enhancing efficiency. Participants highlighted that the system reduced paperwork, made tracking applications easier, and improved transparency in the approval process.

4.5.1.1 Improved communication between researchers and regulators

One of the major advantages of NRIMS was its ability to facilitate quick communication between researchers and regulators. The system provided a centralized platform for interaction, reducing delays in correspondence.

4.5.1.2 Facilitated collaboration and reduced duplication issues

Additionally, NRIMS promoted collaboration among different research bodies, ensuring that approvals were coordinated across institutions.

"NRIMS has helped to ease the REC operations of all the regulatory bodies in Uganda, because it is combining all the different bodies, which are involved in research. It combines NDA, it combines, uh, UNCST, all the recs accredited in Uganda. It means that if it came to, to joint review" (FGD 1, REC administrators).

For researchers working remotely, NRIMS was particularly beneficial as it enabled distant researchers to participate in the review process. Moreover, the platform helped ensure attendance at meetings, as virtual participation became more feasible than in-person sessions.

Another important function of NRIMS was addressing duplication issues in research, the system provided a structured database, helping regulators identify and avoid redundant studies.

"Somebody was claiming that perhaps their idea was

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copied. But fortunately, we had submitted to REC and NRIMS. Almost a year before they ever wrote their thing. So, the fact that you have this platform. If you submit, there's a timestamp" (IDI 10, Researcher).

4.5.1.3 Reduced workload for REC administrators

For REC administrators, NRIMS helped reduce workload by automating several processes that were previously manual.

"And again, the system has actually paved the way of, to ensure that we lessened the burden that our REC administrators had. Initially. We had to do run-arounds with protocols... So, you do the run-arounds to, you know, submit protocols. You do the run-arounds to, and, uh, pick the, the comments. You know, you, send out invitation for meetings and all these people have to come physically. If they don't come physically, you have to cancel the meetings 'because you don't have quorum" (FGD 2, REC administrators).

4.5.1.4 Reduced operational costs for researchers

Researchers also benefited financially, as the digital platform saved money that would have been spent on printing and transport.

"NRIMS has been a blessing for researchers you can imagine previously we had, for example, to make (11) copies of everything when we are submitting to the REC because you had to cater for the number of quos in the REC meeting. So, even if a small, you had to make 11 copies of each document, and you had to submit those copies physically. But now with NRIMS, the application is online" (IDI 14, Researcher).

Additionally, NRIMS sped up the review process by allowing multiple reviewers to assess protocols simultaneously, reducing delays.

"And in terms of feedback, remember you've sent protocols. You have to wait for feedback. Someone tells you, I left the feedback in the protocols in my office. So, you do the run-arounds to, you know, submit protocols. You do the run-arounds to, and, uh, pick the, the comments. You know, you, send out invitation for meetings and all these people have to come physically. If they don't come physically, you have to cancel the meetings 'because you don't have quorum. But with online, there is a way people would actually, at least wherever they are, they would really find time and make sure that they attend the meetings, which actually facilitated at least the turnaround" (FGD 2, REC administrators).

4.5.2 Challenges with NRIMS

However, the transition to NRIMS was not without difficulties, especially in the early stages. Users experienced challenges such as system downtimes, slow responses, difficulty navigating the platform, and limited technical support.

4.5.2.1 Limited IT support and user training

Many REC members and researchers struggled with accessibility issues and centralized IT support, which made troubleshooting slow and inefficient.
"The other challenge is, okay, because we were working from home. You could not, you could not get first hand or prompt, prompt help, which you could, which you can get when you are at office" (KII 02, Regulator).
Some struggled to enrol in NRIMS and adapt to online reviews.

"Most of our members had not yet joined in the NRIMS. So, we had that challenge of our members are already called. They already called. So, they were used to this review of books and proposals and copies. So, it was really a big challenge for them to move their online review" (FGD 1, REC administrators).

The lack of immediate assistance meant that users often had to navigate technical issues on their own, causing further delays in research approvals.

Some of the glitches that NRIMS posed included several system errors and missing features that affected usability. For example, the search button did not work, making it difficult to retrieve previous submissions. Some researchers also reported that older protocols disappeared when new ones were uploaded, while others highlighted protocol numbering errors, which created inconsistencies in tracking submissions. Furthermore, the system was unstable, with frequent glitches disrupting workflow. Users also raised concerns about the system asking for information that was already in the protocol, making the submission process repetitive.

Beyond the transition difficulties, NRIMS was also data-

intensive, making participation expensive. As one REC administrator shared:

"Telling someone to start explaining their projects online, first of all, it was always data consuming, so that would be really hard for them" (FGD 2, REC administrators).

Similarly, virtual meetings, which were meant to ease the transition to NRIMS, were affected by connectivity issues, as noted:

"Sometimes you get interruption while the participants have difficulties with the internet and then goes off and forth. So, which, which, which is not the case if you were able to have face-to-face meetings" (IDI 22, REC Chairperson).

The lack of training on NRIMS functionality was another critical issue. Many REC members were expected to use the system without formal guidance, leading to difficulties in navigating it effectively.

"UNCST such sort of gave us a circular to the different RECs. And then now it was more or less individual initiative, you know, to go and get the details, regarding the implementation of these guidelines" (IDI 02, Researcher).

Without structured training, REC members and researchers had to learn through trial and error, which affected the quality and speed of reviews.

4.5.2.2 System overload and slow processing

System delays and overload issues further complicated the process. At times, NRIMS became overwhelmed by high traffic, causing inefficiencies that affected the turnaround time for research approvals.

"The turnover of the reviewing of protocols was a bit slower. it's a bit, a bit a bit slower because, maybe some people are talking about having internet problems instead of getting the protocol reviewed, and then somebody will feed back, uh, within a week. Uh, some were taking a bit longer and needed reminding. Those are the few challenges" (IDI 22, REC Chairperson).

The inefficiencies in the system meant that some protocols took longer to review than expected.

4.5.2.3 Lack of automatic notifications for researchers

Another major concern was the lack of system-generated notifications. Once a researcher was cleared, the system did not notify the REC, creating a gap in communication. Similarly, there was no acknowledgment message after submission, leaving researchers uncertain about whether their protocols had been successfully received. These missing features created confusion and inefficiencies in research oversight.

4.5.2.4 Challenges in coordinating multiple regulatory systems

Another key limitation of NRIMS was that it did not cater for joint reviews, meaning that different regulatory bodies could not review protocols simultaneously. This created additional delays, as researchers had to go through multiple approval processes separately. The inability of NRIMS to support collaborative reviews added another layer of inefficiency to an already complex system.

4.6 Opportunities brought by COVID-19

While the COVID-19 pandemic disrupted research processes, it also created several opportunities that improved the way research is conducted and regulated. These opportunities included the adoption of new operational methods, exposure to digital technology, increased collaboration, improved research visibility, and the introduction of new regulatory frameworks.

4.6.1 Exposure to new study designs

The pandemic also exposed researchers and RECs to new study designs, particularly those that could be conducted remotely. This expanded the scope of research methodologies and encouraged innovation in study implementation.

4.6.2 Increased funding for research

Another key opportunity was that regulatory bodies received bigger budgets, allowing them to strengthen their research oversight capacities.

"It facilitated regulators to have a bigger budget, which improved research regulation efforts" (IDI 07, REC Chairperson).

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This financial boost also allowed for more trainings and staff recruitment, helping institutions build capacity for handling research reviews more efficiently.

4.6.3 Improved visibility of research

COVID-19 also improved the visibility of research and research regulations, making policymakers and the general public more aware of the importance of research in responding to health crises. The awareness led to increased collaboration between researchers, regulators, and institutions.

Relatedly, the pandemic shifted researchers' perspectives on participant well-being, making them more aware of the need to cater for participants' safety and needs during studies. This contributed to a more human-centered approach in research design.

4.6.4 Development of joint review systems

Additionally, the joint review system became more common, enabling multiple regulatory bodies to review protocols together, reducing duplication and speeding up approvals.

4.6.5 Enhanced online research review processes

Another major improvement was the possibility of online reviews, which allowed research approvals to be processed faster. This led to a reduction in the number of hard copies of protocols submitted, cutting down on paperwork and making the process more efficient. The review process was also streamlined, ensuring that approvals were done more efficiently.

The shift to virtual engagement also had a positive impact on research quality, as it allowed for increased concentration during reviews and better feedback provision. Additionally, online meetings increased the attendance of members, making it easier for research ethics committees to meet quorum.

"The introduction of online meetings meant that more members could attend, even those who were previously unavailable" (FGD 2, REC administrators).

4.7 Recommendations for strengthening research regulations

4.7.1 Improving research online applications

While the online research application system has improved, efficiency in research submissions and reviews, several areas need enhancement to make the platform more user-friendly, reliable, and efficient. Users highlighted the need for system modifications, better communication, training, and improved functionality.

4.7.1.1 Enhancing NRIMS functionality (Automatic saving, dashboard, analytics, system integration)

Users recommended expanding NRIMS functionality to make it more versatile and efficient. This includes introducing a dashboard that provides an overview of submitted protocols, ongoing reviews, and system updates. Another critical improvement is the addition of an automatic saving function, which would prevent data loss when users experience internet disruptions.

"So if we can have a system where whatever you put, whatever type in that comment section mm-hmm. It can be automatically saved. Without you taking a step of saving some, because sometimes they're in the middle of the review and maybe Yeah. That runs out. You haven't saved, so you have to repeat. But if it is some way or automatic saving, whatever you are typing, it'll make me work, work better, easier" (IDI 18, REC chairperson).

They also suggested adding a provision where reviewers start with the protocol number to ensure easier tracking and organization of submissions. Additionally, the system should be improved to accommodate the support staff of Principal Investigators, allowing research teams to engage in the process more effectively.

To enhance feedback and communication, participants recommended ensuring that the system includes feedback from UNCST and provides information on protocol amendments submitted. Furthermore, there should be a section specifically for students to cater to their unique research needs. Similarly, a section on progress reports should be introduced to help track research milestones.

Another major concern was system reliability, with calls to ensure that the system is active at all times and to introduce a backup system to prevent data loss.

Moreover, data safety should be improved as well to enhance security and confidentiality.

"…but the system is usually on and off, I don't know if they can, and usually when you try to relay the complaints to the officer in charge here, Uganda National Council, it seems it also has to address them to someone else. It seems the system has never developed from in-house" (KII 01, Regulator).

Users also suggested creating links with tutorials on how to navigate the system to help new users familiarize themselves with the platform. Similarly, continuous training should be provided to users, ensuring that they can operate the system efficiently.

To address technical and operational inefficiencies, participants emphasized dealing with double entries and resolving the issue of pending submissions by the same researcher. Additionally, reminder messages should be sent to reviewers to prompt them to review protocols on time.

Another important recommendation was to make the system available as a mobile app, allowing users to access and operate it more conveniently. Alongside this, participants emphasized the importance of online stamping, recommending that a provision be include for digitally stamping documents.

To enhance user experience, users suggested that the system should have a hybrid option, allowing it to operate both online and offline. This would improve accessibility, especially in areas with unstable internet connections.

In addition, the concern of lack of a coordinated research regulatory system, leading to inefficiencies and delays. Participants recommended establishing a one-stop center for all regulators to streamline processes and eliminate redundancy.

"What we probably need is a one stop center where, you know I come here and then I don't need to go elsewhere: (IDI 04, REC Chairperson).
NRIMS should be merged with existing research systems to create a more unified and efficient platform.

Lastly, there was a call for standby systems to review protocols in times of emergencies, ensuring that important public health research is not delayed during crises.

"we need to have, uh, a system in place, even from the regulatory world, which is like on standby o, which makes it very easy for someone to, or for these protocols to be reviewed very quickly, uh, that are coming in. I know we tried it, but it was a bit when COVID was, coming. So, we have a standby system" (IDI 17, Researcher).

4.7.1.2 Providing regular training and user support

Participants also stressed the importance of training and capacity building, particularly in public health research and online research submissions. There was a need to train community stakeholders on public health research issues, ensuring they understand the ethical requirements and implications of research conducted in their communities.

"We probably need the ongoing support in terms of when they support their administrators. But I think also the users need to be refreshed. And I think the system's getting more accessories. What do I mean? There are more you can do with it. So, we need to be walked through it on a regular basis. Like a refresh or something., Yes" (IDI 05, Researcher).

"They REC they should really put up a training workshops. To take through people what their business is. There is one team that does it very well. When you're going to do research related to people, there teams that take you through medical ethics." (IDI 16, Researcher).

Furthermore, participants called on UNCST to provide training for universities and researchers on online submissions, to ensure that all stakeholders can effectively use the system.

"UNCST should plan to train different universities and researchers on online submission" (FGD 1, REC administrators).

4.7.1.3 Offering internet bundles for RECs

Another challenge faced by many RECs was the high cost of internet, which limited system access. To address this, participants recommended providing internet bundles to RECs to facilitate engagement with NRIMS.

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4.7.2 Sustaining opportunities from COVID-19

4.7.2.1 Continuous capacity building for researchers and regulators

A key strategy for sustaining these opportunities is continuous capacity building for researchers, regulatory bodies, and RECs. Many participants emphasized the need for ongoing training and skills development to ensure that stakeholders remain well-equipped to handle evolving research challenges.

"We need continuous capacity building to ensure that the skills gained during COVID-19 are not lost" (IDI 03, REC Chairperson).

This includes regular refresher courses on digital research tools, online protocol reviews, and updated ethical guidelines to strengthen research oversight and efficiency. The shift to online research submissions and reviews was a major adaptation during the pandemic and ensuring that all stakeholders are comfortable with digital systems is essential for long-term success.

4.7.2.2 Improving research guidelines and regulatory oversight

Several participants emphasized the need to improve research guidelines and regulatory oversight. One key recommendation was for UNCST to develop research guidelines before pandemics rather than during crises, to ensure a proactive approach. There was also a call for clear guidance on the clearance of researchers using medical devices, as current guidelines were seen as insufficient.

To enhance compliance, participants suggested joint monitoring with UNCST, believing that collaboration would strengthen enforcement and improve research integrity.

"Joint monitoring with UNCST will improve adherence to research ethics and increase accountability" (FGD 1, REC administrators).

4.7.2.3 Resource mobilization to maintain digital research systems

Sustaining the improvements made during COVID-19 also requires strong resource mobilization efforts to ensure that RECs and regulatory bodies have adequate funding and infrastructure.

"We need to mobilize resources to support the sustainability of online research systems and digital tools" (IDI 18, REC chairperson).

Investing in modern technology, reliable internet access, and system upgrades will allow research oversight bodies to maintain and expand the digital tools adopted during the pandemic. Additionally, participants stressed the importance of government and donor funding to support research institutions and ethical review processes.

"We need increased government funding to support research and oversight bodies" (KII 02, Regulator).

Participants also proposed setting aside a side budget for emergencies to ensure that research activities remain uninterrupted during crises.

"There should be a side budget for emergencies to ensure continuous research activities" (IDI 25, REC Chairperson).

The high cost of research fees for local researchers was also a major concern, with calls to reduce these fees to encourage more local participation in critical studies.

"We still have researchers who struggle with these. And, and I don't know if the regulator, 'cause you guys charge, what, 300 for a research review at the UNCST s not review, but registration at UNCST s registration. So about 300 or 400 I think. but the researcher will also have paid another. it means that we are not encouraging research that is locally developed, locally supported, because local support is not too much" (IDI 04, REC Chairperson).

4.7.3 Strategies to mitigate NRIMS challenges

Although the NRIMS has improved research oversight, users have identified several challenges that hinder its effectiveness. To address these issues, stakeholders proposed various strategies, including system enhancements, improved user support, and expanded functionality to make the platform more efficient and user-friendly.

4.7.3.1 Consulting users before system upgrades

A key recommendation was to consult potential users before making system changes, this will help implement modifications that address actual user needs.

4.7.3.2 Decentralizing IT support

Additionally, decentralizing IT support was seen as critical for improving troubleshooting and response times.

"It seems the system has never developed from in-house. So, if a researcher a complains that this protocol is this, then now you tell this its person that this, this person has a challenge. So now he asks you what is the reference for the study? So, he addresses the issue of that researcher not really addressing it in the system. Saying again, another time another researcher calls this. And again, you give them the reference so that person works on that person. So, I, I think me, in future, I would want them to maybe bit develop a capacity in house in the institution to have the system develop here, run from here, but also have a full-time administrator assigned to it (KII 01, Regulator).

4.7.3.3 Providing step-by-step tutorials for new users

To help users navigate NRIMS effectively, participants recommended offering refresher trainings and step-by-step instructional videos. Similarly, a step-by-step video tutorial should be created to provide clear instructions on how to use the system. Relatedly, participants also urged UNCST to simplify the guide for using NRIMS, making it easier for researchers and REC members to navigate the system.

4.7.3.4 Maintaining hybrid submission processes

There was a call to introduce online stamping of documents within NRIMS, as well as ensuring that physical submissions are not entirely phased out to accommodate researchers who may struggles with the online system.

4.7.4 Support provided by UNCST for NRIMS use

The UNCST played a crucial role in supporting the adoption and use of the NRIMS. This support was provided in three key areas: guidance and training, provision of laptops, and provision of data bundles to some RECs.

4.7.4.1 Training researchers and REC administrators

To help users navigate the system, UNCST provided guidance and training on how to use NRIMS, ensuring that RECs and researchers could effectively submit and review protocols online. This training was essential, especially for users who were initially unfamiliar with digital research submissions.

"…so we did lots of training, different courses. Yeah. That's how UNCST helped us. And, uh, we always call Collins. Most of the times he's the IT operator, the other side. So, he helps a lot whenever, whenever, anytime, anywhere" (FGD 2, REC administrators).

4.7.4.2 Provision of Laptops and internet bundles to support online research activities

In addition to training, UNCST provided laptops to REC direct administrators to facilitate their work in reviewing and processing research protocols. This support was particularly important in ensuring that RECs could operate efficiently without technological barriers.

Recognizing the high cost of internet access, UNCST also provided data bundles to some RECs to enable them to use the online system. This helped reduce financial constraints for RECs that struggled with internet costs, allowing them to engage more effectively with NRIMS.

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CHAPTER FIVE: DISCUSSION

The findings of this study bring to light the realities that researchers and regulators in Uganda faced during the COVID-19 pandemic. While research guidelines were put in place to facilitate research continuity, they also came with some challenges that affected study execution, ethical oversight, and researcher well-being. The discussion below reveals these findings in relation to existing literature, highlighting how Uganda researchers' experiences align or differ from those in other African and global contexts.

5.1 Facilitators of research conduct during COVID-19

One of the major enablers of research during the pandemic was the establishment of research guidelines tailored to the demands of the crisis. Similar to our findings, which showed that research guidelines facilitated streamlined protocol reviews and enhanced collaboration among regulatory bodies, it was documented that these guidelines in Uganda provided clear directives on ethical research conduct and expedited review processes, which aligns with findings from (Muwanguzi *et al.*, 2021), who noted that structured guidelines helped sustain HIV clinical trials in the country. However, some researchers argue that while rapid approvals were necessary, they may have compromised the thoroughness of ethical reviews (London & Kimmelman, 2020).

Digital transformation played a pivotal role in keeping research moving forward, as online platforms enabled remote protocol submissions and virtual engagement between researchers and ethics committees (Muwanguzi *et al.*, 2021). Ugandan researchers found that shifting to online systems improved efficiency, a sentiment echoed by (Nabukenya *et al.*, 2022), who documented the benefits of Uganda's Regulatory Affairs Information System in strengthening research compliance. In contrast, studies in high-income countries like Germany and the United States report that transitioning to digital systems introduced new concerns about cybersecurity and researcher accessibility (Archard *et al.*, 2020).

5.2 Barriers to research conduct

Despite these facilitators, Ugandan researchers encountered multiple challenges. The shift to digital platforms, while necessary, posed difficulties, especially for REC members who were accustomed to physical meetings. Poor internet connectivity further delayed reviews and increased frustrations among researchers and ethics reviewers alike (Nabukenya *et al.*, 2022). Similar connectivity issues were reported in Ghana and Nigeria, where researchers also struggled with unreliable digital infrastructure (Owusu *et al.*, 2022). However, in European contexts, institutions had pre-existing digital infrastructure, reducing the severity of these disruptions (Shekhani *et al.*, 2021).

Financial burdens were another significant challenge, with researchers having to adjust budgets to accommodate new expenses such as personal protective equipment and internet costs (Ma *et al.*, 2020). Ugandan researchers noted that limited funding hindered their ability to adapt, a finding also reported by (Almeharish *et al.*, 2020) in Saudi Arabia. However, in some European countries, governments increased funding to support research adaptation, demonstrating different policy responses across regions (Aristei *et al.*, 2022).

A lack of clear communication on evolving guidelines also left many Ugandan researchers struggling to comply, leading to delays and misunderstandings (Palmero *et al.*, 2021). This was also observed in Uganda, where some researchers were unaware of updated protocols, further complicating compliance (Ainembabazi *et al.*, 2021). However, in some Asian settings, such as China and South Korea, structured government-led communication strategies helped mitigate such challenges (Ma *et al.*, 2020).

5.3 Impact of COVID-19 on research regulation and oversight

The pandemic led to significant changes in Uganda's research regulatory environment. Expedited reviews facilitated quick approvals for COVID-19 related studies, but the increased volume of protocols placed immense pressure on RECs. This aligns with findings from (Ainembabazi *et al.*, 2021), who noted that the

surge in research applications overwhelmed Ugandan ethics committees. Similarly, (Faust *et al.*, 2021) report that German ethics committees struggled with balancing rapid decision-making and maintaining rigorous ethical standards.

Limited oversight due to movement restrictions also created gaps in ensuring compliance with ethical guidelines. Ugandan REC members could not conduct routine site visits, increasing the risk of research integrity issues (Silaigwana & Wassenaar, 2019). However, some researchers argue that alternative oversight strategies, such as mandatory video recordings of key study activities, provided an effective means of ensuring compliance even in the absence of physical monitoring (Ganguli & Sethi, 2016). This suggests that while Uganda faced challenges, alternative regulatory measures used in other regions may provide useful lessons.

The pandemic further highlighted the vulnerability of regulatory processes to external shocks, reinforcing the need for pre-established contingency plans for research oversight during crises (Archard *et al.*, 2020). The Pan American Health Organization (2022) similarly emphasizes that preparedness measures should be in place to ensure research continuity during future public health emergencies.

5.4 Coping strategies adopted by researchers and regulators

Ugandan researchers and regulatory bodies adopted various coping strategies. Passive monitoring of studies through researcher-submitted progress reports replaced physical site visits, allowing oversight to continue remotely. This was also noted by (Hashem *et al.*, 2020) in their study of regulatory adaptations during the pandemic. However, (Ford *et al.*, 2021) argue that passive monitoring alone is insufficient and may fail to detect ethical violations, particularly in high-risk studies.

Researchers also adapted by shifting to online consent processes and modifying study methodologies to align with movement restrictions (Muwanguzi *et al.*, 2021). While this ensured research continuity, Ugandan researchers expressed concerns about whether virtual consent processes adequately captured participants' understanding, similar to concerns raised in (Lennon *et al.*, 2022). In contrast, some studies from high-income settings suggest that digital consent methods were well-accepted due to higher digital literacy (Shekhani *et al.*, 2021).

Joint reviews among RECs and regulatory bodies also played a role in streamlining approvals, reducing redundancies, and ensuring efficiency in protocol assessment (Faust *et al.*, 2021). Additionally, some institutions provided data support to their staff, recognizing the financial burden of internet costs (Ario *et al.*, 2023). However, (Shekhani *et al.*, 2021) note that multi-agency involvement in reviews sometimes prolonged approval timelines due to bureaucratic inefficiencies.

5.5 Lessons for future research regulations

The COVID-19 experience offers valuable lessons for strengthening research oversight in Uganda. First, regulatory bodies must invest in digital literacy training to ensure that researchers and REC members are well-equipped to navigate online research processes. Secondly, developing a centralized, well-communicated framework for emergency research guidelines can help mitigate compliance challenges in future crises.

Another critical lesson is the need for sustained funding for research oversight. The financial constraints experienced by both researchers and regulators during the pandemic highlight the need for dedicated emergency response funds to support research continuity in times of crises. Lastly, maintaining hybrid oversight mechanisms, where both online and physical reviews can take place, will enhance flexibility in research regulations.

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CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusions

This study aimed to assess the facilitators, barriers, and impacts of conducting research in Uganda during COVID-19 pandemic, focusing on the regulatory and ethical oversight aspects. Based on the findings, the following conclusions are drawn:

Facilitators of research conduct during the COVID-19 pandemic

The establishment of structured research guidelines was a critical facilitator in enabling the continuation of research during the COVID-19 pandemic. These guidelines not only streamlined protocol reviews but also facilitated collaboration among regulatory bodies, ensuring that research could continue, albeit with adjustments. The adoption of digital platforms for protocol submissions and virtual meetings also significantly contributed to the efficiency of research conduct, despite challenges in access and infrastructure.]

Barriers to research conduct during the COVID-19 pandemic

The study found that poor digital infrastructure, especially in terms of internet connectivity, posed a significant barrier to research conduct in Uganda. This was particularly challenging for ethics committees that were unaccustomed to conducting reviews via digital platforms. Additionally, financial constraints, lack of clear communication about evolving guidelines, and limited support for researchers further hindered the effective execution of studies during the pandemic.

Impact of the COVID-19 pandemic on research regulation and oversight

The COVID-19 pandemic placed immense pressure on Uganda's research regulatory bodies, particularly ethics review committees, which were overwhelmed by a surge in research applications. Although expedited reviews helped maintain research continuity, the lack of in-person oversight due to movement restrictions created gaps in ensuring compliance with ethical standards. However, the introduction of alternative oversight measures, such as passive monitoring and virtual consent, provided interim solutions to maintain regulatory standards.

Coping strategies adopted by researchers and regulatory bodies

Researchers and regulatory bodies in Uganda adopted various coping strategies to mitigate the challenges posed by the pandemic. These strategies included shifting to online consent processes, using virtual meetings for protocol reviews, and conducting passive monitoring of ongoing studies. Despite these efforts, concerns about the adequacy of these strategies especially in terms of ensuring participants' understanding and preventing ethical violations, remained a notable issue.

Lessons for strengthening research regulations in Uganda

The study highlighted critical lessons for strengthening research oversight in Uganda, including the need for better digital infrastructure, clearer communication channels, and sustained funding for research activities during crises. These lessons provide a foundation for improving research regulatory frameworks in Uganda and ensuring that research can continue effectively even in the face of unforeseen disruptions like pandemics.

6.2 Recommendations

6.2.1 For policy

1. **Create a clear plan for research during emergencies**

   Government and policy-makers should develop a well-organized plan that guides how research should continue during emergencies like pandemics. This plan should include rules for ethics review, quick funding options, and faster approval processes. This is to mainly for helping researchers continue their work smoothly even when normal operations are disrupted.

2. **Clear and timely communication of guidelines**

   The regulatory bodies should improve communication regarding evolving guidelines and protocols. Establishing centralized communication platforms where researchers can access up-to-date information and clarify doubts will reduce confusion and compliance challenges, especially during emergencies.

3. **Investment in digital infrastructure**

   Investment in digital infrastructure should be prioritized to ensure reliable internet connectivity to facilitate research activities. This will improve access to digital platforms for researchers, ethics committees, and participants, enabling more efficient communication and review processes.

4. **Funding mechanisms for research during crisis**

   Government bodies and funding agencies should create emergency funds dedicated to supporting research activities during crises. These funds should cover additional costs which are often necessary during pandemics but are not always accounted for in regular research budgets.

6.2.2 For practice

1. **Capacity building for digital research tools**

   Institutions and regulatory bodies should invest in training researchers and ethics committee members on digital platforms for submitting protocols, conducting reviews, and managing research remotely. This will enhance the ability of all stakeholders to adapt to digital systems efficiently and with confidence, ensuring a smoother transition during times of crisis.

2. **Implementation of hybrid monitoring systems**

   Given the limitations of remote monitoring, researchers and ethics committees should adopt hybrid monitoring systems, combining virtual and physical site visits. This will allow for more flexibility in oversight and ensure that compliance with ethical standards is maintained, even when in-person visits are not feasible.

3. **Alternative consent models**

   Researchers should consider exploring and implementing more secure and effective online or virtual consent methods. While the transition to digital consent was necessary during the pandemic, efforts should be made to ensure that these methods are fully understood by participants. Training for researchers on digital consent will be essential in improving comprehension and ensuring ethical compliance.

4. **Regular feedback and review**

   Ongoing feedback and reviews should be incorporated into the research process, particularly when using alternative or digital methods for conducting studies. This will help to identify potential issues early and ensure continuous improvement in research processes and ethical oversight.

6.2.3 Areas for further research

1. **Assessing the quality of ethical oversight in research managed through digital platforms**

   Future research should explore the effectiveness and quality of ethical oversight for research protocols managed entirely or partially through digital platforms. This includes examining how the transition to online systems for protocol submission, review, and approval has affected the rigor of ethical evaluations. Specifically, research should investigate whether digital platforms provide sufficient mechanisms to ensure compliance with ethical standards, especially in areas such as informed consent, confidentiality, and participant safety.

2. **Impact of digital platforms on informed consent and participant understanding**

   One area of concern is the adequacy of digital consent processes. Research could focus on

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how digital consent platforms ensure that participants fully understand the study, its risks, and their rights, especially in settings with low digital literacy. This research should investigate how digital platforms can be improved to capture the nuances of informed consent in a way that is culturally appropriate and accessible to all participants, including those in rural or underserved areas. It will also be important to evaluate the ability of these platforms to effectively communicate complex ethical considerations to participants.

3. **Evaluating the role of digital platform in maintain data integrity and confidentiality**

   As digital platforms are increasingly used for managing research protocols and participant data, ensuring data integrity and confidentiality is paramount. Further research should examine the effectiveness of digital tools used by the researchers and regulators in safeguarding research data. This research could evaluate the security measures embedded in these platforms to prevent breaches of confidentiality and to ensure that data is stored, transferred, and accessed in compliance with ethical and regulatory standards. Insights from this research could guide the regulators in refining digital systems to mitigate the risks associated with data security in a rapidly evolving digital landscape.

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This project has received funding from the European Union's Horizon Europe under GA No 101103296. This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

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This project has received funding from the European Union's Horizon Europe under GA No 101103296. This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

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