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UNIVERSITY OF GHANA

COLLEGE OF HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

ASSESSMENT OF THE ETHICAL STANDARDS FOR RESEARCH WITH HUMAN PARTICIPANTS DURING THE COVID-19 PANDEMIC IN GHANA

BY

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Declaration

I, Angelina Cyendy Sena Adorkor, do hereby declare that except for other scholarly works, which have been duly acknowledged, the materials contained in this thesis are my original efforts and that I have not submitted this work, either in part or in whole, for the award of any degree elsewhere.

Angelina Cyendy Sena Adorkor	.....	31st August, 2022
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Abstract

Introduction: Ethical standards are important for promoting research goals and protecting human research participants from the risks associated with research. During public health emergencies such as the recent COVID-19 pandemic, adhering to ethical standards and procedures that inform the review and implementation of research presents important challenges. The main objective of this study was to assess the ethical standards for research involving human participants and the challenges faced by both researchers and ethics review committees in their work during the COVID-19 pandemic in Ghana.

Methods: This study employed a concurrent mixed-methods design involving qualitative interviews with Chairpersons and Administrators of Six (6) research ethics committees and a survey of 360 researchers across Ghana. Guided by the study's objectives, the qualitative data were analyzed using thematic content analysis, while the quantitative data were analysed using SPSS, where frequency tables and figures were generated.

Results: The study revealed that before the COVID-19 pandemic in 2020, IRB/RECs in Ghana held face-to-face meetings regularly and received protocols manually. However, IRB/REC operations were affected by the COVID-19 restrictions, which necessitated a transition to virtual meetings. Some IRB/RECs collaborated with other regulatory authorities, such as the Food and Drugs Authority, to streamline the ethics and regulatory review process. This included the introduction of online submissions and accelerated reviews for COVID-19-related protocols. While most of the ethics standards for research, such as informed consent, were followed strictly by researchers during the pandemic, there were challenges with implementing some research activities under COVID-19 restrictions. IRB/RECs also experienced challenges during the review process, including poor internet connectivity, the

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workload during review meetings, protocol approval delays, inability to meet schedules and timelines, absenteeism, and inadequate funding.

Conclusion: Ethical standards and procedures for research with human participants were followed by IRB/RECs and researchers during the COVID-19 pandemic. This study has highlighted important ethical challenges experienced by IRB/RECs and researchers in the review and implementation of research during the COVID-19 pandemic. There is a need to anticipate these challenges and identify innovative ways of addressing them in future pandemics to protect research participants and promote the ethical conduct of research in Ghana and beyond.

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Dedication

This thesis is dedicated to the Almighty God for His continued guidance throughout the programme, to my parents Mr. and Mrs. Adorkor, My husband, Mr. Emmanuel Appiah-Kubi, and my children, Emefa, Twumwaa, Eyram, Boakyewaa, and Nana Kwadwo. Finally, to my siblings Mercy and Cosmos for their unflinching support.

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CHAPTER ONE

INTRODUCTION

1.1 Introduction

This chapter presents a general overview of the current study, which seeks to investigate the ethical standards for research during the COVID-19 pandemic in Ghana, based on the perspectives of researchers and members of research ethics committees. Accordingly, the research background and the research problem statement are highlighted. Further, the chapter outlines the research aim and objectives, research questions, significance of the research, research scope, structure of the research, and summary of the chapter.

1.2 Background

In December 2019, the novel coronavirus SARS-CoV-2 disease (COVID-19) which was initially reported in Wuhan, China, quickly spread across the globe, infecting 48,539,872 people, and causing 1,232,791 deaths in 215 countries as at the year 2020 (World Health Organization, 2020). Since the year 2020, COVID-19 has caused widespread health challenges and socio-economic instability worldwide. The pandemic also heightened the important role of research and different types of candidate vaccines and therapeutics have been evaluated and/or are under clinical trials against the COVID-19 disease. Research involving human participants plays a vital role in advancing scientific knowledge and improving healthcare outcomes. The ethical considerations surrounding such research are of high importance to ensure the safety, respect, and justice of research participants. However, conducting ethical research presents key challenges, particularly during global health emergencies, such as the recent COVID-19 pandemic.

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The World Health Organization states that in order to produce high-quality research outcomes, researchers must abide by universal principles and guidelines known as ethical standards of research (Organization, 2020). Ethical standards are critical in research because they provide the framework for protecting the rights and well-being of research participants and promote the scientific and ethical merits of research (Fouka and Mantzorou, 2011). In response to the unethical use of human subjects in World War II, the World Medical Association (WMA) established the Declaration of Helsinki in 1964. Inspired by the Nuremberg Code, the Declaration aimed to safeguard the rights and welfare of human subjects involved in medical research. The Declaration serves as a blueprint for promoting the highest moral standards in studies involving human subjects. It guarantees the protection of participants' rights and welfare by placing a strong emphasis on the values of safety, respect, and fairness. Compliance with the Declaration fosters trust in the research community and facilitates the advancement of knowledge while upholding ethical responsibilities toward those who contribute to scientific progress. Continued adherence to the Declaration's principles is crucial for maintaining public trust in research and safeguarding the well-being of human participants. Further, ethical standards provide the benchmark against which common research language, characteristics, and outcomes are established by research ethics committees (Organization, 2020). They also allow researchers to determine and eliminate potential risks and dangers to guarantee voluntary participation (Akaranga and Makau, 2016).

One important aspect of conducting research is the key role of Research Ethics Committees and Institutional Review Boards (REC/IRBs). The history of IRBs reflects a growing recognition of the importance of protecting human subjects in research and ensuring the ethical conduct of research. They have evolved as essential entities to review and oversee research, aiming to safeguard participant rights, minimize harm, and uphold ethical principles

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in scientific investigations (Arunachalam et al., 2021). Historically, REC/IRBs have faced challenges in the discharge of their duties. Workload and a lack of experience with some of the novel scientific approaches are some of these difficulties that have been highlighted in the literature (Kass et al., 2007; Boateng 2019). Several articles have also documented the challenges with ethics review processes during global health emergencies such as the Ebola Epidemic in 2014 (Hunt et al., 2016; Saxena et al., 2019). But under COVID-19 restrictions, these specific ethical issues are amplified, new ethical issues require innovative mitigation measures, whereas the safety of both researchers and participants must be guaranteed. From this foundation, researchers are expected to anticipate the ethical and social consequences of the pandemic on the processes and procedures of conducting research.

To proceed with the current study, there is a need to specify working definitions for key concepts such as ethical standards, REC, and researchers. Kruger et al. (2014) define REC as a group of persons with the appropriate competencies and authorizations to review and approve research involving human participants. REC could also refer to a panel that reviews the methods proposed for research to guarantee strict adherence to research values and moral principles (Boateng, 2019). For this study, REC is defined as a recognized institution authorized to appraise the ethical virtues of research and protect the safety, anonymity, confidentiality, privacy, and security of research participants and the public in general. RECs play a significant role in the conduct of research because they ensure the scientific integrity of work, trust, accountability, mutual respect, and fairness (Ghana Health Service Ethics Review Committee, 2015). Apart from sanctioning approval for various research activities, REC also provides consistent monitoring, appraisal, resolution, accountability, and quality assurance at all stages of the research process (Agha et al., 2007).

Ethical standards can be likened to the principles and processes that guide the implementation of research (Boaz and Ashby, 2003). They are offer researchers guidelines to enable them to

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conduct and publish responsible research (Gajjar, 2013). In this study, the World Health Organization's definition of ethical standards would be observed as a working definition.

Kothari, 2004 defines researchers as a group of scholars who follow scientific and systematic approaches in search of information, truth, and new facts in any branch of knowledge. These scholars conduct a careful investigation or inquiry to find a solution to a problem (Kothari, 2004). So, in effect, researchers are intellectuals who conduct theoretical, systematic, or empirical research.

From the aforementioned definitions, it can be concluded that universal principles and the gatekeeping role of RECs, create the enabling environment for researchers to create knowledge through the outcome of theoretical, systematic, or empirical research. This will ensure that the process of contributing to the existing stock of knowledge has been accomplished by protecting the safety, anonymity, confidentiality, privacy, and security of participants.

Determining the effect of COVID-19 on research is consequently difficult for Ghana's numerous RECs and researchers. It is extremely challenging for anyone or any organisation to predict how long the pandemic's effects would last. But given the important role of research, there is the need to continue implementing research projects to generate the right evidence for policy-decision making. However, there are still concerns about how such research can be carried out ethically under COVID-19 constraints. Similarly, although RECs, researchers, and project managers struggle to navigate ethical problems related to COVID-19, the integrity of all research and academic projects must be upheld. Therefore, it is highly desirable to conduct a study to evaluate the ethical requirements for research involving human subjects at COVID-19 in Ghana.

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1.3 Problem Statement

COVID-19 has caused widespread health challenges and socio-economic instability worldwide for more than a year. As at the time of conducting this research, there was no definite line of treatment that has been approved, however, different types of potential vaccines and therapeutics have been evaluated and/or are under clinical trials against COVID-19 (Khan, 2020). COVID-19 has caused widespread health challenges and socio-economic instability worldwide for more than a year. The important role of research during disease outbreaks and pandemics in particular cannot be overemphasised (Wright et al., 2020). However, the COVID-19 pandemic altered the daily life to the extent that research had to be conducted within the confines of COVID-19 safety protocols. Ethical standards such as informed consent, non-maleficence (do no harm), respect for anonymity and confidentiality, transparency, security, and respect for privacy; underpin the conduct of any research. The above assertion is premised on the assumption of conducting research during 'normal times. However, in times of a global pandemic such as COVID-19, crucial ethical issues, conflicting values, and lack of clarity on ethical standards, among others, are raised and may consequently affect the outcome of any research. Fortunately, in 2016, the WHO provided authoritative guidance on conducting ethical research during emergencies. This action resulted from experiences dealing with the severe acute respiratory syndrome (SARS) outbreak, the 2009-2010 H1N1 influenza pandemic, and the Ebola Epidemic between 2014 and 2016. The Nuffield Council on Bioethics also developed a set of recommendations on how research should be conducted during global health emergencies (Wright et al., 2020). However, there is paucity of data on how various research institutions and RECs are navigating the complexities involved in the conduct and review of research involving human participants during the COVID-19 pandemic.

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In Ghana, ethical standards that all researchers must follow in the conduct of research during a public health emergency such as COVID-19 were limited at the beginning of the pandemic. Each of the RECs designed separate ethical standards that govern the conduct of research under COVID-19 restrictions rather than a common ethical standard for all RECs in Ghana. Anecdotal reports have suggested that researchers have encountered serious challenges, particularly in recruiting participants in the context of the COVID-19 restrictions. There is a need to design and implement specific national ethical policies to guide Ghanaian researchers to guarantee privacy, transparency, confidentiality, anonymity, and security. Moreover, national and institutional requirements for conducting research under COVID-19 are not readily available, whereas the processes and steps governing informed consent, protection of participants' safety, and the associated challenges of conducting research under COVID-19 restrictions have not been standardized in Ghana. Given the abovementioned problem, this study aimed to assess the ethical standards for research with human participants during the COVID-19 pandemic in Ghana and to identify key recommendations that can inform the review and implementation of research in future pandemics.

1.4 Research Questions

The research questions to be addressed in this study are as follows:

1. What are the current policies and requirements for conducting research during the COVID-19 pandemic in Ghana?
2. How do researchers obtain informed consent under COVID-19 restrictions?
3. What steps do researchers take to ensure the safety of study participants during the pandemic?
4. What are the challenges of conducting research under COVID-19 restrictions?

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1.5 General and Specific Objectives

1.5.1 General Objective

The main objective was to examine the perspectives of researchers and members of research ethics committees on the ethical standards for conducting research during the COVID-19 pandemic in Ghana.

1.5.2 Specific Objectives

The study addressed the following specific objectives:

1. To examine the ethics review processes for research before and during the outbreak of the COVID-19 pandemic in Ghana.
2. To examine informed consent processes in research during the COVID-19 pandemic.
3. To examine the steps taken by researchers to protect participants' safety during research.
4. To explore the perspectives of researchers and members of research ethics committees on the challenges of conducting research under COVID-19 restrictions.

1.6 Justification of the study

Research is conducted to generate new information to inform policies and practices. This means that any research outcomes should contribute to the existing stock of knowledge. Hence, RECs, researchers, research participants, and the Ghanaian public stand to benefit from the outcomes of this study. Specifically, the outcome of this study will clarify the ethical issues governing research in Ghana under the COVID-19 restrictions. Furthermore, all the crucial ethical issues and conflicting values raised will be addressed by the suggested recommendations of this study. Also, the study's outcome will reliably inform researchers about reallocating research resources, participants, facilities, and equipment.

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In academia, a study's findings will become a source of reference for future studies. Consequently, the study's outcome would contribute to the body of knowledge in the area of Ghanaian ethical standards for any research conducted during a pandemic such as COVID-19. Lastly, this study will contribute to the literature on ethical standards and RECs' formation, composition, and responsibilities and the measures that should be put in place to facilitate the ethical conduct of research during pandemics.

1.7 Outline of the Thesis

The study is organized into six chapters as follows. Chapter One presents an overview of the study and provides a background to the general area of research. In addition, the statement of the research problem, research aims, and objectives, together with research questions, have been clearly stated in this chapter. Chapter One also highlights the significance of conducting the research, the research scope, and the research report's structure. Chapter two focused on a review of relevant literature which captures the written contributions, discussions, analyses, and findings in the research area regarding ethical standards and RECs. This chapter has therefore presented summaries of the existing theoretical and empirical literature on ethical standards related to the formation, composition, and procedures of RECs. Chapter three presents the study's methodology, highlighting areas such as the research design, approach, and setting; target population and sampling technique; sources of data, collection, and analysis. Chapter Four presents the key findings of the research. Appropriately, tables and graphs were used to organize the work coherently. Chapter 5 discusses the key findings of relevant literature. Finally, chapter six presents the research's summary, conclusions, and recommendations.

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1.8 Summary of Introduction

The preceding chapter has set the stage for the commencement of the study, following the specification of the aim, objectives, and research questions. Additional guidance regarding the research scope and structure of the thesis have been clearly defined. It is now certain that the outcome of this study has played a significant role in setting the record straight regarding the ethical standards required for conducting research during the COVID-19 pandemic or any emergencies in Ghana.

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CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of literature relating to ethical standards for conducting research during the COVID-19 pandemic. The chapter is therefore organized under the thematic areas as follows: global ethical standards for conducting research during the COVID-19 pandemic, informed consent processes in research during COVID-19, steps taken by researchers to protect participants' safety during research, research challenges under COVID-19 restrictions, an overview of research ethics committees in Ghana, and current requirements for conducting research under COVID-19 pandemic in Ghana.

2.2 A Historical Perspective of the Emergence of IRB/RECs

Institutional Review Boards (IRBs), also known as Research Ethics Committees in some countries, have a history shaped by several landmark events and ethical controversies which led to the development of IRB Regulations in the 1960s and 1970s, when countries started implementing regulations and guidelines for the protection of human research subjects. In the United States, the National Research Act (1974) led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, which produced the Belmont Report. This report laid the groundwork for the establishment of IRBs as the key oversight bodies for human subjects' research (Cassell, 2000).

The Belmont Report, the Tuskegee Study, and the Helsinki Declaration are all significant trials that have had a profound impact on the field of medical ethics and research practices which are the fundamentals for the emergence of Institutional Review Boards (Buxtun et al.,

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1972; "The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research," 1979; World Medical Association, 2013).

The Tuskegee Syphilis Study was a notorious case of unethical research that occurred from 1932 to 1972. It involved the mistreatment and exploitation of African American men who were not informed about the nature of the study or given appropriate treatment for syphilis. The Tuskegee Study exposed the grave violations of ethical principles and human rights in research. Therefore, in the late 1960s, concerns regarding the ethical treatment of human subjects in research led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in the United States. The Tuskegee Study played a significant role in raising awareness about the mistreatment of human subjects and highlighting the need for ethical guidelines. It was one of the key events that contributed to the formation of the National Commission and the subsequent development of the Belmont Report giving way to a commission that was tasked with addressing ethical issues in research and produced the Belmont Report in 1979.

The Belmont Report set forth fundamental ethical principles for the protection of human subjects involved in research: respect for persons (autonomy and informed consent), beneficence (maximizing benefits and minimizing harm), and justice (fairness in the selection of research subjects). The Belmont Report, in turn, served as a crucial document that consolidated ethical principles and provided a framework for the protection of human subjects in research. It has influenced research regulations and guidelines not only in the United States but also internationally.

The Helsinki Declaration, issued by the World Medical Association in 1964, provides ethical guidelines for medical research involving human subjects. It outlines principles such as informed consent, protection of vulnerable populations, and ethical review by independent

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committees. The declaration has been revised multiple times, with the most recent version being the Helsinki Declaration of 2013.

The Helsinki Declaration, although distinct from the Belmont Report, shares a common goal of ensuring the ethical conduct of research involving human subjects. It has provided an important international framework for ethical guidelines and has been influenced by similar historical events and concerns regarding the mistreatment of human subjects. These reports have their unique context and significance in the emergence of the formation of IRBs. They are interconnected in their mission to safeguard the rights and well-being of human subjects in research and to promote ethical standards in medical research practices (Stark, 2019).

Overall, the history of IRBs reflects a growing recognition of the importance of protecting human subjects in research and ensuring ethical conduct. They have evolved as essential entities to review and oversee research, aiming to safeguard participant rights, minimize harm, and uphold ethical principles in scientific investigations (Arunachalam et al., 2021).

According to international guidelines, IRB/RECs must receive all research proposals involving human participants from researchers and review them accordingly based on the required standards and principles. Further, IRB/RECs must be self-governing without associating with the research team, and they must also not benefit financially from any research outcomes to warrant compromises. However, IRB/RECs may receive funding for protocol review activities but not to coerce protocol authorization, approval, or clearance decisions. Based on records of protocol decisions kept in archives, IRB/RECs must conduct additional reviews to monitor the progress of the studies whose protocols have been approved in the past. Also, IRB/RECs must safeguard participants in a way that will guarantee that both participants and participants do not waste their valuable time and resources on unproductive research activities (CIOMS, 2002).

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IRB/RECs are required to select people with the requisite qualification, knowledge, and experience to deliver a comprehensive and adequate review of submitted research proposals and protocols. Individuals with qualifications and experiences in the physical sciences, social sciences, and religion, among others, are often recommended. This selection would ensure a wide range of expertise on the committee to evaluate research risks (CIOMS, 2002).

Additionally, IRB/RECs must design processes to review emergencies and normal protocols. Hence, there should be expedited or unscheduled review processes and normal or scheduled review processes. The choice of which review process to use must depend on the urgency and need of the protocol (Arunachalam et al., 2021).

Fundamentally, IRB/RECs are responsible for ensuring that protocols are reviewed based on competence and in an independent process. Further, IRB/RECs are expected to protect the well-being and rights of human participants involved in any research. Also, they review and oversee that all research meets the national and international ethical principles and the appropriate regulations and guidelines relating to human participant protection. Accordingly, IRB/RECs must, per the ethical principles in their guidelines, issue ethical review statements on the ethics of research plans and other associated research risks upon the request of researchers (TENK, 2019).

2.2.1 Global Ethical Standards for Conducting Research during the COVID-19 Pandemic

For several decades, researchers have gained much experience dealing with infectious diseases such as HIV, SARS, H1N1, Nipah, Ebola, and others. During this period, emergency research and ethics had to be planned, research guidance had to be provided, and individuals' rights had to be treated ethically (Kumar and Muthuswamy, 2020). Notwithstanding, the COVID-19 pandemic has shepherded a new global stage, requiring comprehensive ethical

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standards in research. It is because the outcomes of such research would affect policy-making, ethical investigations, and even how current and future research should be designed (Palacios and Shah, 2019). Therefore, it is not surprising to see several proposals for ethical standards from individuals and organizations in the academic and research space.

To identify the ethical considerations that should guide decision-making in research during global health emergencies, the UK's Nuffield Council on Bioethics Working Group developed a number of key recommendations. These included the need for "more inclusive approach to influencing research agenda and priorities; more inclusive approach to study design and review; Consent – and the wider 'ethics ecosystem'; equitable collaborations and partnerships; respectful and equitable sharing of data and samples and better support for front-line workers (researchers)" (Nuffield Council Report, 2020).

Given the complexities of conducting research with human participants during the COVID-19 pandemic, several research institutions and organisations also developed specific guidelines and recommendations. For example, the Research Ethics Committee of the International Institute for Environment and Development Studies (IIED) came out with a COVID-19 Research Ethics Supplement in May 2020 to guide project managers and researchers as they attempt to mitigate COVID-19-related ethical issues. The supplement was also a policy response to the pandemic and was intended to ensure the responsible conduct of research while protecting the safety, health, dignity, privacy, and rights of research participants (Dodman, 2020).

According to the IIED, all IIED-managed research projects undertaken by IIED staff and partner organizations could be continued after careful considerations have been made based on support and advice from IIED. Hence, all proposed changes in methods, designs, objectives, scope, and timelines, among many others, must be assessed and approved by all

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stakeholders (IIED Staff, partners, participants, and funders). Similarly, an outline of a feasible action plan for all research projects must be assessed. Partners undertaking research projects overseas are also advised to follow the local guidance on COVID-19 (i.e., restrictions on face-to-face interactions and movement) to lessen undesirable or unwarranted risks (Dodman, 2020).

In general, the COVID -19 Research Ethics Supplement offers two options to IIED staff and partner organizations conducting research under COVID-19 restrictions which are outlined in the Table 1 below:

Table 1: Ethical Guidelines for Conducting Research under COVID-19 Restrictions

1. Ethical Standards for Digital Research	• Secure online data collection to prevent digital exclusion resulting from limited access to communications methods (phones and internet data). This data collection scheme could lead to bias in research findings. • Update recruitment documents to reflect online methods more readily and inform your participants about the new updates. • Perform remote data collection via telephone, Microsoft Teams, Skype, Zoom, WhatsApp, or Google Hangouts. Whichever platform is deployed must ensure data security and conform to data protection guidance. • Determine if your digital research would be a financial cost to participants and allocate appropriate resources from project funds to support them. • Use secure methods to collect appropriate data that is regulated by data-protection laws.
2. Modify Data Collection Procedures	• Use discretion, responsibility, and common sense to interpret whether adjustments to data-gathering plans and activities would significantly result in deviation from the methods initially planned, the original project itself, or the potential findings. • Consider the exact impact of these modifications on the participants' dignity, welfare, and rights, and act accordingly. • You may decide to postpone or cancel data collection involving group gatherings as determined by local regulations or advice. • During face-to-face data collection, vulnerable groups must be pre-assessed to ensure that suitable physical distance

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	between research participants and the researcher is maintained – to comply with mitigation measures. • Protective equipment (e.g., masks, face shields, gloves, among others) must be used by both research participants and researchers.

A study by Barroga and Matangguilan (2020), investigating global ethical standards for conducting research during the COVID-19 pandemic, found essential alterations in ethics, peer review, and research, which have set the stage for the development of new, profitable, and extremely flexible research models. Accordingly, they proposed eight (8) ethical standards developed out of interinstitutional and interprofessional collaboration to guarantee the highest data collection and research reporting standards in both the short and long term.

1. Reframe the Research Design – The imposition of COVID-19 restrictions such as partial or total lockdowns by countries across the globe has necessitated the need for researchers to reframe their research objectives, questions, and hypotheses. They must also reexamine their modes of conducting research and reevaluate partnerships to effectively contribute to knowledge production during the COVID-19 pandemic.
2. Adapt Methodologies to Study Type - The pandemic has resulted in new research realities, such as restrictions on the conduct of quantitative and qualitative. For this reason, innovative but ethical research methodologies have been adapted and initiated. For example, mobile methods for capturing social life and interactions, online interviews and focus groups, questionnaire diaries for obtaining reflections, photo/video/voice data collection using smartphones, and video work documentation; are some of the innovative research methods that have been adopted for qualitative research. Similarly, online and phone surveys deploying paid or free online survey tools have been used for quantitative research. The additional quantitative research method adopted under COVID-19 restriction includes but is not limited to content

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analysis, social media analysis, spatial analysis, text mining, and digitization of traditional research methods.

3. Transition Research Mechanics - The COVID-19 restriction has overturned the traditional mechanism for conducting research. Hence, researchers must transition to the online mechanism through methodological revisions. The following online resources have become very handy to researchers and are helping researchers to formulate creative virtual research plans: Skype, Zoom, Google Meet, Microsoft Teams, Cisco WebEx, Moodle, Facebook, Telegram, Yammer, Google Classroom, WhatsApp, and WebEx.

4. Change Research Methodologies - COVID-19 has had dire consequences on participatory and operational research to the extent that changes in research methodologies are required. For example, budget and study time could be reduced, participation could be promoted, generalizability may be strengthened, and publication could be accelerated. Changes required in data collection could include using social media data, reviewing repository data, and virtual interviews. Similarly, evidence gap maps could be developed, network-based online referral strategies can be deployed, whereas electronic tools such as video chat platforms for telehealth, remote focus group platforms, and web forms for screening and enrolment could be relied upon by researchers besides leveraging on the expertise of a local consultant.

5. Overcome Data Collection and Standardization Constraints - COVID-19 protocols such as social distancing and quarantines have created data collection constraints in the form of limited direct interactions. Hence, researchers have had to resort to using online and remote tools to collect empirical data. For example, researchers have tried to overcome data collection constraints by relying on remote research and online

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interactions to mitigate constraints and shift priorities in research capacity and resources.

6. Uphold Research Standards and Ethics - Irrespective of the impact of COVID-19 on research and the numerous changes and shifts that have been proposed, the highest ethical standards must be maintained to lessen apprehensions about research quality brought about by changes in research designs and methodologies. It means that whatever changes are required should not be achieved at the expense of employing unvalidated substitute endpoints, using partial evidence, altering research organization and design, using smaller sample sizes, and disregarding randomization.

7. Maintain Informativeness and Social Value – There is no need for researchers to hastily produce research based on insufficient confirmed results due to time constraints and COVID-19 restrictions. Hence, any research outcome must be thoroughly verified, meet published ethical standards, and be peer-reviewed.

8. Provide Secured Peer Review Flexibility - Open access journals must embrace a more adaptable approach to the peer review process due to COVID-19-related constraints. This approach would enable researchers to respond timely to additional experiments or components required by the peer-review process. However, introducing a flexible peer review process does not mean that the reliability of peer review and ethical standards should be compromised.

Kim and Grady (2020) also observed that the most difficult challenge confronting clinical researchers was how to distribute scarce resources fairly. Hence, they explored ethical standards that have remained the same and those that have changed (Kim and Grady, 2020). The authors indicated that central ethical standards for conducting clinical research had remained the same despite COVID-19 restrictions. These include, but are not limited to:

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- Respect for patient's wishes regarding their medical treatment (autonomy)
- Patients' wishes for end-of-life medical decisions are captured in the advance directives.
- Patients' wishes regarding end-of-life treatments are captured by the 'values and wishes' section.
- Discrimination and stigmatization against patients are not permissible.

With regards to ethical standards that have changed under COVID-19 restrictions, Kim and Grady (2020) also expressed the view that the following have resulted from the COVID-19 restrictions even though they are not universally accepted:

- Guidelines must endorse the priority of short-term survival.
- A long-term prognosis is permissible.
- Scarce resources should be used for 'the greater good.
- Priority should be given to the young rather than the old
- Research frameworks must be designed after the public has been engaged and must reflect their views.

Yeoh and Shah (2021) also observed that the global clinical research community is experiencing ethical challenges due to the COVID-19 pandemic. To circumvent overlapping protocols, RECs were required to prioritize new study submissions and modify ongoing research activities while maintaining the existing ethical standards and international research guidance. The authors suggested ethical standards guide researchers during the COVID-19 pandemic for this and other reasons. They based their suggestions on the pre-COVID-19 ethical standards for research, such as the principles of, justice, beneficence, utility, respect for persons, liberty, reciprocity, and solidarity. In the view of Yeoh and Shah (2021), all

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clinical research conducted after the outbreak of COVID-19 must abide by the following revised research ethics:

1. RECs must expedite the reviewing of new research works without compromising the quality.
    - Fair consent and the safety of study participants must be maintained while ensuring the methodology's validity so that it answers the scientific question.
    - Good publishing practice must be emphasized by scrutinizing the publication strategy.
    - The benefit of expediting knowledge of study results in a rapidly developing pandemic must be balanced with the need for data transparency and peer review.
2. RECs must assess research methodologies within the context of possible scarce clinical resources such as hospital capacity, protective equipment, and staff.
3. RECs must evaluate COVID-19-related research on the same terms as research into other medical conditions. However, research into COVID-19 should be prioritized due to its clinical urgency at this abnormal time.
4. RECs must review and reassess all research works that had already been planned and were ongoing. They must base their reviews and reassessments on the related risks of the research to study participants (i.e., impact on severely ill patients before any approvals).

According to Hashem et al. (2020), researchers have an ethical obligation to continue their research even when implementing COVID-19 restrictions such as stay-at-home measures, quarantines, and travel bans. This means that clinical researchers must adhere to and abide by the pre-COVID-19 ethical standards (e.g., informed consent, committee approvals, external monitoring and audits, shipping trial products, and efficiency, among others). Additionally, researchers must deploy virtual visits, and remote monitoring was necessary to reduce the

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risk of transmission of infection for both participants and research staff (Hashem et al., 2020). Accordingly, Kim and Grady (2020) expressed that the same core ethical standards must oversee research on human subjects regardless of COVID-19 restrictions. Any clinical research conducted within the period must obtain informed consent, ensure efficient use of resources, minimize harm, and the like (Kim and Grady, 2020). On efficient use of resources (fair allocation of scarce resources) during COVID-19 restrictions, Emanuel et al. (2020) specifically recommend four guiding principles based on the utilitarian approach of maximizing benefits as follows:

- The total benefits produced by scarce resources in any research must be maximized.
- Researchers must treat equivalent cases equally.
- Instrumental value (benefit to others) must be promoted and rewarded.
- Priority must be given to the worst off.

Having realized that researchers could provide useful facts, information, and insight to help understand, manage, and control COVID-19, Tindana et al. (2020) discussed the role of community engagement in research during the COVID-19 pandemic. The authors found that the traditional community engagement approaches have been challenged by COVID-19 response strategies such as social distancing; and that the new ways of engaging communities in research are done using web-based platforms (e.g., Zoom, Skype, MS Teams, WebEx and Google HangOut), phone-based platforms (e.g., WhatsApp), telephoning and mass media (e.g., radio, tv, newspapers, mobile information vans and televisions), among others.

Jowett (2020) also proposed that in conducting qualitative research under COVID-19 restrictions, researchers must resort to online data collection techniques or existing textual data rather than face-to-face interviews, focus groups, and fieldwork. Similarly, video-calling (e.g., Skype/Zoom) and text-based instant messaging (e.g., WhatsApp) could be used to replicate the face-to-face interview or focus group. This approach would ensure that the well-

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being of participants and researchers is prioritized over research timelines (Jowett, 2020). We have seen from the above that the traditional ethical standards for conducting clinical and social research under COVID-19 restrictions have changed slightly. Some institutions have proposed changes in research design and methodologies (i.e., revisions in data collection procedures and tools, guidelines, research frameworks, participants' engagement, remote research, and the like). Other institutions have also recommended that research outcomes procedures be altered (i.e., publishing practice, research quality, the peer review process, and research reporting, among others). Nevertheless, some institutions have strongly advocated reviewing and reassessing research logistics (time, funds allocation, and knowledge distribution, for example). However, the above review has shown that all modifications regarding ethical standards for conducting research during the COVID-19 pandemic must be made based on informed consent, committee approvals, benevolence, efficiency, and fairness, among others.

2.2.2 Informed Consent Processes in Research during COVID-19

COVID-19 restrictions such as social distancing and lockdowns affected how researchers deployed the normal and established consent-seeking process. These restrictions necessitated revising ethical standards guidelines with alternative informed consent processes to help researchers interact with research participants under COVID-19 restrictions. However, there was a need to ensure that the processes of informed consent during normal times align with informed consent processes under the restrictions of COVID-19.

When a well-informed individual, acting without compulsion or excessive enticement, willingly approves of a course of action based on adequate and applicable information, it is known as informed consent (WHO, 2020). However, in research, informed consent is a written or verbal agreement by a participant to participate and comply voluntarily in research regardless of the risks or the absence of benefits (Pickering, 2021). It means that the

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processes, risks, and benefits of informed consent must be clarified and agreed upon by both the researcher and the participant.

Informed consent becomes a process when the researcher follows a formalized procedure to educate and recruit participants for either clinical or social research. When this process is followed, participants are accorded respect, the right of willingness, and the decision right of participation to guarantee an impartial research outcome (Pickering, 2021). According to Hoverd et al. (2021), the informed consent process aims to offer prospective participants information to make an informed decision regarding their participation in impending research.

Accordingly, informed consent is a very important ethical standard that must be applied in any research because it is the basis of protection for both researchers and participants; relying on elements such as voluntariness, awareness, and information (Nembaware et al., 2020). De Vries et al. (2020) cautioned, however, that the urgency with which a research outcome is required under COVID-19 restrictions does not warrant a relaxation in the principles underpinning the informed consent processes. Similarly, the *Nuffield Council on Bioethics Working Group on Research in Global Health Emergencies: Ethical Issues* also highlighted the central role of culturally appropriate and respectful consent processes in research during global health emergencies. They however cautioned that consent alone is never the only requirement for research to be ethically acceptable and recommended that other parts of the 'ethics ecosystem' should include responsibilities of researchers and ethics committees and inclusive and collaborative engagement with communities (Wright et al., 2020).

To guarantee high-quality research during the COVID-19 pandemic, Health Canada provides guidance notes and regulatory requirements for informed consent in clinical research as follows (Hashem et al., 2020):

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- The researcher must obtain written informed consent from participants, with specifics on the anticipated risks, benefits, and other relevant information required to enhance the participant's decision to participate in the research.
- The anticipated benefits must balance the risks and inconveniences when participating in the research. Also, participants' health, safety, and well-being should outweigh any professional and academic research interests.
- A participant must, either in person or remotely, go through the processes captured on the informed concern form before he/she is allowed to be involved in any aspect of the research procedure.
- All of the participant's questions about his/her participation in the research must be answered by the researcher.
- Participants must be provided with both original and amended applicable informed consent laws approved by the Research Ethics Board (REB).

Furthermore, Hashem et al. (2020) specify an informed consent process for researchers who are conducting COVID-19 clinical experiments as follows:

1. All informed-consent-process changes must be documented and maintained in the research site file. The documentation should be labelled as COVID-19 Clinical Experiments with dates, signatures, and approvals, among other factors.
2. All informed consent processes should comply with the regulations of the International Council for Harmonization and Health Canada as approved by the REB.
3. Substitute wrote informed consent with electronic methods, as the former would lead to contamination. The electronic system should be detailed and comprehensive; the processes should be validated appropriately, whereas the electronic consent version must have the capacity to keep records for 25 years. Obtain the informed consent orally by phone or videoconference in the presence of an independent witness, and

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document the process accordingly. Electronic consent could also be obtained from participants through the mail after it has been witnessed, reviewed, and authorized. A participant can withdraw his/her consent without written notification, but it must be documented by the researcher and captured by the investigative site file.

4. Standard Operating Procedure – SOP (step-by-step instruction) compiled by the researcher must be available for obtaining informed consent. The SOP must capture the following information: effective date, author, originality, and other related procedures.
5. The researcher must train workers at the site of the clinical experiment on the SOP compliance and documentation of the training manuals to ensure that the informed consent process has been satisfied.
6. Any new information resulting from the changing COVID-19 environment should be explained to participants (or their legitimate representatives) immediately after it becomes available. It would erase any doubt concerning the impact of the clinical experiments on participants' health.
7. Researchers must prove that participants understand the informed consent process and the related documents.
8. The formation of IRBs was a direct response to the ethical violations witnessed in the Tuskegee Study (1964) and the Belmont Report (1979) which are the foundations of contemporary IRBs. Researchers must conform to all existing and applicable regulatory requirements, besides the already established ethical principles, particularly those that originate from the Helsinki Declaration.
9. In an emergency case where informed consent cannot be obtained, the participant's legitimate representative must be informed about the clinical experiments immediately for he/she to consent to the research appropriately. Also, when previous

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informed consent cannot be obtained, the researcher must seek approval from the REB and document it accordingly. This way, the participants' well-being, safety, and rights would be protected, whereas compliance with appropriate regulatory requirements would be guaranteed.

Given the challenges in obtaining informed consent from research participants, de Vries et al. (2020) suggest that researchers may also require remote telephonic or electronic proxy consent from the participants' next of kin. In this regard, the authors proposed a simplified informed consent process under COVID-19 restrictions as follows:

1. Ascertain if the prospective participant can provide valid informed consent.
2. Determine the participant's legitimate representative (next of kin) as an alternative source.
3. Select the appropriate mode (e.g., telephonic, electronic) of capturing the informed consent without putting workers and materials at risk of contamination.
4. Obtain informed consent from participants or their legitimate representative (next of kin).
5. Obtain delayed informed consent from participants who recovered from their ailments during the research.
6. Obtain a possible waiver of informed consent from the REC if the participant dies and for the continuous use of the deceased participant's information for research.

Therefore, the COVID-19 pandemic has warranted the review and revision of the existing informed consent processes, which are of the greatest importance to help protect prospective research participants and researchers from contamination during research. It is imperative, therefore, for researchers to be responsive to the changing environmental conditions to revise informed consent processes in a manner that can help them obtain genuine informed consent for all research carried out under COVID-19 restrictions. However, in doing so, researchers

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must ensure that their revised processes are detailed, documented, and conform to existing regulatory requirements.

2.2.3 Steps Taken by Researchers to Protect Participants' Safety During Research

Well-informed individuals who willingly agree to participate in research are known as participants. These individuals interact with researchers during research surveys, focus group discussions, in-depth interviews, and observations. However, there is no guarantee that participants' rights, safety, and well-being will be protected during the research. This is because participants can be psychologically, financially, and sociologically harmed during their interaction with professional or academic researchers (Liamputtong, 2006). Hence, researchers must determine the type of harm their intended research may cause participants regardless of their good intentions. They should specifically consider their research's negative impact on participants, how they would protect themselves, and how their institutions and supervisors can be protected against a lawsuit and public condemnation. Therefore, it is not a coincidence that over the years, public and private institutions and countries across the globe have designed regulations, laws, and policies to ensure that participants, researchers, and supervisors receive the same high level of protection. These regulations, laws, and policies have been harmonized into steps or guidelines to be followed by researchers to guarantee participants' safety during the research (Organization, 2011).

Before the outbreak of the COVID-19 pandemic, individuals and institution researchers relied on ethical principles to protect participants during the conduct of social research. Specific ethical principles such as the right to autonomy, privacy, and confidentiality were applied to protect research participants from all forms of potential damage while intensifying the practical benefit of their research to the participants and the general public (Association, 1964; Beauchamp, 2008; Žydžiūnaitė, 2018). According to the author, the informed consent process allowed researchers to provide full disclosure to potential participants, explaining the

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benefits, dangers, possibilities, and the opportunity to ask further questions before committing themselves to research.

Some RECs in some countries have designed ways of protecting research participants. For example, in 2006, the National Committees for Research Ethics in Norway (2006) and Israel and Hay (2006) presented revised guidelines for research ethics in the social sciences, law, and humanities. The guidelines 'Respect for Individuals' section provided details on the steps researchers can take to protect participants' safety during research. The following are the steps that apply to individuals and institution researchers, in addition to other entities that exercise control over research and research outcomes in Norway:

1. Researchers must select topics that show respect for human dignity, whereas their research processes must also protect research participants in the areas of; confidentiality, relationships, and autonomy.
2. For research in an institution, researchers must respect participants' integrity, anonymity, independence, and right to participate. It would ensure that nothing happens to them or their lives.
3. Researchers must not expose their research participants to harm and suffering and must weigh the risk of causing harm and suffering to participants against the benefits of the research outcome. They should subsequently give participants the chance to manage difficulties that may arise due to their participation in the research.
4. Researchers must explicitly provide participants with general information about the research, such as research purpose, approaches, risks of participation, funding sources, and the like. This way, participants would be reliably informed about the scope of the intended research, the benefits, and the risks of participating in it.

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5. Researchers must acquire free and informed consent from participants to guarantee them the right to withdraw from participating in the research when so desired, without necessarily resulting in negative penalties.
6. For research involving children and youth, the research's approaches, systems, design, and objectives must be adopted by the researcher to protect children's rights of respect, dignity, and privacy, among others. Accordingly, researchers must obtain parental consent for participants aged 15 and below; however, their consent is required when young participants become old enough to express an opinion.
7. Researchers must respect participants' close relationships and privacy to protect them against unsolicited meddling and exposure to third parties.
8. Researchers must respect participants' confidentiality, particularly concerning the usage and circulation of information provided by participants about their private lives that could harm them.
9. Researchers must responsibly store data that could be traced to participants. Such data (e.g., field notes, lists of names, interview guide) should be stored distinctly and manually for a limited time and then expunged once it has served its original purpose.
10. Researchers must respect participants' values and motives irrespective of public opinion concerning a subject matter. Unreasonable or undeserving motives should only be ascribed by researchers to participants with evidence and convincing arguments.

Vanclay et al. (2013) conducted a study to identify existing ethical research principles involving humans from an ethical professional practice standpoint. The authors found that in addition to the above, four additional steps could be taken by researchers to protect participants' safety during research as follows:

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1. Researchers are obligated to provide participants with the right to check and modify transcripts, and this would ensure that they are not misquoted in draft publications, reports, and records; and that they agree with how the information provided has been recorded.
2. Participants must be informed of the sources of funding for the research so they can make informed decisions regarding their participation or otherwise in current and future research.
3. Researchers must follow a system of ethical governance instituted by RECs to guarantee the proper functioning of ethical procedures. Accordingly, RECs must; appraise research protocols before the commencement of the research, monitor research activities, advise researchers and participants, and decide on research-related complaints.
4. Researchers must provide participants with a grievance procedure and an option for corrective action. This grievance procedure must be fair and appropriately disclosed to participants.

Meanwhile, it is believed that the outbreak of the COVID-19 pandemic may have led to a revision of the above steps intended to protect research participants from contracting the disease. Having been confronted with increased practical and ethical issues regarding research during the COVID-19 pandemic, the British Psychological Society Ethics Committee created a Code of Human Research Ethics highlighting four main ethical principles.

First of all, it is required for researchers to respect the independence, confidentiality, and self-respect of participants. Where there is the need to adapt the research design, methods, and data-gathering techniques to online mediums, researchers are required to document and present the intended changes for evaluation. Also, informed consent must be renewed for participants who may withdraw from the research because of a change from face-to-face data

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collection to online. Secondly, researchers must ensure that their research works are planned, revised, and conducted to guarantee truthfulness and value while advancing knowledge and understanding. Moreover, when online research must replace face-to-face research, researchers must submit modification requests for ethics review and approval.

Also, researchers must develop protocols for dealing with sensitive issues. Thirdly, researchers must ensure that the outcome of their research meets societal needs and respect social structures. Their research must also be of high social value, clarifying who the beneficiaries are. Researchers must desist from accelerating ethics review and institutional approval by branding all research as COVID-19-related. Lastly, researchers must maximize the benefit of their research while minimizing potential harm to participants. Risks greater than participants' exposure to in their ordinary lives must be avoided. For example, if research must be conducted in a practical environment such as a hospital or a school, the burden on participants, likely students, teachers, or medical staff, must be considered and reduced drastically (Wolf et al., 2008).

Accordingly, Kraft et al. (2021) proposed new guidance for protecting research participants after interviewing researchers conducting clinical research. The author recommends that researchers must consider the steps to protect themselves and participants apart from adherence to the COVID-19 protocols such as disinfection, masking, and social and physical distancing.

1. Researchers must follow established advice on new protocols regarding local infection rates, labs and shared spaces disinfection, and protocol modification.
2. For protection purposes, researchers must reduce all risks associated with every stage of the research process. For example, if the meeting room for participants is small, a bigger and more expansive room should be sought to avoid congestion and allow for observing social and physical distancing protocols.

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3. Researchers must design and implement new protocols for greeting participants. For example, researchers may welcome participants by using fist bumps, hand waves to make a connection and verbal compliments.
4. Apart from the research setting risks, researchers must determine risks associated with transporting research participants and how to reduce exposure among participants who use public transportation, for example.
5. Researchers must deploy ICT tools and techniques to decrease the occupancy of research settings/sites. They could, for example, share Google calendars to reserve time slots to plan their schedules.
6. Researchers must amend consent forms where necessary and specify the potential risks along with measures that can be taken to protect participants. Researchers must also let participants know they can withdraw from the research whenever they desire.
7. Researchers must be creative and devise new designs, methods, and approaches to achieve their research objectives whilst protecting participants simultaneously. They could, for example, conduct Internet instead of face-to-face research. Likewise, researchers could use open spaces outside to test rather than in the laboratories.

The above indicates that various RECs, research institutions, and individual researchers have collaboratively put in place measures to protect researchers, students, teachers, medical staff, and most importantly, research participants. The measures are in the form of steps designed out of ethical issues underpinning the conduct of research. In the above steps, ethical research principles such as confidentiality, respect, autonomy, informed consent, dignity, privacy, integrity, anonymity, independence, or right to participate; were captured and explained in detail to ensure that voluntary research participants are protected from possible undesirable consequences. It is important to note that the steps for protecting participants before and during the COVID-19 pandemic were the same except for some modifications made in

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research designs, methods, data-gathering techniques, informed consent processes, and the review and approval protocols for managing sensitive issues. Furthermore, there was a requirement for protocols such as masking, disinfection of labs and shared spaces, and social and physical distancing to be adhered to by research conducted during the pandemic.

2.3 Challenges with research implementation under COVID-19 Restrictions

Research challenges are the complexities associated with the designs, methods, techniques, and processes of conducting clinical and social research to guarantee consistent findings (Žydžiūnaitė, 2018). For example, in the conduct of social research, there is an obligation on the part of the researcher to adhere to ethical issues such as; obtaining approval from RECs, equitably selecting research participants, obtaining informed consent from potential participants regarding the nature and purpose of the research, maximizing the benefits for and at the same time minimizing the risk of harm to the research participant, among others (Wiles et al., 2006). Concerning clinical research, issues such as participant recruitment, adapting to a dynamic research environment, and accountability to national and international RECs, regulatory bodies, and funders are challenges that must be dealt with by researchers (Campbell et al., 2007).

In recent years, however, these research challenges have worsened due to the outbreak of the COVID-19 pandemic. Social researchers are needed to predict the pandemic's social, moral, and economic consequences, and clinical researchers must continue with their knowledge creation without harming themselves and the participants. There is also a vital requirement for clinical researchers to conduct new therapeutic and restraining research on COVID-19. Accordingly, RECs must speedily review specific ethical issues, completely unify the RECs' supervision system, and collaborate with other institutions to improve capacity and

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efficiency. So, we see that the following discussed challenges from conducting research during COVID-19 restrictions have been heightened.

According to Tindana et al. (2020), one challenge confronting researchers under COVID-19 restrictions is in the area of engagement methods. The COVID-19 restriction protocol, such as social distancing, has necessitated a method that would enable researchers to prevent the transmission of the pandemic while engaging with research participants. So, a web-based platform (Zoom, Skype, or Microsoft Teams) could be used to engage participants rather than a face-to-face interview. However, this method may be affected by erratic and poor internet connection, data protection threats, difficulty in controlling private messages, potential misinformation, and a limited number of participants at any time (Tindana et al., 2020).

Additionally, three challenges that confront researchers under COVID-19 restrictions have been identified by (Fegert et al., 2020):

1. Compliance with Paragraph 32 of the Declaration of Helsinki (2013). This declaration requires clinical researchers to obtain informed consent for data collection, storage, and re-usage. According to Fegert et al. (2020), it would not be possible or realistic to obtain informed consent from researchers who use recognizable human data or material confined in biobanks or comparable storehouses. Such clinical research cannot be completed unless RECs are considered and approved.
2. Complying with special considerations guidelines of research ethics during a pandemic. Fegert et al. (2020) note that the responsibilities of researchers, RECs, and front-line medical staff in carrying out daily diagnosis, treatment, and scientific research are enormous. Hence, the difficulty with which these individuals and institutions must balance scientific observation record keeping and informed notification with life-saving obligations; cannot be overemphasized. For example, RECs must thoroughly measure the risk/benefit ratio and obtain informed consent by

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comparing social interest, personal interest, and general ethical considerations. Similarly, the severe nature of COVID-19 has necessitated the urgent need for researchers to find therapy. However, the risks involved in conducting different research, such as Randomized Controlled Trials (RCTs), could be unbearable due to the intricacies of RCTs methods and procedural requirements.

3. Overcoming existing scientific research management laws and regulations gaps during COVID-19 emergencies. To control the COVID-19 pandemic, some governments have categorized it into classes of infectious diseases, with the highest class being the most infectious. Hence, state institutions, organizations, and agencies must adhere to governments' directives in dealing with the pandemic. However, as captured in existing government laws, there must not be discrimination in clinical research and treatment during any pandemic. This situation puts researchers and medical institutions in a difficult position where they have to choose between improving the therapy capacity in line with diagnosis ethics and meeting the therapeutic obligation of the government's public health authority (Fegert et al., 2020).

Concerning obtaining informed consent from research participants under COVID-19 restrictions, Goldman and Gelinas (2021) identified three broad categories of challenges.

1. Researchers' Challenges – These challenges confront researchers due to the rapidly evolving: decisive risk factors for condensed outcomes and genetic aspects of disease and death, daily evidence, and new data on epidemiological spread and symptomatology. In the above situation, researchers find it difficult to evaluate the possible effect of other treatments, decide on the most promising mechanisms of action in drug classes, and confirm differences in drug interactions. Also, the COVID-19 pandemic is new, with little or no background research, making it difficult for

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researchers to assess the impact of new procedures, devices, and experimental drugs on participants. Similarly, the inadequate COVID-19 research background makes it difficult for researchers to obtain informed consent due to non-estimated risks, the likelihood of occurrence, non-available details on risk mitigation measures, unforeseeable risks, or distress to participants (Goldman and Gelinas, 2021).

2. Patient/Participants Challenges – these are challenges resulting from patients/participants' inability to understand robust and clear disclosures by researchers. When it happens this way, researchers and clinicians find it difficult to adhere to rules and regulations governing disclosures under COVID-19 restrictions. Further challenges are raised by participants' reasoning and possibly defenceless statuses, which negatively cloud their decisions at the expense of researchers. Likewise, researchers and clinicians are confronted with time and systems constraints while looking for appropriate legally authorized representatives (LARs) for patients/participants who have been incapacitated by COVID-19. When these LARs cannot give consent on behalf of patients/participants on time, further strains are placed on researchers and clinicians (Goldman and Gelinas, 2021).
3. System Challenges – these are challenges that researchers encounter due to inadequate resources in the form of limited research personnel, tools, and equipment. These challenges are even aggravated when researchers have to serve as researchers and also assist with the research consent process. Similarly, unparalleled strains are placed on researchers and healthcare systems by the increasing number of COVID-19-infected patients/participants who require resource and time-intensive care. Moreover, the COVID-19 pandemic has created urgent conditions requiring timely treatments to save lives globally. It means that the usual timeframe for conducting clinical research has been condensed for all stakeholders (researchers, sponsors, funding agencies, RECs,

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and regulators) who are required to remove barriers to the commencement of clinical research and the enclosure of participants (Goldman and Gelinas, 2021).

However, other challenges under COVID-19 restrictions have been identified by Byrom, (2020) to be affecting researchers. First of all, the ability of researchers to gather data, discuss research findings and insights with co-equals, and publish research discoveries; has been negatively affected by the lockdown. Secondly, their institutions have restrained researchers' access to software and other electronic research platforms. Lastly, some researchers are stressed out due to uncertainty about their research contracts. Some researchers, particularly those whose research was disrupted by the COVID-19 pandemic, are unsure if their contracts would be extended with additional funding. Others are also worried about future research plans as there is no guarantee that funds will be available to support future research.

The above indicates that the COVID-19 pandemic, with its associated restrictions, has severely impacted the works of researchers, RECs, participants, and sponsors. Some of these identified challenges are methodological and procedural, whereas others are in the area of complying with research ethics guidelines. Nevertheless, other challenges have risen out of the need to meet rapidly evolving daily evidence and the need to assess the impact of new procedures, devices, and experimental drugs on participants. The good thing, however, is that most of these research challenges originated from the need to prevent participants and researchers from contracting COVID-19.

2.4 Overview of Research Ethics Committees in Ghana

There are eighteen (18) RECs, ERCs, IRBs, or REBs in Ghana (Boateng, 2019). Among them is the Ghana Health Service Ethical Review Committee (GHS-ERC). This national committee evaluates and authorizes all prospective research applications for health research

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in Ghana, predominantly prospective research conducted in GHS facilities and by GHS staff. The GHS-ERC is one of the units under the Research and Development Division (RDD) of the GHS and can be located within the Adabraka Polyclinic. The Standard Operating Procedures (SOP) of GHS-ERC was developed in 2015, and it outlines the tasks, structure, and executive strategies of the Committee. The SOP further describes the system and procedures underlining research review protocols, categories of reviews, and modification processes. Likewise, the methods for monitoring ongoing research are contained in the SOP, together with documentation and archiving procedures (Standard Operating Procedures for GHS-2015).

The Navrongo Health Research Centre Institutional Review Board (NHRC IRB) is yet another REC. It was established to appraise, assess and approve research protocols involving data collection from persons and institutions in the Upper East, Upper West, Northern, North East, and Savannah regions. The NHRC IRB is located in Navrongo and is mandated to ensure and guarantee the safety, protection, dignity, and rights of all persons and groups participating in NHRC research events (NHRC, 2022).

Another popular REC in Ghana is the Kintampo Health Research Centre Institutional Ethics Committee (KHRCIEC). As its name suggests, it is located in Kintampo in the Bono East Region and was established to appraise, assess and approve the ethical qualities of KHRCIEC research protocols. It is also mandated to improve research activities and to ensure the safety, protection, dignity, and rights of all persons and groups who participate in research activities, particularly within Western, Western North, Brong Ahafo, Bona East, Ahafo, Ashanti, Oti, and Volta Regions of Ghana (KHRCIEC, 2020).

For all research works that require approval and data from persons, groups, and organizations within the Eastern, Central, and Greater Accra Regions, the Dodowa Health Research Centre

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Ethical Review Committee (DHRC ERC) has been established to appraise and approve research protocols based on the principles of welfare, safety, protection, and dignity of research participants; and the scientific integrity of all GHS-related research works (Canadian Coalition for Global Health-Research - CCGHR, 2021).

Additionally, the Korle-Bu Teaching Hospital Institutional Review Board (KBTH-IRB) and

Ethical and Protocol Review Committees (EPRC) were established with their respective Research Policy Guidelines and Procedures to guide researchers, students, and their supervisors, RECs, ERCs, IRBs, or REBs. According to the Hospital, one of its core mandates is to research to advance science and technology in the areas of new or improved products, services, and processes (drugs, vaccines or diagnostic tools, new surgical techniques, and treatment protocols). It means that all research conducted at KBTH or involving their staff must follow the KBTH's Research Policy Guidelines, which have specific procedures for using data from patients' medical records, observations and interviews, surveys, and clinical trials, among others. The KBTH-IRB and EPRC are located at the College of Health Sciences, Korle-Bu Accra (KBTH-IRB Research Policy Guidelines and Procedures, 2016; Boateng, 2019).

Most tertiary institutions in Ghana have instituted their respective RECs, ERCs, IRBs, or REBs to guide their students, supervisors, internal and external research institutions, external consultants, and the like. The University of Ghana, with its internal research institutions such as the Office of Research Innovation and Development (ORID), Noguchi Memorial Institute for Medical Research (NMIMR), and Institute of Statistical, Social and Economic Research (ISSER); have set up and developed their RECs together with Research Policy Guidelines, capturing specific details on good practice, environmental health, and safety, meeting national development priorities, among others. Hence, the ORID and ISSER collaborated and

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established a university-wide REC to superintend and control the integrity of research conducted within the humanities disciplines at the University of Ghana. It is known as the University of Ghana, Ethics Committee for Humanities (UG-ECH), and is located within the College of Humanities, University of Ghana, Legon (Boateng, 2019).

Similarly, the Kwame Nkrumah University of Science and Technology (KNUST), together with the Komfo Anokye Teaching Hospital (KATH), has set up and operationalized the Committee on Human Research, Publications, and Ethics; Humanities and Social Sciences Research Ethics Committee (HuSSREC); and Kumasi Centre for Collaborative Research Ethics Committee (KCCREC). These institutions' Research Ethic Policies and Standard Operating Procedures (SOP) provide the basis for conducting clinical, humanities, and social sciences research at the KNUST and KATH. They also ensure that principal researchers, students, and supervisors are properly trained on research protocols and ethics (Obiri-Danso and Agyare, 2018).

Consequently, the following universities and research institutions and many others in Ghana have their respective research guidelines, protocols, SOP to guide the conduct of clinical and social research: University of Cape Coast IRB (UCC-IRB); the University of Health and Allied Sciences Research Ethics Committee (UHAS-REC); University of Education Winneba's University Research Ethics Committee (UREC); University of Development Studies Research Ethics Committee (UDS-REC); Ghana Atomic Energy Commission Ethical Review Committee (ERC), located within the Ghana Atomic Energy, Accra; Centre for Scientific and Industrial Research Institutional Review Board (CSIR IRB), located at Airport, Accra (Boateng, 2019).

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2.5 Current Requirements for Conducting Research under COVID-19 in Ghana

The contribution of research to the growth of individuals, corporate entities, and countries cannot be overemphasized. Ordinarily, research is conducted to inform action and produce applicable knowledge. However, in times of health emergencies, such as the outbreak of the COVID-19 pandemic, methodologically vigorous clinical and social research is conducted to provide insightful knowledge about the pandemic, protect life, and create sustainable lifetime opportunities for individuals, organizations, and nations efficiently and effectively. For example, when suggestions were made that chlorhexidine or hydrogen peroxide could be used as mouthwashes to prevent transmission of the COVID-19 virus, with no significant proof, there were calls for urgent clinical trials and laboratory analyses to be conducted accordingly (Bonney et al., 2020).

To succeed in this regard, appropriate research requirements must be designed and implemented to guarantee an actual and well-organized response to such pandemics. Therefore, it is not a coincidence that the government of Ghana responded to the COVID-19 pandemic with timely crafted targets to deal with the possible effects of the virus in Ghana. The government was clear and emphasized the need to reduce and prevent the importation of the virus; quell the transmission of the virus within the country; deliver sufficient care for the infected; reduce the negative effect of the virus in communities, on trade and industry; and encourage the growth of national capacity in dealing with future infectious diseases (Ogunleye et al., 2020).

The above goals have become the basis for which the various RECs, may revise their research guidelines under COVID-19 in Ghana. However, before the outbreak of the COVID-19 pandemic, the RECs in Ghana had developed and operationalized their distinct ethical

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policy documents to standardize research activities within their respective institutions and also to consistently enhance the sharing of research findings among local, state and global partners.

In 2013, the Food and Drugs Authority (FDA) developed Guidelines for Good Clinical Practice in Ghana and updated them in 2019. As specified in part 8 of the Public Health Act 2012 (Act 851), the guidelines were developed to support the regulatory requirements of the FDA. Similarly, the Guidelines are a partial derivative of the International Ethical Guidelines for Biomedical Research on human subjects, designed by the following organizations: International Conference on Harmonization Good Clinical Practice (ICH GCP), Council for International Organizations of Medical Sciences (CIOMS), and World Health Organization (WHO). Also, the guidelines are intended to provide researchers in Ghana with clear standards and frameworks for good clinical practice. It would provide the expected public assurances and protect trial participants' rights, safety, and well-being. Hence, to guarantee a regulated and ethical approach to clinical research implementation in Ghana, all RECs, researchers, participants, and benefactors; are required to use the guidelines developed by the REC of FDA (Food and Drugs Authority, 2015).

However, none of the state agencies/authorities, research institutions, universities, teaching hospitals, and their respective RECs, mentioned in the previous section have been able to design and implement guidelines and SOPs for conducting clinical and social research under COVID-19 in Ghana. The only current reference guidelines are those developed by the Ministry of Health (MOH) in June 2020. It is the closest guideline as far as the conduct of clinical research under COVID-19 restrictions in Ghana is concerned. The guidelines, labelled '*National Guidelines for Laboratory Testing and Reporting on Respiratory Infections Diseases in Health Facilities in Ghana*', are intended to provide a framework for

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which the following research and academic institutions may design their respective clinical research policy guidelines and SOPs (Zuber et al., 2022).

To guarantee sufficient clinical and therapeutic innovations in averting and controlling the transmission of COVID-19, inform case management, and support prevention policies, sections 3, 4, 5, 6, and 7 of the National Guidelines have been specified as follows (Zuber et al., 2022):

a) Section 3: Regulatory Requirements
   - Legitimate enrolment and certification from appropriate state and legislative institutions are required from all private and public research institutions.
   - All research institutions must follow the guidelines and policies corresponding to their legitimate obligation.
   - The capacities of research institutions shall be assessed based on test site assessment tools available.

b) Section 4: Human Resource Requirements for Sample Collection, Processing, and Testing
   - All researchers must be certified biosafety and biosecurity professionals.
   - Only qualified and licensed researchers (pharmacists, doctors, scientists, disease control officers, etc.) must perfume sample collection.
   - Only qualified and licensed sample collectors are allowed to transport samples.

c) Section 5: Specimen Archival
   - All infectious disease specimens must be properly archived to enhance research investigations, improve insight, and for the advancement of diagnostic tools.
   - Archiving procedures must ensure that samples are appropriately documented, capturing details of timeliness, indexing, retrieval process, storage conditions, maintenance, and monitoring.

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- Researchers working on archived samples must seek approval from the GHS Ethical Review Board, Institutional Committees, and MOH.

d) Section 6: Sample Collection, Processing, and Testing

- Sample Collection - First, infection prevention and control guidelines must be strictly followed by researchers collecting, handling, or transporting clinical specimens. Second, the safety of researchers and participants must be guaranteed with personal protective equipment (PPE) during sample collection. Third, communication must be timely among researchers and other clinical and laboratory staff to improve suitable infection prevention and control. Fourth, researchers must adhere to existing sample shipping protocols and revise them if necessary.
- Processing and Testing – One, the biosafety level of the test site, biosafety behaviour, safety conditions, use of PPEs, capacities of researchers, disinfection, and waste management; should form the basis of assessment to determine the capacities of processing and testing sites. Two, quality assurance processes must be operationalized to receive 10 % of the positive and 1% of the negative samples tested per month from authorized processing and testing sites (public or private). Three testing methods approved by MOH must be used by all processing and testing sites. Four, national and international quality assurance programs must be the basis for which all processing and testing sites are registered. Five, to ensure effective clinical management and vigorous epidemic response, a maximum target turnaround time (sample collection to results availability) of 48 hours must be set and upheld.

e) Section 7: Data Capture and Reporting Results - To ensure effective national data capture, all processing and testing sites must submit test results to their respective

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district, region, and case management centre. This would help create a linked processing and testing sites platform and establish surveillance and case management teams. For those using Laboratory Information Systems (LIS) or electronic medical records (EMR), the following must be adhered to:

- All processing and testing sites, public or private, involved in testing must use the national automated data capturing and analytical software procured by the MOH for purposes of data capture and reporting.
- Participating research institutions have the responsibility to capture sample data, process, test, and transmit results to their respective regional and national surveillance and case management centres.
- MOH-approved automated systems must ensure real-time data reporting.
- All data and information on samples and testing shall be government property.
- All specified processing and testing sites, public or private, must install an MOH automated system.
- Measures and procedures to guarantee data protection must be taken by all specified processing and testing sites.
- Internal review mechanisms must be established by research institutions to allow for the review of results before they are released to the District Rapid Response Teams (DRRTs).

From the guidelines above, it is evident that there are no specific guidelines and SOPs for conducting either general or social research under COVID-19 in Ghana. However, there are national guidelines produced by MOH to help guide researchers conducting clinical research under COVID-19 restrictions. Meanwhile, the MOH has directed that all agencies/authorities, Research Institutions, Universities, Teaching hospitals, and their respective RECs, produce and implement their respective clinical research policy guidelines and SOPs based on the

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above national guidelines. Therefore, by implication, MOH's national guidelines are, by proxy, the current requirements for conducting research under COVID-19 in Ghana.

2.6 Conceptual Framework

Figure 1 presents the Conceptual Framework of the study. It visually illustrates the factors that affect the assessment of ethical standards for research with human participants during the COVID-19 pandemic in Ghana.

Key variables like Ethical standards, COVID-19 restrictions, Research challenges and Research with Human participants are central to conducting ethical research during the COVID-19 pandemic. How these variables influence and are influenced by the ethics review, consenting, and monitoring processes and its effects relationship on IRB activities, methods of engagement, government directives as well as autonomy, privacy and confidentiality of research participants.

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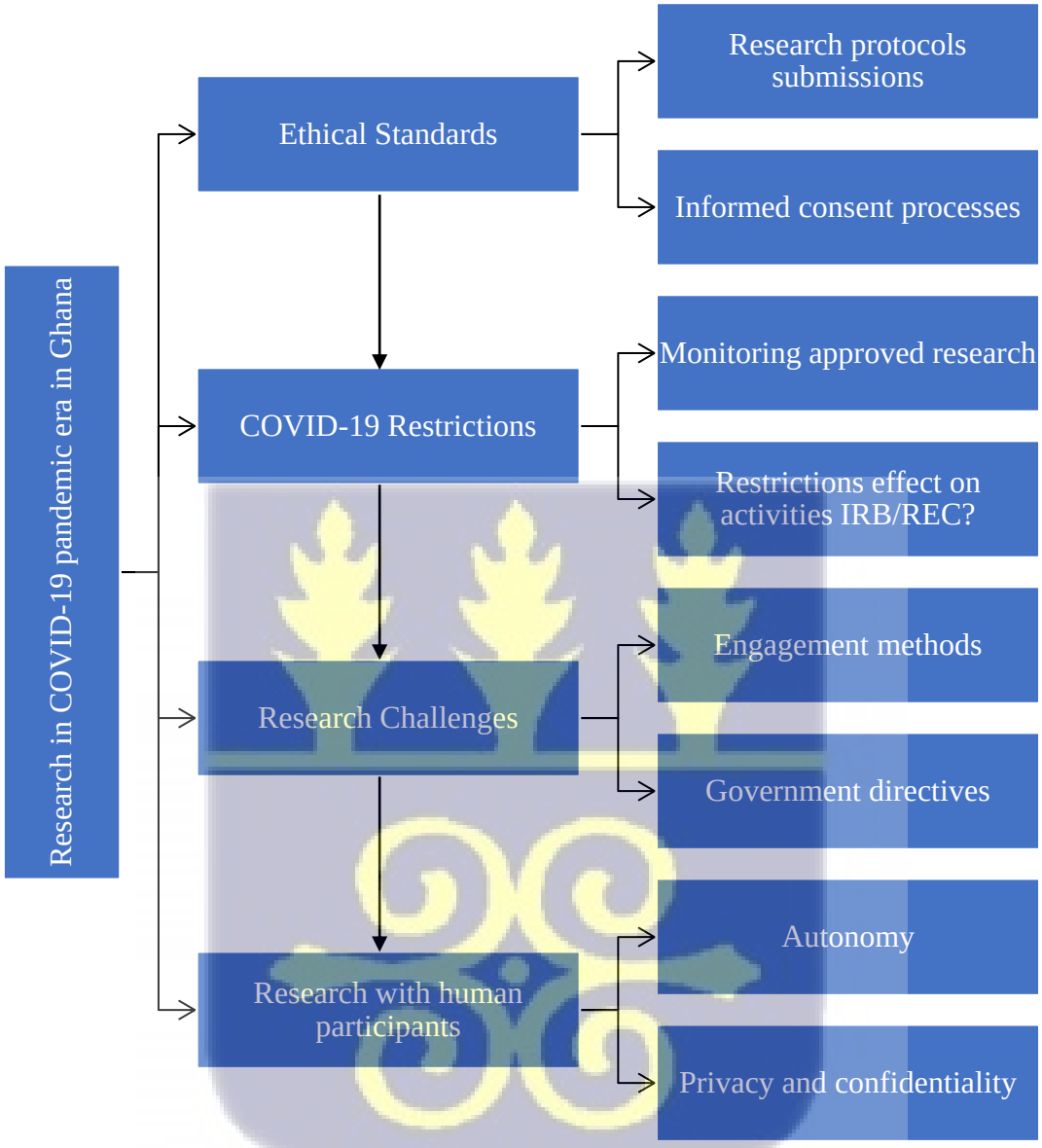

Figure 1: Conceptual Framework of the Study

The conceptual model underpinning this study encapsulated four pivotal dependent variables: Ethical Standards, COVID-19 Restrictions, Research Challenges, and Research with human participants (Figure 1). These variables were intrinsically interconnected, each influenced by an array of key factors.

Firstly, Ethical Standards were scrutinized in the context of Research Protocol Submissions and Informed Consent Processes. The study aimed to discern the impact of the Research Protocol

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Submissions and Informed Consent Processes on upholding ethical standards during research endeavours in the COVID-19 era in Ghana.

Secondly, the intricate web of COVID-19 Restrictions was explored, guided by the two pillars of Monitoring Approved Research and the far-reaching effects of these restrictions on the activities of Institutional Review Boards (IRB) and Research Ethics Committees (REC). The study delved into the uncharted territory of Monitoring Approved Research and sought to unveil the ripple effects of COVID-19 restrictions on the intricate workings of IRB/REC activities.

Thirdly, the realm of Research Challenges was dissected, concentrating on the dynamic interplay of Engagement Methods and Government Directives. Through this lens, the study sought to unearth the multifaceted challenges researchers encountered, emanating from the fusion of Engagement Methods and the prevailing directives of the government during the COVID-19 pandemic in Ghana.

Lastly, Research with human participants was examined with a focus on the twin pillars of Autonomy and Privacy and Confidentiality.

2.7 Summary of Literature Review

It has been gathered from the reviewed literature that the COVID-19 pandemic has led to some changes in research design and methodologies and alterations in research outcomes procedures. Research logistics, like timelines, funds allocation, and knowledge distribution, have been affected. The same can be said of the existing informed consent processes, which the COVID-19 pandemic has necessitated their review and revision. Hence, for research to be conducted under COVID-19 restrictions, whatever changes are required should be made to uphold the integrity of scientific and social research. Moreover, the changes must conform to existing regulatory requirements and be documented accordingly.

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Reviewed literature likewise indicates that the COVID-19 pandemic has impacted the work of researchers, particularly in the area of compliance with existing research guidelines; protecting participants; research methodological and procedural modifications; the need to meet rapidly evolving daily evidence; besides the need to assess the impact of new procedures, devices, and experimental drugs on participants. Meanwhile, since the outbreak of COVID-19, RECs, and researchers have taken steps to protect research participants through modifications in research designs, methods, data gathering techniques, informed consent processes, review and revision of approval protocols for managing sensitive issues, and the MOH's issued COVID-19 safety protocols.

Accordingly, the reviewed literature established limited guidelines and SOPs for conducting general or social research under COVID-19 in Ghana. However, there is a proxy guideline and SOPs developed by MOH in June 2020 to help guide researchers and the existing 18 RECs, ERCs, IRBs, or REBs in Ghana, in the conduct of clinical and social research under COVID-19 restrictions.

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CHAPTER THREE

RESEARCH METHODS

3.1 Introduction

This chapter describes the methodology of the study and the various approaches, and techniques that were employed to address the research objectives. The eight (8) sub-sections of the chapter include: study design, study population, sampling, sources of data, data collection, data analysis, ethical consideration, and a summary of the chapter.

3.2 Study Design

Research design is broadly defined as a universal plan that guides researchers in conducting their research (Zain, 2022). It could also be defined as established rules and guidelines instructing researchers while addressing a research problem (Haydam and Steenkamp, 2021).

The current research employed a concurrent mixed-method design involving quantitative and qualitative methods to answer the research questions. The choice of design was influenced by the need to accurately describe, infer, and explain observed field information from researchers and research ethics committees in Ghana. The approach allowed for collecting qualitative and quantitative data and integrating these data for analysis; based on philosophical assumptions and theories. The mixed method offers a more comprehensive understanding of a research problem than using either approach alone while helping researchers answer all research questions (Creswell and Clark, 2017; Bhattacherjee, 2012).

3.3 Study Population

The study population is a collection of persons, substances, or events with a common observable characteristic (Murugaiah and Oscandar, 2015). It is the total number of research participants from which a sample is chosen. For the current research, the study population

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comprised all Chairpersons and, Administrators of the 18 IRB/RECs, and Researchers who submit protocols to conduct research to these 18 IRB/RECs. The basis for targeting this population was underscored by the fact that they possess comprehensive knowledge of the topic under review.

3.4 Inclusion and Exclusion Criteria

3.4.1. Inclusion Criteria

Key informants such as the Chairs and administrators of REC/IRBs who have worked in this capacity for more than three (3) years, with practical knowledge and understanding of ethical standards governing research in Ghana, were included in the current research. Additionally, researchers who have conducted one or more research in the last (1) year (since COVID-19) were recruited for the study.

3.4.2. Exclusion Criteria

Chairs and administrators and researchers who declined to participate in the study or who were not available at the time of conducting this study were excluded.

3.5. Sample Size Determination

The sample size is a fraction of the entire research population and is determined based on a formula, and a researcher's judgment, among others (Babbie, 2020). For the quantitative arm of the study, all researchers in the six (6) purposively selected research institutions in Ghana were targeted while the qualitative arm targeted the chairpersons and administrators of the IRB/RECs in the research institutions.

3.6. Sampling Technique

The current study used a non-probability sampling technique. Specifically, the study employed the purposive sampling technique to select participants for the qualitative study and

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convenience sampling technique to select participants for the quantitative arm of the study (Creswell and Clark, 2017).

From the 18 IRB/RECs in Ghana, 6 IRB/RECs were conveniently selected due to time constraints on the part of the researcher. The administrators and chairpersons of the selected IRBs were then interviewed for the qualitative study while researchers from each of the institutions where these IRBs reside were surveyed for the quantitative part of the study.

The participants were sampled from Six (6) IRB/RECs in Ghana: Noguchi Memorial Institute for Medical Research (NMIMR), Ghana Atomic Energy Commission (GAEC), Dodowa Health Research Centre (DHRC), Kintampo Health Research Centre (KHRC), Council for Scientific and Industrial Research (CSIR), and Navrongo Health Research Centre (NHRC).

3.7. Sources of Data

In this current research, both primary and secondary sources of data were extensively used. The researcher reviewed the literature to augment the primary data collected from the interviews and surveys. The researcher also reviewed policies and guidelines as part of the literature review for the conduct of the study. These sources provided the relevant data, which were analyzed following the research objectives (Hakim, 1982).

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3.8. Data Collection

3.8.1. Pretest of study instruments

The research instrument was pre-tested with graduate students at the School of Public Health to enable data collectors to familiarize themselves with the research instrument and data collection technique. This helped to fine-tune the research instrument as questions that were found to be ambiguous were modified, and those found to be redundant were deleted. The data from the pretest were not included in the final data analysis.

3.9. Data Collection Tools and Techniques

The current research used both questionnaires and interview guides as data collection instruments. The questionnaire and interview guide were cautiously designed and structured to cover the scope of the research and consequently administered to participants. These were also effective in gathering relevant data for specific objectives and monitoring the interview processes respectively (Haydam and Steenkamp 2021).

To guarantee a smooth data collection, executive management of the IRB/RECs was contacted for authorization to interview their members. After the approval was granted, a list of all researchers that had conducted at least one (1) research in the past one (1) year; was requested from the research institutions.

3.9.1. Qualitative Interviews

All the Chairpersons and Administrators of the IRB/RECs targeted for this study were purposively recruited to participate in the qualitative study. Open-ended questions were used to collect qualitative data from participants which allowed them to bring up new ideas and speak to the issues raised in the research (Edwards and Holland, 2013). Interviews were conducted remotely, as opposed to the traditional face-to-face method, as part of satisfying the requirements for conducting research under COVID-19 restrictions. The interviewer

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worked with an experienced observer/note-taker for all data collection activities. After each data collection activity, the interviewer and note taker discussed the process and outputs and maintained detailed field notes from the session.

The main topics explored in the interviews were perceptions, attitudes, experiences, and behaviours concerning COVID-19 studies (during development and implementation), including the aim of the study, activities, and impacts in the short and longer terms. A guide to the topics included across data collection methods is provided in Appendix 1. The interviewer asked the questions and recorded participants' responses using either dedicated password-protected project laptops or internet-enabled mobile phones. For either method, the researcher used a secure end-to-end encrypted platform (Skype for Business and Microsoft Teams, depending on availability).

3.9.2. Quantitative survey

After all approvals and authorizations, the self-administered questionnaire was emailed to all six institutions to be shared with their researchers, and participants were asked to tick (√) the appropriate options that suit their opinions, perceptions, and understanding of the phenomenon under study. Likert-scale closed- and open-ended questions were contained in the questionnaire. Research participants were given ten (10) working days for responses and were required to return the completed questionnaire to the researcher via email or make them available for pickup in cases where it was difficult to send them via email (Barnett, 1991).

3.10. Conducting Research Under COVID-19

With the outbreak of the COVID-19 pandemic, research staff and participants must adapt to new ethical guidelines, national regulations, and COVID-19 protocols in their data collection The study's methodology was adapted so that data collection could be done online rather than administering hard copies of questionnaires to study participants (Mourad, et al., 2020).

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The study considered the risk of infection and avoided the exchange of smartphones, tablets, digital devices, papers, and pens during the data collection process. For the qualitative interviews that were conducted face to face, the study participants were provided with nose masks and sanitisers (PPEs).

3.11.Data Analysis

Two types of data (quantitative and qualitative) were collected and consequently analyzed.

3.11.1. Quantitative Data Analysis

The Statistical Package for Social Sciences (SPSS) software was used to analyze the quantitative data. The SPSS allowed for the computation of percentages for comparison purposes based on frequency tables created out of collected responses. Accordingly, demographic profiles of participants were created using descriptive statistics, while statistical tools (i.e. tables, bars, and pie charts) were used to present the research outcomes (Bhattacherjee, 2012; Sullivan, 2001).

3.11.2. Qualitative Data Analysis

Qualitative data were analyzed using thematic content analysis. This kind of analysis allows for determining the relationships between concepts by comparing them with the simulated data. It also helps researchers provide interpretations to participants' opinions, views, experiences, values, and knowledge against their backgrounds (Campos and Turato, 2009). The data were organized into themes and subthemes after transcription. Then coding frameworks were developed and adapted to include additional codes/themes emerging from the data. The thematic content analysis technique was used to search for important themes and patterns in the data, grouping and noting these themes and similar patterns. These were then used to compose a narration and interpretation of the themes and patterns with outstanding quotes to support the narration. Lastly, the research outcomes were compared to ethical standards,

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principles, and concepts reviewed under the literature to guide the research's conclusions and recommendations (Franzosi, 2008).

3.12.Ethical Considerations

3.12.1. Ethical Clearance

Ethical clearance was obtained from the Ghana Health Service Ethics Review Committee. Permission was obtained from the Directors of all the Research Institutes and Centres to carry out the research. Participants were pre-informed about the information required, why it was sought, the purpose of the research, and how they were expected to participate in the study.

3.12.2. Consent Processes

The traditional consent-seeking processes had to be revised in line with COVID-19 restrictions such as the ban on mass gatherings, social distancing, and other protocols. The researcher devised ways of interacting with research participants and seeking their consent through a clarified participation agreement between the researcher and the participant. The study adopted the following consent processes:

1. The researcher answered participants' questions regarding their participation in the current study.
2. Participants were provided with both original and amended applicable informed consent rules approved by RECs, ERCs, IRBs, or REBs.
3. Participants were allowed to remotely go through the processes captured on the informed consent form before being recruited.
4. Both the anticipated benefits and the potential risks and inconveniences of the study were explained to the participants.
5. Verbal informed consent was obtained from participants through telephone and WhatsApp.

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3.12.3. Potential Risks

The risks of researching under COVID-19 restrictions were mitigated by modifying the methods to limit interactions to only online engagements. The initial engagements with research institutions where permissions for the study were sought were done under strict observance of the COVID-19 prevention protocols.

Specifically, a self-administered questionnaire was used to collect quantitative data, whereas qualitative data were collected with an interview guide through phone interviews. It helped eliminate all face-to-face interactions between the research and research participants.

3.12.4. Benefits of the Study

Research participants did not benefit financially from the current study. However, individual researchers and executive management of the affected IRB/ERC/RECs; stand to benefit from the study's outcome in the form of knowledge expansion and in-depth understanding of the guidelines and SOPs for conducting either clinical or social research under COVID-19 in Ghana. For this reason, copies of the research findings would be shared with interested participants (individual researchers and executive management of the affected IRB/ERC/RECs). Specifically, these groups and individuals would benefit from the latest information about ethical standards governing research in Ghana under the COVID-19 restrictions. Similarly, the groups and individuals would benefit from new ideas to address crucial ethical issues.

3.12.5.Cost of Participation

The cost of participation, on the part of research participants, is in the form of data that they used to download the questionnaire and upload it after self-administration. Another cost of participation was in the form of the valuable time that participants used to self-administer the

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questionnaire or to respond to the interview guide. All selected participants were duly informed of their consent.

3.12.6.Compensation

There was no compensation whatsoever for either the researcher or the research participants. The study is academic research intended only to explore the perspectives of researchers and members of RECs, ERCs, IRBs, or REBs on the current requirements for conducting research during the COVID-19 pandemic in Ghana. Moreover, the study's purpose, approaches, risks of participation, and funding sources were explicitly described and explained. Hence, there were no funds allocated to compensate participants for harm and suffering they may have encountered while participating in the research.

3.12.7.Privacy and Confidentiality

Participants were assured that the information given would be treated solely for the research and would not be disclosed to third parties with their identity attached. This approach ensured that only participants willing to participate in the study were selected.

To ensure responsible and ethical research, secondary data used in the current research have been duly acknowledged to avoid plagiarism. Further, appropriate confidentiality procedures have been implemented throughout the study. During the data analysis, no names or institutions were linked to any responses, which was done to maintain anonymity in the report.

3.12.8.Data Security and Storage

Primary data collected from all 372 participants were securely stored on the researcher's electronic hard drive. Accordingly, all 'sent' and 'received' emails transmitted between the researcher and participants have been deleted. Similarly, participants have been advised to delete the same to ensure that the collected data would not be tracked.

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Since the collected data has served its intended purpose, the Folder containing the stored data would be kept for approximately one (1) year and then be deleted from the researcher's storage device. Lastly, participants were informed of their rights to check and modify the drafted research report to prevent all forms of misquotations. In that regard, copies of the drafted research reports have been sent to participants requesting them.

3.12.9.Voluntary Consent and Withdrawal

Moreover, participants were informed about the nature of the research and what would become of the findings once completed. Participants were therefore informed and reminded throughout the data-gathering process that their participation was voluntary; hence, they could withdraw from participating in the study at any time.

3.13.Summary of chapter

This chapter presents the methodology that underpinned the current research. It justifies the decisions made concerning research designs, research approach, sampling technique, sample size, data collection procedure, and data analysis, among others. The chapter also indicates that the choice of the above methods, approaches, and procedures was informed by existing literature. As proven by the results and analyzed data in the ensuing chapter, it is obvious that the selected methods and instruments have been very useful for the current research because they have successfully helped in the collection of the required data.

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CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter presents the key findings from this study. It is divided into five sections; the first section presents data on the socio-demographic characteristics of participants; the second section presents data relating to researchers' COVID-19 experience with the ethics review process; the third segment analyses issues about the steps taken by researchers to protect participants' safety during research; the fourth section examines research challenges that confronted researchers during the COVID-19 restrictions.

4.2 Socio-demographic Characteristics of Study Participants

The study included 372 participants comprising 360 researchers who completed the survey questionnaire and 6 Chairman/Chairperson and 6 Administrators from the 6 IRB/RECs in Ghana who participated in the qualitative interviews. Table 2 shows the socio-demographic characteristics of participants, which included: Sex (gender), age, working experience, and researcher type.

Table 2: Socio-demographic characteristics of researchers (N=372)

Factors	Frequency	Percentage (%)
Sex		
Female	187	50.3
Male	185	49.7
Age, years		
25-34	219	58.9
35-44	133	35.8
45 and above	20	5.4
Working experience		
3-5 years	203	54.6
6-10 years	86	23.1
>10 years	83	22.3
Types of research conducted		
Biomedical research	128	34.4
Social science research	244	65.6

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The table indicates that out of the 372 participants, 187 (50.3%) were females, and the remaining 185 (49.7%) were males. Most of the study participants were females. 219 (58.9%) were in the 25 - 34 age cluster; 133 (35.8%) were within the 35 - 44 age cluster; whereas 20 (5.4%) constituted the 'More than 49 Years' age cluster. Two hundred and three (203) representing 54.6% of participants have had between 3 and 5 years of professional research experience. Eighty-six (23.1%) of the participants, on the other hand, have had between 6 and 10 years of working experience, whereas the remaining eighty-three (22.3%) of the participants have had more than 10 years of professional research experience. One hundred and eight (34.4%) participants are engaged in biomedical research, whereas the remaining (65.6%) are engaged in social science research.

4.3 Background of IRB/RECs included in this study: Results from the Qualitative Data

Six institutional review boards/ethics review committees (IRB/RECs) were involved in this study. The data gathered on the committees' years of existence confirms that the IRB/RECs had a diverse number of years and experiences ranging from 22 years for NMIMRIRB, being the oldest and 11 years for the DHRC IRB.

In terms of IRB profile, it was reported that DHRC IRB consists of seven (7) members who are well-trained and experienced in the fields of Pharmacy, Nutrition, Medicine, Biostatistics, and Epidemiology, among others. The GAEC IRB comprises 14 members with different backgrounds, such as social science, and radiology. The diversity of the board is very important as boards receive protocols from diverse fields of study including social science, biomedical, clinical trials, nursing, pharmacy, students' protocols, animal care, and environmental sciences, among others. Participants also confirmed that IRB/RECs collaborate with the Ghana Food and Drugs Authority (FDA) and other regulatory institutions to approve some

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studies such as clinical trials and experimental studies for which these regulatory institutions may be key.

4.4 Review Processes Before the COVID-19 Pandemic

The interviews with Chairs and Administrators of IRB/RECs revealed that before the COVID-19 pandemic in 2020, some of the IRB/RECs combined both manual and electronic processes for the review of protocols. Specifically, four (4) IRB/RECs (DHRC IRB, Noguchi IRB, and CSIR Committee) combined both manual and electronic submissions and review of research protocols prior to the COVID-19 pandemic. The IRB/RECs reported that protocols were mostly submitted manually or electronically using either the normal stream of submission or the expedited stream. The time it takes to receive feedback from the IRB/RECs on either stream is two months and two weeks respectively. Researchers submitting their protocols are at liberty to pick and choose the stream that suits their needs and tailor their submission documents to meet the standards of their chosen stream. Key to the activities and processes of the IRB/RECs are meetings. Participants reported that they mostly held face-to-face meetings but opted for virtual meetings on very rare cases pre-covid. Each IRB/REC had varying but structured periods for meetings. For instance, the CSIR committee held quarterly meetings to review protocols while NMIMRIRB met every other month before COVID-19. All IRB/RECs had a system of checking submitted protocols and assigning a three-member board that reviewed the protocol and gave feedback to investigators to respond before a final report on the protocol was presented to the board which approved or rejected the protocol. A few excerpts of the interviews are quoted below.

> *"Before COVID-19, Noguchi IRB was meeting every other month. When protocols are submitted, there is a deadline attached to them. Protocols are assigned to three board members, which are the primary reviewer and two secondary reviewers. The*

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lead reviewer will take the board through the review and be supported by the two secondary reviewers. After it's brought to the board either to approve or reject the protocol. After the review, we give the investigators two weeks to respond, and when they send then we send it to the reviewers for approval." (IDI with Chair)

There was also the need to ascertain the workload of the IRB/REC before the COVID-19 pandemic. Two committees confirmed that they received a manageable number of protocols before COVID-19. But in the case of Noguchi IRB, it was established that the workload was high initially but reduced drastically when other IRB/RECs were established. The difference in workload is reflected in the number of meetings and the number of protocols reviewed per meeting. The data shows that GAEC IRB held quarterly meetings because the board does not receive many monthly protocols for review but relies on Korle-Bu or Ghana Health Service for protocols. In contrast, the NMIMRIRB held one or two meetings per month to review an average of 30 protocols. What is notable here is the flexibility of the IRB/RECs to hold special or emergency meetings to augment the number of protocols they have to review as a way to make the conduct of ethical research more appealing to researchers. Most IRB/RECs therefore found it difficult to give definite answers to the questions around the number of meetings or protocols reviewed per month as this varied from month to month depending on the number of protocols they received.

P3:"... our peak season ... we can receive as many as 60 protocols for the meeting because of the school of nursing and public health. During a meeting, we decided to review about 20 protocols and schedule another meeting in 2 weeks to continue the review because most students are time bonded." (IDI with IRB/REC administrator)

P5: "The huge number of protocols was the board's major challenge. Sometimes the board is overloaded at a meeting; and not all protocols are reviewed, resulting in the

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delay for approval of the protocols. Unfortunately, researchers do not understand why their document is submitted earlier and yet they do not get the protocol reviewed." (Interview with an IRB/REC member)

P4: "We have a certain quota of documents that when we receive within a period, you have to sermon the board, for instance, fifteen (15) protocols within a period and it's not time for a board meeting, we schedule a board meeting to work on the protocols, but when the protocol is one or two, we follow the procedures of the quarterly meeting. Sometimes we can review about ten (10) to eighteen (18). Some years back, twenty (20) protocols depending on the period." (IDI with IRB/REC Chair)

4.5 Challenges in Review Processes during the COVID-19 Pandemic

The study also examined the key challenges the IRB/RECs and researchers faced during the COVID-19 pandemic. The Chairpersons and administrators highlighted several challenges, including workload, and challenges with holding virtual meetings.

P1: Yes, the COVID-19 restrictions affected the board in many ways, such as internet challenges, and the contribution of board members was reduced due to their dislike of participating online. Also, due to the online meetings, some of the board members do not come at all or participate. When you compare the face-to-face and online, I prefer the in-person to the online because the in-person tends to be fruitful... not... like the online." (IDI with Chairperson)

P4: "The COVID affected every aspect of the work of the IRB… board members wish they would meet physically to have a direct conversation on the protocols received, but as a result of COVID… even sending documents to them, we rely on courier services. During the lockdown… we had to sort through virtual meetings and softcopy submissions, and other means." (IDI with Administrator)

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Participants also mentioned funding, lack of quorum, and monitoring difficulties resulting from the restrictions as some other challenges they encountered in the review process during the pandemic. Some IRB/RECs suspended the review processes entirely at the peak of the pandemic while the few who stayed on struggled with transitioning from physical meetings to virtual meetings. They reported that the transition was challenged by poor connectivity and the reviewer's lack of interest in virtual meetings.

> *P4: "The challenge was the restrictions caused an inability to move out for monitoring and protocol submission declined. Our swift ability to shift from face-to-face meetings to virtual meetings was what worked well." (IDI with Chairperson)*

> *P1: "Internet challenge was encountered especially during online meetings. Other internet devices such as modems were collected to resolve it but couldn't solve it fully." (IRB Administrator)*

Another challenge was the pressure on IRB/RECs to improve the approval times for protocols owing to the urgency of some of the studies. IRB/RECs reported that they had to hold several meetings in a month to be able to meet the demand for ethics approval from researchers during the pandemic as most researchers were applying for expedited review. The change in review time before COVID and during the pandemic was however different from IRB to IRB with some experiencing no change at all, depending on the number of people submitting protocols to the IRB. For instance, DHRC's approval time before COVID was 2 months, but during COVID, it ranged between 4 and 5 weeks, requiring a meeting every month. A similar situation was reported by NMIMRIRB as most protocols they received during the pandemic were quite urgent.

> *P4: "Depending on the study being done, we look at the science and relate it to the ethics because some of the studies applied without a scientific basis…The board looks*

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at it and the scientific merits, does it require wasting the participant's time, and whether we protect the participants." (IDI with Chairperson)

P2: "The main challenge is getting all the reviewers to stick to the timeline of submission." (IDI with Administrator)

4.6 Timelines for Ethical Clearance during COVID-19 Pandemic

The study sought to determine the time it took researchers to receive ethical clearance during the COVID-19 pandemic. As indicated in Figure 2 below, the majority of the researchers interviewed 39.5% (147), reported that they received ethical clearance within three months of submission, with 20.2% (75) of researchers having their approval within a month. 17.2% (64) of researchers reported that they received approval within six months, 22.6% (84) of researchers had their approval in a year and 5.0% (2) of researchers had their protocols approved more than a year after submission.

Figure 2: Duration of Ethical Approval During COVID-19 Period

Source 1: Field Data, 2022

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4.7 Effect of COVID-19 Restrictions on Informed Consent Processes

As indicated in Table 3 below, 278 (74.7%) of researchers agreed with the above statement that "COVID-19 restrictions have resulted in the revision of our informed consent processes, thereby affecting the way we interact with research participants". 57 (15.3%) of participants responded as unsure of the statement, while 37 (9.9%) of participants disagreed with the statement.

Table 3: Revision of the Informed Consent Processes during COVID-19

COVID-19 restrictions have resulted in the revision of our informed consent processes thereby affecting the way we interact with research participants.					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	37	9.9	9.9	9.9
	Agree	278	74.7	74.7	84.7
	Not sure	57	15.3	15.3	100.0
	Total	372	100.0	100.0	

Source 2: Field Data, 2022

4.8 Steps Taken to Protect Research Participants during the COVID-19 Pandemic

The study sought to examine the steps taken by researchers to protect participants' safety during research. Accordingly, participants were asked to use a 3-point Likert Scale: Disagree = 1, Agree = 2, and Not Sure = 3; to express their opinions on the subject matter. This section presents participants' responses to three (3) statements that were used to examine participants' opinions in this regard. Participants' responses have been summarized and presented in the graph below.

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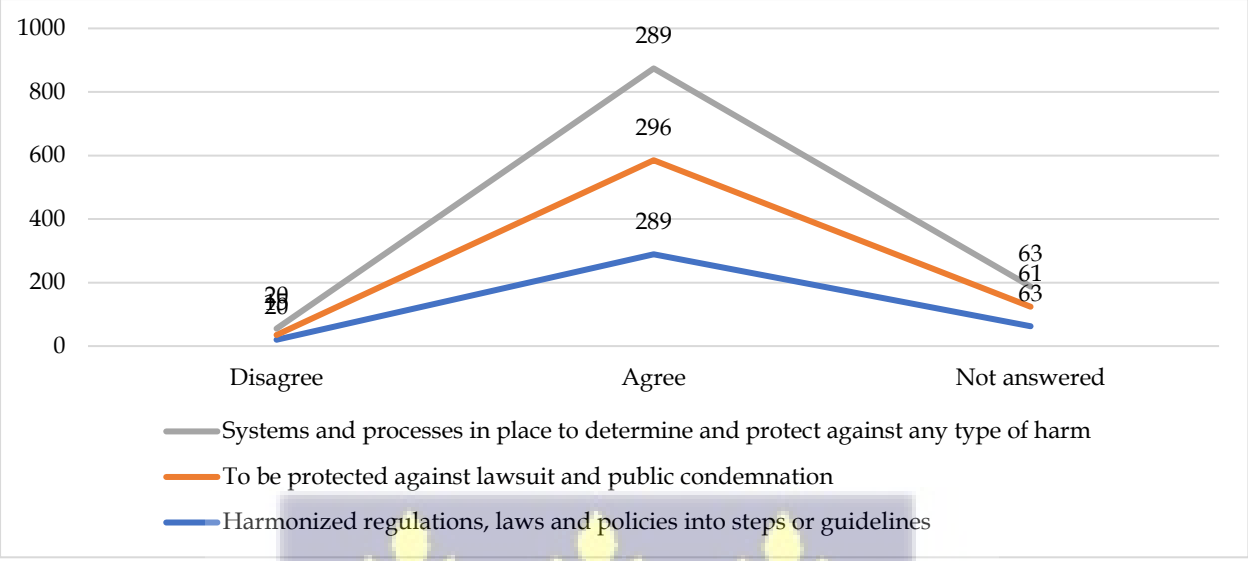

Figure 3: Institutional Standard Operational Policies

Source 3: Field Data, 2022

As illustrated in Figure 3 above, 77.7% (289) of participants agreed that their institutions have harmonized governing regulations, laws, and policies into steps or guidelines for all researchers to guarantee participants' safety during research. However, 5.4% (20) of participants disagreed with the statement and 16.9% (63) of participants were not sure of the statement.

Similarly, Figure 3 revealed that 79.6% (296) of participants agreed with the statement that their institutions carefully consider the negative impact of their research on participants to be protected against a lawsuit and public condemnation. The remaining 4.0% (15) and 16.4% (61) of the participants disagreed and were not sure of the statement, respectively.

Lastly, Figure 3 indicated that 77.7% (289) of participants agreed that their institutions have systems and processes in place to determine any type of harm that their intended research may cause participants. 5.4% (20) and 16.9% (63) of participants, on the other hand, said they disagreed and were not sure of systems and processes.

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4.9 Challenges with Research Implementation Under COVID-19 Restrictions

The third objective of the study was to explore the challenges of conducting research under COVID-19 restrictions. Here, four (4) statements were presented to participants for them to express their views using the Likert scale, below presents a summary of participants' responses to the statements.

4.9.1.Existing Challenges Before COVID-19

Figure 4 revealed that 299 (80.4%) of participants agree that research challenges existed before the outbreak of the COVID-19 pandemic. Meanwhile, 9.9% (37) and 9.7% (36) of participants said they disagreed and were unsure of such research challenges respectively.

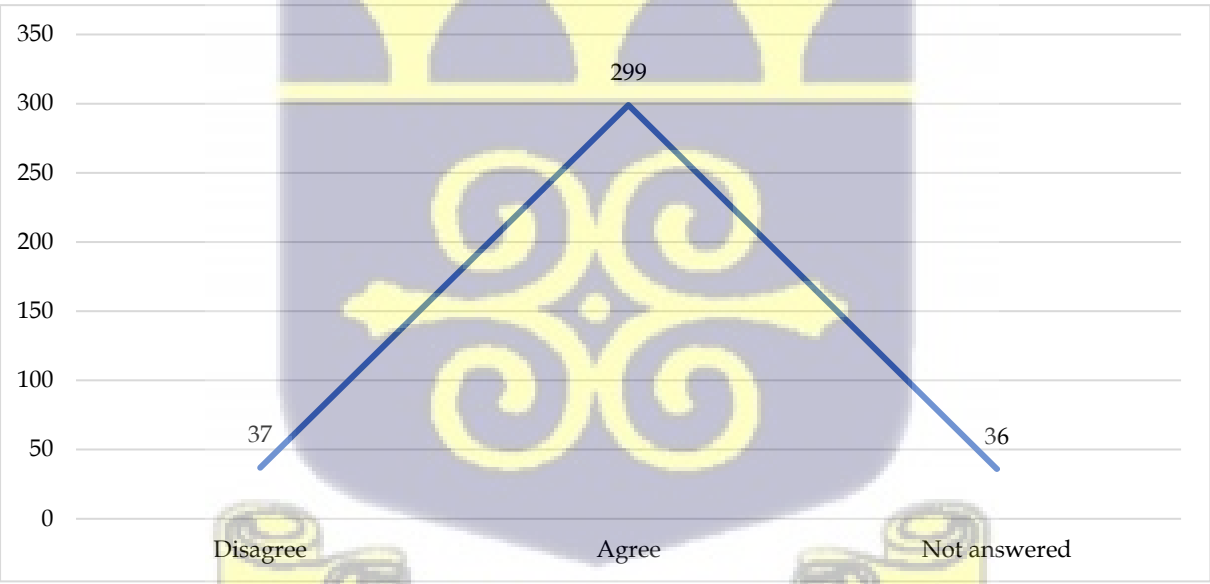

Figure 4: Challenges that existed before COVID-19

Source 4: Field Data, 2022

4.9.2.Challenges exacerbated by the COVID-19 Pandemic

The second statement, as indicated in Figure 5, shows that 265 (71.2%) out of the 360 participants agreed that the COVID-19 pandemic has worsened existing challenges in the form of complexities associated with the designs, methods, techniques, and processes of

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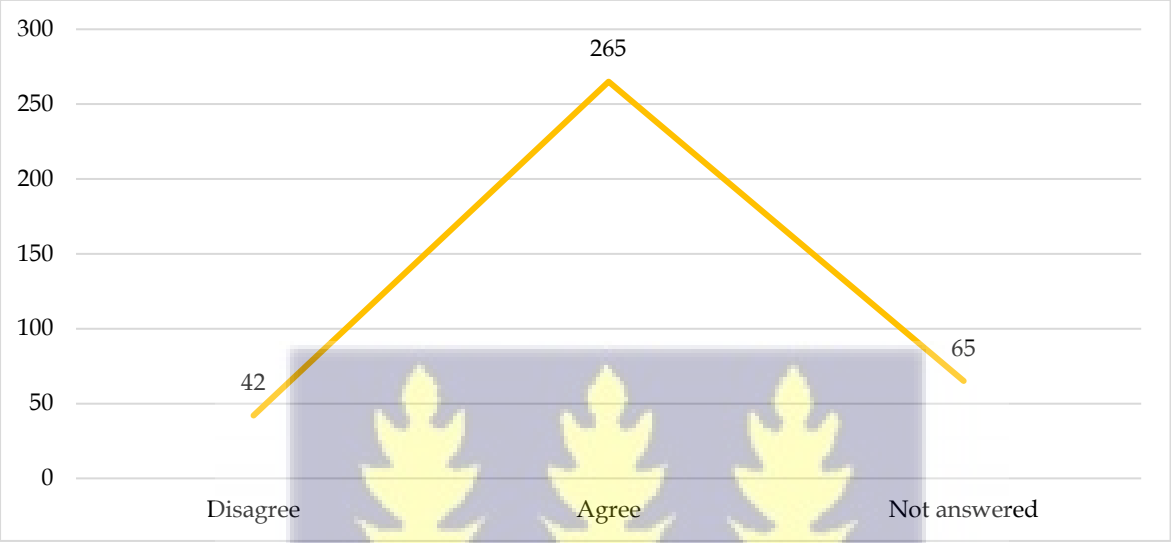
conducting clinical and social research. Nevertheless, 42 (11.3%) and 65 (17.5%) participants



expressed that they disagreed and were unsure of any worsened existing challenges.

Figure 5: Challenges worsened by the COVID-19 Pandemic

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CHAPTER FIVE

DISCUSSION

5.1 Introduction

This chapter presents a discussion of the key study findings concerning existing literature. The study aimed to assess the ethical standards for research with human participants during the COVID-19 Pandemic in Ghana. Specifically, the study examined the ethics review processes of conducting research before and during the outbreak of the COVID-19 pandemic in Ghana. It also examined the informed consent processes in research during COVID-19, and the steps taken by researchers to protect participants' safety during research. Lastly, the study explored the challenges of conducting research under COVID-19 restrictions. To the best of my knowledge, this is the first study to document the ethics review processes during the COVID-19 pandemic as well as the difficulties that research ethics committees and researchers had to deal with in Ghana.

5.2 Ethics Review Processes Before and During the COVID-19 Pandemic

The first specific objective of the study sought to examine the ethics review processes of conducting research before and after the outbreak of the COVID-19 pandemic in Ghana.

5.2.1.Ethics Review Processes Before COVID-19

IRB/RECs have existed in Ghana for the past twenty (20) years, performing oversight responsibilities to facilitate the ethical conduct of research in the country (Boateng et al., 2019; Kass et al., 2007). With a membership of between seven (7) and fourteen (14), several IRB/RECs in Ghana including the Navrongo Health Research Centre (NHRC) IRB, Ghana Atomic Energy Commission (GAEC) IRB, and Noguchi Memorial Institute for Medical Research (NMIMR) IRB collaborate with the Food and Drugs Authority (FDA) and other

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domestic and foreign regulatory institutions for approvals, coordination, and knowledge sharing in the areas of clinical trials, research protocols, and research proposals, among others.

Consistent with the findings from a study by Owusu et al. (2022), the current study has shown that prior to the outbreak of the COVID-19 pandemic, IRB/RECs held face-to-face meetings routinely and received protocols manually, irrespective of whether they were dealing with the regular review or expedited review. It was also revealed that, on average, it took between one month and three months for regular reviews, whereas expedited reviews took a maximum of two weeks to be completed. According to the study respondents, specific protocols that the IRB/RECs receive include, but are not limited to clinical trials, biomedical, nursing, pharmacy, environmental, social science, students' protocols, and animal care. These findings are consistent with the experiences of the WHO Ethics Review Committee which was reported by Alirol et al. (2017).

The study also found that the workload of IRB/RECs prior to COVID-19 was manageable because they received between 10 to 30 protocols each month for review. As a result, depending on the workload, Board meetings were either held monthly or quarterly. These findings are also consistent with studies by Boateng (2019) and Owusu et al. (2022) which also reported that some RECs conduct monthly and bi-monthly meetings, while meetings.arterly

Participants in this current study reported that in the course of their regular ethics review procedures, several IRB/RECs encounter challenges such as delays in the approval of protocols, inability to meet schedules and timelines, absenteeism as well as inadequate funding. Previous studies by Boateng 2019 and Owusu et al. (2022) have also highlighted these challenges, particularly with funding of IRB/REC activities. Not surprisingly, this study also found that a major challenge facing most IRB/RECs is regular funding to support their

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activities including monitoring of approved research. To address the challenges with funding, some IRB/RECs have introduced fee-paying for the protocols as an internally generated source of funding to mitigate the funding challenge. Also, to mitigate delays in protocol approval, schedules, and other delays, some IRB/RECs have conducted a pilot test to help determine the possibility of scheduling monthly board meetings. Further, it was revealed that while some IRB/RECs had reviewed their research designs to protect participants and to expedite the review process, others had not. Overall, this study suggests that while some IRB/RECs have made progress in addressing their challenges and streamlining their review processes, some of the challenges documented in previous studies (Owusu et al., 2022) persisted prior to the COVID-19 pandemic.

5.2.2. Review Processes During the COVID-19 pandemic

The first case of COVID-19 in Ghana was reported in March 2020 which triggered national responses including instituting COVID-19 restrictions such as social distancing and partial and total lockdowns in major cities in the country (Kenu et al., 2020). Naturally, these new measures to curb the spread of the virus affected the implementation of research activities which required human contact. This study reveals that some IRB/RECs quickly switched from holding physical meetings to online platforms to assist the efficient functioning of the IRB/REC activities after the ethics review processes were initially stopped because of these restrictions. While some IRB/RECs migrated to online submissions and meetings without a hitch, others struggled with internet connectivity and board members who were not interested in the new platforms. Due to this, fewer people participated in virtual Board meetings, especially those who did not want to switch to electronic platforms. This suggests that IRB/RECs need to take this challenge into consideration and provide support for members who may encounter challenges with internet access.

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Furthermore, the study found that the number of research protocol submissions received by IRB/RECs was affected. Whereas some had their numbers reduced, others increased due to the COVID-19 pandemic. For this reason, some IRB/RECs had to amend their work plans to reflect the changes. Moreover, the work of some investigators and researchers, particularly in biomedical sciences and social sciences, had to be halted because they required the interaction of researchers and human subjects, which was against the COVID-19 protocols. Accordingly, it was found that the percentage of COVID-19-related protocols submitted to IRB/RECs was, on average, a little above twenty (20) percent. In terms of the number of COVID-19 clinical trial protocols, it was found that an average of 25 COVID-19-related protocols were submitted.

In addition, the study found that the COVID-19 pandemic brought both positive and negative memorable experiences. For some IRB/RECs, the COVID-19 pandemic allowed them to acquire an online database management system. There were no memorable experiences or challenges for others because they were already used to working on virtual platforms. However, some IRB/RECs had issues validating the COVID-19 safety measures embedded in the protocol because they were new. Similarly, other IRB/RECs had issues such as switching their review processes from manual to electronic a couple of times, making the entire review process difficult and cumbersome.

The challenges that IRB/RECs encountered and the measures they initiated to resolve them were highlighted in this study. Some virtual meetings were disrupted by internet connectivity and technical malfunctions. Mobile internet connection devices were used to resolve these challenges. Although some of the challenges mentioned in previous studies during the Ebola epidemic (Alirol et al., 2017) are similar to those IRB/RECs encountered during the COVID-19 pandemic, the latter caused unique challenges because of the restrictions that necessitated moving to virtual platforms to support the ethics review process as well as the

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implementation of research projects. Tindana et al. (2021) also noted that the COVID-19 response strategies, such as social distancing, posed a challenge to traditional community engagement approaches and that new methods of involving communities in research had to be conducted using, among other things, web-based platforms (such as Zoom, Skype, MS Teams), phone-based platforms (such as WhatsApp), telephoning, and mass media (such as radio, television, newspapers, and mobile information vans). Agrawal et al. (2020) have alsosuggested that video conferencing meetings are a feasible option for ethics committees' early decision-making, particularly for research projects that are related to the COVID -19 pandemic. The authors also recommended that there is a need to develop guidelines to facilitate the coordination and conduct of key EC meetings during public health emergencies (Agrawal et al., 2020).

The study also found that approval times before and during COVID-19 changed for some IRB/RECs but not for others because applicants applied for expedited review due to the urgency of their proposed studies but also because IRB/RECs scheduled more meetings to meet the demand for ethics approval by researchers. Some IRB/RECs already had an expedited/accelerated review process to respond to the COVID-19 pandemic. This process is initiated when a protocol is sent to a certified number of sub-committee members, who must review and submit the report within 3–7 days from the day of receipt of the protocol. The expedited/accelerated review processes did not significantly impact IRB/RECs' response strategy because a criterion, such as risk and urgency, among others or a combination of them, is/are used. These review processes are similar to what was described in the article by Alirol et al., 2017.

Again, the current study found that some IRB/RECs prioritized COVID-19-related research while others did not. In the case of IRB/RECs that did not prioritize COVID-19-related research, their reason was that those cases were not high-risk or urgent and hence, were

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reviewed in good time. But for the others, they prioritized as follows: biomedical research works were prioritized based on the spread, social science research works were prioritized based on staff stress level adjustments, and environmental research works were prioritized based on the virus' ability to survive in sewage systems. These findings support the study of Kim and Grady (2020), who asserted that it is difficult to fairly distribute scarce resources by applying traditional ethical standards. They expressed further that ethical standards for conducting clinical research have remained the same despite COVID-19 restrictions.

Likewise, the study found that some IRB/RECs developed strategies that worked well during COVID-19 review processes, whereas others did not. Those without strategies treated cases as they were reported. But for some, their already existing email and phone call systems were improved, and they also organized one-on-one research sessions when clarifications were required. Others introduced Dropbox for online submission of minutes and reports to provide easy access for board/committee members. Additionally, the study found that IRB/RECs are certain that they have performed well in terms of both COVID-19-related protocols and non-COVID-19 protocols. Specifically, some IRB/RECs had to expedite the review of the COVID-19-related protocols without compromising on relevant ethical issues. Other IRB/RECs deployed measures to protect participants' and researchers' safety and well-being and provided training and advisory roles for non-COVID protocols. These findings are consistent with the findings from studies by Dodman (2020) and Barroga and Matanguihan (2020). It is not a coincidence for the study to find that IRB/RECs have performed well in terms of developed strategies and measures for both COVID-19-related protocols and non-COVID-19 protocols. It is because IRB/RECs made essential alterations in ethics, peer review, and research; to guarantee the development of new, profitable, and extremely flexible research models.

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In this study, IRB/RECs developed their SOPs based on international guidelines such as the Declaration of Helsinki, and the guidelines of the US Department of Health and Managerial Services. Even though IRB/RECs did not explicitly indicate the number of international guidelines they have developed, it became apparent that such guidelines are useful because they serve as a reference guide in IRB/RECs' review processes and activities. Secondly, such guidelines led some IRB/RECs to platforms that brought benefits such as grants to help improve ethics systems within the sub-region and at national ethics committee levels in Ghana and GCP compliance training for board/committee members. Also, some IRB/RECs had their SOPs even though they had not been reviewed for some time. Such IRB/RECs had to quickly improve some aspects to include the COVID mitigation factors during the COVID-19 pandemic.

IRB/RECs had to refer to international ethical guidelines to make other necessary revisions. However, it became apparent that some IRB/RECs do not formulate their guidelines but have to rely on internationally developed guidelines such as the WHO guidelines and the Nuffield Council report (Wright et al., 2020). These outcomes are indirectly consistent with literature by Health Canada (2019) and the Finnish National Board on Research Integrity guidelines (2019). As stipulated in these guidelines, IRB/RECs are expected to review and oversee that all research meets the national and international ethical principles and the appropriate regulations and guidelines relating to human participant protection. Likewise, it is asserted that all informed consent processes should comply with the regulations of the International Council for Harmonization and Health Canada as approved by the REB.

Moreover, the study found that some IRB/RECs are confronted by challenges such as funding for the committee and delays in meeting submission deadlines. They have consequently resolved the timeline submission delays by introducing initiatives that ensure that Board/Committee members work within schedules and timelines. However, it became

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obvious that IRB/RECs are still exploring the best possible funding sources for their programs and projects. Accordingly, it was found that some IRB/RECs were confronted with some challenges during the COVID-19 pandemic but managed to initiate some mitigation plans to resolve those challenges. An example is acquiring mobile-connected devices such as a modem to resolve internet connectivity. Also, it became apparent that some IRB/RECs could not conduct face-to-face meetings.

Furthermore, a lack of motivation on the part of the Board members was mentioned. Besides, it was found that virtual meetings negatively affected the discussions, interactions, and deliberations of IRB/RECs. Some negative effects are internet connection difficulties and reduced membership participation. With regards to the types of review challenges that researchers and IRB/RECs experienced during the COVID-19 pandemic, the findings from this study are consistent with assertions made in the literature by Tindana et al. (2020), Ma et al. (2020), as well as Goldman and Gelinas (2020). Specifically, systems, methods, procedures, processes, finances, time constraints, and the like were mentioned except for mitigation plans put in place by researchers and IRB/RECs.

During the COVID-19 period, some IRB/RECs received funds and administrative support from host Institutions but not from the government; to cope with the emerging challenges. Moreover, it was revealed that some IRB/RECs did not receive training or additional staff compensation except for the regular remuneration, finance, and logistics from host Institutions. These findings are consistent with existing literature because the MoH, the FDA, and other government agencies only provided guidelines upon which IRB/RECs were required to design their respective clinical research policy guidelines and SOPs, but not administrative support (MOH, 2020).

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Some IRB/RECs have SOPs for dealing with emergencies, pandemics, or lockdowns; others do not. There were also some IRB/RECs whose SOPs had to be modified accordingly to include COVID mitigation factors to contain the virus during the conduct of research works and clinical trials. Meanwhile, it was discovered that both the existing and the modified versions of the SOPs were available, but there was a need for requests and/or authorization before a copy could be made available.

Likewise, it was found that the requirements for obtaining informed consent and conducting virtual interviews vary across IRB/RECs. Some of the requirements depend on the study type and associated risks. But in general, informed consent and virtual interview requirements of IRB/RECs were found as follows: a relationship is established with the prospective participant, and a consent form is sent electronically for perusal. Then a meeting date and time are scheduled for the interview after the prospective participant has agreed. The recruited participant must provide a consent approval or virtual signature to confirm participation and return a copy of the consent form to the researcher. It is also an agreement that the researcher would protect the participant's privacy. These outcomes are indirectly consistent with literature assertions by Vanclay et al. (2013) who identified existing ethical research principles involving humans from an ethical professional practice standpoint.

Similarly, the study found that IRB/RECs did not set up ad hoc, national sub-regional, or district committees to review only COVID-19-related research. Some of the reasons provided to justify the above are: Ghanaian IRB/RECs do not have the mandate to set up a national committee to examine the ethical merit of COVID-19 protocols other than a committee established by the Minister of Health. The number of cases received by each IRB/REC did not justify establishing such committees. IRB/RECs have sub-teams on the Board/Committee who are impanelled based on their expertise, occupation, and resourcefulness; to review

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protocols based on the merits of each protocol. These outcomes are not consistent with literature review assertions.

One of the study's findings was that IRB/RECs changed their records management system due to the COVID-19 pandemic. Specifically, some IRB/RECs switched to an online database management system that provides an accurate filing system for proper documentation handling. Others also acquired software to help them keep records well for easy identification, verification, and storage. The study further found that some IRB/RECs had systems to authenticate the COVID-19 protocols, which enhanced their approval decisions to guarantee participants' rights, fairness, privacy, and safety. Meanwhile, it was found that some IRB/RECs certified only COVID-19 protocol attachments but left the safety of participants at the discretion of researchers. These are supported by the assertions made separately by Barroga and Matanguihan (2020) and Yeoh and Shah (2021) in the literature regarding ethical standards for conducting research during the COVID-19 pandemic. The authors recommended that researchers and IRB/RECs adopt an online mechanism through methodological revisions, use online and remote tools to collect empirical data and expedite reviewing new research works without compromising the quality.

Lastly, under this theme, the study found that some IRB/RECs reviewed direct COVID-19-related research to ensure rapid and rigorous processes, whereas others did not. For those IRB/RECs that did, there was a guarantee for applying strict guidelines for COVID-19-related human subjects' research. Moreover, it was revealed in the study that some IRB/RECs prioritize high-risk research rather than monitoring all research locations. They accordingly select and monitor researchers that do not comply with the guidelines. Similarly, other IRB/RECs rarely carry out passive research and action research because of the risks associated with some studies and funding limitations. These outcomes are supported by the assertion made by Mathur (2020) that IRB/RECs must design their reviewing processes based

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on the urgency and need of the protocol to guarantee that both emergencies and normal protocols are processed.

According to Ford et al. (2021), the COVID-19 pandemic changed the clinical research landscape in America. The most urgent challenge has been to rapidly review protocols submitted by investigators that were designed to learn more about or intervene in COVID-19. IRB/REC offices developed plans to rapidly review protocols related to the COVID-19 pandemic. An online survey was conducted with the IRB Directors at Clinical and Translational Science Awards (CTSA) institutions as well as two focus groups. Across the CTSA institutions, 66% reviewed COVID-19 protocols across all their IRB committees, 22% assigned protocols to just one committee, and 10% created a new committee for COVID-19 protocols. Fifty-two percent reported COVID-19 protocols were reviewed much faster, 41% somewhat faster, and 7% at the same speed as other protocols. Three percent reported that the COVID-19 protocols were reviewed with much better quality, 32% reported slightly better quality, and 65% reported the reviews were of the same quality as similar protocols before the COVID-19 pandemic. IRBs were able to respond to the emergent demand for reviewing COVID-19 protocols. Most of the increased review capacity was due to extra effort by IRB staff and members and not changes that will be easily implemented across all research going forward. The bottom line is that there was no one-size-fits-all response. The COVID–19 process and procedures varied across IRBs similar to the pre-pandemic.

The current study established that it took between 0 – 3 months for IRB/RECs to receive ethical clearance after the outbreak of the COVID-19 pandemic. This particular outcome is not supported by any literature reviewed on informed consent processes in research during COVID-19 (Cheng et al., 2020).

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5.3 Informed Consent Processes in Research during COVID-19

The survey with the researchers found that because COVID-19 constraints forced researchers to revise their informed consent procedures, their interactions with research subjects were impacted. This finding supports an assertion made in the literature by de Vries et al. (2020). The authors expressed that the principles underpinning the informed consent processes must not be relaxed due to the urgency with which a research outcome is required under COVID-19 restrictions. Therefore, although revision and relaxation are not the same in this situation, they may both lead to the same outcome—a revised informed consent procedure.

Furthermore, the study found that IRB/RECs' informed consent processes are applied to protect both researchers and participants. This outcome is consistent with assertions made independently in the literature by Nembaware et al. (2020). According to these authors, informed consent is a very important ethical standard that must be applied in any research to protect both researchers and participants.

5.4 Steps Taken by Researchers to Protect Participants' Safety During Research

The study found that IRB/RECs have harmonized governing regulations, laws, and policies into steps or guidelines for all researchers to guarantee participants' safety during research. This finding is not a coincidence but supports reports by Nadirshaw et al. (2006) and The National Committee for Research Ethics in the Social Sciences and the Humanities (2016.). These Institutions have asserted that IRB/RECs, when confronted with increased practical and ethical issues, usually come out with a Code of Human Research Ethics or revised guidelines for research ethics in the social sciences, law, and the humanities. This new code of ethics or revised guidelines are intended to maximize the benefit of research while minimizing any potential harm to participants.

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5.5 Research Challenges under COVID-19 Restrictions

The current study found that the COVID-19 pandemic has worsened the existing challenges in the complexities associated with the designs, methods, techniques, and processes of conducting clinical and social research. This is consistent with the assertion made by Tindana et al. (2020) that researchers' engagement method of face-to-face interviews must now be done on web-based platforms. Some of these online media, including Zoom, Skype, and Microsoft Teams, are mostly affected by erratic and poor internet connection and a limited number of participants at any time. The above outcome also supports reports by Kudhail et al. (2022) that the severe nature of COVID-19 and the risks involved in conducting different research such as Randomized Controlled Trials (RCTs) could be unbearable due to the intricacies of RCTs methods and procedural requirements.

The study also highlighted that the need to meet rapidly evolving daily evidence and assess the impact of COVID-19 on participants is the cause of some of the challenges that researchers and IRB/RECs are confronted with. This outcome supports the assertion made by Kudhail et al. (2022) that the responsibilities of researchers, IRB/RECs, and front-line medical staff involved in daily diagnosis, treatment, and scientific research have become enormous.

The study also found that researchers' and IRB/RECs' ability to ensure reliable research findings has been impacted by both old and new research problems. This study's findings are in line with the assertion that gaps in current laws and regulations governing scientific research management during the COVID-19 emergency forced researchers and medical institutions to make a difficult decision between increasing the capacity of therapy in accordance with diagnosis ethics and fulfilling the therapeutic obligation of the government's public health authority. Lipid et al. (2020) highlighted the ethical challenges faced by Institutional Review Boards. According to the authors, the pandemic has impacted the

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workload and priorities of IRBs, with an increased emphasis on ensuring the ethical conduct of COVID-19 research. COVID-19 biospecimen research also raises accompanying ethical concerns and practical challenges for investigators and participants in vaccine development and public health research. The pandemic has also introduced new ethical considerations, such as participant safety during face-to-face interactions, remote data collection, and the rapid review of research proposals to address urgent public health needs (Hooper et al., 2020). This suggests the fact that the COVID-19 challenges are not unique to IRBs/ERCs in Ghana alone.

5.6 Experiences of Researchers and IRB Chair/Administrators

Assessing the ethical standards for research with human participants during the COVID-19 pandemic in Ghana involved the active involvement of both researchers and chair/administrators. While their roles may differ, both play crucial parts in ensuring ethical practices are followed. A comparison of the experiences of researchers and chair/administrators in this context shows that researchers were involved in assessing ethical standards for research with human participants during the COVID-19 pandemic in Ghana and they have a hands-on role in research. Their experiences include designing the study to suit the ethical implications which include participant recruitment, data collection methods, and potential risks or benefits to participants. They adapted their research protocols to align with the COVID-19 safety guidelines and they ensured the well-being of participants (Ashcraft et al., 2007).

Again, researchers' experience with informed consent showed that all researchers were responsible for obtaining informed consent from participants during the pandemic. The researchers modified the consent processes to accommodate remote interactions or adhere to physical distancing protocols. Furthermore, during data collection during the pandemic period,

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they ensured the confidentiality and privacy of participants' data, especially when collecting sensitive information remotely. They employed secure technology and data management practices to protect participants' identities and information. Researchers further shared their experience on the risks of virus transmission during in-person interactions and implemented necessary safety measures.

The experience of Chair/Administrators on the other hand indicated that Chairpersons or administrators are typically responsible for overseeing the research process and ensuring compliance with ethical standards. Their experiences in assessing ethical standards during the COVID-19 pandemic involved Reviewing Research Proposals, Chairpersons or administrators played a crucial role in reviewing research proposals, assessing their ethical implications, and ensuring they complied with national and international guidelines for research with human participants Ethical Committee provided oversight responsibilities. They were responsible for managing and coordinating the ethical review committee, which evaluates research proposals, monitors ongoing studies, and ensures adherence to ethical principles (Sirotin, et al., 2010).

In summary, researchers and chair/administrators have different roles in assessing the ethical standards for research with human participants during the COVID-19 pandemic in Ghana. Researchers focused on study design, informed consent, data collection, and risk assessment, while chairpersons or administrators oversee the review process, policy development, the committee management. Collaboration between researchers and chair/administrators is crucial to ensure that ethical standards are maintained while conducting research during these challenging times.

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CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1. Introduction

This section of the thesis presents the conclusion and recommendations from the study findings.

6.2. Conclusions

Following the discussion of study findings concerning relevant literature, the study concludes that IRB/RECs and researchers followed ethical standards and procedures for research with human participants during the COVID-19 pandemic. This study has highlighted important ethical challenges experienced by IRB/RECs and researchers in the review and implementation of research during the COVID-19 pandemic. There is a need to anticipate these challenges and identify innovative ways of addressing them to promote the ethical goals of research and protect the rights and well-being of research participants in future pandemics.

6.3. Contributions to Knowledge

The theoretical contribution of this current study is that it adds to the literature base of the ethical standards required to conduct research using human participants during pandemics. The ethics review processes, informed consent processes, and the steps to protect participants have all been studied extensively in this research. The results from the study would go a long way to serve as reference material for researchers who would like or intend to replicate this study in the future but would also inform researchers and IRB/RECs on how to uphold ethical standards in future pandemics.

The study has also put forth some recommendations to researchers and the management of IRBs/RECs in the country. These recommendations are more likely to help the management

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and board of the various IRBs/RECs in revising their standards to accommodate or alleviate some of the difficulties encountered by researchers in this country while they conducted studies using human participants during the COVID-19 pandemic to prepare for future pandemics.

6.4. Recommendations

Based on the key findings of this research, the following recommendations are made:

6.4.1. Research Institutions

- Research Institutions should provide adequate funding to support the operations of IRB/RECs so that they are better prepared to conduct the review of research protocols during pandemics. These could include securely efficient virtual platforms to support online protocol submissions and review meetings.

6.4.2. Research Ethics Committees

- IRBs/RECs should develop specific ethics guidelines or standard operating procedures on the requirements for conducting research during public health emergencies. These guidelines should address issues related to how virtual consent should be obtained.
- IRB/RECs should reconsider the composition of their membership to address the challenges with the workload during meetings.
- IRB/RECs should organize periodic workshops with researchers to understand the challenges they experienced in implementing research during the COVID-19 pandemic to inform preparedness for future pandemics.

6.4.3. Researchers

- Researchers engaging in studies that generate information to aid response efforts have the ethical obligation to share the information with policymakers and participants as soon as possible. To achieve the greatest impact of the study, the

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information should be shared with the people involved in the response efforts, the research participants, the affected population, and the global community.

- Researchers should document and communicate the challenges experienced in implementing research during the COVID-19 pandemic with their institutions and IRB/RECs to inform the development of appropriate measures and guidelines for future pandemics.

6.4.4. **Future Studies**

- Future studies should explore the perspectives of research participants and communities on the key ethical issues that should be considered when conducting research during a pandemic.
- Future research should focus on the experiences of regulatory authorities such as the Food and Drugs Authority in the regulatory review of research, particularly clinical trials during pandemics.

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APPENDIX

APPENDIX I: QUESTIONNAIRE

My name is Angelina C.S. Adorkor, a student from the School of Public Health (University of Ghana) who is conducting a study ''Assessment of the ethical standards for research with human participants during the COVID-19 Pandemic in Ghana'. The administration of this questionnaire is to solicit your response on the above topic. All the information provided is strictly for academic purposes and will be treated with the greatest level of confidentiality.

Thank you.

Participants consent: Yes [ ] No [ ], If No, end of interview

QID	Questions	Coding categories	Skip to	Codes
Section A: Socio-demographic Characteristics of Respondents				
1	Age of respondents			AGE
2	Gender of respondents	Female……..…1 Male……..…2		GEN

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3	Number of years as researcher	3-5 years……..……1 6-10 years……..……2 More than 10 years……3		YRES
4	Type of researcher	Biomedical……1 Social science……..….2		TOR
SECTION B: EXPERIENCE WITH ETHICS REVIEW PROCESS				
Informed Consent Processes In Research During COVID-19				
5	Since the COVID-19 pandemic, how long did it take you to receive ethical clearance?	Less Than One Month……..……..…1 Three Months..……2 Six Months..……3		ETHC
6	COVID-19 restrictions have resulted in the revision of our informed consent processes thereby affecting the way we interact with research participants.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		RICP

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7	The Institution's informed consent process is a very important ethical standard applied by our researchers to protect both researchers and participants.	Strongly Disagree……..…1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		ICPA
8	The Institution's informed consent processes are intended to guarantee high-quality research during the COVID-19 pandemic	Strongly Disagree……..…1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		HQICP
9	The Institution's informed consent processes accord participants with the respect, right of willingness, and the decision right of participation to guarantee an impartial	Strongly Disagree……..…1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		IRICP

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	research outcome.			
Steps Taken By Researchers To Protect Participants' Safety During Research				
10	My Institution has harmonized regulations, laws, and policies into steps or guidelines for all researchers to guarantee participants' safety during research.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		HRLP
11	To be protected against lawsuit and public condemnation, my Institution carefully considers the negative impact of our research on participants.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		LPCP
12	My Institution has systems and processes in place to determine any type of harm that our intended research may cause participants.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		SPIP

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Research Challenges under COVID-19 Restrictions				
13	Research challenges existed before the outbreak of the COVID-19 pandemic.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		RCE
14	The COVID-19 pandemic has worsened these challenges in the form of complexities associated with the designs, methods, techniques, and processes of conducting clinical and social research.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		CDMTP
15	Some challenges have risen out of the need to meet rapidly evolving daily evidence and the need to assess the impact of COVID-19 on participants.	Strongly Disagree……1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		REDE

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16	These research challenges have affected me and the Institution's capacity to guarantee consistent research findings.	Strongly Disagree……..…1 Disagree……2 Not Sure……3 Agree……4 Strongly Agree……..5		RCAU

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APPENDIX II: INTERVIEW GUIDE

(Chairs and Administrators of Research Ethics Committees/Institutional Review Boards)

Main Questions	**Probes/Prompts**
Normal Ethics Review Processes	
1. Tell us a little bit about the Ethics Review Committee/Research regulation committee that you are a member of, and your role in the IRB/ERC/REC	How long has the committee existed? How was it created? How does it relate to the country's FDA and other research regulators?
2. Under normal circumstances (pre-covid19), what process does the committee follow in reviewing protocols, and how long do these usually take?	Probe for paper and online submissions Probe for primary mode of operation before COVID-19, i.e. face-to-face meetings, online, and so on. Prompt for different types of protocols (Challenge studies, phase I, II and III 3 clinical trials, social science protocols, multi-country studies and the like)

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3. What was the IRB/ERC/REC's workload before the COVID-19 pandemic?	Probe for number of protocols reviewed per month Number of meetings held per month
4. What challenges did the IRB/ERC/REC normally face in the routine review processes; how were these handled?	Probe for new research design, reviewers to review, workload and others)
Post-COVID-19 Review Processes	
5. How did COVID-19 restrictions affect the activities of your IRB/REC?	Probe for suspension of ethics review How was the long ethics review suspended?
6. How did COVID-19 affect the number of research submissions to your IRB/ERC/REC	Probe for increase or decrease in the number of submissions
7. What percentage of protocol submissions were related to COVID-19	Probe for the number of COVID-19 clinical trial protocols
8. What were some of the memorable experiences you went through at these initial stages, what challenges did you encounter, and how did you resolve these? What worked well? What didn't and why?	Probe for suspension of the review process Did the time to approve submissions change compared to the pre-COVID-19 period?
9. *Expedited/accelerated review:* rigorous protocol review during times of emergency is important, and feedback is expected within a very short period (fast	Probe what an expedited/accelerated review process involves (reviewers,

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turn-around); how did/are you responding to this urgency for much-needed research to inform response strategy?	documents, submission processes, turn-around time)
10. What types of COVID-19-related research were prioritized?	Probe for clinical trials, social and behavioural research, and other types of research (please specify)
11. What has worked well in this process? What has been the most challenging, and why? How did you make the trade-offs?	Did your ethics committee develop any strategies in the submission process to streamline communication between ethics committee members, investigators, collaborators/funders?
12. Many international guidelines have been developed to anticipate and respond to ethics and scientific review during global health emergencies. How useful did you find such documents to be? Did you formulate your guidance documents, and how did you go about it? Who did you involve/ engage in the process? What is different from your guidelines?	Probe for WHO guidelines/Nuffield Council report
13. Over time, what review challenges have persisted,	Probe for internet connectivity,

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and why? How are you addressing these? How have you found the communication with study PIs/ applicants for ethics approval?	and study design, among other challenges
14. Overall, how do you think the committee is/has performed with regards to a) COVID-19-related protocols, b) non-COVID-19 protocols c) other functions of the committee?	
15. What support have you received from your host institutions/government during this period to cope with the emerging challenges (if any); what do you think of this support (e.g. is it in line with what you need? OR if not, support yet, what are your expectations from your host institutions and/or government?)	Probe for training opportunities, recruitment of additional reviewers, logistical support, i.e. internet costs, and compensation for time, among many others
16. Did your IRB/ERC/REC have standard operating procedures for dealing with emergencies, pandemics or lockdowns?	Please provide a copy Probe for requirements for obtaining informed consent, conducting virtual interviews and the rest
17. How has the use of virtual meetings affected discussions, interactions or deliberations at meetings?	Probe for positive and negative effects
18. What alternatives did you consider for your Ethics Committee meetings? Please indicate all that apply.	

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i. Set up Adhoc committees for review of only COVID-19-related research ii. Set up a national committee for review of only COVID-19-related research iii. Set up sub-regional/district committees for review of only COVID-19-related research iv. Designated one or more ethics Committees/institutional review boards to review only COVID-19-related research	
19. What changes did you make to your records management system?	
20. How did your ethics committee ensure that COVID-19-related human subjects research was conducted rapidly and rigorously?	Probe for methods of monitoring approved research
21. What were the main challenges your Ethics Committee experienced during the pandemic, and what mitigation plans have you put in place?	
22. What were some key considerations during decision-making that ensured that the safety of	

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participants, researchers and health workers were not compromised by the need to gain scientific knowledge about COVID-19 (e.g., obtaining informed consent)?	

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APPENDIX III: ETHICAL CLEARANCE

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Digital Address: GA-050-3303
Mob: +233-50-3539896
Tel: +233-302-681109
Email: ethics.research@ghsmail.org

My Ref. GHS/RDD/ERC/Admin/App 122/191
Your Ref. No.

24th May, 2022

Angelina Sena Cyendy Adorkor
University of Ghana
School of Public Health

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 058/03/22**
Study Title	"Assessment of the Ethical Standards for Research with Human Participants During the Covid-19 Pandemic in Ghana"
Approval Date	24th May, 2022
Expiry Date	23rd May, 2023
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
Mr. Kofi Wellington
(GHS ERC Vice Chairperson)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra