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RESEARCH ARTICLE

A Qualitative Exploration of Stakeholder Experiences and Perceptions of Uganda's Clinical Research Policies and Guidelines During the COVID-19 Pandemic

[version 1; peer review: 1 approved with reservations]

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Abstract

Background

The COVID-19 pandemic disrupted research globally, placing unprecedented pressure on regulatory systems. In Uganda, research ethics committees (RECs) and regulatory bodies faced challenges in maintaining oversight, ethical compliance, and continuity of research. Specifically, the study explored stakeholder experiences and perceptions of how Uganda's clinical research policies and guidelines were implemented and how they influenced the conduct of ethical and safe research during the COVID-19 pandemic.

Methods

A qualitative descriptive study was conducted across seven districts, involving all UNCST-accredited RECs. Data were collected through in-depth interviews, focus group discussions, and key informant interviews with 56 participants, including REC Chairpersons, administrators, researchers, and representatives from research

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1. **John C Marshall**, University of Toronto , St. Michael's Hospital, Toronto, Canada

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regulatory authorities in Uganda. Purposive sampling ensured recruitment of participants with relevant expertise. Virtual interviews were audio-recorded, transcribed verbatim, and analyzed using thematic analysis. Ethical approval and informed consent were obtained.

Results

Uganda's research policies and guidelines were reported by participants to support continuity of research through strengthened collaboration, including joint protocol reviews and coordinated regulatory processes. Standardization and adaptive measures, such as digital submissions, virtual meetings, remote monitoring, and hybrid consent models, were perceived to enhance efficiency and facilitate study adjustments. However, constraints including increased workload, limited oversight due to movement restrictions, and financial challenges persisted, highlighting the need for more adaptable and resilient regulatory systems.

Conclusions

Uganda's research policies and guidelines were perceived to supported continuity of ethical research during the pandemic through strengthened collaboration and standardized yet adaptable regulatory processes. However, operational and resource constraints highlighted gaps in system resilience. Strengthening digital infrastructure, institutionalizing collaborative review mechanisms, embedding adaptable procedures, and securing emergency research funding will be critical to enhance the responsiveness and resilience of Uganda's research regulatory system in future public health emergencies.

Plain Language summary

This study looked at how Uganda's rules and guidelines for clinical research worked during the COVID-19 pandemic, when research everywhere was disrupted and regulators were under intense pressure. Through interviews and group discussions with ethics committee leaders, researchers, and officials from key national agencies, the researchers found that Uganda's policies generally helped important health studies continue while still protecting participants. Collaboration between regulators improved, with joint reviews of study plans and more coordinated processes. New flexible practices like online submissions, virtual meetings, remote study monitoring, and mixed in-person/remote consent made it easier to keep research going and adjust studies to the changing situation. At the same time, the system struggled with heavier workloads, limited on-the-ground oversight because of travel restrictions, and financial pressures. The authors conclude that, although the system broadly supported ethical research during COVID-19, it needs stronger digital

tools, permanent structures for joint review, more flexible procedures, and dedicated emergency funding to be more responsive and resilient in future health crises.

Keywords
Research policies; Uganda; COVID-19 pandemic; Research guidelines; Research Ethics Committees, Research Regulation



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Introduction

Public Health Emergencies (PHEs) are events that threaten population health beyond routine response capacities. The World Health Organization defines a PHE as an occurrence or imminent threat of illness caused by bioterrorism, epidemic or pandemic disease, or novel infectious agents with substantial risks of fatalities or long-term disabilities.[1,2] Alsayed-Omar similarly describe PHEs as situations whose health consequences overwhelm routine systems due to scale, timing, or unpredictability.[3] Recent PHEs, including H1N1 influenza, Ebola, Zika, and COVID-19, demonstrate persistent global vulnerability.[4] Each year, over 362 million people are directly affected, with additional threats from bioterrorism and antimicrobial resistance.[5,6]

Effective response to PHEs requires strong national preparedness, a core capacity under the International Health Regulations.[2] Many low- and middle-income countries, however, face gaps in regulatory infrastructure, including policies, institutional capacity, and operational tools, hindering timely deployment of medical products.[7] Research regulation remains central to emergency response as scientific investigations are essential for understanding and mitigating emerging threats.

Africa experiences frequent outbreaks, with roughly 100 events annually and over 1,900 between 1970 and 2019.[7,8] Uganda is particularly vulnerable due to proximity to the Congo Basin hotspot, high mobility, and demographic pressures.[9] Its research oversight system includes the Uganda National Council for Science and Technology (UNCST), Research Ethics Committees (RECs), and the Ministry of Health's Public Health Emergency Operations Centre (PHEOC), which collectively regulate and guide research during emergencies.[10]

PHEs disrupt routine regulatory operations by increasing protocol volumes, compressing review timelines, and intensifying ethical scrutiny.[11,12] Lockdowns further challenge oversight, especially for institutions lacking digital submission or review platforms,[13,14] while ethical dilemmas around benefit–risk balance, equity, and vulnerability are amplified.[15,16]

Globally, regulators introduced emergency pathways, including fast-track procedures in Europe, rapid turnaround systems in Pakistan, and joint regional reviews in Africa.[17–19] Uganda adapted by issuing the *National Guidelines for Conduct of Research During Coronavirus Disease,*[20] enabling expedited ethical reviews and remote operations. Despite these measures, increased protocol complexity, limited reviewer expertise, and surging submissions presented operational challenges.[21]

Although COVID-19 reshaped regulatory practice in Uganda, limited empirical evidence exists on how policies and guidelines were implemented in practice, how they were experienced by different stakeholder groups, and how they were perceived to support or constrain ethical and timely research conduct during public health emergencies. In response, this qualitative study explores how Uganda's research policies and guidelines were experienced and operationalized by key regulators and stakeholders during the COVID-19 pandemic, focusing on how these frameworks supported or constrained ethical and timely research conduct.

Methods

Study design

A qualitative descriptive design was employed to examine how Uganda's research policies and guidelines were experienced and operationalized by key regulators and stakeholders during the COVID-19 pandemic.[22,23] This approach is suitable for systematically capturing participants' perspectives on how these frameworks facilitated or constrained the ethical and timely conduct of research, without establishing causal relationships. The study was based on retrospective participant accounts, reflecting experiences and perceptions of research oversight and regulatory processes throughout the pandemic.

Study setting and participants

The study was conducted across seven districts in Uganda: Gulu, Mbale, Mbarara, Bushenyi, Wakiso, Mukono, and Kampala, with participants selected from all UNCST-accredited RECs as of March 2023. At the time of the study, UNCST had 35 accredited RECs, of which 29 were operational between March 2020 and March 2023. For each operational REC, one Chairperson and one administrator participated.

The participants for the study included; REC Chairpersons, researchers, REC administrators and representatives from national regulatory authorities (NRAs) such as UNCST, the National Drug Authority (NDA), and the Uganda National Health Research Organization (UNHRO). In total, 56 participants were included: 16 REC Chairpersons, 11 researchers, 24 REC administrators, and 5 NRA representatives (one from UNHRO, two from NDA, and two from UNCST).

Inclusion and exclusion criteria

Inclusion criteria: Participants who provided informed consent; REC administrators and Chairpersons actively serving in their positions; and researchers who led clinical trials between March 2020 and March 2023 during the COVID-19 and Ebola public health emergencies. **Exclusion criteria:** Individuals not actively serving as REC administrators or Chairpersons, those who declined consent, or REC members from newly accredited RECs were excluded.

Sampling and recruitment

Expert purposive sampling was employed. Participant information was obtained from the UNCST database, followed by outreach via phone or email. Participants were engaged according to their convenient schedules. Four FGDs were conducted, each with six participants (total = 24), stratified by host institution and research type: (i) hospital-based RECs, (ii) education institution-based RECs, (iii) RECs primarily reviewing social sciences and humanities protocols, and (iv) RECs primarily reviewing medical and health sciences protocols. Additionally, 16 REC Chairpersons and 11 researchers participated in in-depth interviews, while 5 key informant interviews were conducted. Sample sizes fell within recommended qualitative ranges (3–6 FGDs, 5–15 key informants, and 10–30 in-depth interviews).[24] Thematic repetition across stakeholder groups indicated adequate information power and saturation.

Data collection

Data were collected using structured, method-specific semi-structured guides covering experiences of research conduct and regulation during public health emergencies and implementation of the National Research Information Management System (NRIMS). In-depth and key informant interviews involved REC Chairpersons, researchers, and NRA representatives, while REC administrators participated in FGDs. Interviews and FGDs were conducted in English, lasted appropriately 60 minutes, either in private, quiet locations or virtually via videoconferencing, with participants' consent. FGDs were facilitated by at least two trained research assistants from Makerere University College of Health Sciences, with one moderating and the other documenting non-verbal cues and group dynamics. All sessions were audio-recorded, transcribed verbatim, and securely stored on password protected computers.

Data analysis

Data analysis employed thematic analysis as outlined by some scholars.[25,26] Transcripts were read repetitively to achieve familiarity, followed by inductive, line by line coding, allowing codes to emerge from the data rather than being predetermined. Similar codes were iteratively grouped into clusters, forming a preliminary coding framework that was refined as patterns became apparent. Two analysts independently coded the transcripts, with discrepancies resolved through discussion and reference to the original data to ensure consistency and minimize bias. Researcher reflexivity was maintained through reflective discussions, acknowledging potential preconceptions and their influence on interpretation. Clusters were subsequently organized into overarching themes, which were reviewed, refined, defined, and named to ensure coherent representation of the data. Study findings are presented through these themes, illustrated with participants' quotations to capture diverse stakeholder perspectives.

Ethical considerations

Ethical and scientific approval was obtained from the National HIV/AIDS Research Committee (NARC-2023-10), and final clearance was sought from the Uganda National Council for Science and Technology (UNCST) for registration and approval (SS2192ES). Administrative clearances were sought from UNCST, NDA, and UNHRO before study commencement. The study was conducted in compliance with national and international guidelines for research involving humans.[20] Written informed consent was obtained from all study participants before they were enrolled in the study, and no minors were enrolled in the study. Only the approved study protocol, informed consent forms, and study tools were used when conducting the study.

Results

Continuity of research

> *We were supposed to do regulatory activities, which involves review of research protocols, site visits, and regulatory work. During that period … studies were on hold, especially those with sites far away from the main sites* (FGD 1, REC administrators).

In certain cases, studies had to close entirely due to budgetary constraints arising from pandemic-related modifications:

> *… some of the studies closed because of the budgetary … transport had to go up for participants. These studies had been approved before the pandemic and were running on that budget* (KII 01, Regulator).

Collaboration

> "I think the guidance enhanced collaboration … so that researchers may not look at us only as regulators … we also advise on the possible contents … so, troubleshooting all of us together" (KII 02, Regulator)."All COVID-19 related studies were supposed to be jointly reviewed by the different stages like in the RECs and National Council and NDA … so that the different concerns will be addressed … by the time the researcher comes back, at least everything is being addressed" (IDI 04, Researcher).

> "… allow people to continue conducting research … but also it facilitated the operations of the REC because members were able to continue meeting to discuss protocols … facilitated the review of protocols in spite of people not meeting physically" (IDI 07, REC Chairperson).

Standardization and adaptation of protocols

> "… during that period, we had many studies undergo amendments … researchers coming in to amend, for example, follow up participants virtually … for some new studies … innovative ways of consenting" (KII 01, Regulator).

This contributed to standardizing research review processes across institutions, ensuring adherence to ethical and safety requirements:

> "All researchers had to make sure they align with the policy. For me personally, I took it very positive … you just need to declare how you're going to protect" (IDI 13, REC Chairperson).

Constraints

Increased workload

> "The overwhelming workload also relates to resource constraints … very many people are bringing in protocols or proposals, COVID-related, and the numbers were so high" (FGD 2, REC administrators).

> "An environment where you are in a virtual meeting, at home with families, small children running around … that was also one of the challenges" (FGD 2, REC administrators).

Movement restrictions hindered in-person monitoring of studies, creating gaps in oversight and raising concerns about adherence to mitigation strategies:

> "… we're not sure whether our researchers would adhere to the risk mitigation strategies they submitted … we could not verify that what they submitted is what they were doing" (IDI 03, REC Chairperson).

Resistance to online review processes by some researchers further limited the effectiveness of guidelines:

> "There are some who are resistant to the idea of all the time meeting online … we need to be in the same room … can we postpone this until the lockdown is over?" (IDI 06, REC Chairperson).

Financial challenges

> "Imagine if you don't have funding, you can't organize a joint review … previously you could send your protocol to the REC" (IDI 01, Researcher).

Discussion

Continuity of research

The results demonstrate that the COVID-19 pandemic significantly disrupted research in Uganda, with many studies temporarily halted or closed due to movement restrictions and institutional adjustments. Studies requiring fieldwork or in-person engagement were particularly affected, resulting in delays in protocol approvals and methodological modifications.[39] This agreed with studies in Germany and other high-income settings, where research continuity faced similar challenges.[21,27] Expedited reviews for COVID-19-related studies facilitated continuity, but the surge of protocols placed immense pressure on RECs. These findings revealed the importance of pre-established contingency frameworks that enable rapid decision-making while maintaining ethical oversight, confirming recommendations from prior studies on emergency preparedness in research.[16,28]

Collaboration

The study shows that structured guidelines promoted collaboration among RECs, UNCST, and other regulatory bodies, enabling joint reviews and reducing redundancies.[39] This coordination enhanced efficiency and ensured comprehensive feedback for researchers. These findings relate to global evidence where multi-agency collaboration improved regulatory responsiveness during emergencies.[27,29] Hence, institutionalizing joint review mechanisms, the results extend understanding of how collaborative models can strengthen ethical adherence and preparedness, particularly in the context of public health crises.

Standardization and adaptation of protocols

The findings demonstrate that clear research guidelines provided a standardized framework for protocol amendments, virtual consent, and ethical conduct, enabling studies to continue under pandemic constraints without compromising integrity.[30,31] Adaptation strategies such as remote follow-ups and digital consent reflect a practical need for flexible methodologies, confirming similar strategies observed in other contexts.[10,32] This study highlights the novelty of integrating adaptive protocols with training for REC members and researchers in resource-limited settings during public health emergencies.

Constraints

Increased workload

The results indicate that the surge of research proposals, particularly COVID-19-related studies, substantially increased the workload for RECs.[39] While virtual platforms enabled continued operations, limitations in digital literacy and internet connectivity delayed reviews and increased stress.[33,34] Movement restrictions also constrained physical oversight, risking research integrity.[35] Hybrid oversight models combining virtual and in-person monitoring, supported by digital literacy training, emerge as a practical strategy for enhancing flexibility and compliance in future crises.

Financial challenges

The study demonstrates that the pandemic introduced unanticipated financial burdens, particularly for students and independent researchers, including costs for internet, virtual meetings, and protocol amendments.[10,36,37] This highlights the need for dedicated emergency research funds to support both compliance and continuity. Hence, establishing such mechanisms can mitigate financial barriers during crises, ensuring ethical oversight and operational efficiency.

Study contribution

The results show that well-structured research policies and guidelines are critical for sustaining ethical and safe research during public health emergencies.[39] Therefore, strengthening digital infrastructure, institutionalizing joint reviews, and establishing flexible funding mechanisms, the study contributes novel evidence on enhancing the resilience of research regulatory systems, particularly in low-resource public health contexts.

Limitations

Interviews were time-consuming due to the sensitive nature of discussing participants' experiences during the COVID-19 pandemic, and recall bias was possible given the retrospective reflection on REC operations since March 2020. These limitations were minimized through careful research question selection, appropriate data collection methods, and rigorous strategies for data quality. Trained research assistants ensured rapport with participants while maintaining privacy and confidentiality.

Conclusion and recommendations

The COVID-19 pandemic significantly tested the resilience of Uganda's research regulatory system. Ethics review committees and other regulatory bodies faced unprecedented workloads, delays, and challenges in monitoring ongoing studies due to movement restrictions and remote working. Despite these pressures, the introduction of structured research policies and guidelines proved critical in maintaining research continuity. These guidelines facilitated joint protocol reviews, enhanced collaboration between researchers and regulators, standardized research procedures, and provided clarity on necessary study amendments. The adoption of digital platforms for submissions and virtual meetings further supported regulatory oversight and efficiency, although limitations in infrastructure and resistance to online processes were noted.

Overall, Uganda's research policies and guidelines were effective in sustaining ethical and safe research during the pandemic, while highlighting vulnerabilities in regulatory systems, including increased workload, limited oversight, and financial constraints. Institutionalizing joint review mechanisms, investing in digital infrastructure and literacy, developing adaptable protocols, and establishing emergency research funding are essential strategies to enhance resilience, ensure compliance, and maintain continuity of research during future public health emergencies.

Recommendations

1. Establish a clear emergency research framework with expedited ethics review, flexible funding, and centralized communication to ensure research continuity during public health crises.

2. Adopt hybrid monitoring and strengthen digital research capacity, including training on virtual review, protocol submission, and online consent, to maintain ethical oversight during emergencies.

Data and software availability

Data underlying this study are available from the Zenodo repository: Dataset Supporting the Study on the Effect of Public Health Emergencies on Research Regulatory Systems (DOI: 10.5281/zenodo.20556164).[38] The repository contains the COVID 19 STUDY ANONYMIZED NVIVO DATA (NVivo R15.2.1).nvp, comprising the anonymized study dataset and supporting files. The data are available under the terms of the Creative Commons Attribution 4.0 International (CC BY 4.0) License.

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This manuscript reports a qualitative study evaluating the research response to COVID-19 in Uganda from the perspective of local research ethics committees (RECs). The authors have engaged all the RECs in Uganda and included 56 people in their interviews. They document adaptation to the demands of the pandemic through virtual and hybrid meetings, allowing continuity of the process. They also document limitations including an increased workload and decreased oversight. They identify a number of needs and opportunities to enhance the resilience of the review system.

The manuscript is generally well written and provides a useful perspective on the impact of the pandemic on research oversight in a resource-limited settings. The Results are under-developed, limited to a handful of quotes on various themes that do not provide sufficiently granular detail to form confident conclusions. Additional development of the qualitative work, accompanied by some quantitative information as discussed below would greatly increase the value of the work.

Specific comments

1. It would be helpful to differentiate Covid and non-Covid studies. A number of jurisdictions paused non-Covid-19 research with the objective of facilitating trials relevant to the pandemic. Did this happen in Uganda? Did the increased volume of requests adversely impact both pandemic and non-pandemic trials?

2. Can you provide quantitative data on research activity in Uganda during Covid-19 – how many Covid-19 trials were approved? How many recruited patients? How many were led by Ugandan researchers as opposed to researchers from another country?

3. One of your respondents states "Imagine if you don't have funding, you can't organize a joint review ... previously you could send your protocol to the REC". Please provide further information on the theme presented here.

4. While the quotes from participants are helpful, the underlying themes are not explored in

depth, nor is there any indication about how prevalent amongst your interviewees these perspectives were. Further detail would enhance confidence in the conclusions you draw in the Discussion.

5. The recommendations are similarly under-developed and generic. More specific suggestions would increase the probability that changes to improve the system might be made.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and does the work have academic merit?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Critical care, Pandemic research, clinical trials

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.