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Assessment of the Operational Characteristics of Research Ethics Committees in Ghana

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Abstract

There were eighteen Research Ethics Committees (RECs) operating in Ghana as of December 2019 but no empirical assessment of their operational characteristics had been conducted. We assessed the characteristics of Ghanaian RECs using an existing Self-Assessment Tool for RECs in Developing Countries. We present results from nine RECs that participated in this nation-wide assessment. Our results indicate that the RECs are generally adherent to the recommendations in the Tool including being composed of members with diverse expertise. They also reviewed and approved research protocols as well as had access to some limited funding for their activities. There is no national policy on research human protections or an ethics authority to regulate the activities of the RECs. We recommend the establishment of this authority in Ghana while encouraging institutions to sustain efforts aimed at making their RECs operate independently.

Keywords

Research Ethics Committees, operational, characteristics, ghana

Introduction

Research Ethics Committees (RECs) or Institutional Review Boards (IRBs), herein referred to as RECs, have been established by some international, national, institutional, local or private entities to oversee ethical conduct of both human and animal proposed research studies. The establishment of these RECs forms part of efforts to minimize or eliminate research wrongdoings while improving research quality, robust scientific research methodology, active engagement and respect for research participants and their communities as well as enhancing the protection of research subjects. The RECs, as described by Barrett, "are intended to oversee the entire scope of one or more medical research studies including protecting the rights and welfare of human research subjects" (2019, p. 11), while Emanuel et al., also described them as individuals who are unaffiliated with the research but review "the design of the research trial, its proposed subject population and risk-benefit ratio" (2000, p. 2703). With the goal of balancing the needs of society for advancement in science against the rights of the human subject, RECs consider the potential risks and benefits of the research to the community within which the research will be conducted, thereby ensuring that the research protocols conform to internationally and locally accepted ethical standards. RECs therefore play an integral and critical role in advancing the conduct of ethical research.

The study conducted by Mokgatla et al. (2018) to map the RECs in Africa listed some key attributes of functional RECs. They identified availability of infrastructure, information on processing of proposals (hard copies or electronic), membership (with fair gender representation) and administrative staff as well as capacity building requirements for members as key characteristics of functional RECs. Thus, the RECs require some basic administrative infrastructure such as office furniture, computers and their accessories, internet connectivity and data storage facilities for both soft and hard copies of documents. Similarly, the RECs, based on the United States Common Rule (45 CFR 46), are to be composed of members who are sufficiently qualified or professionally competent with diversified members that embraces race, gender and cultural backgrounds as well as being sensitive to issues such as community attitudes as a means of promoting respect for its advice

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and counsel and safeguarding the rights and welfare of research participants (Department of Health & Human Services, 2018).

In applying the Self-Assessment Tool earlier developed by Sleem et al. (2010) to assess the operational characteristics of RECs in low- and middle-income countries, Silverman and his associates (2015) indicated, among others, that the necessary conditions that could sustain the establishment of an ethical culture include transparency such as availability of conflict of interest policies, appointment policies for the chair and members, and open communication and interaction with the local community, research participants, investigators and other stakeholders. They further provided conditions such as accountability (including appropriate monitoring and review) and integrity (consisting of membership diversity, requirement of ethics training for investigators, legitimizing the authority of RECs and safeguarding the independence of RECs from institutional pressures and other biases). Finally, they asserted that availability of an adequate budget to support the required financial and human resources as well as compliance with national laws and guidance are required for effective functioning of RECs.

The first two RECs in Ghana were set up in 2000 (GHAAREC, 2015) and at the end of 2019 there were eighteen RECs that were operational in the country. Ghana currently has no National Ethics Committee, Authority or Commission that oversees or regulates the activities of the various RECs. The RECs operate independently of one another and have their own operational guidelines or structures based on some existing international recommendations such as the US Common Rule or research ethical principles set forth in the Belmont Report, Council for International Organization of Medical Sciences (CIOMS), the World Medical Association's Declaration of Helsinki and the Nuremberg Code. For instance, each REC develops and approves its own Standard Operating Procedures (SOP) which specify their research protocol review processes, administrative structures and operations, membership composition, training activities and funding sources. They may respectively formulate other operational guiding documents such as conflict of interest and research misconduct policies as well as research protocol application manuals or guidelines to aid their prospective clients. There are also no separate national entities that conduct follow-up monitoring of approved research protocols or review research misconduct or other research breaches such as conflicts of interest like those in some countries including the US. Instead, this falls within the purview of the various RECs in Ghana whose primary mandate is to have oversight responsibility over human research studies to ensure that they are conducted soundly, both scientifically and ethically.

The Ghana Association of Administrators of Research Ethics Committees (GHAAREC) comprises all the Administrators of existing RECs in Ghana with the mission of creating a networking platform for its members through activities such as conferences, workshops or seminars as well as sensitization of the members and the Ghanaian public on issues that relate to adherence of high ethical research standards or advancing the conduct of ethical research (GHAAREC, 2015; Laar et al., 2020). It must be noted, however, that membership of the Association is purely voluntary.

Most studies conducted on RECs in Africa have largely focused on capacity development and training of their members due to the fact that most of the RECs are still in their infancy (Bain et al., 2019). Indeed, there have been few studies that have examined the operating procedures, strengths and challenges of RECs on the African continent (Sleem et al., 2010). Silverman et al. (2015) have asserted that many low-and middle-income developing countries have established and strengthened RECs in response to increased clinical research involving human participants. Nonetheless, empirical research studies that have been conducted to assess the operational characteristics of RECs in Ghana remain insufficient. There are some questions that are yet to be comprehensively answered or empirically documented especially as they relate to the operational characteristics of RECs in Ghana. For instance, how should the various training initiatives be contextualized when information on the real operational challenges of RECs in Ghana is not known? Further, are the RECs in Ghana operating with approved and functional SOPs? Are the RECs composed of the requisite membership with expertise in research ethics? And do the RECs have the basic infrastructure and adequate funding to support the implementation of their activities?

This study is an effort to fill this gap. It was modelled on a previous study conducted to assess the operational characteristics of RECs in low-and middle-income countries by Silverman and his colleagues (2015). The current study was, among other specific objectives, conducted to determine the preparedness of RECs in Ghana to advance the conduct of ethical research in the country. Besides serving as a baseline study for future evaluations, it was also intended to assess the RECs' operational activities, challenges and support needed to guide interventions that could be rolled out to strengthen their activities.

Method

Study Design

This was a cross-sectional study that used both quantitative and qualitative methods to assess the operational characteristics of RECs in Ghana. This research approach permits quantitative and qualitative data gathering concurrently. The quantitative and qualitative strands were weighted equally in this study (Terrell, 2012). The data was integrated during the analysis and interpretation stages to determine confirmation, corroboration or divergence of responses.

The primary data from the RECs consisted of their responses to a survey questionnaire and interview guide.

Population and Sample

Records available at the Secretariat of GHAAREC indicate that eighteen RECs were operational in Ghana as of December 2019. Adopting a census approach, we invited all eighteen RECs to participate in this assessment. The primary target respondents were the chairpersons or their authorised representatives. Nine of the eighteen RECs agreed to participate, representing a 50% response rate (quantitative analysis is rather based on responses from eight RECs while the 9th REC opted for just a qualitative session).

Instruments

Two main instruments were developed to facilitate primary data collection: a survey questionnaire and an in-depth interview guide. The instruments were designed to determine levels of institutional commitment (authority of the appointing person, dedicated funding, auditing processes), availability and operationalization of policies and procedures of their activities, membership composition (experience, gender, diversity), legitimacy (operating within tenure or expired tenure) and training activities implemented. Other operational activities of the RECs that were captured by the instruments included ethical clearance application processes, post-protocol review mechanisms, feedback processes to research investigators and participants as well as administrative structures (availability of administrators, support staff, office equipment).

The questionnaire used to elicit quantitative data was configured electronically using Kobotoolbox software, developed by the Harvard Humanitarian Initiative open-source system platform (https://ee.humanitarianresponse.info/x/30ARCcdL). This software was adopted due to its simple coding systems and several deployment modes that work well with or without internet. This was also in line with our intention to minimize data gathering errors, reduce the turnaround time for data entry and provide real time data collection updates as well as adhere to social distancing protocol due to the COVID-19 pandemic. The interview guide was used to gather qualitative data and generally contained open ended questions that were used to gather detailed responses on the activities, experiences, achievements, challenges and recommendations from the RECs.

Methods of Data Collection

We first liaised with the Secretariat of GHAAREC to obtain contact information for the various RECs in Ghana. The primary data collection was preceded by an advance notice to all the RECs informing them of the assessment, their respective roles, duration of the assessment and schedule for the interview sessions. This was intended to facilitate the process and avoid undue delays or missed appointments. The questionnaire was deployed by means of a simple Hypertext Transfer Protocol (HTTP) through an email link to enable easy accessibility and completion. The software is very flexible and enables the respondents to save their incomplete responses as drafts. Respondents were required to click a "submit" button that automatically forwarded the data to a central server being managed by the authors.

Two RECs (one university- and the other hospital-based) were purposefully selected to participate in a qualitative component of the study. Our assumption was that one of them would have been playing a lead role in reviewing *national* research protocols, while the other was a relatively new REC. The qualitative data from these RECs provided in-depth perspectives on the history, key milestones and challenges in the functions or operations of RECs in the country and shed light on some of the quantitative responses provided by the surveyed RECs. The in-depth interviews were conducted by phone and in-person. The responses were tape-recorded. The entire data collection phase of the study lasted for four months (November 2020 to February 2021). Eight completed questionnaires and two in-depth interview transcripts were generated from this study.

Data Analysis

The quantitative and qualitative data collected were cleaned, processed and analysed to provide evidence-based descriptions of the operational characteristics of the RECs in Ghana. The quantitative data submitted by the respondents was received in the central server in a Microsoft Excel format. The data was then converted into an SPSS format (version 20) for analysis. The quantitative data was then analysed using descriptive statistics such as frequencies, percentages, and cross-tabulations. We did not conduct inferential statistical tests due to the relatively low number of the RECs that participated in the assessment. The findings from this study should not be generalized for the entire RECs in Ghana but must be contextualized based on the relatively small number of the sample size and the diversity of the RECs.

The authors transcribed the qualitative interviews and thoroughly read the details to identify common themes to aid in the analysis based on the principle of grounded theory, in which theory emerges from the data (Strauss, 1987). The framework analysis, often called the thematic analysis framework, was adopted to analyze the qualitative data. Salient quotes were identified and used to complement the quantitative analysis that was done. We collectively performed all the above data collection activities through daily in-brief sessions to review the data collection processes to ensure that we were progressing according to schedule and plan for the next activities. The in-briefs were used to review the responses received for the day to assess their completeness.

Ethical Issues

The study was evaluated by two randomly selected RECs in Ghana for review and approval (reference numbers 37MH-IRB/NF/IPN/419/2020 and GHS-ERC014/07/20) who deemed the study to be ethical to conduct.

Table 1. Background Characteristics of RECs.

Responses	Frequency (N = 8)	%
Ownership status		
Hospital-based	2	25.0
university/research Institute	6	75.0
Years of operations		
Between 2-5 years	1	12.5
More than 5 years	7	87.5
Reasons for establishment		
Incessant request from main clients	2	25.0
To meet a funded project requirement	2	25.0
Due to institutional strategic focus	4	50.0
Average protocols approved in 2019		
Students		
1-500	6	75.0
>501	2	25.0
Faculty/Lecturers		
None	2	25.0
1-20	2	25.0
21-40	3	37.5
41-50	1	12.5
Health professional		
None	2	25.0
1-20	7	87.5
21-40	1	12.5
Ghanaian public		
None	6	75.0
1-20	2	25.0
International development partners		
None	2	25.0
1-20	5	62.5
21-40	1	12.5
Approved humanities protocols		
1-20	3	37.5
21-40	3	37.5
41-80	1	12.5
>81	1	12.5
Approved medical sciences protocols		
1-20	4	50.0
41-80	0	0
81-100	1	12.5
>100	3	37.5
Approved natural sciences protocols		
None	5	62.5
1-20	3	37.5
Approved other disciplines protocols		
None	4	50.0
1-20	3	37.5
21-40	1	12.5

Source: Field survey, 2021.

Results

Background Characteristics

Nature of REC and Approved Research Protocols. Six of the eight RECs that provided the quantitative data were university-or research-based institutions, while the remainder were situated within hospitals. The main clientele of the RECs were students, faculty members, health, humanities and international development partners. It is instructive to note that the majority of the RECs surveyed (87.5%) had been operational for more than five years with half of them indicating that the strategic focus of their institutions led to their establishment. Similarly, the need to meet requirement(s) of a funded project informed the establishment of two RECs while incessant requests from prospective clientele prompted the establishment of the other committees (Table 1). Another factor that was ascertained during the key informant interviews was the issue of institutional control or regulation of the activities of researchers who use their facilities or materials for research purposes. The issue of a funded project is further elaborated upon by one of the key informants:

> *Our REC was not established out of a recorded research misconduct or impropriety but we received a National Institute of Health funding to conduct research in the country. The research protocol had to be ethically reviewed by a well constituted Institutional Review Board in accordance with all the guidelines for the operations of the Board and the United States of America Federalwide Assurance mechanism, hence the establishment of our REC. This was part of the conditions on the release of funds for the project.*

Six out of the eight RECs surveyed reported that they reviewed and approved between 1 and about 350 student research protocols between January 2019 and December 2019 (15, 23, 27, 78, 86, 347, 640 and 1,500 protocols respectively), while 25% of the RECs did not approve any research protocols from faculty/lecturers, health professionals, the general public and international development partners. Re-categorizing the approved protocols in 2019 by subject disciplines indicated protocols in the medical sciences dominated, while those in the natural sciences were least represented Table 1).

Membership and Regularity of Meeting. We asked our respondents a series of questions as a proxy to determine institutional acceptability and commitment to their activities, legitimacy of operations and, perhaps, the expanse of their authority to enforce research ethical breaches. With regard to their appointing authorities, all the eight institutions surveyed and the two key informants indicated that

the vice-chancellors of the universities or the chief executive officers of the hospitals, first and foremost, constitutes the RECs and make subsequent appointments of new members to serve on the RECs. The key informants, in particular, further explained that appointments of new members are usually by recommendations of the RECs to the appointing officers for consideration and approval. This finding was very consistent with the appointment of administrators of the RECs.

Both our survey results and key informant interviews indicated that the RECs were composed of members with varied backgrounds including academics, research scientists, health practitioners, lawyers, religious leaders, community members, psychologists, bioethicists and biostatisticians. All eight RECs surveyed had academics/research scientists and medicine/health practitioners currently serving as board members. Other dominant membership background included lawyers, religious leaders and community members (75.5% each). Conspicuously underrepresented were members with philosophy or ethics backgrounds and representatives of local Civil Society Organizations. Indeed, only one REC reported having a member with a philosophy background (Table 2). A desk review of some SOPs of the RECs did not indicate mandatory inclusion of members with ethics backgrounds but we presumed that since the core mandate of the RECs was to review ethical issues related to proposed research studies, its members would, at least, comprise experts with this specialized philosophical knowledge. The local Civic Society Organizations usually represent members who are unaffiliated with the institution that sets up the REC but largely represent the interest of the communities.

All the RECs indicated the existence of formal meeting schedules to transact their business. Between a quarter and two-thirds indicated that they conduct monthly and bi-monthly meetings, respectively, while the other RECs meet at different scheduled intervals such as quarterly or once every two weeks (Table 2). In terms of gender, more (75%) of the surveyed RECs reported lower female representation (just about 40% of the members) than males. Contrasting the gender membership composition by type of REC, our survey results indicated that both hospital-based RECs and most of the university/research institute RECs (66.7%) had lower female representation on their boards. Similarly, one hospital-based REC and one university REC were yet to fully assemble a complete board (Table 2). All the RECs reported operating within their mandated tenures (data not shown).

These findings reported above were similar to the responses provided by the two key informants. For instance, key informant 'A' indicated that their REC is composed of:

> *A mixture of technical and lay members or we can also say it is a mixture of people from the university and from outside the university. Furthermore, we can also look at it as a mixture of males and females. For us, at least, we have an epidemiologist, a social scientist, a clergyman and bioethicist as members of our Board.*

Table 2. Membership Composition.

Particulars	Frequency (N = 8)	%
Appointing authority of Members		
Chief executive officers	4	50.0
Vice-chancellors	4	50.0
Appointing authority of Administrator		
Chief executive officers	4	50.0
Vice-chancellors	4	50.0
Membership composition	**Yes [F (%)]**	**No [F (%)]**
Academia/research scientist	8 (100.0)	0 (0.0)
Lawyers	6 (75.5)	2 (25.0)
Religious Leaders	6 (75.5)	2 (25.0)
Medicine and health practitioner	8 (100.0)	0 (0.0)
Community member	6 (75.5)	2 (25.0)
Philosophers	1 (12.5)	7 (87.5)
Administrator/ biostatistician	1 (12.5)	7(87.5)
Psychologist and a biostatistician	1 (12.5)	7(87.5)
Regularity of meetings	**F = 8**	**(%)**
At least five times in a year	1	12.5
At least once a month	3	37.5
Bi-monthly	2	25.0
Every two weeks	1	12.5
Once a quarter	1	12.5
Membership composition by gender		
About 21%-40% females	6	75.0
About 41%-60% females	2	25.0
Gender representation by type of institution	**About 21%-40% female**	**About 41%-60% female**
Hospital-based	2 (100.0)	0 (0.0)
University/research institute	4 (66.7)	2 (33.3)
Nature of membership composition	**Partially composed**	**Fully composed**
Hospital-based	1 (50.0)	1 (50.0)
University/research institute	1 (16.7)	5 (83.3)

Source: Field survey, 2021.

Funding of REC Operations. Half of the surveyed RECs indicated they had a dedicated annual budget allocated for their operations by their institutions or appointing authorities (Table 3). Of the institutions that had dedicated budgets, half indicated that their budgets ranged between US $3,490.00[1] to US$8,724.00 for the 2020 fiscal year while

the remaining two were allocated amounts between US $1,745.00 to US$3,490.00 and over US$8,724.00, respectively. Instructively, three of the four institutions with dedicated budgets further indicated that their budgets for the 2020 fiscal year remained the same as the allocation they received for the 2019 fiscal year. The RECs that did not receive any budgetary allocation from their institutions indicated that they relied principally on ethical clearance application fees charged to research investigators to run their activities. Five of the eight surveyed RECs declined to comment on the adequacy of funding for their activities; nonetheless, when the remaining three were asked to indicate the adequacy or otherwise of their funding, the general picture depicted a somewhat inadequate funding source: two rated this at between 41%-60% adequate while the other rated it 21%-40% adequate. It must be noted that adequacy of funding for the activities of the RECs may largely depend on the workload or activities of the RECs that were assessed. Almost all the RECs reported that they have a system of auditing their financial statements by their institutional internal auditors (50%), external auditors (12.5%) or both (25%). We also contrasted availability of dedicated budget allocations by type of institutions. Our results indicated that both hospital-based RECs did not have dedicated institutional budget to support the operations of the activities of the RECs while four (66.7) out of the six university/research institute RECs had dedicated funding to implement their activities (Table 3).

Both key informants expressed faint knowledge of the nitty-gritties of their funding and budget allocations for the institutions. This was partly due to their role as chairperson whose primary responsibility includes convening board meetings, steering the meetings and guiding the process of communicating review feedback to research investigators. Both indicated that these funding or budgetary issues are generally under the purview of the administrators of the RECs. They were thus unable to explicitly confirm or deny availability of dedicated budgets by the institutions to fund the activities of the RECs.

Table 3. Funding of REC Operations.

Particulars	Frequency (N = 8)	%
Availability of dedicated budget		
No	4	50.0
Yes	4	50.0
Budget allocation for 2020 Fiscal year		
More than US$8,724.00	1	25.0
US$1,745.00 - US$3,490.00	1	25.0
US$3,491.00- US$8,725.00	2	50.0
Changes in budget allocation		
Above 2019 budget allocation	1	25.0
Same as 2019 budget allocation	3	75.0
Sources of funding not from dedicated budget		
Fees charged investigators	3	75.0
Donations from institution	1	25.0
Adequacy of funding		
Adequate (41%-60%) of required funding	2	25.0
Low (21%-40%) of required funding	1	12.5
None response	5	62.5
Auditing of accounts		
External auditors	1	12.5
Institutional internal auditors	4	50.0
External and internal auditors	2	25.0
No formal auditing	1	12.5
Availability of dedicated budget by type of institution	**Yes**	**No**
Hospital-based	0 (0.0)	2 (100.0)
University/research institute	4 (66.7)	2 (33.3)

Source: Field survey, 2021.

Availability of Office Space and Other Logistics. The RECs were also assessed on the availability of permanent office space and other administrative logistics to facilitate their operations. Some institutions may treat their RECs as any other board or committee and not provide a full range of this type of support to undertake their activities. Significantly, all except one REC reported not having a permanent office space for its activities (Table 4) but it must be noted that the availability of office space(s) for the RECs may be dependent on the size of the RECs operations. The REC with permanent offices also reported of owning a variety of office equipment such as computers, printers, scanners and furniture in various quantities. All the RECs reported having approved Standard Operating Procedures (SOPs) with the majority (75%) being operational for the last five years. Copies of some RECs' SOPs reviewed as well as an unpublished 2016 seminar report by GHAAREC indicated that the documents are to guide the RECs to ensure quality and consistency in their review of research protocols to be able to safeguard and protect research participants as well as guide the operations of the RECs in accordance with best international practices as enshrined in documents such as the Declaration of Helsinki, the Belmont Report, the Common Rule and the Council for International Organization of Medical Sciences. It sets out the mandate of the RECs, membership composition and functions, research protocol review processes, administrative procedures, record keeping procedures, archiving processes and post-protocol approval activities including field monitoring. An approved and functional SOP plays a critical role in the determination of the authority or legitimacy of RECs in Ghana, especially in the absence of a national regulatory body. Besides the SOPs, most of the RECs also indicated that they had adopted and are being guided by other operational

Table 4. Availability of Office Space and Other Logistics.

Responses	Frequency (N = 8)	%
Availability of office space		
Yes	7	87.5
No	1	12.5
Office equipment		
Computers, furniture and internet connectivity	1	12.5
Computers, printers, furniture and internet	2	25.0
Computers, printers, scanners, furniture internet	4	50.0
None response	1	12.5
Number of computers		
One	1	12.5
Two	2	25.0
Three	3	37.5
Five	1	12.5
None	1	12.5
Number Printers		
One	4	50.0
Three	2	25.0
None	2	25.0
Number of Scanners		
One	2	25.0
Two	1	12.5
Three	1	12.5
None	4	50.0
Availability of Standard Operating Procedures		
Yes	8	100.0
Years in operation		
Between 1 and 5 years	6	75.0
More than 5 years	2	25.0
Other policy documents		
Conflict of interest policy and Ethical clearance application guidelines	1	12.5
Ethical clearance application guidelines only	7	87.5

Source: Field survey, 2021.

documents such as conflict of interest policy and ethical clearance application guidelines (Table 4). The ethical clearance guidelines, according to the RECs, are documents or notes that explain or guide research investigators on their research protocol application preparations and submission processes.

Training Activities of RECs

Regular training activities for members of the RECs, research investigators and the research public could be described as an essential feature of the administrative characteristics of the RECs. Scientific approach to the conduct of research is dynamic and always evolving due to factors such as advances in scientific knowledge, innovation explosion and improvements in technology. The dynamic and evolving nature of research are also associated with changing ethical thinking and requirements. It is therefore prudent for RECs to train their members in some of the contemporary knowledge, approaches, resources or materials that enhance the ethical review processes and decision-making. Indeed, few of the SOPs reviewed have provisions for organization of training programs for their members and administrators through activities such as participation in international and national conferences, workshops and seminars. There are also research investigators who are informed about some research ethical issues or how research designs should be aligned to ensure ethical conduct of research studies. Although this may not be regarded as a core mandate of RECs, it may also become imperative to routinely orient or provide some training to research investigators or prospective researchers such as students on ethical issues like fair selection of research participants, respect for persons and assurance of beneficence. Lastly, the RECs exist to ensure the welfare of research participants by reviewing proposed research protocols and granting ethical clearance before commencement of proposed studies. In a country where community awareness of research ethics is relatively low, it may also be an additional duty of RECs to train some community members in some basic ethical issues such as autonomy, confidentiality, minimization of harms and valid consent processes. Indeed, the mission of GHAAREC includes sensitization of the general public to adhere to high ethical research standards (GHAAREC, 2015).

Six (75.0%) of the RECs surveyed indicated that they have organised training activities for their members and their clients (data not shown). These activities principally included orientation sessions, public/community sensitization, workshops and conferences. Significantly, most of these activities targeted the committee members instead of research investigators (Table 5). Of note, as indicated in Table 5, community or public outreach by RECs on issues of research ethics were rarely part of the activities of the RECs who participated in our study. Indeed, only one REC reported ever organising an event of this type, at least during the time of our data collection. Just one REC reported having organized a national or international conference. Specifically, the survey found that there were no regular timelines for the organization of such training activities. For instance, none of the RECs had a regular schedule for orientation sessions for researchers (75.0%), orientations for board members (37.5%), public education through mass media (75%) or international conferences for members and administrators. Only one REC indicated that it provided annual training for its clients (researchers) and opportunities to members/administrator to participate in international conferences.

The issue of training activities also featured predominantly in the two interview sessions with the key informants.

Table 5. Capacity Building Activities of RECs.

Responses	Yes [F (%)]	No [F (%)]	Total [F (%)]
Capacity building activities organised by RECs			
Orientation sessions for research investigators	2 (33.3)	4 (66.7)	6 (100.0)
Orientation sessions for members	5 (83.3)	1 (16.7)	6 (100.0)
Public education (radio, TV, or newspaper)	1 (16.7)	5 (83.3)	6 (100.0)
Community durbars	1 (16.7)	5 (83.3)	6 (100.0)
Workshops/seminars for board members	5 (83.3)	1 (16.7)	6 (100.0)
Workshops/seminars for researchers	5 (83.3)	1 (16.7)	6 (100.0)
National conferences for researchers and members	0 (0.0)	6 (100.0)	6 (100.0)
International conferences for members/administrator	1 (16.7)	5 (83.3)	6 (100.0)
Regularity of capacity building workshops	**F**	**%**	
Orientation sessions for clients			
Annually	1	12.5	
As and when need arises	1	12.5	
None	6	75.0	
Orientation sessions for board members			
At appointment of new members	1	12.5	
Bi-monthly	1	12.5	
Annually	3	37.5	
None	3	37.5	
Public education (radio, TV, or newspaper)			
Yes	1	12.5	
None	7	87.5	
Workshops/Seminars for board members			
Once a quarter	1	12.5	
Once every two years	1	12.5	
Annually	2	25.0	
Bi-monthly	1	12.5	
None	3	37.5	
Workshops/Seminars for clients			
Once every two years	1	12.5	
Annually	4	50.0	
None	3	37.5	
International conferences for members/administrator			
Annually	1	12.5	
None	7	87.5	

Source: Field survey, 2021.

What was generally clear from their responses was that some activities are episodically organised for REC members and other research investigators such as students and their faculty supervisors. We describe this as episodic because the sessions offered for REC members were generally meant to orient new members appointed to the committee or during protocol review meetings where ethical issues come up for thorough discussion. For instance, key informant B indicated that:

> Apart from the initial training that was organized for *members before the committee was established, I also provide training for the members, when they come on board but this happens once in a while. On the other hand, at certain points in time when we are doing the review and something comes up, I take the opportunity to address the issue and then it turns to some form of training for them*.

Similarly, key informant A asserted that

> *when new members are appointed to join our committee, we take them through training or an orientation on the mandate of the REC and its core activities.... Ideally, every year, they should have some training including international conferences but we are constrained by funding to carry out these activities as envisaged. We also organise orientation sessions for some faculty members and students especially when we observe that the protocols that we were receiving from them are below standard…*

Research Protocol Approval Processes and Post-Approval Activities

Most of the RECs that participated in our survey (75.0%) indicated that their prospective applicants for ethical clearance could obtain the application forms online or from their websites (Table 6). This is intended to facilitate or expedite their activities by enabling the support of information communication and technology (ICT) and as a means of easing the ethical clearance application process for research investigators. For the institutions that were yet to host their forms online, the dominant application process is the manual system, where applicants either receive the forms electronically through email or walk into the REC Secretariat to pick up hard copies of the application forms. It must also be noted that the RECs that rely on hard copies often demand a number of copies of the whole protocol for each member, irrespective of the number of pages. The number usually varies but largely depends on the number of the REC members. Half of the institutions reported that it takes an average of three weeks between receipt of research protocol and communication of first review decision to an applicant while some (38%) take more than a month to complete the process[2].

Table 6. Protocol Approval Processes and Post-Approval Activities.

Responses	F (N = 8)	%
Mode of accessing application forms		
Website	6	75.0
Through emails	1	12.5
Walk-in to office	1	12.5
Turn-around processing time		
More than a month	3	37.5
One month	1	12.5
Three weeks	4	50.0
Duration for submission revised protocols		
No deadline	2	25.0
Less than one week	1	12.5
Two-three weeks	2	25.0
One month	1	12.5
More than one month	2	25.0
Implementation of post approval activities		
No	3	37.5
Yes	5	62.5
Reasons for no post-approval activities		
None	5	62.5
No funding	2	25.0
We do not know anything like that	1	12.5
No skills for such activities	1	12.5
Post-approval activities implemented	**Yes**	**No**
Field monitoring	4 (80.0)	1 (20.0)
Reports to appointing authorities	1 (20.0)	4 (80.0)
Mentoring of clients (researchers)	1 (20.0)	4 (80.0)

Source: Field survey, 2021.

Silverman et al., indicated that accountability, usually measured by monitoring and research review activities, forms part of the characteristics of RECs. Indeed, the GHAAREC unpublished report on a harmonization of the various SOPs in Ghana indicated that almost all the RECs had post-protocol monitoring activities incorporated as part of their mandates. This monitoring could either be administrative through review of progress reports received from research investigators or field monitoring of on-going implementation of approved protocols. We therefore asked our participants to provide information on their post-protocol approval activities. Most (62.5%) of the RECs reported that, beside the protocol review and approval activities, they undertake other post-approval activities such as field monitoring and writing of reports for their appointing authorities. Funding and limited capacity to implement these activities were the main reasons provided for the non-expansive implementation of post-approval activities (Table 6).

Implementation of post-protocol approval activities also featured extensively in our interviews with both key informants. One crucial post-approval activity they often cited was field monitoring of approved protocols, but this largely has not been implemented for some time now. They lucidly provided various reasons why this activity should be implemented. For instance, they mentioned protection of volunteer participants from abuse or exploitation by research investigators, ensuring investigators' compliance with approved ethical directives or procedures, recording of adverse findings and maintenance of ethical standards in the conduct of research as well as enhancement of community engagement. Nonetheless, the key informants indicated the unavailability of committee members to undertake field monitoring activities as the prime reason that this all-important activity was not carried out. According to the informants, members of the RECs have other responsibilities that often conflict with scheduled field monitoring.

In addition, the informants, like the relatively few survey participants (25%), cited lack of funding to undertake field monitoring activities. They opined that implementation of such activities requires basic logistics such as a vehicle, fuel, accommodation and allowances for the resource persons but this is hampered due to the limited budgetary allocation or funding of RECs activities. Narratives from the two informants are summarized below:

> *Ideally, we are to monitor the study after approval so that we are assured that the research investigators are implementing what we have approved for them. The trouble we have had is really the financial challenge of carrying out these monitoring activities and also the availability or time constraints of the Board members who happen to be so busy it's always a challenge getting them to commit…. The bigger bother is the financial component to go and conduct the field monitoring. But some studies have been monitored in the past* (Key informant A).

> *Our research investigators produce annual reports at the end of the year but that is if the research is going to go for a long time. On paper yes, but in practice, this is very minimal…The members of the RECs are usually specialists or experts and these are people who do not have time because of their other important activities like teaching or doing clinical work almost for the entire day…it boils down to the investigators. We trust they will do the right thing* (Key informant B).

Research Misconduct, Achievements and Challenges

Research misconduct is defined as the fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results (Office of Science & Technology Policy, 2000; Resnik et al., 2015). In some countries such as the US, RECs are not charged with tracking research misconduct, especially since other ethical issues such as authorship disputes are included

Table 7. Issues on Research Misconduct.

Response	F (N = 8)	%
Nature of misconduct		
Plagiarism	1	12.5
Falsification	1	12.5
Plagiarism/Falsification	1	12.5
None	5	62.5
Recent misconduct/violation		
Plagiarism	2	25.0
Falsification	1	12.5
None	5	62.5
Follow up actions		
None	5	62.5
No mandate to act	1	12.5
Research was terminated	1	12.5
Approval denied	1	12.5
Research misconduct by type of REC	**No**	**Yes**
Hospital-based	1 (50.0)	1 (50.0)
University/research institute	4 (66.7)	2 (33.3)

Source: Field survey, 2021.

along with the conduct of human or animal research. There are also separate entities that are charged with the responsibility of assessing misconduct and recommending remedial courses of action. This is not the case for research misconduct in Ghana although there are some state regulatory bodies that are charged with ensuring compliance of some activities such as medicines and public administrative misconduct. We referred to human related research misconduct in this study as comprising issues such as research protocol violations, noncompliance or putting research participants at risk. The RECs in Ghana, as they exist currently, also have the mandate to undertake these activities.

Generally, reports of research misconduct were not recorded by most of the RECs surveyed (62.5%). The few reports of such misconduct centered on plagiarism and falsification of research data or information. It might not be surprising from our relatively small dataset that the university-/research-based institutions recorded the higher rates of misconduct; nonetheless, it is important to note that one out of the two hospital-based RECs recorded a misconduct. Subsequently, the identified proposed studies that were involved in the misconduct were either terminated or ethical clearance approval was denied (Table 7).

When asked to provide examples of what their REC may consider a research protocol violation, a key informant enumerated issues including not operating according to the tenets of the approved protocol by, for instance, not obtaining informed consent from research participants before recruiting them into a study or making amendments to an approved protocol without authorization from the REC, or implementing a revised protocol such as proposing to take a blood sample from the finger prick but later deciding to draw the blood from the veins. They both indicated that these violations are infrequently recorded.

Main Achievements, Challenges and way Forward

The RECs provided various responses in response to a question on their achievements after becoming operational. The main achievement cited by 35% of the RECs surveyed was their ability to ethically review and approve protocols submitted by research investigators while 25% also indicated their organisation or participation in various training activities (Table 8). Other achievements cited were organisation of community sensitization events, improved administrative operations, enhanced protection of research participants and registration approval from the US Department of Health and Human Services.

The respondents also reported some challenges that have been hampering the smooth and effective implementation of their activities. These challenges were usually recurring or common for all the RECs that participated in this study. Limited access to adequate funding for their activities appeared as one of the two predominant challenges in their responses. This challenge, according to the participants, mostly hinders their ability to engage technical staff, procure office equipment to support their activities and their manifest over-reliance on manual processing of their ethical review processes. Along with inadequate funding, the absence of a national research ethics authority or commission was a considerable hindrance to the activities of the RECs (65%). This challenge, according to the participants, seriously affects regulation, accreditation, standardization and supervision of the activities of the various RECs in Ghana (Table 8). As indicated above, the GHAAREC is a voluntary association of the Administrators of the IRBs without a mandate to function as a national regulatory body which requires national parliamentary approval and presidential assent.

The respondents suggested that, to improve the operational activities of Ghanaian RECs, the establishment of a national ethics authority (65.0%) should be paramount to unlocking the full capacities of the various RECs. This would set the framework to regulate their operations and establish standards in key functional areas such as standardization or harmonization of research protocol submission, review and approval processes. It would also eliminate or minimize the current high incidence of multiple applications and reporting to various supervisory agencies (12.5%). Eventually, this will assure transparency in interactions with all stakeholders in the research industry. A participant also proposed a mandatory monitoring of approved research protocols (12.5%) to ensure that research investigators comply with approved ethical practice. Others also did not rule out access to sustained funding to support the activities of RECs.

Table 8. Main Achievements, Challenges and way Forward.

Responses	Yes [F (%)]	No [F (%)]	Total [F (%)]
Main achievements of RECs			
Review and approval of research protocols	3 (37.5)	5 (62.5)	8 (100.0)
Training and staff development	2 (25.0)	6 (75.0)	8 (100.0)
Community sensitization	1 (12.5)	7 (87.5)	8 (100.0)
Improved administrative operations	1 (12.5)	7 (87.5)	8 (100.0)
Enhanced protection of research participants	1 (12.5)	7 (87.5)	8 (100.0)
Registration with US HHS	1 (12.5)	7 (87.7)	8 (100.0)
Non-response	1 (12.5)	7 (87.5)	8 (100.0)
Main challenges			
Inadequate funding/board members & no national REC	1 (12.5)	7 (87.5)	8 (100.0)
Limited logistics, inadequate funding & no national REC	1 (12.5)	7 (87.5)	8 (100.0)
Limited logistics, inadequate funding/board members/technical staff & conflicts with investigators	1 (12.5)	7 (87.5)	8 (100.0)
Limited logistics, inadequate funding/board members, manual procedures & conflicts with investigators	1 (12.5)	7 (87.5)	8 (100.0)
Limited logistics, inadequate technical staff/funding, no national REC & manual procedures	1 (12.5)	7 (87.5)	8 (100.0)
Limited logistics, manual procedures & no national REC	1 (12.5)	7 (87.5)	8 (100.0)
No national REC	2 (25.0)	6 (75.0)	8 (100.0)
Absence of national REC a problem for Ghanaian RECs	**6 (75.0)**	**2(25.0)**	**8 (100.0)**
Problems with absence of national REC			
No coordinated regulation of RECs, no supervision & no accreditation of RECs	1 (12.5)	7 (87.5)	8 (100.0)
No coordinated regulation of RECs, no supervision, no accreditation of RECs & no training of RECs	3 (37.5)	5 (62.5)	8 (100.0)
No coordinated regulation of RECs	1 (12.5)	7 (87.5)	8 (100.0)
No supervision/accreditation of RECs & limited funding	1 (12.5)	7 (87.5)	8 (100.0)
None response	2 (25.0)	6 (75.0)	8 (100.0)
Recommendations			
Establishment of national REC	6 (75.0)	2 (25.0)	8 (100.0)
Composition of multidisciplinary review REC members	1 (12.5)	7 (87.5)	8 (100.0)
Reduction in multiple protocol approvals	1 (12.5)	7 (87.5)	8 (100.0)
Mandatory post-approval monitoring	1 (12.5)	7 (87.5)	8 (100.0)
Regular training of members/administrators	1 (12.5)	7 (87.5)	8 (100.0)
Electronic protocol submission processes	1 (12.5)	7 (87.5)	8 (100.0)

Source: Field survey, 2021.

These issues were also explored during our interviews with the key informants which they expressed as follows:

> *The bigger challenge is the availability of the people and that I think is the same across the two boards that I have served on… The availability of time of the committee members to be involved in field monitoring activities is also one of our challenges… The RECs in Ghana should talk to each other or collaborate in their activities…We have GHAAREC and we should have a similar one of the chairpersons of the various RECs. There should be also joint meetings of these two which will serve as a forum for sharing experiences, learning from each other and moving ahead with the process…The other issue is the multiplicity of the ethics committee and the requirements for approval before conducting the work. We may have a protocol which has to go to a number of ethics committees for approval from all of them before the researchers can go and do their work. If there was a way by which they could harmonize the process so that some shed off their approval rights to another sister REC which they think can handle it for them, then maybe it will be less of a strain on the investigators… It will also speed up the process* (Key informant A).

> *Funding is a huge problem… We need equipment in the office: laptops, computers, shredders, cabinets. If you are not very careful, you will charge the research investigators very high… There should be money somewhere. How they are able to get the money, I cannot tell…The other challenge is also expertise because these things are so dynamic…We need to build capacity with our members but in our SOPs, it says that, after 3 years, your time is up but renewable for another term of 3 years so by 6 years the person is so good with the review but…And then also, pressure from the investigators. They will say we have the money for research and you are wasting our time, you do not want to review this little thing. After all who are you? I want to know the members of the*

committee… My recommendation is one, we should be able to build the capacity of members. Two, we should also focus on finding a mechanism of trying to get new members from time to time…The other thing is that we should all put our heads together to ensure that we have a National Ethics Committee so that we can have the National Ethical Guidelines. We do not have it now but we are working. And then dedicated offices or rooms for meetings (Key informant B)

Discussion

In line with some existing measurable international indicators or frameworks to assess the operational characteristics of RECs in low and middle income countries such as the Development of an Accessible Self-Assessment Tool for Research Ethics Committees in Developing Countries by Sleem et al. (2010), our results have provided some operational characteristics of the RECs in Ghana that participated in our study. For instance, they are recognized independent entities by their institutions and are duly appointed by authorized high-ranking institutional authorities such as vice-chancellors or chief executive officers. Moreover, the surveyed RECs were composed of members with diverse expertise and operated within their mandated tenure in office. We consider these as very significant in our assessment of the legitimacy, competency and capacity of the RECs to fulfil their mandates. For instance, being appointed by high-ranking institutional officials provides some guarantees to the RECs that they will be able to implement their mandates without much interferences from external parties while being composed of diversified members who are operating within their legitimate tenure gives some assurances that comprehensive and independent review of submitted research protocols will be performed. There were also reported accounts of the RECs receiving, reviewing and approving proposed research studies in addition to having access to some limited funding for their activities or operations. In addition, these members were reported to be undergoing periodic training, although these were largely unstructured, but there was no reported national ethics authority or commission to regulate the activities of RECs in Ghana; each operated independently and in a silo. Relatedly, this means limited collaboration among the RECs as evidenced in the multiple application processes of research protocols.

Our key informants cited institutional *control or regulation* of the activities of research investigators as one of the motivating factors for establishing RECs. We are of the view that this reason raises an ethical issue for reflection. If the RECs were established by institutions such as hospitals to monitor the activities of research investigators on patients or research participants involved in studies conducted by university or other research institutions, then this is a motivation worth applauding since it stands to maximally protect the welfare of research participants in the institutions. However, this issue of control and regulation has the potential of leading to multiple approvals for one proposed research study by different RECs, which would delay the implementation of the proposed research as indicated by key informant B as well as duplicate payment of application fees by researchers.

We earlier reported that one of the eight surveyed RECs reviewed and approved some 1,500 research protocols in 2019, which is highly commendable. Nonetheless, if we consider the high number of students in addition to studies conducted by health practitioners, faculty members and other scientists, it appears that there other several other research studies that are implemented in Ghana without adequate RECs ethical scrutiny. Certainly, we are not oblivious to desktop or systematic review studies conducted by researchers as well as our considerable limitation of not presenting a generalized result of the approval rates of all Ghanaian RECs. But comparing our aggregated approved numbers based on our findings with the perceived high number of students and other research studies conducted on an annual basis in Ghana, we are of the belief that a greater proportion of these studies are conducted in the country without proper ethical scrutiny. The relative low humanities and natural science approved studies could also serve as reference point to buttress our claim.

Clearly, the RECs that participated in our study were composed of members with varied technical and professional backgrounds that could significantly position them to discharge their mandate. Nonetheless, the irregular training activities offered to the members is a phenomenon that may negatively affect their judgment and functionality. Ethical judgments are very dynamic and evolving. For instance, the evolution and involvement of information communication technology in the conduct of research raises several ethical issues involving privacy, virtual or online recruitment, consenting, data collection, processing and analysis. Similarly, human advancement in science and specific disciplines such as neuroscience, organ transplant and artificial intelligence, as well as involvement of some vulnerable populations like pregnant women, prisoners, children and adolescents in research, ought to constantly invoke training and re-training of REC practitioners to enable them function optimally. We are of the view that the training that is offered to new members and the episodic training offered in focused areas when issues arise seem an appropriate approach to training the members especially within the context of their limited resources. We are also of the view that other formalized training programmes that have been proposed by Laar and his collaborators (Laar et al., 2020) would complement the training requirements of the RECs in Ghana

Central to the episodic training activities implemented by our assessed RECs for their members and the general public is the issue of limited funding for the operations of RECs, although this may not be the case for all the RECs. It was

evident from our data that the various RECs were constituted by high powered appointing authorities, but the RECs were nonetheless poorly funded for their activities. Even if the establishing institutions, in practice, are committed to the activities of the RECs, adequate funding for research activities remains a major determinant of conducting ethical research. "Adequate" as used here means RECs having the minimum sufficient funding to implement all their intended activities. Inadequate funding could also potentially compromise the implementation of some key ethical requirements espoused by Emanuel and his colleagues such as independent review, scientific validity and social value of research (Emanuel et al., 2000, 2004). Resorting to fees from research investigators may also occasion payment of high or arbitrary fees to sustain the activities of RECs. While this is not well documented in Ghana, examples in other African countries such as Tanzania and Kenya may serve as pointers (Puppalwar et al., 2015). Relatedly, resorting to fees charged to researchers may also affect the judgment of REC members. This inadequacy, in addition to other factors such as limited availability of time and personnel, no doubt accounted for limited or no implementation of vital post-approval activities such as field monitoring, data management, verification of accuracy of reported findings, and surveys such as research participants' satisfaction survey. Furthermore, the inadequacy of funding for the RECs might be the prime or contributory reason for their inability to engage technical staff to assist in the implementation of these post-approval activities. The often-cited reason was the unavailability of board members to embark on these activities, though these may be delegated to trained staff to be implemented. Alternatively, the establishing institutions might consider their RECs activities as full-time engagement, not a side job for overburdened professionals as is currently the case in Ghana.

On the other hand, all the RECs surveyed reported having operational SOPs that guide the conduct of their activities. They serve as a quality assurance mechanism to authenticate the activities of the RECs. At a minimum, an SOP sets, in clear terms, the authority of the appointing officer, the membership composition, function, procedures and tenure of the REC. Nonetheless, there are other guiding documents or policies such as having a research misconduct policy, conflict of interest and ethical clearance application manuals or guidelines that support the activities of RECs in Ghana. Apart from the manuals, most of the other documents were not available, at least during the period of our data collection. Perhaps these issues have already been incorporated into their SOPs so separate policy documents for these are unnecessary.

Limitations

Our main limitation is the challenge usually associated with self-accounts/self-administered surveys. The researchers were unable to verify, query or probe responses for clarification. The 50% response rate as well as the diversity of the RECs surveyed also makes it impossible for us to generalize the findings to cover the activities of all RECs in Ghana.

Best Practices

Our study provides an empirical national overview of the operational characteristics of RECs in Ghana. Firstly, we will strongly encourage institutions that have set up RECs in the country to sustain efforts aimed at making the RECs operate independently. This will be achieved through ongoing appointment of diverse and competent members as well as inclusion of more members with ethics or philosophy backgrounds. This will also require targeted and sustained funding for the activities of RECs including well-structured capacity building activities and implementation of post-approval activities such as field monitoring.

Secondly, and more crucially, is the establishment of a national policy on human subject protections and the establishment of a National Ethics Authority or Commission to oversee RECs in the country so that all the RECs operating in Ghana will follow similar guidelines, principles and procedures. This is imperative to prevent/ensure that almost every research study conducted in Ghana is implemented with proper ethical scrutiny. This should not be a peripheral matter but something that ought to actively engage the attention of all stakeholders. This will be in line with international best practices, which will also position the RECs to act proactively on issues that relate to advancing the conduct of ethical research in Ghana.

Protocol post-approval monitoring is important in advancing the conduct of ethical research. However, making REC members who are already burdened with protocol reviews in addition to their engagements in other professional activities, lack expertise and limited number, undertake this activity as indicated by one of the key informants, may explain the near non-existence of post-protocol monitoring activities. Lastly, we suggest that all RECs operating in Ghana should hire at least a research compliance officer, who will undertake regular protocol post-approval monitoring and report the results to the RECs for consideration and remedial actions. In addition to this routine protocol post-approval monitoring, this officer can also be tasked to undertake protocol audits when there are reports or allegations of serious protocol violations or noncompliance.

Research Agenda

Assessment of the operational characteristics of a REC could be approached from two perspectives: from that of the RECs and that of their users or clients. We focused on the former. It is imperative and, perhaps urgent, to also assess the latter. This will provide a holistic picture of the

operational characteristics of RECs in Ghana. We have also indicated that half of the eighteen RECs in Ghana did not participate in this study. It will be worthwhile to reach out to all of them as a means of gathering a comprehensive national database on RECs operating in Ghana. The eighteen identified RECs operating in the country also raise questions for consideration by researchers to inform a research agenda on this topic. For instance, how are Ghanaian research institutions, both private and public, without RECs advancing the conduct of ethical research in their institutions? Furthermore, what challenges have been stifling their abilities to do this, if any, and what could be implemented to facilitate their efforts aimed at advancing the conduct of ethical research in Ghana?

Educational Implications

Our results suggests that key indicators for measuring the operational characteristics of RECs including transparency, accountability, integrity, training activities for investigators and researchers as well as legitimacy and independence should always be highlighted to appointing authorities and research investigators as a means of facilitating the efficiency of RECs in Ghana.

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Author's Contribution

BR, AL and LK conceived the idea to conduct this study. SAO and GA led in writing of the introduction and methodology sections as well as development of the research instruments with inputs from BR, AL and LK and PA. SAO and GA collected the primary data and led in the analysis of the results. All the Authors contributed in the write up of the final draft of the manuscript.

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declaration of Conflicting Interests

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Notes

1. US$1.00=GH¢5.73141
2. Our application for ethical clearance for this study lasted for an average of four months after submission to two RECs. Perhaps the experiences of other research investigators will illuminate the operational timelines of RECs.

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