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RESEARCH ARTICLE

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# Strengthening Research Ethics Systems in Liberia: Challenges, Prospects and Implications

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## ABSTRACT

Despite the tremendous growth of Research Ethics systems in resource-limited settings, structural and systematic challenges persist. Therefore, effective ethical frameworks must be cultivated and further implemented to promote the rights of human subjects and vulnerable populations, strengthen the implementation of high quality research, and engage the participation of communities for the sustainable growth of research ethics systems in Low and Middle Income Countries (LMICs). To explore those challenges, we conducted a cross-sectional study among prior and current members of research ethics committees in order to determine the facilitators and gaps that are impeding the growth of the research ethical systems in Liberia, a resource-limited country, and subsequently utilize the findings to formulate country-specific ethical and regulatory frameworks. The results revealed plethora of ethical challenges, ranging from the inadequacy of infrastructure to limited, non-inclusive, funder-driven, capacity building initiatives. While the findings have program and policy implications, the results could likely create a platform to support future ethics-based research efforts directed at developing effective ethical frameworks to strengthen and sustain research ethical systems in resource-limited settings.

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## Introduction

The global response strategies for the 2014 unprecedented outbreak of Ebola Virus Disease (EVD) led to the design and implementation of diverse and complex research projects to investigate risk factors, the natural history of diseases, and potential intervention measures [1-3]. However, the proliferation of research studies, including clinical trials, were unevenly distributed [4-5].

The rapid increase and complexity of inter-disciplinary, multi-partner, cross-border health driven research studies, especially those conducted in resource-limited settings [3-5], support the urgency to strengthen ethical frameworks for the protection of human subjects. The availability of robust ethics review systems is required for efficient application of structured ethical guidelines to enhance the quality and outcomes of research studies that protect the rights of communities and vulnerable populations [6-7]. This is particularly relevant for a resource-limited setting such as Liberia wherein the country may likely benefit from research studies that effectively address the burden of existing and emerging health challenges [4-5].

A number of issues hamper the ethics and regulatory systems in resource-limited settings including the lack of harmonization of ethical and regulatory guidelines, inadequate legislative protection for vulnerable populations and inconsistent ethics and regulatory procedures [6-7]. Nevertheless, ethical review sys-

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tem remains central to health research activity in the context of timely discoveries and enhanced access to new therapies, technologies and interventions. However, in order to attract clinical trials, there must exist adequate ethical and regulatory infrastructure to ensure that efficient review and approval procedures occur for the protection of Most-At-risk Populations (MARPs), including social responsibilities for disenfranchised communities [3,6-7].

The operations of Research Ethics Committees (RECs) in a post-conflict, post-EVD epidemic and resource-constraint country like Liberia is a major challenge associated with social, cultural, anthropological, economic, structural and political implications [6-7]. The task of recruiting and retaining competent professionals and community members for the performance of voluntary services becomes an overwhelming task. The RECs lack the required incentives for its members and as such, recruiting professionals of diverse expertise becomes a challenge [3-4,6-7]. The interpretation and transcription of conventional western instruments into feasible locally resourced materials relative to the social, traditional and cultural contexts, while retaining the scientific contents and ethical standards, can be a perplexing factor [6]. In addition, monitoring of research activities in these settings is also a daunting challenge. However, individual sacrifices and commitments to research could likely change the attitudes of professionals and subsequently motivate them to serve on RECs. Securing the commitments of local Subject Matter Experts (SMEs) to serve on RECs as ad-hoc reviewers could also have a lasting impact on the lives of subjects enrolled in research studies in developing countries.

Furthermore, the operations of ethical and regulatory systems must be within the context of a sustainable infrastructure [3,6-7]. Generally, the RECs in resource-limited settings faced critical challenges due to the lack of resources. For example, the secretariat tends to be understaffed with limited quantity of competent reviewers to evaluate complex research protocols. Additionally, the training programs for RECs are generally provider-directed. That is, decisions for the selection of capacity building related training courses tend to be guided by providers [1-2,3]. However, for RECs to be more robust in resource-limited settings there is a significant need to conduct well-structured internal and external needs assessments to identify capacity-related gaps and prioritize the challenges by thematic areas in order to inform the development of mitigation strategies.

Globally, the development of protocols, funding, implementation and leaderships of clinical trials are unevenly distributed wherein resource-limited settings are significantly unrepresented [7]. This uneven distribution of clinical trials inevitably leads to neglected public health needs as well as untapped resources. Importantly, it is of great importance to attract clinical trials due to its numerous benefits, including the strengthening of research infrastructure, ethical and research systems, health systems, partnership and collaborative frameworks, scholarly productivity, and policy and intervention strategies.

Despite the tremendous growth of RECs during the pre- and post-EVD periods in Liberia, challenges and/or gaps have persisted regarding its structures, systems and/or strategic directions for the sustainable protection of human subjects and vulnerable populations, promotion of high quality research, community participation in research and related benefits, and policy-related acceptance. Accordingly, there is an urgent need to conduct thorough assessments of the various components of a functional, operational and sustainable ethical system.

Herefore, the overall goal of this study was to conduct a global assessment of the ethical platform in Liberia in order to identify the facilitators and gaps impending the systematic growth of sustainable ethical and regulatory systems within the country. As such, the objectives were to identify the:

- Infrastructure requirements for the growth of sustainable ethical systems in Liberia.
- Training needs and requirements for REC members and researchers.
- Standardized ethical procedures (e.g., pre-, intra- and post-review, etc.) and/or requirements for country-specific application.

By generating real time data, we expect to understand the challenges and/or gaps associated with the ethical systems within the country and utilize the findings to guide and further inform country-specific frameworks for the sustainable growth of the ethical and regulatory systems in Liberia. Specifically, we propose that the findings may have the likelihood of improving the administrative, management and/or operational requirements and processes, and leadership, membership and/or organizational requirements for the growth of sustainable ethical systems in Liberia.

## Methodology

There are two (2) functional RECs in Liberia, the National Research Ethics Board (NREB) and University of Liberia-Pacific Institute for Research and Evaluation Institutional Review Board (UL-PIRE IRB), with unrestricted tenures. The NREB has statutory responsibility to regulate the ethical space within the country while the UL-PIRE IRB is situated at the University of Liberia, the largest public degree-granting academic

and research institution in the country. To address the gaps associated with the limited quantity of RECs in the country, the NREB, besides its statutory mandates, actively review research protocols. Lastly, the study protocol, pre-test of the study materials for local acceptance, consent and questionnaire were approved by the UL-PIRE IRB.

**Study methods**

Individuals were eligible for participation in this ethics-based cross-sectional study if they were prior and current REC members of the NREB and UL-PIRE IRB, including ad-hoc reviewers and administrators and/or coordinators. Since the purpose of the study was to understand the facilitators and gaps hindering the progressive growth of the ethical and/or regulatory systems in Liberia, the target populations were considered to be well-suited respondents who could provide the required real-time data to inform the goals and/or objectives of the study.

**Inclusion and exclusion criteria**

To qualify for enrollment into the study, a participant must have been a prior or current member, administrator, and/or coordinator of the NREB or UL-PIRE IRB in Liberia. They must have completed a structured human subjects protection and/or Good Clinical Practice (GCP) course(s), whether Face-to-Face (F2F) or online. And have been physically present in Liberia to complete the assessment tool or reachable by electronic communication (e.g., email) to complete an electronic version of the assessment tool. Participants who did not meet the aforementioned inclusion criteria were excluded from participating in the cross-sectional study and no further data were collected.

**Enrollment procedures**

Eligible participants were approached through general emails, during REC review meetings, and/or phone calls by one of the key members of the study team. At the REC review meetings, the surveys were distributed for completion if an eligible member had elected to participate. During the REC review meetings, the average duration for survey completion was 60 minutes.

For eligible members who were unavailable, the surveys were individually sent *via* emails. There were a maximum of four reminder messages, whether by emails, text messages and/or phone calls, for the completion of the survey. Duration of two weeks was required, from the distribution of the survey to an enrolled participant, to the completion, submission and collection of the questionnaire.

**Study participants**

For this study, we used convenient samples of prior and current REC members in Liberia as respondents. From the review of the rosters of the memberships of the RECs in the country, we identified thirty-five (35) eligible participants to complete the survey. The rosters consisted of the names, the specific RECs, and contact information such as cell phone number and email address. To validate the relevant status of eligible REC members, we engaged the senior members, including the leaderships, of the respective RECs, as well as secondarily verified the information *via* phone calls and/or text messages, where applicable.

Based on detailed validation of the 35 eligible participants, 4 (11%) were deceased, 29 (83%) of them were present in Liberia while 2 (6%) were out of the country. Accordingly, we approached the 31 eligible participants; of which, 27 (87%) of them completed the survey. Of the 4 (13%) unresponsive individuals, 3 (75%) were males and 1 (25%) female, all above sixty (60) years; one was out of the country, and all professionals, respectively. Therefore, for the purpose of this study, our convenient sample size (N), for data imputation and subsequent analysis, was restricted to those 27 respondents.

**Study measures**

We conducted database searches of suitable assessment tools to elicit responses regarding challenges and/or gaps within ethical systems in Low and Middle Income Countries (LMICs). While we were unsuccessful in identifying suitable assessment tools, continual collaborative discussions, as part of the current grant, directed us to an appropriate instrument used by one of the European ethical groups for system analysis. We obtained permission for country-specific adaptation and further conducted an iterative review and pre-testing procedures to ensure its relevance for our setting.

Accordingly, we developed a comprehensive one hundred and four (104)-item 60-minute adapted self-administered Pencil-and-Paper (P&P) questionnaire to elicit relevant real-time data based on the following thematic-related categories: (1) REC Members Non-Identifying Characteristics, (2) REC Characteristics, (3) REC Documentation Procedures, (4) REC Financial Information, (5) REC Membership, (6) REC Application Submission Procedures, (7) REC Review Meeting, (8) REC Monitoring Procedures, and (9) REC Evaluation, respectively.

**Data collection procedures**

To ensure confidentiality, we developed a master roster of the 31 eligible participants by columns for names, REC affiliation, cell phone number(s), Email Address (es), study code(s) and comments (e.g., status of survey), respectively. This master roster was accessible by the key members of the study team, stored under lock-and-key in the file cabinet and computer-password

protected. Each non-identifier-related self-administered survey was coded. Accordingly, the blank survey questionnaires were distributed to the respective respondents by only the Principal Investigator (PI) of the study. The instructions were self-explanatory. Respondents requested either paper- or electronic-based surveys. Each respondent, who collected the survey, returned the completed assessment tool in brown envelopes (if paper-based) and individualized email (electronic-based) to only key members of the study team within the required study window for data collection from enrolled participants.

### Data analysis

First, survey data were entered into a customized data management system by an experienced data entry staff. Second, a more experienced data entry staff rechecked all data entries for verification purposes. Wherein error existed, the particular survey item was reviewed and the appropriate correction made in the data management system by the second level data verification staff. Prior to data analyses, all variables were checked for normality of distribution, including out-of-range and non-logical responses. All analyses, basically frequency distributions, were performed using the Statistical Package for the Social Sciences (SPSS; SPSS Inc., Chicago, IL) version 17.

## Results

### General description

Overall, of the twenty-seven (27) eligible respondents who completed the self-administered paper-and-pen questionnaires, 67% (18) were males and 33% (9) females. The response rate for the completion of the survey was 87%. No additional study-related information was collected from non-responders after the expiration of the study window.

### Membership

Descriptive analyses by 56% (15) of respondents revealed that the RECs had standard procedures for the appointments of members; 82% (22) stated that the composition of the RECs should include non-scientific members; 52% (14) opposed to diverse representation of the REC composition while 56% (15) did not support representation from religious group. Of the membership on the RECs, 89% (24) of the respondents were regular members (Table 1).

**Table 1.** Membership Composition of RECs.

| Variables | N | % |
|---|---|---|
| Epidemiologists | 3 | 11 |
| Ethicists/Bioethicists | 5 | 19 |
| Lawyers | 3 | 11 |
| Medical Doctors | 3 | 11 |
| Others (MH Specialist, Parasitology, etc.) | 4 | 15 |
| Pharmacists | 2 | 15 |
| Public Health Physicians | 6 | 22 |
| Religious Leader | 1 | 4 |

Additionally, 33% (9) had REC tenures of greater than five (5) years, 22% (6) were Public Health Physicians, 19% (5) Ethicists/Bioethicists, 15% (4) classified as Others (Mental Health Specialist, Sociologist, Parasitologist, Finance/Research Assistant) and 11% (3) each as Lawyers and Doctors, respectively (Table 1).

### Infrastructure

Regarding the availability of suitable infrastructure for the operations of the RECs, 48% (13) of respondents revealed the lack of institutional office; 48% (13) the lack of adequate space; 93% (25) the lack of adequate office equipment; 93% (25) the lack of online submission portals; and 56% (15) the lack of adequate staffing.

### Capacity building

Regarding the integration of capacity strengthening initiatives, over half of the respondents, 52% (14), indicated that they had not participated in any capacity building workshop over the prior twenty-four (24) months and over two-third, 74% (20), revealed that their respective RECs is not a member of any forum for ethics committees wherein capacity building events are regularly administered.

### Documentation

Regarding documentation as one of the key tenets of records, 85% (23) of the respondents confirmed the availability of their Curriculum Vitae (CVs) with the respective RECs; 78% (21) indicated that the RECs had structured forms for the submission of protocols; 89% (24) indicated the availability of documentation checklist and 93% (25) the existence of Standard Operating Procedures (SoPs) for the operations of the RECs, including the protocol review process.

### Adherence to guidelines

Regarding compliance to acceptable standards, 96% (26) of the respondents revealed that their respective RECs adhere to the national ethical guidelines; 93% (25) adhere to international ethical guidelines while 89% (24) adhere to its institutional guidelines.

### Research ethics committees

For the RECs, 41% (11) of the respondents revealed that their respective RECs can best be described as part

of the government; 78% (21) indicated that their RECs are considered as national ethics committees, 82% (22) stated that their RECs are registered, 92% (25) considered their RECs to be operational and functional based on internationally acceptable standards; 78% (21) mentioned that their respective RECs have not been audited, surveyed or inspected; 89% (24) indicated that their RECs have not reviewed animal research applications while 78% (21) stated that their RECs have reviewed laboratory-based research applications (Table 2).

**Table 2.** Descriptions of RECs.

| Variables | N= 27 | % |
|---|---|---|
| Institutional Review Board (IRB) | 8 | 30 |
| National Ethics Committee (NEC) | 13 | 48 |
| Research Ethics Committee (REC) | 6 | 22 |

## Discussion

During the period of the EVD outbreak, there was concerns raised by stakeholders that the RECs were structured to review behavioral and/or clinical research studies. To strengthen its mandate to integrate models for the review of high quality clinical trials and complex study designs, the country's Ministry of Health (MoH) re-appointed its membership to enhance its roles and responsibilities during health emergencies and related outbreaks.

In the post-EVD period, the governance of ethical practices has evolved in parallel with the types and quantity of research studies that are conducted to effectively address the shift in the epidemics. Accordingly, the RECs have made significant strides regarding the protection of human subjects in research in Liberia and the review of rigorous clinical trials as well as human resource development at the national and international levels. To date, the RECs have maintained safety of research participants in line with best practice, while simultaneously upholding its fundamental ethical norms. Additionally, for the last five years, members of the RECs have benefited from both local and international training experiences in the fields of Research Ethics, Bioethics, Research Methods and Research Conducted in Emergency Settings, among others. There is a need for continued capacity strengthening and clear definition of objectives and functions, particularly in the context of post-EVD challenges within the health sector.

Hence, in 2018, the RECs conducted a strategic planning workshop to review and reflect on its achievements and challenges during the prior years since its reconstitution, including lessons learned and strategic directions. The evaluation led to a proposed Action Plan, or Ethical Framework, to strengthen the ethical guidelines to fulfill its obligations to protect research participants according to the relevant ethical guidelines, including internationally recognized regulations. Additional aims were directed at upholding societal interest and the obligation of researchers by applying the principles of research ethics and relevant socially and culturally acceptable guidelines and regulations. Moreover, the workshop created a platform for the RECs to identify potential gaps regarding the submission of applications, organization of review procedures, administrative structure and effective operation, respectively.

### Composition

The composition of the RECs is not well defined. The composition should basically consist of 50% scientific and 50% non-scientific members. The classifications could be based on available record within the Human Resources (HR) folder of each participant. Additionally, the secretariat could generate a form with the appropriate listing of its membership based on the defined designation(s). Within the scientific and non-scientific categories, members with expertise in key thematic areas could be represented.

### Capacity building

Training programs for the NREB have generally being provider-directed. That is, the determination regarding the selections of requisite training courses and related contents were made unilaterally by the provider(s). Thereafter, targeted and time-dependent prioritized support must be elicited based on the needs of the RECs by proactively engaging academic, research, national, regional and/or international institutions and securing funded grants. If such a strategy is effectively implemented, there is an increased likelihood that the capacity building initiatives for the RECs could be significantly enhanced and strengthened to play its ethical and/or regulatory roles and responsibilities within the country.

### Review procedures

The RECs have made significant stride in strengthening its review procedures. However, several gaps persist. The gaps, if not adequately addressed, have the potential to affect its transparency processes and diminish its stipulated mandates. The gaps include, for example, the lack of Pre-Review and Post-Review Conflict of Interest (CoI) Checklist, the lack of Membership Disclosure Checklist (e.g., Institutional Affiliations, Professional Relationship with Key Study Investigators, Project Roles, etc.), the limited number of Administrative staff, lack of capacity, the lack of appropriate Institutional Infrastructure, the lack of customized Database for the effective operations of the RECs and the lack of website for user-friendly Information Dissemination, among others.

## Conclusion

The RECs must assume their respective mandates as national ethical bodies in the country in order to ensure that high standards and best practices are maintained regarding the implementation of ethical and regulatory compliance for the protections of research subjects, especially for the welfare of most-at-risk and highly vulnerable populations.

The RECs have the potential to reshape the ethical and regulatory space in Liberia. With the proposed restructuring, the systems and structures of RECs in Liberia could likely be strengthened, its capacity enhanced and institutional roles and responsibility reinforced. By so doing, human subject protection could eventually become a cardinal driving force during the development and implementation phases of research programs in Liberia.

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## Competiting Interests

None

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