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Funding modalities of Ethics Review Committees: perspectives of representatives of selected ERCs in Ghana

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Abstract

Background: Ghana and other African countries contend with issues of funding Ethics Review Committees (ERCs), which limits their effectiveness and benefits to researchers, host institutions and other research ethics stakeholders.

Objective: This study aimed to elucidate the funding challenges of ERCs in Ghana and to seek views on how ERCs could be adequately, ethically, and sustainably funded.

Methods: With a purposive maximum variation sampling approach, five research institutions with well-established ERCs were selected for this study. Views of representatives of their ERCs were sought on the adequacy of funding for their work by interview.

Results: All those interviewed were unanimous in their view that funding was inadequate for ERCs to fulfill their mandate of protecting the research public. This posed ethical dilemmas to the ERCs, especially in adopting a fee-paying policy for the review of protocols that disadvantaged poorly endowed institutions and researchers. To address these challenges, the respondents proposed a multifaceted funding model to include government subsidies, reliance on internally generated funds of the host institutions, and funding supplementation from external agencies and non-governmental organisations. Other recommendations include improvement in the efficiency of the financial administration of the ERCs and the establishment of a legislative instrument for a governing national research ethics committee that will also advocate adequate funding for ERCs

Conclusion: The multifaceted funding model, which includes government funding as proposed by the respondents, would go a long way to ensure adequate and sustainable funding of ERCs. However, the consideration of fee-charging may pose ethical challenges. To address the funding challenges, the government must, as of utmost importance, recognise the critical roles ERCs play in protecting the research public and establish a national ethics review committee for effective governance to ensure research integrity and adequate budgetary allocation.

Keywords: Funding modalities, Ethics Review Committee, ethical funding

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INTRODUCTION

It is trite knowledge that many harsh and unethical practices in the name of medical research have

targeted poor and vulnerable populations in different parts of the world. Among these were the Nazi medical experiments on human subjects and the Tuskegee syphilis study [1-6]. The abhorrence of these and other unacceptable research practices resulted in the development of research ethics codes and guidelines to protect the rights and safety of research participants and their communities. Prominent

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among these are the Nuremberg Code, first formulated in 1947 [7,8], and the Helsinki Declaration adopted in 1964 [9] and updated in 2013 [10,11]. Subsequently, Ethics Review Committees (ERCs) or Institutional Review Boards (IRBs) emerged [12-16]. The primary roles of these committees include protecting research participants from exploitation and harm, ensuring high standards in biomedical research, and establishing distributive justice in the conduct of research [12,15-17].

In Ghana, as in most other African countries, the formation of ERCs was primarily influenced by the insistence of major research funding agencies, such as the US National Institutes of Health (NIH), Wellcome Trust, Fogarty Foundation, and the Rockefeller Foundation, on ethical clearance of research protocols prior to approving funding for the research. Institutions of external research collaborators also insist on ethical clearance of the research to be conducted [18,19]. The European and Developing Countries Clinical Trials Partnership (EDCTP) and the Food and Drugs Agencies of most advanced countries also require ethical clearance for clinical trials involving humans and animals [18,19]. In Ghana, public awareness of possible adverse effects of medical research is also not strong. Unsuspecting communities might, therefore, be taken advantage of by unscrupulous researchers. This lack of awareness of research risks is evidenced in the paucity of national legislation and policies for the ethical conduct of research involving human participants. For example, unlike some other countries, Ghana does not have a National Ethics Committee to regulate biomedical research, including clinical trials, to protect the public [20,21]. Neither is there a governing body to regulate the conduct of research and to adjudicate complaints about the conduct of research [22,23]. Additionally, a National Ethics Committee is required to assist the operations of organisations such as the Food and Drugs Authority and the Ghana Standards Authority.

Most ERCs in other African countries also contend with issues of limited appreciation of the role of ethics committees, weak research governance, and limited research funding [12,24,25]. The responsibilities of these ERCs and the workload they carry are enormous. In addition to these, most of the members of the ERCs work with limited skills in bioethics. Monitoring the conduct of approved research, obtaining adequate funding to function properly, the need for in-house training for capacity building, determining the impact of research outcomes on communities, and handling complaints about the approved research are major issues ERCs are hardly able to address. Due to these and other issues, the operations of ERCs in several countries, including Ghana, have been too focused on the examination and approval of the ethics of the study to be prosecuted, as well as, in some cases, research monitoring to assure compliance. Additional challenges of ERCs include monitoring of research outcomes, how these challenges impact the health of the public, and how the research they approve is to be funded [12,17,24-27].

These challenges must be addressed to enhance the effectiveness and benefits of ERCs to researchers, research institutions, and other stakeholders, collectively referred to as the “research public” [28,29]. When adequately funded, the ability of ERCs in Ghana and the rest of Africa to fulfill their mandate of protecting research participants and the general public could be improved in a non-excludable and non-rivalrous manner [28].

Factors that pose a challenge to the ethical funding of ERCs and their survival in most developing countries are 1) the inadequacy of public funds, 2) external sources of funding and issues of conflict of interest, and 3) sustaining the level and sources of funding [30,31]. These factors must be addressed to ensure that funding does not limit fairness and distributive justice of benefits and does not compromise the autonomy of the ERC or raise conflict of interest issues [30-34]. Funding of ERCs is considered to be adequate if what is available to the ERC includes what is needed for upgrading their knowledge in bioethics, for investment in appropriate tools for their work, conducting reviews of the research and research outcomes and products, monitoring the conduct of the approved research, and for ensuring there are no serious adverse effects in the research being conducted [25,35]. These duties clearly show that ERCs require substantial funding to ensure quality and timely delivery of services and for the ERC to grow. It is important, therefore, to engage ERCs in Ghana to identify and address the challenges they face in regard to the adequacy and sustainability of funding for their work.

MATERIALS AND METHODS

Study design

In this cross-sectional study, six representatives from five reputable ERCs that were chosen from Ghanaian universities and other research organisations were interviewed. This study was designed to highlight the financial difficulties faced by ERCs in Ghana and to get opinions on how these organisations would be able to secure adequate, ethical, and lasting funding.

Selection of ERCs and Interview of ERC members

Based on the information received from the Ghana Association of Administrators of Research Ethics Committees, at the time of the study, there were about 20 ERCs operating in Universities, Research Institutions and Hospitals in Ghana. Of these, nine (9) institutions that have operated for more than 10 years (which is long enough to have experienced challenges in funding after its establishment) were selected. These institutions were grouped into five categories, depending on their areas of research focus, as shown below.

Category 1: Institutions whose ERC reviews health and industry-related research nationwide, including research proposals from universities and other research institutions in the country.

- The Ghana Health Service

- The Council for Scientific and Industrial Research.

Category 2: Institutions whose ERC reviews mostly biomedical research from universities and other research institutions in the southern half of the country.

- The Noguchi Memorial Institute for Medical Research, University of Ghana

Category 3: Institutions whose ERC reviews public health, community, and hospital-based social and health research for universities and research institutions in the southern belt of the country.

- The Dodowa Health Research Centre.
- The University of Ghana, Legon
- The University of Health and Allied Sciences, Ho

Category 4: Institutions whose ERC reviews nuclear science-based research nationwide.

- The Ghana Atomic Energy Commission (Radiological and Medical Sciences Research Institute).

Category 5: Institutions whose ERC reviews public health and hospital-based social and health research in the northern half of the country.

- The Navrongo Health Research Centre.
- The Kintampo Health Research Centre.

Out of the nine ERCs invited to participate in this study, only five responded and agreed to participate. Five (5) of them responded to our invitation and participated in the study. They are the Ghana Health Service, the Noguchi Memorial Institute for Medical Research, the Dodowa Health Research Centre, the Ghana Atomic Energy Commission, and the Kintampo Health Research Centre. After completing the informed consent process, interviews were conducted via Zoom due to the COVID-19 pandemic.

For each of these five committees, the administrator of the ERC was interviewed since they (and the chair of the ERCs) are best placed to provide the information sought by the study. In one institution, both the administrator and the Chair of the ERC participated in the study. A semi-structured interview guide was used to collect data for this study. This was structured to align with the study objectives. The primary questions were categorised as follows: a) views on the current funding model of the ERC and challenges faced, b) suggestions offered for new funding models, and c) the ranking of the suggested models based on potential ethical issues, adequacy, and sustainability. On average, each interview session lasted 30 minutes.

Data Management, Analysis, and Reporting

Each interview was digitally recorded, labelled, and transcribed verbatim to maintain the originality of the information. The transcripts were organised and analysed using qualitative data analysis software (NVIVO version 12). Based on the objectives of the study to determine the adequacy of funding and the ethical nature of such funding, the transcripts were coded inductively and deductively

using a pre-designed codebook. Information obtained was reported according to the consolidated criteria for reporting qualitative research information (COREQ)

Research standards and quality control

To eliminate ambiguity in the collected data, the questions were pre-tested for clarity/understanding by interviewing the members of the ERCs who were part of the NYU-UG Research Integrity Training Fellowship Project under which this study was conducted. The interviewer also transcribed the audio recordings. Data from the transcripts were extracted. Any conflicts in the coding were resolved at a meeting of the interviewers and the principal researchers. The research team analysed the information obtained and agreed to use deductive and inductive coding for narratives that did not align with the pre-determined codes.

RESULTS

Views of Respondents on sources of funding for ERC in Ghana

All respondents stated that the main source of funding for their ERCs was from their host institution as part of government subvention for the institution. The amount received covered the administrative expenses of the ERCs only. All the ERCs, therefore, relied also on fee-charging for transportation of ERC members to meetings and for sitting allowances. Some ERCs received external funding support from time to time. Below are two direct statements from respondents on the sources of funding. Funding (for ERC) comes from outside and from the government (through subvention, which is indirect); however, the government does not directly fund research (projects) and related activities in the country” in-depth interview IDI-Participant 3. “Funding of the ERC depends on the institution. Our institute, for example, established its IRB with a grant from the US National Institutes of Health (NIH) and, later, from the African Malaria Network Trust and the European and Developing Countries Clinical Trials Partnership (EDCTP)” IDI-Participant 5.

Views on the adequacy of funding for ERCs in Ghana

The respondents indicated that the funding received was grossly inadequate for the work of their ERCs. Without external funding, the host institution bore a huge burden, making sacrifices for their ERCs to function and maintain the quality of research in their academic departments. Below is a narration from a stakeholder on this matter. “Yes, I think it’s important that they should be adequately funded. I’m not sure how that will happen, but as somebody who has worked in a research institution or research institution for the past twenty years, I recognise that funding the Ethics Committees is a bit of a burden on the host institutions. Knowing how important ethics committees are, their absence would allow unethical conduct of research that could be harmful. We have the responsibility to protect research participants and the public” IDI-Participant 4.

Views of Respondents on Fees charged

Some respondents expressed concern that charging fees to supplement the meagre funding from their host institution posed ethical challenges for the ERC. According to them, the level of fees charged by ERCs differed and depended on the sources of the application. In general, the fee is lower for protocols from the social sciences, followed by those from biomedical investigations. Protocols for clinical studies, including those for drug and vaccine trials, attract the highest fees charged. Research protocols of students attract little charge, if any. Fees charged also differed between local and external applicants, the fee being higher for research protocols from external institutions. It was also observed that funding from both government and external agencies for institutions that primarily conducted research was dwindling. According to respondents, this trend could push ERC in research-based institutions to charge higher fees, compounding their ethical challenges. It was noted that ERCs did not include funding for training and capacity-building of ERC administrators and reviewers in their budgets. Unless host institutions and/or each member of the ERC raised funds on their own, the training and capacity building of ERCs would continue to suffer. It was also noted that, in the past, some ERCs received grants for institutional development from organisations such as the NIH, AMANET Network Trust, and EDCTP. Respondents noted that such grants had diminished over the years.

Budgets for ERCs

ERCs face insufficient funding for protocol reviews and lack budgets for training activities aimed at enhancing the capacity of administrators and reviewers, monitoring approved research conduct, and supporting other essential functions necessary to fulfill their mandate. Two respondents shared their views: “I think that each ethics committee should have well-developed budgets before the beginning of the academic year” IDI-Participant 6. “Government should give preference to ethical review activities in the budget for us” IDI-Participant 1.

ERC funding models recommended by respondents

Respondents indicated that the most appropriate funding models must be those which ensure the autonomy of the ERC to act to fulfill its mandate of protecting the interest of research subjects and the public. They noted that no single funding model currently satisfied the needs of ERCs to achieve that end. The respondents suggested a multifaceted funding model that would include adequate government subsidies, funds generated internally by the institution, and financial assistance received from external organisations, including multilateral organisations. Two comments on this are captured: “It would be proper if the government can allocate adequate funds to ERCs, even though it is the primary responsibility of the public institutions to ensure that. Such government funding should also cover ERCs in private institutes” IDI-Participant 2. “All the funding models are currently in existence. What we need is to explore more external funding to supplement existing funding sources” IDI-Participant 6.

Limitations of some of the recommended funding models

Some respondents noted that private, not-for-profit ERC in Ghana may not benefit from public funds, even though their research services are for the public good. An example is the ERC of the Christian Health Association of Ghana (CHAG). For the non-public ERCs, the emphasis should, therefore, be on the other modes of funding, including grants and internally generated funds of the institution.

Government awareness of the value of ERCs

Respondents noted the low priority placed on the possibility of health hazards from health research and on ERC by the government in its funding of public institutions. Respondents were of the view that support for research ethics committees might increase if the executive arm of government and parliament recognise the important roles ERCs play in protecting the research public from risks associated with research misconduct. The need for the government to prioritise funding for ERCs is captured in the statement: “Globally, government funding for ERCs is limited. This also pertains to Ghana, where research is not prioritised by the government” IDI-Participant 3.

Ranking of funding models in relation to ethical challenges

Respondents expressed different views on the ranking of the financing options for ERCs in relation to how they minimised ethical challenges, contributed to the adequacy of funds, how context-appropriate they are, and the degree to which they would make the work of ERCs sustainable. While some felt adequate funding from government subventions would be the best model to address the above issues, others thought sourcing funds outside government sources would address the ethical and other challenges. Still, others thought that, even though funding from NGOs or other international or national organisations might be helpful, reliance on these sources alone might be risky, as the support from these organisations might decline or even fail. Below is a statement recommending enhanced government funding as the best model. “For me, direct public funding of ERCs would be the best. That will address the ethical challenges, adequacy, context appropriateness and sustainability” IDI-Participant 1.

Efficiency of Use of Available Funds for ERC Activities

With regard to ensuring the adequacy of funding, respondents suggested an improvement in the efficient use of funds by ERCs. That is, ERCs should have i) a well-established budget that clearly spells out items to be funded and expenses that would be made and ii) an administrative system for approving and authorising funding for accounting for the use of funds released. A view expressed on this is captured as: “For efficient use of funds, there should be a budget at the beginning of the academic or calendar year that would indicate what is needed to adequately fund ERCs, including training, monitoring, and board meetings” IDI-Participant 6.

What ERCs should do to maintain trust and support from funding agencies

On this subject, almost all respondents emphasised transparency and accountability of their processes and procedures to maintain the confidence of funding agencies in the ERC. Transparency may be ensured by preparing and making available financial reports and audited accounts to donors. In addition to transparent operations, ERCs must follow standard operating procedures (SOPs) that govern their operations to ensure that protocol review processes and research implementation plans are completed within specified time frames. The quote below is an opinion expressed by a respondent.

“To ensure Ethics Review Committee follow SOPs to the letter, these standards should be clearly stated, with timelines for the review of protocols and for monitoring the study well documented” IDI-Participant 3.

Host Institution and Researcher Attitude towards ERCs

Some respondents stressed the importance of the role of leadership in their institutions. Faced with financial challenges, the leader of an institution might overlook the importance of ethics in research and the value of that for academic advancement and, therefore, hold back funding of the ERC. It was felt that some host institutions of ethics committees also underestimate the workload of ERCs, hence not providing sufficient funds for their work. Again, amidst financial difficulties and the effect of delays in approving protocols, some researchers might be frustrated, regarding ERCs as an impediment to their progress. Such researchers, therefore, would only access the services of an ERC because they are required to and not because they find them valuable. Below is a quote from one of the stakeholders on this issue.

“There is a lack of what I call ‘political will’ of some institutions that host ERCs to prioritise research ethics to invest in them. The work of the ERC is not considered a priority, and so they are starved of adequate funding for their activities. Some researchers are not allocated funds to ethically review their research protocols” (IDI-Participant 3).

Further inquiry revealed that, in addition to this attitude by the leadership of host institutions, researchers of the institution show a similar attitude towards ERCs. Here is a quote from the response of the same respondent to a follow-up question on the problems within institutions that impair the work of ERCs. “Researchers themselves, we are not properly allocating resources for ethical review. What I mean is that on a number of occasions, you review protocols, and you see that people have budget without factoring in funds for the ethical review process” IDI-Participant 3.

Given the sensitivity of the issues in this regard, the respondents in the present study were not able to provide further information, as indicated in the narrative. “So, these are the factors I can speak of right now” IDI-Participant 3.

Views on how inadequate funding affects the role of ERCs

Some of those interviewed noted that inadequate funding of ERCs hinders the ability of ERCs to monitor the conduct of research the ERC has approved. Another concern from inadequate funding is the inability of the ERCs to update their knowledge in the fast-growing field of science and bioethics to build capacity for sustainable services. Besides these, there is a delay in processing research protocols for approval. An example of these challenges is shared by a respondent: “If you are not ready to sponsor members of your ethics committee, they will remain dormant; they will not learn new things such as required in processing proposals for genomic research. How many of our ethics committee members are knowledgeable about the ethical issues concerning genomics? That is the point I am making. You can take a look at their expertise. It really affects research because you make uninformed decisions without realising how it negatively affects the community in the long run. With adequate training in ethical issues about genomics, you know what to look for when reviewing such a protocol. Publications from genetic studies could stigmatise a whole community” IDI-Participant 6.

Role of Government and Parliament in Adequate Funding of ERCs in Ghana

Commenting on what the government and parliament must do to ensure adequate funding for ERC work, some respondents proposed that parliament should enact a law to establish a National Health Research Ethics Council as the regulatory authority for the conduct of health research in the country. This governing body will also ensure the proper establishment of ERCs and monitor their activities to ensure they are protecting the research public. This body will also play an advocacy role in government and parliament for adequate funding for ERCs. A quote on this is captured: “First of all, there is the need to have a National Health Research Ethics Council, which will be a regulatory body. The Ministry of Health should initiate a bill to be approved by parliament. Currently, health research ethics is subsumed under the Food and Drugs Authority section of the Public Health Act, and it is only focused on clinical trials, which is not adequate” IDI-Participant 1.

DISCUSSION

This study assessed the adequacy, sustainability, and ethical implications of existing funding models based on a recent study that showed little information on funding as one of the areas of challenges that ERCs face [24]. Notwithstanding the small number of ERCs/respondents that participated in the present study, which may limit the generalizability of the findings of this study, the information gained underscores the need for government to pay more attention to the need and to recognise the critical role ERCs play in protecting the research public from harm. It is in this that the government would recognise the need to establish a governance body to regulate research and to ensure adequate funding for ERCs. Adequacy of funding

will ensure that ERCs in Ghana function to meet international standards to better protect the public and the global community from research-related harm [29].

This study also highlights ethical challenges associated with fee-charging to enhance funding of the work of ERCs. This practice, however, is seen globally. Even the World Health Organization (WHO) recognises and endorses the practice [35]. Also, the Oxford Regional Research Ethics Council charges pharmaceutical corporations fees to review their research protocols [28]; ERCs in Africa and Asia charge fees for services rendered [19,36–38]. As a matter of fact, fees charged for the review of research protocols should not be considered unethical. In some research grants, provisions are made to fund the cost of ethical review, as the work of the ERC is not pro bono [35,38]. The financial contribution researchers make to the work of the ERC benefits them, reducing the risk of the research to participants and enhancing the social value of the research to the public [35]. The ethical challenges in fee-charging come from the arbitrary determination of levels of fees charged. The prioritisation of protocol reviews based on high fees paid is ethically and contextually objectionable [28,34].

To increase public funding of ERCs, it has been suggested that funds generated by the host institution from consultancy and other services rendered by that institution should not be paid back to the government in full. Respondents would like the government to allow research institutions that generate funds from consultancy services to keep a large percentage of that amount for research. The proposal to establish a “Ghana National Research Fund” (GNRF) to support research in tertiary institutions is a most welcome policy [39]. This fund, which will be set up by the government, will support national research in tertiary and research institutions. Amongst its sources of funding are taxes [39]. This funding mode should contribute to making ERCs more independent in the discharge of their mandate, making funding for the services they render more sustainable [40].

Although funding of ERC from multilateral organisations and other agencies is useful, it is important for institutions with ERC to ensure that such funding is context-appropriate and ethical to protect their autonomy and integrity. The proposal for the establishment of a National Health Research Ethics Council in Ghana is a key recommendation in this study. The attention of the government and parliament is called to it as a prerequisite for research governance, improved funding, governance of ERCs, and the protection of the health of the research public.

Conclusion

This study, though limited in scope, reveals that funding for ERCs from government subventions, external grants, and fees charged is inadequate to fulfill their mandate of protecting the research public. The other funding models proposed in this study include the funding set by the government specifically to support research, which would

most likely improve the adequacy and context-appropriateness of funding ERCs. In receiving funding from sources other than public funds, ERCs must ensure that their autonomy is not compromised. To avoid such risks, it is suggested that these external funds be designated for capacity building of ERCs, including enhanced academic training in bioethics for their staff and researchers.

Attention should be paid to the proposal that the government establish a National Health Research Ethics Council for governance and more adequate funding of ERCs. It is recommended that public education be enhanced by ERCs and their host institutions to create awareness of the importance of investing in research ethics and integrity to protect research participants and their communities from harm. That awareness should, in turn, drive advocacy for increased funding for ERCs to fulfill their mandate of protecting the public.

DECLARATIONS

Ethical consideration

The study was approved by the Ethics Review Committee of the Ghana Health Service, with the designated number GHS-ERC018/10/20. All participants gave approval for the publication of the results of this study.

Consent to publish

All authors agreed on the content of the final paper.

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Competing Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Author contributions

AKA and JA contributed to the conceptualisation, data analysis, interpretation, and drafting of the manuscript. AKA, JA, AL, KF, and SA were involved in the study design and critically reviewed the paper. Data collection was conducted by AKA, JA, and AL.

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Availability of data

Data is available upon request to the corresponding author.

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