BMC Medical Ethics

RESEARCH Open Access

Behind the scenes of research ethics committee oversight: a qualitative research study with committee chairs in the Middle East and North Africa region

Catherine El Ashkar[1], Rima Nakkash[2], Amal Matar[3,4] and Jihad Makhoul[1*]

Abstract

Background Research cites shortcomings and challenges facing research ethics committees in many regions across the world including Arab countries. This paper presents findings from qualitative in-depth interviews with research ethics committee (REC) chairs to explore their views on the challenges they face in their work with the oversight of research involving human populations.

Methods Virtual in-depth interviews were conducted with chairs ($n=11$) from both biomedical and/or social-behavioral research ethics committees in six countries, transcribed, coded and subject to thematic analysis for recurring themes.

Results Two sets of recurring themes impede the work of the committees and pose concerns for the quality of the research applications: (1) procedures and committee level challenges such as heavy workload, variations in member qualification, impeding bureaucratic procedures, member overwork, and intersecting socio-cultural values in the review process; (2) inconsistencies in the researchers' competence in both applied research ethics and research methodology as revealed by their applications.

Conclusions Narratives of REC chairs are important to shed light on experiences and issues that are not captured in surveys, adding to the body of knowledge with implications for the region, and low- and middle-income countries (LMICs) in other parts of the world. International research collaborations could benefit from the findings.

Keywords Research ethics committees, Middle East North Africa, Qualitative research, Research ethics, Challenges

*Correspondence:
Jihad Makhoul
jm04@aub.edu.lb
[1]Department of Health Promotion and Community Health, Faculty of Health Sciences, American University of Beirut, Bliss Street, Beirut 1107 2020, Lebanon
[2]Global and Community Health Department, George Mason University, Fairfax, VA, USA
[3]Clinical Immunology and Transfusion Medicine, Uppsala University Hospital, Uppsala, Sweden
[4]Centre for Research Ethics & Bioethics, Uppsala University, Uppsala, Sweden

Background

Research ethics committees (RECs) were originally established post World War II as official bodies to protect the welfare of human beings, their dignity and confidentiality when involved in clinical and social research supported by US federal and non-federal grants [1]. Their role also entails ensuring the scientific merit of the research methodology. These roles were endorsed by the Helsinki Declaration and the World Health Organization's Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants [1, 2].

Despite the many advantages to human subjects protection and the increase in the number of RECs globally, RECs have been a focus of controversy and criticism [3]. Research cites shortcomings and challenges facing RECs in many regions across the world from the perspectives of REC members, both biomedical and the social and behavioral sciences (SBS); REC chairs; and researchers in low income countries, such as Sub Saharan Africa, Middle East North Africa (MENA) countries. However, the majority of these studies have utilized cross-sectional survey methods (both online and in person), evaluated functionality, operational procedures, membership characteristics, review and communication processes, resources and challenges for RECs in big data and genetic research, as well as community based and qualitative research methodologies [4–10]. The challenges reported by REC members include high workload, lack of rewards or incentives, poor administrative capacity/ lack of time, inadequate knowledge of research ethics and national guidelines, and more recently difficulty evaluating scientific rigor of COVID-19 research [5, 8, 11–13]. Other challenges at the level of the RECs highlighted include inadequate resources, concerns about conflicts of interest for their members, ambiguity as to what guidelines to follow in their reviews, challenges with complex consent forms, and inadequate frameworks for biomedical research protocols [4, 5, 14]. There is a need for research that presents a more detailed narrative from the perspectives of REC members on the challenges that they experience with insights on moving forward.

The MENA context

With a noticeable increase in research funding for human subjects research in the MENA region accompanied by an increase in tertiary education and research institutions [15–19], attention to applied research ethics in this region has grown as well. This interest in the practice of research ethics has particularly arisen due to sensitive issues, widespread vulnerability and marginalization among the region's populations [19]. The MENA region has historically witnessed social turmoil, wars, impoverishment, economic recessions, and deeply rooted social injustices which continue to have adverse impacts on people's health [20]. Consequently, the number of publications on war-affected populations in the region has ensued since the start of the 21st century and extending to the study of the civil uprisings in 2011 [21] and during the COVID-19 pandemic when a substantial increase in COVID-19 related research has taken place in Saudi Arabia, funded by local and international agencies [22].

The body of knowledge around research ethics, while in its infancy in the region, points to areas for further investigation given that formal training for researchers in the field of applied research ethics has not been consistently established [19]. The lack of culturally and contextually sensitive frameworks to support research ethics and oversight has led many researchers to adopt western or international guidelines and standards without careful consideration of their applicability [18]. A scoping review of publications from research studies among marginalized and war affected populations in the region found a deficit in ethical research practice, such as ethics approval and informed consent in publications between 2000 and 2013; ethics approval was also deficient in the research published in national journals [21].

With this challenging context, it is not surprising that RECs may not be widespread and well-functioning [23]. This paper will present prominent findings from interviews with a sample of REC chairs from six countries in the MENA region about the challenges they face at an institutional level, and their perspectives on the quality of the applications that are submitted for review, which reveal the researchers' capabilities and inadequacies in applied research ethics. The findings are of relevance to research integrity and research ethics in the MENA region, but are also pertinent to low- and middle-income countries (LMICs) in other parts of the world, and have implications for international research collaborations.

Methods

Original study and sampling approach

This paper stems from an original three-year study that aimed at mapping drivers, capacities and needs related to applied research ethics in the Middle East and North Africa, and led by a research team at the American University of Beirut. It was a multi-component, multi-stakeholder and multi-method research approach in six countries: Morocco, Tunis, Egypt, Jordan, United Arab Emirates, and Oman. This larger study aimed at analyzing the research ethics landscape in the MENA region using findings from an extensive desk review, empirical data generated from focus group discussions (FGDs) with academic researchers, and in-depth interviews with REC chairpersons and directors of research institutions (see [24] for a detailed description of the study research protocol). The country sites were selected based on criteria relevant to the aims of the study and that capture

variations in country characteristics, as well as the availability of contact persons that the research team could identify from their networks. The countries represent variations in social and economic conditions of the region to the best of our knowledge. This paper focuses on the findings from the in-depth interviews with REC chairs exploring their views on the challenges they face during their oversight of research involving human populations.

Data collection

Research teams from each site conducted the empirical research using virtual research methods. Each country team consisted of a focal person and research associate. In-depth interviews were chosen to allow the construction of knowledge about the social world through the interaction between interviewer and interviewee [25], utilizing open-ended interview guides to direct the interaction while giving interviewees flexibility in expressing their thoughts and feelings [26]. An interview guide of open-ended questions which the research team developed was used in the interviews (see supplementary file) to ask about the type of applications the committees receive, the review processes, interactions with other RECs, problems with the applications, types of trainings they hold, guidelines they refer to, any challenges, and suggestions for improvement. Interview guides, invitation scripts, and consent forms were developed first in English, shared with the country teams for feedback, and then translated into Arabic. The in-depth interviews sought to collect data from two research ethics committee chairs in each country but actually interviewed 11 as explained in the results section. An IRB approved invitation script and consent form were sent by the country focal point through email. The interviews were conducted virtually in English, Arabic, and French based on the preference of the participants after they provided informed consent to participate by signing the IRB-AUB approved consent form.

Data analysis

The recorded interviews were then transcribed, coded and subject to thematic analysis for recurring themes using the Braun and Clarke framework [27]. Country research associates read the transcripts several times for immersion, and excerpts from the first two or three pages were shared with the lead team to participate in the coding verification process. The codes were transferred onto a matrix which was populated by the incoming codes from the six country sites. The lead team analyzed the data and shared results with the country teams in two regional meetings.

Ethics approval

The study was approved by the Institutional Review Board of the American University of Beirut (IRB-AUB). Ethics committee approvals were also obtained from country sites where available, namely, Jordan, UAE, and Oman. The other three countries did not require an ethics review for social science research, and consequently, AUB-IRB approval sufficed. All members of the country teams completed the Collaborative Institutional Training Initiative online ethics training (CITI) [28] or the University of Montana training in the case of no CITI [29].

Results

The 11 participants in the study represented research ethics committees from all the countries in the study and included 7 biomedical (from Egypt, Jordan, Oman, Morocco, Tunisia, and United Arab Emirates (UAE) and 4 (from Egypt, Jordan, Oman and UAE) social-behavioral science committees. There are no social science RECs in Tunisia and Morocco. The committees at the time of the interviews were affiliated with universities, governments, hospitals and one was independent (affiliated with American universities in the United States and undergoes periodic license renewal). The RECs varied in size between 6 and 20 members per committee, and the disciplinary backgrounds of their members were in line with the committees they serve on (Table 1).

The narratives of our participants reveal two sets of recurring themes related to the internal and external challenges that seem to impede the work of the committees and pose concerns for the members; but also reveal variations in the researchers' competence in applied research ethics by reflecting on the applications they submit.

I. Procedures and committee level challenges

Limited resources and heavy workload

Our participants reported heavy review workloads of 500 to 2000 proposals per year with the highest number reported by an REC in the UAE, and reduced financial resources as a result of reallocation of funds to other units.

> *"Sometimes they are on vacation, and most of the reviewers are actually lecturers, senior lecturers. They are overwhelmed with teaching tasks or marking exams. So they are really overloaded." (SBS/Biomedical REC, Oman).*

This situation was reported to continue even during the pandemic when both the application and review processes were set up using virtual platforms, and reviews conducted as expedited or full board reviews. Social and behavioral science RECs in Oman and Jordan reported

Table 1 Characteristics of RECs in the study

Biomedical Research Ethics Committees	Proposals reviewed	REC Composition
Egypt	Medicine, density and pharmacy For research conducted at university hospital	Seven professors, retired professors
Jordan	Social, medical/health/clinical research proposals Investigational, clinical, and pharmaceutical proposals Approval for research by academic faculty and hospital staff	20 members, different disciplines; includes quality control representatives for international guidelines
Oman	Medical research	Researchers, healthcare providers from same/outside institution (physicians, nurses, radiology, faculty). Researchers from college of medicine and of science
Tunisia	bioethical advice	Advisory committee No information on composition
United Arab Emirates [1]	medicine, dental medicine, pharmacy, and health sciences colleges	Members from medical colleges
United Arab Emirates [2]	clinical trial observational and interventional research sponsored by pharma companies, medical reviews, tissue and cell studies, social science studies	N/A
Morocco	Review observational, interventional and therapeutic studies	Self-appointed committee 11 members with diverse backgrounds (social sciences and biomedical sciences)
Social Science Research Ethics Committees	**Proposals Reviewed**	**REC Composition**
Egypt	Social sciences, and research by biology department	Six to seven reviewers in committee different backgrounds (internal and external member)
Jordan	Medical, health, and social science proposals	Members selected based on ethics expertise/certification New members and president selected by the dean of research
Oman	Clinical, biomedical, clinical and health science, General academic research (human subjects research)	N/A
United Arab Emirates	Humanities, education and social science research	N/A

reviewing more biomedical/health research than SBS protocols because of the COVID-19 related research surge. Some participants described these virtual platform meetings as more convenient, but more frequent, while others reported they were challenging and time consuming.

> *"We were reviewing face to face before [the pandemic]. But when COVID-19 came, we met online. It was very good to meet online, and it was so convenient because we have members from different areas in the committee." (Social/Biomedical REC, Oman).*

> *"We worked more during COVID because the disease was new, and there were online meetings. The meetings were longer. There were more reviews. The focus was on tools like Google Forms and online research, and the work has increased." (Biomedical REC, Jordan).*

Variations in REC members' qualifications

Participants pointed to variations in ethics trainings for the REC members. The majority reported a lack of structured training for the review process as members were assumed to be knowledgeable in research ethics because of their credentials. For example, some reported selecting REC members based on professorial degrees, previous research and ethics expertise, previous ethics courses, such as the Middle East Research Ethics Training Initiatives (MERETI), and publications record.

> *"Most of the REC members need to be professors, I cannot accept anyone less (i.e., with lower degree). Honestly, most are retired professors. For example, one has 20 or 15 years of experience. I cannot accept an assistant professor in the committee for example; they would not have a vast experience." (Biomedical REC, Egypt).*

A few reported offering trainings for biomedical REC members including: virtual training upon appointment, orientation and/or opportunities to attend REC meetings, and trainings with international experts. One SBS REC

chair reported that their committee conducts training twice a year for its members and mandates CITI training for reviewers. In addition, the committee shares a recording of the session with new members and holds an explanatory meeting about the review process. Another SBS REC chair reported conducting a 3-day training for new members.

"The Dean of Scientific Research selects the head and members. During the past three years, the council members were selected based on their research in the field of ethics, or a certificate they took from a university regarding ethics that contained all the information." (SBS/Biomedical REC, Jordan).

"All persons on the committee .they're all practicing researchers, published researchers, and many of them have actually published in research ethics." (Social Science REC, UAE).

"It [ethics training] wasn't a formal training, but an orientation. We had a number of new members and I didn't assign any projects for them to review until they attended three or four meetings with us. They listened to the discussion, they had the opportunity to see the documents, and they had the opportunity to also see how people talk about those and express their concerns. They also had the opportunity to read the emails that were sent to the applicants as a feedback. So, this is what we consider as the orientation." (Biomedical REC, UAE).

Intersecting socio-cultural values in the review process

Our participants reported variations in the use of the guidelines they referred to in the review process. These include written international guidelines consistent with Helsinki Declaration, Good Clinical Practice and International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, principles of safeguarding dignity for persons and data sharing. Nevertheless, they also reported referring to internal guidelines and checklists that align with cultural and/or religious values; for example, married women's participation in research contingent on the husband's consent.

"So we have our own guidelines which have been written and edited over the years, and they are available on the website… They are consistent with the Declaration of Helsinki." (Biomedical REC, UAE).

Implicit guidelines, mentioned in two interviews, are those based on the committee's judgement and discussions in countries where national guidelines are absent.

"The instructions the REC uses to review research proposals are taken from written guidelines from another public university. The instructions are comprehensive and take into consideration religion and culture." (Biomedical/SBS REC, Jordan).

"It is kind of both explicit and implicit guidelines. For the explicit guidelines, we are following the recommended ethical principles that are available on the WHO website and medical ethics. But generally, we refer to the implicit ones, I mean personal judgment of the committee members based on moral values." (SBS/Biomedical REC, Oman).

Impeding bureaucracy

Bureaucratic requirements of the countries, such as security clearance and multi-center/multi-site study approvals seem to delay the review process.

"We cannot start the ethics review for any application without prior security clearance, and that usually adds three to four weeks. That's completely out of our control." (Social Science REC, UAE).

"Suppose that you're conducting a study, a multicenter study that involves participants from the Ministry of Health, as well as from (university name). You need to get the approval from the Medical Ethics committee at the hospital and also you need to get another separate approval from the Ministry of Health, even though you submit this application" (SBS/Biomedical REC, Oman).

"The unification or some form of memorandum of understanding between different research ethics committees, some form of a database for research ethics committees in different universities and in different government organizations would be necessary. This creates is consistency in the review process and in the decision-making process, as helps avoid several committees reviewing when one single committee approves a project. I think this is necessary, and I hope this will happen and it is not too difficult." (Biomedical REC, UAE).

II. Concerns regarding the researchers and the quality of their applications

All our participants voiced their concerns about the researchers' competence in research design, their ability to complete the applications for ethics approval and follow the procedures, as well as the mediocre quality of their applications.

> *"One of the problems is the weakness of scientific writing… any recommendation to researchers is taken as criticism." (Biomedical/SBS REC, Jordan).*

> *"Many research teams ask for the opinion of our ethics committee a posteriori. It is after implementation of their research and manuscript submission to journals which require the approval of the ethics committee that they reach out to us. That is a serious problem." (Biomedical REC, Morocco).*

> *"The researchers say the journal does not require an REC approval, and I tell them of course it does require one. There is an information sheet in the journal about required documents, even before you submit. So they know REC approval is required. But the researchers claim not all the journals do so, which is not true. They claim that they do have REC approval but in fact they do not. No way do we provide an approval for research that was already published and that did not initially get approved." (Biomedical REC, Egypt).*

The applications that the RECs receive were described by all our participants as problematic and missing information at several levels related to the 1) research methodology (design, sampling, misalignment between objectives and methodology, issues in sample size calculations and data analysis); and 2) research ethics (poorly written consent forms, missing human subjects protection measures such as privacy, confidentiality and protection of health data, and missing or outdated CITI certificates).

> *"Of the challenges we face, are the feasibility of the research- if the researcher can answer the research questions- and if the data collection is specified and aligns with the title. If these features are unclear, then we consider it to be a poor proposal." (Biomedical REC, Jordan).*

Ill-suited research topics and research methodologies

The research topics and questions put in the applications were deemed to be repetitive, and the methodologies used in the applications described as lacking in contextually sensitive research. For example, in two out of four interviews with SBS RECs, the participants pointed to the direct use of questionnaires used in the West without being revised to fit the local context, consent forms that are problematic, and research that offers no innovative ideas.

> *"…issues with the cultural adaptability of the survey. Sometimes people come up with an English-made version, and they try to translate that one to fit our patients. But then we spend quite a lot of time going through all of these types of items one by one to find out whether they are culturally sensitive." (SBS/Biomed REC, Oman).*

> *"We are only concerned about human participants, so sometimes I read research that I would love to say that it's not really that good, or you need to change something about it; but it's not my position. My position is just to look at the human participants, make sure that they are protected, their identity protected- if they are going to be harmed, if there's something that could be done to stop that harm and so on. This is my role." (SBS REC, Egypt).*

Deficiency in knowledge about research ethics

Another weakness that the participants mentioned was that the research applications often demonstrated deficiency in their understanding of research ethics. Examples cited were problematic applications of the universal research ethics principles of human subjects protection including safeguarding privacy, confidentiality and anonymity throughout their proposals. Possible reasons cited include unfamiliarity with research ethics rather than deliberate misconduct, and researchers not reading the guidelines when submitting their applications.

> *"A main issue is the education of faculty and students in research ethics, especially in humanities, and social science education. They don't always quite realize the implications of meeting research ethics requirements when you're dealing with human subjects." (Social Science REC, UAE).*

> *"Many times, dermatology specialists ask for approvals for research based on injecting materials on patients' faces. When I ask them if the material is tested or approved, they tell me "No", but there is research conducted on the same material. I tell them I need to see the reference for the safety of injecting the material." (Biomedical REC, Egypt).*

> *"I got somebody applying for an ethics approval extension and when she applied, I noticed that her*

previous approval had expired six months before the new application. So, I told her that any data that has been collected between the two IRBs has to be thrown away." (Social Science REC, Egypt).

Discussion

Our study has revealed the challenges that research ethics committees encounter throughout the oversight process in the MENA region. The increased workload in many of the RECs, even during the pandemic, reflects the continuous upward trend in conducting scientific research in the MENA region as confirmed by the literature [15–19]. In turn, this increase has not been reflected in increased resources to support the RECs in their review. Indeed, compared to earlier studies in MENA region, lack of resources seems an ongoing difficulty [30]. Challenges with regards to institutional commitment to RECs is reflected by the lack of human and financial resources. This direly disrupts the proper functioning of RECs and sometimes leads to scrapping some of RECs tasks, such as monitoring and follow-up of research. However, these issues are not unique to the region. As in other low-income countries in Africa [31] and Asia [32] financial challenges are common. A scoping review of RECs in Sub-Saharan Africa reported challenges in recruiting and retaining REC members due to the high workload involved and the lack of compensation or incentives to participate in meetings or training thus impacting the quality of the reviews. Other challenges include poor administration capacity and lack of time and attention to review tasks [11]. *In order for RECs to conduct the oversight they are entrusted to do, institutions need to provide them with sufficient human and technical resources to do their work.*

A major challenge that emerged is the variation among RECs with regards to research ethics training requirements and the consequent effectiveness evaluation of such training. Inadequate training of REC members, limited resources both human and capital, the absence of continuing education opportunities have also been acknowledged [33]. Participants did not express the need for continuous training for their members who were assumed to be knowledgeable because of their seniority which overlooks the pivot of keeping REC members in line with emerging research ethics topics, such as gene editing or artificial intelligence. This inconsistency of requiring ethics training has been documented by research in the region by [6] in Jordan and [11] in Sub-Saharan Africa showing that it is not seen to be necessary; while other research studies in Saudi Arabia describe proper training mechanisms and guidance for RECs [7]. REC members in Saudi Arabia are required by law (Law of Ethics of Research on Living Created by the National Committee of Bio-Ethics NCBE) to complete training on ethics and regulations in order to be registered [7], which could explain the attention to this training initiative there. If institutional policies and national laws require *continuing education related to procedural ethics as well as applied research ethics in general for RECs and researchers, then all parties involved in research and research oversight would benefit.*

Some RECs require to undergo only the self-administered CITI training which may seem detached from the local socio-cultural context as described by our participants. However, additional challenges lie in its readability as an English language text for community members who may serve on RECs [34]. This also means that most researchers in the MENA region may find the CITI training program too complex if they are novice researchers or those whose first language is not English, which is the case in the MENA region where Arabic is the mother tongue in the majority of the countries. *Consequently, there is a need for alternative locally developed research ethics training programs.*

Regarding RECs membership, some respondents expressed the need to employ only highly trained REC members (only professors or retired professors) as they were perceived as having the necessary skills and experience to review research proposals. This practice may accentuate lack of diversity with regards to age and gender within REC membership, an important element of REC membership guidelines [35]. The preferential enrollment of older REC members such professors regardless of considering other requirements reflects cultural norms pertaining to respect for elderly and hierarchy [36].

The import of western ethics concepts and guidelines, seen as universal, from research intensive countries like the USA to the MENA region has been criticized, and calls have been made to adapt them to the Arab context [37]. However, it is important to point out cultural underpinnings that may have prompted some of the responses given by the participants in our study. For example, obtaining the husband's informed consent as part of the woman's consent to participate in research may be founded in male guardianship laws in some ME countries such as Saudi Arabia [38]. While this may be regarded as antithesis of autonomy, which is historically founded on individuality and rationality, feminist scholars and care ethicists have emphasized the importance of recognizing autonomy as relational. A person's autonomy is, in fact, situated in a context of family relations as well as cultural and societal norms [39]. While ascertaining the impact of these relations, it is crucial to guard against patriarchal coercion or hijacking the decision-making process from women altogether. Other contextual issues such as the lack of self-governance with universities being centrally organized. Several topics cannot be researched due

to fear of repercussions and criminalization of research, these include topics on role of the army, political Islam, or other topics that the government deems inappropriate. The disciplines most subject to scrutiny are the social sciences and humanities, this involves bachelor, master's and doctoral theses. As a result of this scrutiny, researchers often engage in self-censorship in their research [40]. Thus, *there is a need to develop culturally acceptable guidance and policies to improve the practice and safeguard ethical principles in research.*

The REC chairs reported receiving applications that they described as deficient in methodological rigor, are weak in applied research ethics and show symptoms of non-compliance with REC requirements of their institutions. The deficiencies in methodological ability can be argued to be stemming from their disciplinary training which may be remedied by continuing education or mentorship in their fields. Meanwhile, the lack of training on research ethics for researchers continues to be a commonly reported barrier to ethical research practice among researchers engaged in research with human participants both in the region [6, 9, 41–44] and globally [45–47]. This was documented in research for example, which assessed knowledge among Jordanian researchers, indicating that the majority had not received training in research ethics but were nonetheless involved in research with human subjects [9, 10], and who were also unable to accurately describe the role of RECs and types of reviews. However, knowledge in research ethics was not associated with previous training [41, 46, 48] which raises questions about the training itself and the gap between the content of the training and the applicability in practice. This is important to expand the framework of research ethics beyond procedural ethics limited to REC oversight requirements, to other framings such as ethics of care for example, which places weight on interpersonal relationships between researchers and their participants or human subjects and which suggests that researchers have a moral responsibility towards their research participants [49]. Dire consequences of being unable to practice research ethics could entail placing the researchers at risk of inadvertently harming human subjects, themselves, as well as risking breaches to academic integrity. Findings highlight the importance of having ethics trainings that are well planned, evaluated and perhaps integrated into other academic activities. As has been affirmed in our findings, there needs to *be careful consideration of the content of these trainings which might benefit from discussions involving ethicists, and not just experts in the field of study or RECs.*

Many programs aiming to strengthen research ethics capacity in LMICs are available such as the Fogarty International Center of the US National Institutes of Health programs, the European and Developing Countries Clinical Trial Partnership, Medical Education Partnership Initiatives, Training and Resources in Research Ethics Evaluation group [50]. In the MENA region, MERETI and the University of California San Diego in collaboration with the Jordan University of Science and Technology are some examples of ethics training programs [51]. However, contextually developed ethics graduate programs are sparse (4 programs according to UNESCO database) [33]. Short courses that are isolated from the curriculum can conversely marginalize the discipline and deter appropriate reflection on the topic [52]. There is a need for increased research on the efficacy of online learning on research ethics education in non-industrialized countries [33]. Courses need to cater to the contexts of LMICs and educational practices [33, 53, 54].

Lastly, the non-compliance with REC requirements indicates either inadequate outreach or information sharing by the RECs with the researchers in their institutions. Previous research by the authors has shown that researchers from the region conveyed their concern about the lack of effective communication and outreach by their RECs to address the reported ambiguity pertaining to REC processes, roles, and requirements [53]. In addition to the responsibility of the researchers to produce methodologically and ethically sound actionable research, there is a collective responsibility of other key players, such as the researchers' institutions and funding bodies, to develop clear policies and procedures that mandate ethics approvals for single and collaborative research across institutions before research implementation. Steps for ethics review *need to be outlined by the institutions, and early engagement with RECs emphasized and clearly communicated to the researchers to avoid ambiguity and reduce errors in the application process.*

Strengths and limitations

The study contributes to the emerging body of knowledge on applied research ethics in low income countries with a particular focus on REC narratives. This study is of particular value as it captures these insights in contexts where research ethics is relatively new, with research oversight focusing to a large extent on biomedical research and research on research ethics is it its infancy. The findings can be useful to similar global contexts where applied research ethics is mainly procedural which frames research ethics as approval by RECs. The study has relied on local researchers to conduct the interviews using the locally spoken language which means the meaning was well preserved, and the quotes only translated to their equivalent in English for this paper. Meanwhile, the fact that interviews were conducted by researchers from the same country who are academics themselves, and recruited through convenient sampling could have resulted in socially desirable responses.

Despite our strong efforts to recruit social behavioral RECs to the interviews, the findings are more heavily representative of views of biomedical RECs, although the recurring themes present insights related to important issues such as competence of researchers through their applications. Lastly, Saudi Arabia although cited in this paper, was not in our final sample. Omitting Saudi Arabia, which houses many ethics committees and is active in research could be considered a limitation. However, as clarified on our protocol paper [24] it was dropped from the original sample due to political tensions between the two countries at the time of the study.

Conclusion

The difficulties faced by RECs in the MENA region have shed light on deficiencies at the institutional at national levels which hinder their work, and consequently challenge the efficiency of research oversight. The findings also present many angles of a larger problem pertaining to researchers' competence in research and research ethics. Increased institutional support for RECs and researchers by higher education and governmental organizations is needed to enhance the rigor of research in the region. Continuously engaging researchers and RECs in developing and evaluating educational programs on research and research ethics are necessary to develop a of a culture of responsible research conduct in the region.

Abbreviations

CITI	Collaborative Institutional Training Initiative
IRB	Institutional Review Board
LMICs	Low and Middle Income Countries
MENA	Middle East and North Africa
MERETI	Middle East Research Ethics Training Initiatives
REC	Research Ethics Committee
WHO	World Health Organization

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-024-01083-3.

Supplementary Material 1

Acknowledgements

The authors would like to acknowledge the country teams in the six country sites for their efforts in conducting and coding the interviews.

Author contributions

CE participated in the design of the data collection instrument, the coding and analysis of the data with the country teams and in drafting the manuscript. RN contributed to the discussion and revised the manuscript for consistency. AM contributed to the discussion section and the review of the results and conclusion sections. JM coordinated the study design, contributed to the introduction, edited the methodology and results and led the writing of the discussion. All authors approved the final version of the manuscript.

Funding

The study was funded by the International Development Research Center, Canada. Grant number 103899.

Data availability

Data cannot be shared openly to protect study participant privacy as stipulated in the signed consent form used in the data collection.

Declarations

Ethics approval and consent to participate

Approval was obtained from the Social and Behavioral Sciences Institutional Review Board at the American University of Beirut (SBS-2022-0196) for the in-depth interviews. Approvals were also obtained from country sites where available; Jordan University of Science and Technology Institutional Review Board (Ref.: 10/142/2021), United Arab Emirates (United Arab Emirates University Ref Number ERS_2022_8469), and Oman Medical Research Ethics Committee (MREC), College of Medicine and Health Sciences, Sultan Qaboos University-(REF. NO. SQU-EC/614/2021). The other three countries did not require an ethics review for social science research, and consequently, AUB-IRB approval sufficed. Informed consent was obtained from all the participants in the study.

Consent for publication

There are no data in the manuscript that can be used to identify any of our participants.

Competing interests

The authors declare no competing interests.

Received: 28 March 2024 / Accepted: 22 July 2024
Published online: 08 August 2024

References

1. World Health Organization. Standards and operational guidance for ethics review of health-related research with human participants 2011 [https://www.who.int/publications/i/item/9789241502948]. Accessed January, 2024.
2. World Medical Association. WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS. 2022 [https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/]. Accessed May 2023.
3. Holm S. Declaration of Helsinki. In: The International Encyclopedia of Ethics. 2019. pp. 1–4. https://doi.org/10.1002/9781444367072.wbiee230.pub2.
4. Mohammed Z, Abdelgawad F, Ahram M, Ibrahim ME, Elgamri A, Gamel E, et al. Opinions and attitudes of research ethics committees in arab countries in the Middle East and North African region toward ethical issues involving biobank research. Res Ethics Rev. 2024;20(1):1–18.
5. Onakomaiya D, Pan J, Roberts T, Tan H, Nadkarni S, Godina M, et al. Challenges and recommendations to improve institutional review boards' review of community-engaged research proposals: a scoping review. J Clin Transl Sci. 2023;7(1):e93–e.
6. Al Omari O, Khalaf A, Al Delaimy W, Al Qadire M, Khatatbeh MM, Thultheen I, et al. Perceptions of challenges Affecting Research Ethics committees' members at Medical and Health Science Colleges in Omani and Jordanian universities. J Acad Ethics. 2022;20(2):227–41.
7. AlFattani A, AlBedah N, AlShahrani A, Alkawi A, AlMeharish A, Altwaijri Y, et al. Institutional review boards in Saudi Arabia: the first survey-based report on their functions and operations. BMC Med Ethics. 2023;24(1):50.
8. Ferretti A, Ienca M, Hurst S, Vayena E, Big Data. Biomedical Research, and Ethics Review: New challenges for IRBs. Ethics Hum Res. 2020;42(5):17–28.
9. Tarboush NA, Alkayed Z, Alzoubi KH, Al-Delaimy WK. The understanding of research ethics at health sciences schools in Jordan: a cross-sectional study. BMC Med Educ. 2020;20(1):121.
10. Ayoub NM, Qandil AM, McCutchan JA. Knowledge, attitudes, and Practice Regarding Research Ethics Committees among Health Care Faculty at two public universities in Jordan. J Empir Res Hum Res Ethics. 2019;14(4):372–82.
11. Chaudhry I, Thurtle V, Foday E, Leather AJM, Samai M, Wurie H, et al. Strengthening ethics committees for health-related research in sub-saharan Africa: a scoping review. BMJ open. 2022;12(11):e062847–e.
12. Tamariz L, Hendler FJ, Wells JM, Anderson A, Bartlett S. A call for Better, not faster, Research Ethics Committee Reviews in the Covid-19 era. Ethics Hum Res. 2021;43(5):42–4.

13. Burgess T, Rennie S, Moodley K. Key ethical issues encountered during COVID-19 research: a thematic analysis of perspectives from South African research ethics committees. BMC Med Ethics. 2023;24(1).
14. Drolet M-J, Rose-Derouin E, Leblanc J-C, Ruest M, Williams-Jones B. Ethical issues in Research: perceptions of researchers, Research Ethics Board Members and Research Ethics experts. J Acad Ethics. 2023;21(2):269–92.
15. Chin LJ, Rifai-Bashjawish H, Kleinert K, Saltman A, Leu C-S, Klitzman R. HIV/AIDS Research Conducted in the developing World and Sponsored by the developed world: Reporting of Research Ethics Committee Review in two countries. J Empir Res Hum Res Ethics. 2011;6(3):83–91.
16. Neitzke AB. Globalizing Research Ethics: Justice & Biomedical Research in Developing Countries. Perspectives on global development and technology. 2012;11(1):145 – 53.
17. UNESCO. Mapping research systems in developing countries. 2009 [https://unesdoc.unesco.org/ark:/48223/pf0000183365]. Accessed December 2023.
18. Sleem H, El-Kamary SS, Silverman HJ. Identifying structures, processes, resources and needs of research ethics committees in Egypt. BMC Med Ethics. 2010;11(1):12.
19. Silverman H. Research Ethics in the Arab Region. 1st 2017; ed. Silverman H, editor: Springer International Publishing; 2017.
20. Makhoul J, Taket A, Khoury M, Kabakian-Khasholian T. Insights into theorizing social exclusion and inequities: a perspective from the Arab World. J Social Inclusion. 2019;10(1):24–40.
21. Makhoul J, Chehab RF, Shaito Z, Sibai AM. A scoping review of reporting 'Ethical Research Practices' in research conducted among refugees and war-affected populations in the Arab world. BMC Med Ethics. 2018;19(1).
22. Saad RK, Abu Khudair S, El Rabbat M, Omar M, Al Nsour M, Khader Y, et al. Published research on COVID-19 in the Eastern Mediterranean Region: bibliometric analysis. Interact J Med Res. 2022;11(2):e38935–e.
23. Sleem HM, Silverman H. Challenges of Research Ethics Committees in the Arab Region. Research Ethics Forum. 5. Cham: Springer International Publishing; 2017. pp. 273-9.
24. Makhoul J, El Ashkar C, Nakkash R, Bjelobaba S. A qualitative Multi-methods Research Protocol: Applied Research Ethics in the Middle East North Africa Region. Int J Qualitative Methods. 2023;22.
25. Sparkes AC, Smith B. Qualitative research methods in sport, exercise and health: from process to product. 1 ed. London;New York;: Routledge; 2014. pp. 1–280.
26. Tolley EE, Ulin PR, Mack N, Robinson ET, Succop SM. Qualitative methods in public health: a field guide for applied research. 2nd;2;1;second. ed. Hoboken: Wiley; 2016.
27. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Res Psychol. 2006;3(2):77–101.
28. Collaborative Institutional Training Initiative. Human Subject Research [https://about.citiprogram.org/series/human-subjects-research-hsr/]. Accessed December 2023.
29. Office of Research Integrity. Online Research Ethics Course. [https://ori.hhs.gov/education/products/montana_round1/issues.html]. Accessed December 2023.
30. Matar A, Silverman H. Perspectives of Egyptian research ethics committees regarding their effective functioning. J Empir Res Hum Res Ethics. 2013;8(1):32–44.
31. Silaigwana B, Wassenaar D. Biomedical Research Ethics Committees in Sub-saharan Africa: a collective review of their structure, functioning, and outcomes. J Empir Res Hum Res Ethics. 2015;10(2):169–84.
32. Reyes MV. An update on research ethics in Asia. J ASEAN Federation Endocr Soc. 2012;27(1):10.
33. Silverman H, Strosberg M, Luna F, Philpott S, Hemmerle CA. An Analysis of Online Courses in Research Ethics in the Fogarty-Sponsored Bioethics Training Programs. J Empir Res Hum Res Ethics. 2013;8(5):59–74.
34. Hadden KB, Prince L, James L, Holland J, Trudeau CR. Readability of human subjects training materials for Research. J Empir Res Hum Res Ethics. 2018;13(1):95–100.
35. Council for International Organizations of Medical Sciences (. International ethical guidelines for health-related research involving humans. International ethical guidelines for health-related research involving humans. 2017. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf. Accessed December 2023.
36. Al-Ghanim K. The hierarchy of authority based on kinship, age, and gender in the extended family in the Arab Gulf States. Int'l J Jurisprud Fam. 2012;3:329.
37. Makhoul J, Nakkash R. Challenges to Research Ethics Regulations: Academic Researchers'Voices in the Arab World. Research Ethics in the Arab Region. 2017:281 – 90.
38. Khalid A. Are the male guardianship laws in Saudi Arabia, a challenge to human rights of women as advocated in Islam. J Hum Rights Law Pract. 2018;1(1):1–11.
39. Mackenzie C, Stoljar N. Relational autonomy: Feminist perspectives on autonomy, agency, and the social self. Oxford University Press; 2000.
40. Saliba I. i. Academic freedom in Egypt. Kinzelbach,Katrin, editor: researching Academic Freedom guidelines and Sample Case studies. Erlangen: FAU University; 2020. pp. 141–74.
41. Silverman H, El-Dessouky HF, Abdel-Aziz AM, Ibrahim C, Moni M, Abul Fadl R, Knowledge. Awareness, and attitudes about Research Ethics among Dental Faculty in the Middle East: a pilot study. Int J Dent. 2011;2011:694759–13.
42. Silverman H, Sleem H, Moodley K, Kumar N, Naidoo S, Subramanian T, et al. Results of a self-assessment tool to assess the operational characteristics of research ethics committees in low- and middle-income countries. J Med Ethics. 2015;41(4):332–7.
43. Rababa'h AM, Alzoubi KH, Ababneh M, Khabour OF. Awareness of Jordanian Investigators about the Importance of Ethics Review Committees: a pilot study. Sci Eng Ethics. 2020;26(2):821–31.
44. Al Demour S, Alzoubi KH, Alabsi A, Al Abdallat S, Alzayed A. Knowledge, awareness, and attitudes about research ethics committees and informed consent among resident doctors. Int J Gen Med. 2019;12:141–5.
45. Ateudjieu J, Hurst S, Yakum MN, Tangwa GB. Biomedical research ethics in Cameroon: a survey to assess training needs of medical residents and students. BMC Med Educ. 2019;19(1):5.
46. Ahn S, Jeong GH, Shin HS, Kim J-I, Kim Y, Song J-E, et al. Nursing faculties' knowledge of and attitudes toward Research Ethics according to demographic characteristics and institutional environment in Korea. SAGE open. 2020;10(1):215824402091454.
47. Bain LE, Ebuenyi ID, Noubiap JJ. Research and publication ethics knowledge and practices in the health and life sciences: Findings from an exploratory survey. Ethics, medicine, and public health. 2022;23:100803.
48. Than MM, Htike H, Silverman HJ. Knowledge, awareness, attitudes, and practices towards Research Ethics and Research Ethics Committees among Myanmar Post-graduate Students. Asian Bioeth Rev. 2020;12(4):379–98.
49. Burton B, Dunn CP. May Ethics of Care. 2023 [https://www.britannica.com/topic/ethics-of-care]. Accessed 2024.
50. Deutsch-Feldman M, Ali J, Kass N, Phaladze N, Michelo C, Sewankambo N, et al. Improving institutional research ethics capacity assessments: lessons from Sub-saharan Africa. Problemi Di Bioetica. 2020;31(1):120–32.
51. Ahmed WS, Nebeker C. Assessment of research ethics education offerings of pharmacy master programs in an arab nation relative to top programs worldwide: a qualitative content analysis. PLoS ONE. 2021;16(2):e0238755–e.
52. Wong MK, Hong DZH, Wu J, Ting JJQ, Goh JL, Ong ZY, et al. A systematic scoping review of undergraduate medical ethics education programs from 1990 to 2020. Med Teach. 2022;44(2):167–86.
53. Makhoul J, El-Alti L, Qutteina Y, Nasrallah C, Sakr C, Nakkash R, et al. Protecting or policing: academic researchers' view of IRBs in an arab context. J Empir Res Hum Res Ethics. 2014;9(5):25–35.
54. Mudar K, Hashweh M, Giacaman R. Research Ethics Review: its need and ethical limitations in the arab context [المراجعة الأخلاقية للبحث العلمي: الحاجة إلى وجود هيئات أخلاقية في السياق العربي]. Tabayyun. 2021;10(38):79–106.

Publisher's Note