FINAL TECHNICAL REPORT_AMERICAN UNIVERSITY OF BEIRUT

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Project Title: Research Ethics Discourses, Practices and Leadership in the Arab Region:

Addressing Intersectionality and Fragility

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1. Executive Summary

This final technical report outlines AUB's component of the study titled "Research Ethics Discourses, Practices and Leadership in the Middle East and North Africa – Innovative Learning Platforms in Fragile Settings". This three-year multi-component, multi-stakeholder and multi-method study began in 2020 and engaged researchers from 6 Arab countries: Morocco, Tunisia, Egypt, Jordan, Oman, United Arab Emirates. It assessed practices, resources, structures and gaps for ethical research conduct in the MENA region. The first phase was a desk review of relevant websites, literature, e-courses, and grey literature which indicated the dearth of research ethics guidelines in regional journals, publishers, and social science research centers and scarcity of Arabic online research ethics courses; where available guidelines focus on clinical research and are adopted from the West with no local contextualization. UN agencies in the region emphasize the need for capacity building and development of national ethics committees, but do not provide contextually relevant guidelines. The second phase consisted of empirical qualitative research in the country sites by engaging researchers across the six countries from social sciences and health/medical disciplines in focus group discussions which revealed the discouraging research environment in the region with limited opportunities for formal research ethics training, multiple barriers at the organizational and national level due to complicated ethics review procedures, lack of funding, infrastructure, and support for research, vague or missing research ethics guidelines, and lack of adoption of research findings at a national level. A notable barrier is the marginalization of social science research and researchers. These barriers were investigated through in-depth interviews with research ethics committee chairs and research center directors who highlighted, in addition to the prior mentioned barriers, the poor research methodology and research ethics skills among researchers, the frequency of research misconduct, and the foreign research agenda which contribute to the lack of contextually relevant research studies. The final phase consisted of a cross-sectional online survey which aimed to understand the prevalence of these findings among researchers in the region and for which analysis is ongoing. The study findings highlighted the influences of the broader factors on how responsible research conduct is perceived and applied in the MENA region by shedding light on the barriers that researchers, research centers, and research ethics committees face at university, country, regional, and global levels while probing about trainings, guidelines, resources, donors, and agendas. The study produced several manuscripts and participations in international conferences as well as an infographic which was disseminated on social media and the AUB website.

2. The Research Problem

The MENA region suffers from multiple variabilities such as poverty, armed conflict and political instability, all of which create a challenging environment for human subject research. The increased interest in human participant research has not been accompanied by increased attention to research ethics practice or with ethics guidelines that cater to the sensitivity and context of the region.

Research ethics, where applied, is heavily focused on biomedicine and biomedical guidelines, thus not attributing sufficient attention to research ethics issues in social sciences, public health, and humanities research. The region suffers from lack of or inadequate formal training for researchers in the field of applied research ethics and little attention is paid to the impact of the broader social, political, and economic context on the researcher despite the latter being at the heart of a complex web of relations. Previous literature points to deficits in institutional approval and informed consent, as well as research governance systems and contextually sensitive frameworks to guide research practice. The COVID-19 pandemic shed further light on issues pertinent to human subjects research. This study aims to investigate the broader factors that impact the responsible conduct of research in the MENA region. It employs frameworks that place research ethics and the researcher within a network of stakeholders and responsibilities such as the institutional, national, and regional level that constantly exert influence on the researcher. With this network of responsibilities in mind, it becomes important to analyze the landscape of research ethics in the MENA region while accounting for the barriers or enablers for ethical research conduct at multiple levels. The findings from this study will serve a valuable baseline for regional leadership who can then take informed steps to strengthen and encourage ethical research conduct in the region and beyond.

3. Objectives

This report covers the entirety of the research study from April 2020 to September 2023. This section demonstrates to what extent the objectives stated in the proposal were met:

Specific Objectives	Extent of Achievement
1. Map existing capabilities, training initiatives/continuing education, practices, and structures for applied research ethics in contexts of fragility using rigorous methodological inquiry.	o Country reports from Morocco, Tunisia, Egypt, Jordan, United Arab Emirates and Oman on the state of research production and research ethics highlighted available resources as well as gaps and challenges o Focus Group Discussions (12 focus group discussions with 85 researchers) provided feedback on research and research ethics training, guidelines and guidance researchers resort to, enabling and constraining factors for research at the

2. Explore the role of the social and structural determinants on research resources, practices, and conduct.	national, institutional, community, and personal levels; and suggestions to improve skills in ethical research conduct. o In-depth interviews with 11 research ethics committee chairs in the 6 study sites discussed their affiliation, review processes, time for decision making, interaction with other IRBs, role after approval, issues in proposals received, training for REC reviewers, guidelines, challenges impeding review, impact of COVID-19 on review process, review of pharma funded studies, and suggestions for improvement.
3. Determine needs /gaps in capabilities, training initiatives/continuing education, practices and structures for applied research ethics in contexts of fragility using rigorous methodological inquiry.	o In-depth interviews with 14 research centre directors brought insights on sources of funding, decisions on research agenda, issues encountered in the applications, impact of COVID on centre's work, research agenda from pharmaceutical companies, guidelines for proposals and ethics. o Cross-sectional survey with 117 researchers region aimed to gather information from researchers from a wide variety of disciplines across the region. and covered the breadth of the research process with questions about training, guidelines, research ethics committees, challenges with international collaborative research, challenges at the institutional and national level, and issues of research misconduct while also seeking input from participants about preferred training topics and modalities, and ways to enhance research ethics and collaborative research in a contextually relevant manner.

4. Methodology

The study methodology was explored in depth in the published paper by Makhoul et al. (2023) *A Qualitative Multi-Methods Research Protocol: Applied Research Ethics in the Middle East North Africa Region[1]* and which we utilized in writing this section. The methodology was phased with findings from one phase feeding into the next as follows:

- **A desk review for background information relevant to the research topic**:

The AUB team (JM, RN, CE) engaged in an extensive desk review of a purposive sample of relevant websites, literature, e-courses, and grey literature around research ethics in the MENA region. The desk review explored research ethics requirements in journals (social science and medical), predatory journals, publishers (regional and international), research funding agencies and networks, universities, and UN agencies. The methodology adopted was a spiral iterative approach grounded in initial rounds of findings and weekly discussions.

- **Identifying participating countries:**

We selected six countries from the MENA region for in-depth empirical research, and added country teams of two researchers from each country: a focal person and a research associate. Country team members:

Name	Role in study
Dr Yousef Saleh Khader	Jordan Focal Person
Dr Driss Maghraoui	Morocco Focal Person
Dr Hany Sleem	Egypt Focal person
Dr Murtadha Al Khabori	Oman Focal Person
Dr. Iffat Elbarazi	UAE focal person
Dr Habiba Ben Romdhane	Tunisia Focal Person
Dr. Mohammad Alyahya	Jordan Research Associate
Dr. Saloua Zerhouni	Morocco Research Associate
Dr. Inas Abdelwahed	Egypt Research Associate
Dr. Amal Al Balushi	Oman Research Associate

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[1] Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A qualitative multi-methods research protocol: Applied research ethics in the middle east north africa region. International Journal of Qualitative Methods, 22https://doi.org/10.1177/16094069231204820

Ms. Mahanna Elsheik	UAE Research Associate
Dr Meriem Sellami	Tunisia Research Associate

The study initially aimed to include 8 Arab countries from various income groupings as identified by the World Bank. Of these eight, two were to be countries that are experiencing war, occupation or conflict. In addition to the economic criteria, university research activity, research output, and fragility were identified as important criteria impacting the choice of countries. Initially, nine countries were first chosen based on all the above included Oman, Jordan, Morocco, Egypt, Bahrain, Saudi Arabia, Iraq, Sudan, and Somalia. Both Qatar and Lebanon have high ranking universities and research output, but they were excluded from the sample because the research team had already conducted research in those countries and the ongoing multiple economic, financial and refugee crises in Lebanon would have made it unethical to explore research ethics when there are so many pressing needs in the country. Somalia, Sudan, and Iraq had been selected, particularly to include countries that have a less active research landscape and that are experiencing fragility. However, Iraq, Somalia and Sudan had to be excluded because of concerns over local safety protocols in COVID-19, potential security risks for researchers, and difficulties in paying researchers in those countries. Political tensions led to the breaking of the work with Bahrain and Saudi Arabia. Consequently, the countries that were chosen were Morocco, Tunisia, Egypt, Jordan, United Arab Emirates, and Oman.

- **Writing country reports:**

Upon recruitment of the country sites, focal persons engaged in writing reports that would give an idea about the landscape of research conduct and ethical practice in their respective countries. The reports were written based on an outline that the AUB team developed and shared with them for feedback (Appendix 1). The reports included information on universities & research centers, IRBs/RECs & ethics approval processes, editorial practices in local journals, resources for researchers (funding, training, continuing education, support structures), research being conducted on research ethics in the country, influence of social and structural determinants on research and research ethics, and areas of improvement. The reports were used by the AUB team to familiarize themselves with the context and in developing the research tools.

- **Empirical data collection using Focus Group Discussions (FGDs) and In-depth Interviews (IDIs):**

6 COUNTRIES in the region

12 FOCUS GROUPS

25 ONE-ON-ONE in-depth interviews

85 Researchers from social and behavioral sciences, and medical/health fields

about research ethics in their work and the challenges they face while doing research

11 Research Ethics Committees (REC)

14 Research Institutions

(biomedical/health and social sciences fields)

about current parctices, research infrastructure, contextual factors, challenges, and suggestions

The understanding of the research and research ethics landscape attained from the desk review and country reports allowed the team to develop a contextually sensitive interview guide for the FGDs. (Appendix 2). Focus groups involved researchers in the biomedical/health and social sciences fields from universities and research institutions. Before commencing data collection, the AUB team held a virtual meeting with all the country teams, a mock FGD was moderated by JM, and the teams went over the data collection tools. The study research coordinator (CE) followed up with the research associates frequently through meetings and emails. Once FGDs had commenced, another virtual meeting was held to reflect on and discuss any challenges experienced and to introduce the coding process. In total, 12 FGDs were conducted virtually with 85 researchers, two in each country between March and July 2022. The participants included 49 biomedical/health researchers and 36 social science researchers.

After the coding and preliminary analysis of the FGDs were completed, two interview guides were developed for the in-depth interviews, one aimed at research ethics committee chairs and the other for research center directors (Appendix 3). In-depth interviews were conducted in-person between November 2022 and January 2023 with due attention to COVID-19 precautionary measures. A total of 25 participants were interviewed, 14 research center directors (7 social sciences and 7 biomedical) and 11 REC chairs (7 biomedical and 4 social sciences).

Due to COVID-19, in-person meetings with the team members and in-person data collection was impeded. Conducting meetings virtually allowed research associates to include participants all over the country, however, it also impacted rapport in situations where connectivity and technical difficulties caused participants to turn off their cameras. The FGDs and IDIs conducted were recorded, transcribed verbatim in the country sites, and de-identified. After reading the transcripts several times, each research associate manually coded the transcripts using an open coding system. Guidance on coding had been provided in a meeting and step-by-step written document; research associates shared short coded excerpts (2-3 pages) with the AUB team for coding verification prior to completing all the coding. Short excerpts of the French transcripts were translated to English to allow the AUB team to partake in the coding process and pairs of research associates also peer reviewed each other's codes. Thematic

analysis using Braun and Clarke (2006)[2] 6-stage framework was conducted and codes were transferred to a matrix developed by the AUB team. The end result included 4 matrices, two for the FGDs (one biomedical and one social sciences), one for interviews with research ethics committee chairs (biomedical and social sciences together), and one for the interviews with research center directors (biomedical and social sciences together). The AUB team conducted a preliminary analysis of the matrices and discussed the findings in the in-person meetings in Jordan and Lebanon.
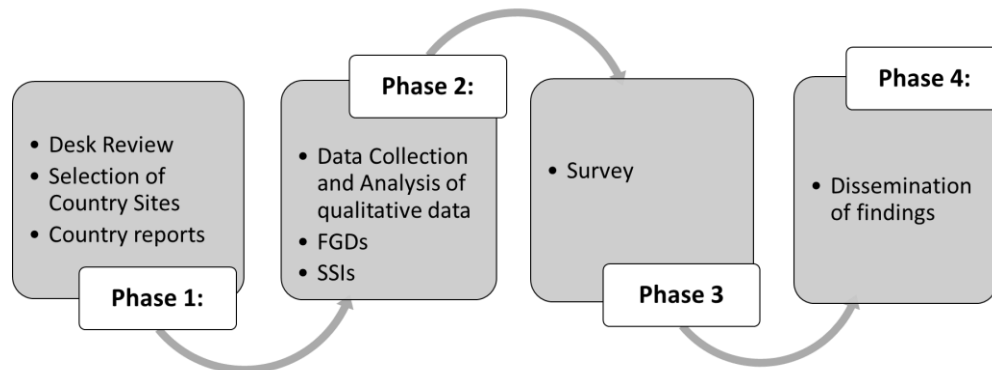
- **Online survey:**

The final phase consisted of developing an online survey that aimed to capture the perceptions and self-rated capabilities for research and applied research ethics, and the resources available for researchers engaged in human subjects research in the MENA region as a whole and covers the breadth of the research process (Appendix 4). This is in contrast to the available literature which often focuses on only one or two Arab countries and fails to present information on the types of trainings attended by participants, the methods of instruction of research ethics training and researchers' personal perceptions of their skills. The questionnaire was informed by the literature and the findings from the previous phases. The draft survey was shared with the country teams and collaborators on the project (Arab Council for the Social Sciences and Birzeit University) for feedback. It was evaluated according to the Questionnaire Appraisal System QAS-99 which aims at assisting in evaluation of survey questions and dealing with any issues prior to the survey being published by two team members at the Center for Research on Population and Health (CRPH) at the American University of Beirut. The questionnaire as well as the consent forms and invitations scripts were developed in English and translated into Arabic and French by professional translators. Translations were shared with country team members from Egypt and Tunisia respectively for any additional comments. A hard copy Arabic version was pretested with three faculty members at the American University of Beirut, while the English version was pretested on Kobo toolbox with two faculty members. The French hard copy was pretested by two team members from the Morocco team and a research fellow at the Faculty. The final version of the questionnaire consisted of 5 sections and included a series of 43 closed-ended questions about demographic characteristics, research methods and research ethics training and guidelines, resources available for conducting research, challenges to research, and future implications to improve the research experience (two open ended questions). It was available in English, Arabic and French. Different question formats were used; multiple-choice questions were more than one answer can be chosen, yes or no questions, and five-point Likert scale questions (for ex. To a great extent, somewhat, to a very little extent, to no extent at all, don't know).

Country teams and the AUB team shared the survey with their networks and a list of research centers that was developed by the country teams. The aim of the survey was to explore the research ethics capacities and resources available to researchers across the region. The Center for Research on Population and Health (CRPH) at AUB assisted in developing the survey and uploading it on Kobo Toolbox for dissemination, and also assisted in data analysis. The survey received 195 submissions with 117 of them eligible for analysis. The survey was launched late May 2023 and closed early September 2023. Data are currently being analyzed by CRPH.

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[2] Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

A strength of this study methodology is that it applied triangulation, different methods and stakeholders were involved to help generate a holistic and thorough picture of research ethics practice in the region.

The different methods and stakeholders stated similar challenges, this congruency in themes indicates that the results are credible and confirmable.

Another aspect of methodological rigor was the involvement of local researchers who are knowledgeable of their local contexts in the development of all survey instruments. All data collection documents and participant inclusion criteria were developed and shared with country teams for feedback. Interview guides, invitation scripts, and consent forms were developed first in English, they were shared with country teams for any feedback or comments and then translated to Arabic which is the language spoken in the majority of these countries. Virtual meetings were held with the country teams throughout the data collection and research associates were followed up by the research coordinator through meetings and emails.

5. Project Implementation and Management

Primary Activities supported under the project (Appendix 5: Study timeline)

1- **Desk review: May-August 2020**
   The search for data and writing of the desk review spanned 4 months and 14 virtual meetings among the AUB team members due to COVID-19. Meetings were held on a weekly basis to discuss findings and next steps. A problem that was encountered was the missing journals and dead links in the journal databases. The information was synthesized and presented in power point format during a meeting with ACSS and Birzeit partners, and IDRC in September 2020. The online research ethics courses are currently being analyzed using content analysis for a manuscript around available online research ethics courses in the region (both regional and international courses) and an assessment of their suitability for the context.

2- **Selection of Country Sites: Oct 2020-May 2022**
   The choice of 8 sample countries was informed by theoretical sampling rather than representative sampling. The process of arriving at the country choices was iterative, taking into consideration criteria including World Bank income-level ranking (high, upper-middle, lower-middle, and low income), university rankings as an indicator for research output and publication,

fragility indices, and feasibility. A 10-page document was written on the above thought process and the 8 sample countries along with potential focal and contact persons. This document was shared with partners for feedback and a meeting with IDRC, ACSS, and Birzeit included further discussion of comments and responses. Limitations pertinent to the choice of country sites have been described in the methodology and indicated the complexity of choosing country sites in a region marred by conflict and political disagreement.

3- **Recruitment of Country Teams: April 2021- May 2022**
The study recruited 2 researchers in each country site who are skilled in qualitative research, understand the research ethics landscape in their countries, are able to secure IRB approval and communicate with their research networks for recruitment. Individual virtual meetings to discuss the study, terms of reference and timeline were conducted with each team member. Focal persons were responsible for applying for and obtaining IRB approvals, identifying and communicating with participants for recruitment, and writing country reports. The research associates the FGDs and IDIs, transcribing them, and coding the data.
The country reports were being written as teams were being recruited, thus they were received at separate points in time between December 2021 and August 2022. A significant limitation to project implementation was time commitment and responsiveness of country team members. Given that the country team members were academics and had other work commitments, constant follow-up and reminders were needed to get the work done on time and often the pace of the work differed among the countries. This led to some delays in the completion of tasks and took up significant time and effort from the AUB team. The variability in the proficiency of the team members in qualitative research and English language also impacted the study. In addition, the Beirut meeting led the country team members to express interest in leading and writing several manuscripts, and abstracts were prepared; however, despite many meetings and reminders, a number of manuscripts did not materialize.

As country teams were being recruited, discussions were held about the need to obtain ethics approval from each country site. Jordan, Oman, and United Arab Emirates were able to obtain IRB approval for the study, while Morocco, Tunisia, and Egypt reported that there are no social science IRBs in their countries and AUB approval would suffice. These country IRB approvals were then used to secure AUB IRB approval. All team members completed the CITI training for human subjects research or a free online training from the University of Montana consisting of 3 modules. The AUB IRB approvals for each phase were obtained in a sequential manner. This meant that 3 IRB applications were submitted to the AUB IRB, one for the FGDs, one for the IDIs, and one for the survey. Delays in IRB feedback and approval led to significant delays to commencing data collection.

4- **Empirical Data Collection: FGDs and IDIs: September 2021-January 2023**
Two virtual meetings with country team members related to the FGDs (February 18 2022) to discuss preparation and implementation with a mock FGD were moderated by JM. A step by step process for conducting the FGDs was developed and shared. The country teams were followed up closely while conducting the FGDs through email and WhatsApp to communicate any challenges they were facing. In one country, the topic of research ethics was perceived as

sensitive and participants were worried about the privacy of virtual meetings. The focal person suggested that videos be turned off and pseudonyms used; however, the AUB team agreed that this would increase suspicion and impact the FGD dynamics. Consequently, it was decided that JM would join the first 5 to 10 minutes of the FGDs, introduce herself to the participants, introduce the study and put everyone at ease with the purposes of the study. This proved very helpful and participants discussed their ideas and opinions openly. Towards the end of conducting the FGDs and as transcriptions were being prepared, another meeting was held to guide the research associates on coding and thematic analysis. Once coding began, constant follow up and communication was conducted by the research coordinator. For the in-depth interviews, the interview guide was developed using the matrices from the FGDs and shared with the country teams for feedback, interviews were conducted between November 2022 and January 2023. At this point, research associates had become more proficient in coding and thematic analysis, so coded excerpts and filled matrices were received as soon as ready. Where there was a need for clarifications by AUB team, online meetings, emails, and WhatsApp communication were used.

In some instances, the sampling strategy for the empirical research varied with input from the sites and was influenced by contextual factors including COVID-19, feasibility and common practice in each country site. Country teams reported that the agreed upon recruitment strategy recommended by IRBs was very difficult to follow because of its formality, and required a lot of effort in follow-up. Research associates suggested that snowball sampling be adopted in some country sites since it was contextually appropriate and if often used in recruiting participants in collectivist societies like those of the Arab world.

5- **Cross-sectional Survey: May – September 2023**
The aim of the online survey was to "capture the perceptions and self-rated capabilities for research and applied research ethics, and the resources available for researchers engaged in human subjects research in the MENA region as a whole" (Makhoul et al., 2023)[3]. It relied on a questionnaire developed using the literature and the findings so far. The online survey was disseminated within the research networks and centers of the research and country teams. The survey experienced delay due to the AUB IRB and the request for amendments, in addition to significant delays from one of the country sites which required a new IRB approval from each of the research centers where the survey would be disseminated. Another important barrier was the low response rate despite sending multiple reminders, this was anticipated given the low response rates for online surveys in general and the end of the academic year. During the three months of summer regional researchers were less engaged in work and less responsive to emails.

6- **Dissemination: January 2023- Ongoing**
Two regional meetings were held in Jordan (January 2023) and Beirut (March 2023). These meetings occurred towards the end of the study timeline to ensure that data collection for the qualitative component had been finalized and also due to the delay imposed by COVID-19. The

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[3] Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A qualitative multi-methods research protocol: Applied research ethics in the middle east north africa region. International Journal of Qualitative Methods, 22https://doi.org/10.1177/16094069231204820

Jordan meeting allowed for sharing of the preliminary results with the country teams as well as with stakeholders from Jordan including researchers, research ethics committee chairs, research center directors, and government representatives. The meeting in Beirut discussed the final findings from the empirical data collection (FGDs and IDIs) and agreed on manuscripts to be written up and the teams responsible for each.

The communication office at the Faculty of Health Sciences (FHS) and a graphic design company designed an infographic that explains the study objectives, methodology, and findings from the qualitative component in a visually appealing and succinct manner. JM and CE checked the Arabic A translation, and a Twitter campaign was also created with the help of the FHS communications office, and summary brief was shared on the Faculty of Health Sciences page and social media.

6. Gender Equality and Inclusion

The study can be classified as 'gender aware' in the sense that gender equality and inclusion were considered in the research project's rationale in terms of the country team composition and the recruitment of study participants, yet gender equality was not an operative concept in the design and methodology. The composition of the country teams ensured gender equity and inclusion. Both focus group discussion and interview participants ensured diversity among participants. Everyone had equal opportunities to co-author manuscripts and to indicate which manuscripts they are interested in contributing to and/or leading. The study engaged local research teams who are familiar with the research context in their countries and speak the languages. The AUB research team were all women. Issue relevant to gender equality also emerged from the empirical data collection. One focus group discussion brought up issues related to the lack of advancement of female professors despite having more research and publications, the lack of visibility of research by women, and the discouragement faced by female researchers. Moreover, researchers spoke of the lack of participation of women in research studies in the region due to issues with consent from husbands/family.

7. Project Outputs and Dissemination

Published Articles:

- Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A Qualitative Multi-Methods Research Protocol: Applied Research Ethics in the Middle East North Africa Region. International Journal of Qualitative Methods, 22. https://doi.org/10.1177/16094069231204820

Manuscripts in preparation:

- Ethical Research (mis)conduct: an insider's view from research ethics committee chairs in MENA- Jihad Makhoul, Catherine El Ashkar
  - Paper will present prominent findings from interviews with a sample of REC chairs from the countries in the study about the challenges they face at an institutional level as well as the deficiencies of the applications that come to them, which are revealing about the researchers' capabilities in applied research ethics. It will present issues that are of

relevance to research integrity and research ethics in the MENA region but are of relevance other parts of the world.

- Impact of COVID-19 Pandemic on Research Ethics Practices- Iffat Elbarazi, Amal Al Balushi, Catherine El Ashkar, Jihad Makhoul
    - This paper will analyze the impact of covid-19 pandemic on research ethics practices as experienced by researchers. It will highlight how COVID-19 came and uncovered the gaps in the system and the implications of these behind COVID-19.

- Influences on Research Integrity and Academic Freedom: Insights from the MENA Region- Jihad Makhoul, Sonja Bjelobaba, Catherine El Ashkar, Rim Nehme, Meiya Saad
    - This paper will present prominent findings from focus group discussions and in-depth interviews. It aims to shed light on the factors that influence academic integrity for researchers in the MENA region considering internal and external factors. The paper will present issues that are important to academic integrity and academic freedom in the MENA region that are of relevance to other low and middle-income countries or countries with authoritarian regimes.

- Evaluation of Online Research Ethics Courses (3 Regional and 3 international courses)- Ahmed Shanah, Iffat El Barazi, Catherine El Ashkar, Jihad Makhoul
    - This paper aims to evaluate 6 online research ethics courses (3 regional and 3 international) to analyze their suitability to the MENA context and the degree to which they satisfy the need for research ethics skills that came up in the FGDs and IDIs.

Manuscripts planned :

- Research ethics practices and leadership: online survey findings from Arab researchers

Social Media and websites:

Ethical Research in the MENA Region: Current Situation and Gaps (aub.edu.lb)

https://www.facebook.com/photo?fbid=779769337485226&set=a.487263756735787

https://www.instagram.com/p/CwX14QSN1aP/

https://www.linkedin.com/company/96215341/admin/feed/posts/

Faculty of Health Sciences at AUB on X: "Contextually sensitive research ethics guidelines are missing and ethical research conduct is lagging behind in the #MENA region. 2 Faculty members from #FHS analyzed the landscape of research ethics in the region. Read below to know more 👇 #researchethicsMENA #researchethics https://t.co/tdGGAQ1pbv" / X (twitter.com)

Faculty of Health Sciences at AUB on X: "A groundbreaking study led by the #research team at #FHS #AUB examines the current state of applied research ethics in six countries in the MENA region. The

Conference presentations:

- El, Ashkar, C. (2023). Mapping Drivers, Capacities and Needs for Research Ethics in the Middle East and North Africa. Oral presentation at Arab Council for Social Sciences in Beirut, Lebanon- May 26, 2023.
- Makhoul, J., El Ashkar, C., (2023). Ethical Research (mis)conduct: an insider's view from research ethics committee chairs in MENA. Oral presentation at BRIDGE (Bridging Integrity in Higher Education, Business, and Society) project International Conference on Integrity in Higher Education, Business, and Society- May 18, 2023.
- Makhoul, J. (2023). Qualitative Research Challenges in a Multi-Country Study in the Middle East and North Africa region. Oral presentation at the Qualitative Report 14th Annual Conference "Living in a Post-COVID World" Virtual Conference, February 16-18, 2023.
- Part of a presentation by J. Makhoul focusing on results related to Pharma funding and ethical practices in the MENA region: Commercial Determinants of Health Workshop for researchers AUB, October 11, 2023.

Capacity Strengthening:

- The research teams have completed an Online Research Ethics course of three modules, ethical issues for research, institutional responsibility, and human participation in research. The UAE research associate has received training on conducting focus groups under the guidance of the UAE focal person. All research associates have received training on conducting focus group discussions through participating in a mock focus group and through discussions and comments. Research associates also improved their skills in coding and thematic analysis.
- The CRPH team who helped in the development of the survey gained several technical skills in using Kobo but also benefitted from the increased attention and awareness of research ethics dilemmas in the region.
- Stakeholders from Jordan who attended the regional meeting had lively discussions about research ethics and the challenges across the different sectors (academia, IRBs, government) and started thinking of networking opportunities and opportunities to take the work further and create a framework for research ethics in the region. The Beirut meeting presented an opportunity for everyone to analyze the findings and write abstracts and outlines.
- The project contributed to a long-term process of changing the culture of research conduct in the region by producing a baseline portrait of common practices, challenges at social and structural levels and a rich description of the context within which research takes place. This output will also be useful material to guide the development, and testing of culturally relevant guidelines and interventions to address needs in the area.

8. Project Outcomes

The study led to increased awareness of the research teams of the barriers to research ethics in their local context and it also contributed to showcasing the similarities and differences to research ethics practices and barriers across the region. It is evident that many similarities exist across the six countries such as the lack of training and expertise, interest in research ethics, absence of clear ethics guidelines, the frequency of research misconduct practices and influence of pharmaceutical companies in clinical research processes. However, there are differences that also emerged such as the absence of social science research ethics committees in the Maghreb countries, the authoritarian regimes in Egypt and UAE, the fragmentation of the health and ethics oversight system in the UAE, and others. These findings can help the countries tailor future research studies or interventions that are rooted in the context. The dissemination the findings in the regional meeting in Jordan in the presence of stakeholders from governmental, academic, and research disciplines allowed people to understand each other's perspectives and become engaged in finding solutions. This discussion is further strengthened by the work that ACSS is doing in developing novice social science researchers' skills in research ethics. The engagement of local researchers greatly enriched the study in terms of the awareness of local context that the researchers brought in and allowed for richer data than would have been the case had the AUB team alone done the data collection.

9. Overall Assessment and Recommendations:

Several lessons were learnt from this multiphase multi-method research study. It was a huge undertaking, and therefore required the ability to apply research methodology to 6 country sites. The qualitative research approach we used gave space for insights, stories and detail that would not have been captured otherwise. Reliance on local researchers in general enhanced these research interactions with participants and allowed discussions to flow. Virtual meetings were very useful and were much needed for one-on-one follow-up with the country teams to move the work forward.

The implementation of the research was challenged by the COVID-19 pandemic in that we were unable to conduct the launching meeting in-person in one country. Managing the study and conducting the actual data collection and analysis was a big challenge because of the variation in competence and time management of the country teams, whose work ethos proved to be incongruent with ours and this delayed the work and required much follow-up. The larger IDRC grant was preplanned to include ACSS and Birzeit, however, as each team worked on a separate component of the study, there were few opportunities for real input and collaboration. Both Birzeit and ACSS provided input on the choice of countries and the survey questionnaires, and assisted in the dissemination of the survey to researchers in their network; ACSS provided a platform for the dissemination of our findings through their regional meetings on two occasions, and the Jordan regional meeting was attended by one ACSS staff member. The AUB research coordinator helped in evaluating the Birzeit ethics portal and the Birzeit tool is currently being referred to in the analysis of existing online courses by the AUB team. The 3 parts were independent although integrated when we redrafted the parts of the grant proposal to IDRC. We welcomed IDRC's interest in and regular meetings with the research team to listen to our progress and provide feedback on our decisions.

The study contributed to our understanding of the impediments to ethical research conduct in the MENA region and the urgent need to support rigorous research in more than one way as there seems to be deficiencies in core research methodology and research ethics training for reliable knowledge production, a core engine in community and social development, especially the social sciences. We also learnt that oppression is deeply rooted in the structure of society and shows up in many aspects of life albeit in different ways, and affects how academics work, what they are allowed to do and what resources are (un)available for them. That researchers perceive themselves as socially excluded in decision making, have limited academic freedom and have little say in their own research funding indicates an oppressive research landscape, and demystifies the grandiose image of university researchers and research institutions in the MENA region.

Appendices:

Appendix 1:

Country Reports Outline

<div style="border:1px solid black; padding:10px;">

<p align="center">Outline for the FP Country Reports</p>

(word limit: 3000 words max with references if used, pls use subheadings as suggested below)

An overview of the landscape of applied research ethics in the country:

1. Research institutions, research funding
2. History and types of:
    a. Research institutions (academic, independent, state),
    b. Review boards and numbers/types/spread throughout the country (geographically, others where applicable)
3. Approval practices/processes (institutional and government level) for biomedical and social science research (type of guidelines and regulations used (Western, local, regional, etc.), responsiveness of IRBs, ease/difficulty of communication with IRB, etc.)
4. Any particular attention to or note of editorial practices in regional journals (and local journals if available)
5. Resources for researchers (funding, training, continuing education programs, support structures in place) to support and enhance research ethics practices and needs.
6. Types of research conducted/ anything written about the topic of "applied research ethics" in general, or in particular disciplines (if applicable)
7. Any perceived or documented influence of social and structural determinants in the country on research and applied research ethics (if there is nothing written on this, then can write based on your experiences and knowledge or obtain output from trustworthy sources)
8. Areas of possible improvement

</div>

Figure 1. Country Reports Outline

Appendix 2:

1. Let's take a moment to <u>introduce ourselves</u> and our experience in research.
    a. Disciplinary training, years, type of research..
2. What <u>type of research training</u> have you had?
    a. Formal/informal, duration, format, content ...
3. What <u>type of res ethics training</u> have you had?
    a. Formal/informal, duration, format, content...
    b. Is this typical for other researchers?
4. What type of <u>guidance</u> do you use/refer to?
    a. Codes, guidelines, guides...
    b. If you have a dilemma in the field/while you are conducting your research, what do you do? Can you give an example?
5. What from your experience are factors that <u>enable/support</u> research in your field?
    a. Country level factors (political env, approvals/permissions, review boards, trainings, funding, resources, collaborations,...)
    b. Institutional (funding, time, resources i.e. IT, library, data, staff, mentorship...)
    c. Community/cultural (people's expectations, access, relationships,...)
    d. Personal level characteristics
    e. External funding (industry/corporations...)
6. And what are the <u>constraining factors for researchers in your fields?</u>
    a. At the same levels as above if applicable...
    b. Can you give an example/tell us a story?
7. What do researchers in your fields need (resources, training, etc.) to improve their skills in ethical research conduct?

Figure 2. Interview Guide for the Focus Group Discussions. Obtained from Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A qualitative multi-methods research protocol: Applied research ethics in the middle east north africa region. International Journal of Qualitative Methods, 22https://doi.org/10.1177/16094069231204820

Appendix 3:

1. Can you give me an overview of the research institution?
   a. History, type (public/ independent), who are the researchers in it?
   b. What type of research does it conduct or fund, scope...
   c. How is the research agenda or studies decided on?
2. Tell me about the sources of funding that the institution gets
   a. how often do you receive it?
   b. Who decides?
   c. Any conditions attached to the funding for the institution? Exs?
   d. Any problems with that?
3. What types of issues do you encounter in the applications you get?
   a. (knowledge of their topics, appropriate research skills...)
4. How has COVID-19 affected the work of the institution's research?
5. In focus groups with researchers from this country and others in the region, we were told that there is a lot of funding coming in from Pharma and other corporations. How does this affect the research agenda and the institution? (ask only for biomedical research institutions)
6. What type of guidelines does the institution refer to for such research proposals?
   a. Process, COI, ethics?
   b. What is missing? (ex. areas guidelines do not cover/protect)?

Figure 3. Interview Guide for In-depth Interviews with Research Center Directors. Obtained from Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A qualitative multi-methods research protocol: Applied research ethics in the middle east north africa region. International Journal of Qualitative Methods, 22https://doi.org/10.1177/16094069231204820

1. Tell me about the REC
    a. Related to/ governed?
    b. Type of applications it receives (biomedical, social, collaborative research); from where? frequency of applications (per year for ex)?
    c. Types of ethics review processes
    d. Time it takes to review and to make a decision?
    e. Interaction and relationships to other IRBs?
2. What role does the REC have after the study has been approved (continuing review, progress forms, auditing)? dealing with reports of research misconduct?
3. What are the types of issues or problems that you see in these proposals? why do you think these problems arise? (research skills, res ethics skills, forms...)
4. What type of training or expertise do the REC reviewers have/need to have to be able to contribute to the committee/review?
    a. Your opinion on these trainings/expertise?
    b. Type of training the REC/institution provide for its members?
5. What type of guidelines does the REC refer to for its reviews?
    a. implicit or written?
    b. your opinion on these guidelines? (re the context of the country/type of research...)
6. What type of challenges do you face that impede the ethics review you do? Why do you think these challenges arise? (different levels)
7. How has COVID-19 affected the REC review process?
8. In focus groups with researchers from this country and others in the region, we were told that there is a lot of funding coming in from Pharma and other corporations. How does the REC deal with reviews associated with such funding?
9. How can the practice of ethical research conduct be improved in your institution, in the country?

Figure 4. Interview Guide with Research Ethics Committee Chairs. Obtained from Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A qualitative multi-methods research protocol: Applied research ethics in the middle east north africa region. International Journal of Qualitative Methods, 22https://doi.org/10.1177/16094069231204820

Appendix 4

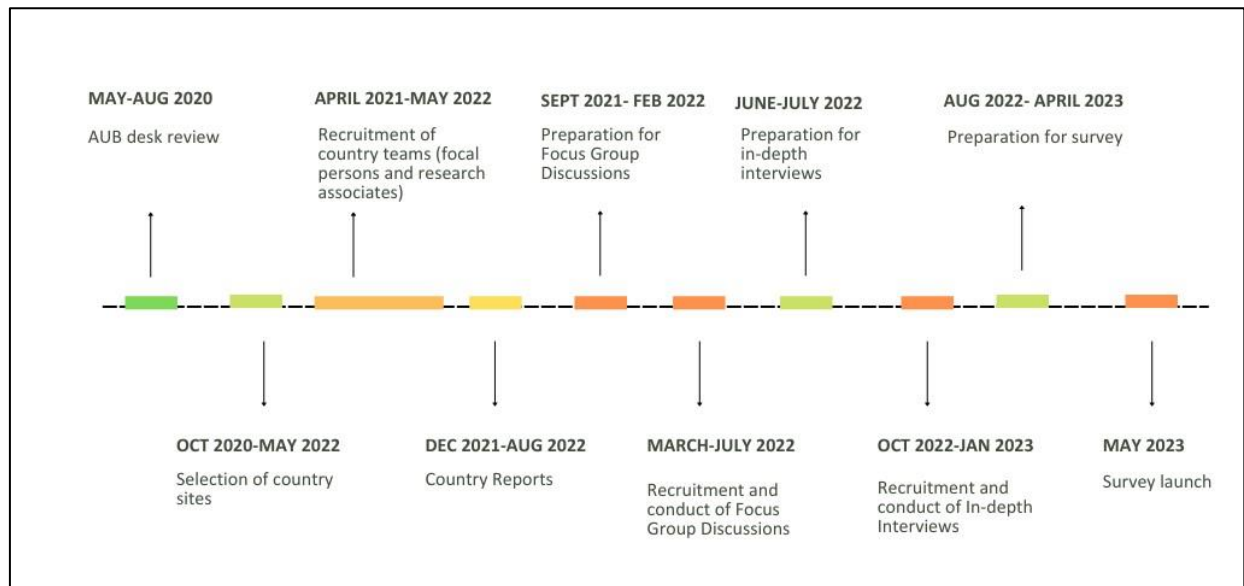**Survey Questionnaire (attachment)**

Appendix 5: Study Timeline

Figure 5. Study Timeline. Obtained from Makhoul, J., El Ashkar, C., Nakkash, R., & Bjelobaba, S. (2023). A qualitative multi-methods research protocol: Applied research ethics in the middle east north africa region. International Journal of Qualitative Methods, 22https://doi.org/10.1177/16094069231204820