Perspectives of Egyptian Research Ethics Committees Regarding Their Effective Functioning

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Abstract

The recent increase in research in the Middle East has been associated with the establishment of research ethics committees (RECs). Our aim was to obtain perspectives of RECs regarding the challenges that impede their effective functioning. We conducted in-depth interviews using a semi-structured interview guide. We transcribed and analyzed the interviews to uncover major themes and subthemes. We identified the following themes: membership composition; training needs of members; availability of human and capital resources; role of the national government; concerns with the informed consent process; government scrutiny of research; investigator-related issues; and concerns with transfer of biological samples to other countries. Our interview study revealed several barriers that need to be considered by appropriate stakeholders to enhance adequate functioning of RECs.

Keywords

In recent years, research has increased in the developing world (Normile, 2008). According to the CenterWatch analysis of 2009, there was an almost 10% increase in clinical trials in the developing countries from 2003 to 2007 (CenterWatch, 2009). In Egypt, the number of clinical trials nearly tripled between 2008 and 2011 (U.S. National Institutes of Health, 2012). In response, international organizations have developed research ethics guidelines for conducting biomedical research involving human participants (Council for International Organizations of Medical Sciences [CIOMS], 2002; Nuffield Council on Bioethics, 2002; World Health Organization [WHO], 2008). These guidelines recommend the establishment of research ethics committees (RECs) to review the ethical aspects of research. Despite these guidelines, commentators express concern that the ethics review capacity of RECs is lacking in the developing countries (Bhutta, 2002; Hyder et al., 2004). Accordingly, there have been research-related scandals with occasionally tragic consequences (Krishnakumar, 2001; Lakshmi, 2012; Willyard, 2007).

Studies from developing countries have shown that RECs face challenges that include lack of member diversity, inadequate training of members, scarcity of human and capital resources, and absence of national regulations (Abou-Zeid, 2010; El-Dessouky et al., 2011;

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Kandeel et al., 2011; Lakshmi, 2012; Office for Human Research Protections [OHRP], 2010). Similar findings have also been shown for RECs in Egypt, where more than 40 RECs have registered with the Office for Human Research Protections (OHRP, 2010).

Despite the previous quantitative studies that have explored issues that affect the functioning of RECs in several developing countries, including Egypt, many questions remain regarding the challenges they face in their daily operations. For example, what are the specific issues that impede member diversity; what are the barriers to providing training to REC members; what are the concerns regarding informed consent; how do RECs function in the face of inadequate resources; and what are the specific concerns regarding certain types of research. Also, there is little in the literature regarding the beliefs and perceptions of those responsible for reviewing the ethics of research, particularly REC chairs. Qualitative research consisting of in-depth interviews can add further specificity and insights to results obtained in quantitative survey studies. Accordingly, the purpose of this study was to interview the chairs (or their designees) of RECs in Egypt in an attempt to further explore previously known REC challenges, as well as to uncover others not investigated in previous quantitative studies.

Methods

Study Design

We used a qualitative methodology consisting of in-depth interviews of REC chairs or their designees. We designed a semi-structured interview guide based on items identified as barriers to REC functioning from previous investigations. Accordingly, the guide consisted of the following domains: REC operations and their barriers, member composition, members' training needs, REC resources, national regulations, and major ethical concerns encountered by RECs.

Participants

We recruited participants via several methods. First, we accessed the list of RECs from the Egyptian Network of Research Ethics Committees. Second, we obtained a list of REC chairs from the former trainees of the Middle East Research Ethics Training Initiative, a training program sponsored by the Fogarty International Center/ National Institutes of Health that aims to enhance individual and institutional research ethics capacity in the Middle East. The sample from both sources included RECs from medical schools and research institutes located in greater Cairo, the Delta region, and Upper Egypt. We contacted the chairs or their designees and explained the purpose and nature of the survey study. We conducted the interviews between September 2010 and January 2011.

Interview Methods

We conducted all interviews in English, either face-to-face or online using videoconferencing software (e.g., Skype). Our interviews were driven by our semi-structured guide, and in the context of discussing the issues in this guide, the participants raised other issues that we further explored in depth during the interviews. All of the interviews were digitally recorded and transcribed verbatim.

Analysis

We used elements of grounded theory to analyze the data. Essentially, we adopted an emergent coding approach, whereby the authors (AM and HJS) independently analyzed the content of the transcribed texts to identify key points that were marked with a series of codes. Subsequently, these codes were grouped into similar concepts or categories, which became the basis for the creation of themes. The authors discussed their independently

created themes to reconcile areas of disagreement until consensus was reached. In the final stage of analysis, a matrix was developed to compare major themes and patterns within and across interviews (Bernard, 2000; Miles, 2003).

Ethics

We obtained verbal consent from all participants. To maintain confidentiality, names were not identified on the recordings and transcripts were assigned a unique code. Interviews stored on a laptop were password protected. This study was approved by the Research Ethics Committee at the American University in Cairo and the Institutional Review Board at the University of Maryland School of Medicine.

Results

Characteristics of the RECs

We contacted 15 RECs and 13 agreed to participate in our study. Representatives from two RECs refused participation: one due to discomfort with the taping of the interview and the other due to a heavy travel schedule that even prevented online participation. We conducted 10 interviews online and three face-to-face. As summarized in Table 1, respondents included six chairs, two vice-chairs, and five moderators. Table 1 also shows the characteristics of these RECs. Most of the RECs were located in urban areas and all RECs were located in public institutions. Many of the RECs had been established for longer than two years and all had more than five members. Representation of women in the RECs ranged from 12% to 60% of the total membership (average was 37% ± 14%). Seven RECs reviewed an average of five protocols or less per meeting; one REC reviewed 6–7 protocols per meeting; and three RECs viewed greater than 20 protocols per meeting. To reach a decision, eight RECs used a consensus approach, while four depended on a majority vote;one REC used both methods depending on the risk level of the protocol—specifically, a consensus was used if the study was considered high risk. Most RECs (7/13) adopted both a primary/secondary reviewer system; two had a primary reviewer method; and one REC utilized three reviewers for each protocol.

Major Themes and Subthemes

Table 2 shows the identified major themes and associated subthemes. Also indicated are newly identified subthemes associated with these previously known themes, as well as the new themes that emerged from these interviews.

REC MEMBERSHIP

Gender Representation: The extent of female representation differed among the RECs, with half of the RECs having less than 40% of their members as women. One respondent justified the underrepresentation of women by stating, ''We are the department of surgery and in the department of surgery we do not have females at all.?

Multidisciplinary: Many of the RECs were multidisciplinary in regards to the presence of scientific expertise. However, seven respondents thought that additional members were needed, especially those from the community. For example, one respondent stated: ''Also we were trying in the future … to include more laypersons. They are very interested actually. And I think it is very nice and important to include more laypersons in the committee.''

However, maintaining members from the community proved difficult for several RECs. One said, ''keeping laymen is a very hard job''; another comment was that ''we invited a lawyer,

he started to come, he was very optimistic at first then he stopped to come, we invited two others and they came and they stopped coming. Maybe they find us boring.'' Another respondent stated, ''we used to invite people from outside the institute, but the compliance was a big problem so we stopped doing that.''

<u>**Overrepresentation of Senior Staff:**</u> A new issue that emerged involved the imbalance between senior and junior faculty on the committees. Although most RECs (11/13) had at least one junior member, all participants mentioned that their members were drawn mainly from the senior staff. Several reasons can account for the lack of junior faculty representation. One respondent mentioned that senior investigators would refuse to submit their protocols to be reviewed by junior REC members. Another implied that junior members of RECs would be reluctant to criticize studies carried out by senior faculty: ''They are afraid of the conflicts, if the researcher is a senior one and the subcommittee member is a junior one, this is a conflict, you know.''

Several respondents, however, stated that meetings would respect the voices of the juniors. For example:

> Junior staff is not intimidated by the senior staff and they are not scared to voice their concerns or their reservations … like when there is a point of conflict the junior are asked to give their opinions. And sometimes they give their opinions because maybe they do not have the experience or the seniority but they have the knowledge … [junior members] maybe they have attended certain courses. They are members in other IRBs so they have been exposed to certain situations or whatever. So the opinion of each and everyone is respected. And they are not intimidated.

MEMBER COMPENSATION—Several respondents raised the issue of compensation for REC members. One REC had members who were minimally compensated, while seven RECs offered no compensation to members. Perspectives regarding the issue of compensation were mixed among the RECs. One respondent held the perspective that compensation was not appropriate:

> From my experience in quality assurance, some people get motivated with appreciation. All the members joined the committee and were not looking for any money but we found the people you must at least appreciate their work and we have submitted our managerial bylaws to be a specialized unit. Specialized unit got the independence and this is like when you want your independence and increase your resources you must work like this. You cannot depend on resources of the faculty because we got very limited resources.

Comments reflecting the alternative position included:

> But usually we do not give a lot. Most of them we stayed for one and half year as volunteers. Most of us but you know, for myself I give a lot of time and for the others they give a lot of time and they started to ask our time means money we have lots to do otherwise but so we do not give an undue inducement. We give very little particularly for statisticians. I started with the statisticians because their time means money, because they use this job anywhere else with money.

> I think it is fair [compensating members on the REC], but we do not have enough money.

A few respondents suggested that compensating REC members could improve their attendance.

ETHICS TRAINING FOR MEMBERS—Most (12/13) chairs (or their designees) expressed concerns regarding inadequate research ethics training for their members. One stated:

> The training received is not enough and I am suffering with them for not understanding a lot of expressions, a lot of things regarding ethics, regarding contents of consent forms.

Another said:

> When you are having new members that are qualified and trained it makes life much easier and then it really upgrades the service. We are struggling when we are discussing any type of protocols.

In contrast, one respondent remarked on the continuous training of the REC:

> [A]ctually we have several workshops on research ethics and then all the members new and old ones attend the workshop and other faculty members attend the workshops too. And there is a lot of experience gained in these workshops. [We have] on average of four workshops per year.

To obtain ongoing training, one respondent encouraged members to access the Internet or attend workshops abroad, which could be partially funded by the institution.

Several participants brought up the differences in training between senior and junior faculty. Three respondents stated that junior people are keener to receive research ethics training and that several had already received such training. Another stated:

> They [senior REC members] are all professors and they are very busy and we cannot count on online training for them. There is nothing to [force] them to do this training. So they will not waste their time for doing this (online) training.

In regards to continuing education, one respondent mentioned he would allocate the first half-hour of their monthly meetings to introduce a new research ethics topic and discuss it with the members.

AVAILABILITY OF HUMAN AND CAPITAL RESOURCES—The shortage of human and capital resources represented a major barrier to the proper functioning of RECs, which was mentioned by 9 of 13 RECs. Several RECs did not have administrative assistants and several stated that they would perform administrative work, including the taking of the minutes. One respondent remarked:

> Unfortunately I am the secretary and coordinator. This is a problem, yes, but I think it will be resolved because I applied for a project for accreditation and we will get money and we have to set this.

Regarding capital resources, respondents mentioned the lack of computers, a dedicated room, photocopiers, and paper and file cabinets where confidential documents (e.g., protocols and review forms) can be stored. One REC was established with no resources and the members paid from their own pockets to sustain the REC.

ROLE OF THE NATIONAL GOVERNMENT

Lack of National Guidelines: All REC chairs (or their designees) stated that they received little to no guidance from the Ministry of Health (MOH) and lamented about the lack of national research ethical guidelines in Egypt. One respondent's reason for needing national guidelines included:

> We have a special society, special habits and special beliefs and something [national guidelines] must exist that satisfies all members of committee, all members of the faculty of education, and all members of the society.

Another respondent stated:

> I think there must be a law for ethics in research in Egypt and a law to regulate these ethical issues … this is number one.

Additional Bureaucracy: Instead of receiving direction from the National Government, several RECs remarked on the additional bureaucracy that occurs when they interact with the MOH. One participant said, ''they send us some ethical issues to put down and then we would need to find the answers for these,'' while another stated, ''they want to know our activities and they send us papers to fill, about how many researches we have done and how we are acting just lately.'' Some RECs stated they would need the additional approval of the MOH to carry out specific studies in their institutions, e.g., biological sample research.

ISSUES REGARDING INFORMED CONSENT—Many respondents raised issues regarding informed consent. For example, there were concerns with complex language used in informed consent forms (ICFs) and how to make such forms more understandable for laypeople. One respondent stated:

> Researchers wrote the consent form in way that the patient cannot understand what he means .… I tell [the investigator] after he finished reading if you understand anything? And he laughs because it is written in a jargon way so this is one important thing we tell him please write [it] in a suitable way for the patient to understand.

Some respondents mentioned the presence of language barriers. For example, although the ICF is written or translated to standard Arabic, it is quite different from the colloquial form that research participants understand. Another issue involved the length of the ICF, which could also undermine participants' understanding.

Several respondents also had doubts with the process that investigators would follow to obtain consent from potential research participants. For example, one respondent commented:

> The committee was not fully convinced that the investigator will explain this 15 paper consent to the patients in details and … we would like very much to have this ICF reduced to not more than three pages. We asked the investigator and the sponsor to reduce the ICF, but they refused, telling us that it is an international document used all over the world in 800 centers and hence, it will be extremely difficult to remove a single word from ICF. So we asked the investigator to allocate a special person to sit with the patient and give the necessary time to explain the full details of this 15 pages consent form.

Several RECs expressed concerns that investigators would fail to include all of the items required in the ICF. For example, one respondent stated:

> Sometimes they are missing some information. In their point of view it is not very important but we let him know that it is very important to be mentioned in the ICF, so some of the corners of the ICF are sometimes missing. But once we agree on it we stand and it is the final version that it will be followed later.

Trusting investigators to convey what is written in the ICF to potential participants was also a concern, as one chair stated: ''It is written in the ICF that it is research and different from clinical care but I am worried that the investigator himself doesn't tell the entire story to the

patient.'' Another respondent stated: ''We heard that an investigator did not take the informed consent properly. You see what I mean. He is not telling them what is in the informed consent and asked them to sign (it).''

Several believed that investigators may intentionally omit information about risks and methodology, or overemphasize benefits. One respondent said the following:

> Most researchers in the beginning said there is no risk at all [to the research] and [sometimes described] the benefits [of the regular treatment received by patients as the benefits of the research] but this is not right. Because the research subject can take this benefit without participating in the research. But mainly the explanation of what the researcher will do and the type of risk are the debatable items in the informed consent and also the background of the research. Most of the time it is very limited and not clear.

Several suggested more supervision of the process itself, for example:

> We actually have the feeling that it needs more supervision more than just writing the consent and taking the signature of the patient. We have the feeling that we need more supervision of the process itself of taking the consent and applying all its aspects.

Another confirmed: ''We have to have a monitoring committee to monitor the consent [process] done in a good manner.''

Another issue involved the signing of the ICF, as providing a written signature, especially in rural areas, would be unacceptable. This was explained as follows:

> The patients get scared when they see the IC and they do not want to sign it. And I say [to] take verbal consent rather than signing. The patients would say I would sign on my death certificate and birth of my son not to sign anything else, only my marriage, death of a parent or a newborn but he wouldn't approve the signing.

RECs raised alternative methods of taking consent that included verbal consent, but several remarked that there is a lack of guidance regarding when it would be appropriate to use verbal consent.

Several RECs raised the concept of patients' rights and how Egyptians patients ''are poor and ignorant and they may not ask for their demands or rights so the PI may take advantage of this point and do the [informed consent] process quickly and make him sign.''

Several RECs discussed the issue of assent from children. Two mandated assent from children participating in research above a specific age (10–12 years old) in addition to the consent from their legal guardians. A related issue was the age of adulthood at which adolescents can provide their own consent. Presently, Egyptian regulations are lacking with regard to this point. For example, one respondent claimed that although the legal age was 21, individuals above 18 years of age can obtain an ID card, a driver's license, and can legally get married. Obtaining clarity on this issue is important, as many researches are conducted involving university students who are mostly 18–21 years of age. One REC resolved this issue by allowing only low risk research, such as anonymous survey studies, on campus to not require parental consent.

New Themes That Emerged from the Interviews

GOVERNMENT SCRUTINY OF RESEARCH—One respondent discussed at length the control of research by the National Government and revealed the following about how research might be censored in Egypt:

In Egypt some have complained there is too much self-censorship going on because things have to go to Central Agency for Public Mobilization and Statistics [CAPMAS] to get approved after the REC review, it is an Egyptian organization. I do not know which ministry is it in. Technically, if you are surveying more than five people in Egypt you have to get approval from CAPMAS. It wants to make sure nobody's asking dangerous protocol questions. There have been complaints in some parts of *** that their ability to do so makes world class research harmed, because CAPMAS is not going to approve what government thinks it is politicized. In effect this could put off ''international granting agencies'' and will be less likely to give us the money because they know we are not capable of carrying out research.

INVESTIGATOR-RELATED ISSUES—Many RECs (12/13) reviewed investigator-initiated protocols submitted by the junior faculty, which included master's or doctorate thesis projects. Respondents remarked that junior investigators have limited knowledge of research ethics; for example, one respondent said:

We are in need of extensive training for the junior investigators and even our senior staff about protocol writing, research methodologies and consent form.

Another respondent said:

The main point is the bad methodology, the study design, the inclusion and exclusion criteria, because the inclusion and exclusion criteria are very important for the safety of the participants. And the justification of the research and bad review of literature and very short research protocol, very short, the methodology is just one paper or half a paper.

Only one respondent was satisfied with the knowledge and competency of investigators and only two were confident with the knowledge in research ethics of senior professors who supervised junior investigators. Finally, several respondents (4/13) indicated that their institutions started some sort of formal training for junior investigators and for the medical doctor (MD) and master's students on research ethics and methodology.

Respondents also expressed concerns regarding the lack of research innovation in investigator-initiated studies, which was explained by one respondent in the following manner:

The time allowed for the investigator to complete his MSc degree is not enough to fulfill very complete original research, so many of the research is for confirmation (replication) or doing what others have done in the west. So the originality (of ideas) is very little in our research.

RECs raised issues regarding compliance with the requirement to submit research to the REC. Seven respondents stated that it was mandatory in their institutions to submit protocols to the REC. However, not all investigators complied; for example, one respondent stated that ''some still go behind the REC and do research without approval.'' One participant said: ''The resistance is from senior professors. They say 'How can a junior faculty member review the protocol that is supervised by a senior professor?''' One REC chair/ designee suggested that if ''all the Egyptian academic journals require approval of REC, there will be no resistance [from faculty members].''

Several participants mentioned issues regarding research carried out by the more senior faculty members to obtain a promotion. For example, one participant stated:

> All protocols for promotion, they never bother to submit them to REC. They say why bother when I can go publish it in any Egyptian [medical] journal. Some investigators desire to submit to international journals and only after they finish the research do they come to REC and cause a problem. They want an approval of the completed research.

Another participant expressed the following:

> I guess [promotional research] should [be reviewed by RECs] more than the theses [MSc and MDs], because these are really not ethical. These researches are the unethical researches not the theses.

To encourage ''senior faculty members'' to submit their promotional research to the REC for review, one REC conducted workshops to raise the awareness of research ethics among the seniors. In another institution, the scientific committee that reviewed promotional research required an ethical approval from the REC and several Egyptian medical journals were mandating ethical clearance before considering promotional research for publication.

CONCERNS WITH BIOLOGICAL SAMPLE RESEARCH—Several respondents were not in favor of the collection and storage of biological samples for future studies. One respondent expressed: ''I am giving you my biological samples for a particular reason. Don't tell me I am going to use it 10 years later for I don't know what.'' Another respondent said:

> [S]torage for five years, many members are against this. And many members we ask the investigators to write explicitly that we are going to discard the biological materials once they get it.

When asked whether the decision for storage of biological samples for future studies should be decided by the research participant, one respondent said the following:

> We thought about that but we thought that our patients are naïve for clinical research and we are not fully convinced that the consent process will be done 100% right so we see as research ethical committee that we have the role to protect the patient if even they accept to store the samples. For example we can allow risky research to be done provided that the patient consents. We put this item the same as approving risky procedures.

Respondents raised several concerns regarding biological sample research. One involved the potential for stigmatization of the Egyptian population. One respondent stated the following:

> We just write [in the informed consent] that they [researchers] won't stigmatize the Egyptian population. We just write that they won't stigmatize the Egyptian population if something will appear during publications.

Another respondent indicated that the REC should review results before publication to ensure that stigmatization of Egyptians will not occur. Another stated that restricted approval would be given to protocols if there were concerns that ''the research might lead to stigma to the community or the Egyptian population.''

Three respondents did not express major concerns with the potential for stigmatization; for example:

> What is the stigma? We are talking about facts. We must get awareness about this. We are doing research for the benefit of human subjects. So try to assure the people it is not a scandal it is a fact. You must. When I compare, I got comparison for example between breast cancer. I am doing some research dealing to find out some genes that they are involved in carcinogenesis and I got comparison between

samples between UK and Egypt what is the stigma here you are comparing biological differences. Many things environmental, it will help you know the predisposing factors, the genetic difference and I do not know what the stigma is. We are known in the whole world we have hepatitis C, what is the stigma this is a fact. We have to face.

Exportation of biological samples proved to be controversial, as nine RECs said that such transfer out of Egypt required national security clearance, which may take 3–6 months to obtain. Three respondents refused to answer the question regarding biological sample transfer to foreign countries, claiming they don't know or ''it's a political issue.'' Two respondents said that the REC would require a justification for sending the samples abroad; for example, the technology is not available in Egypt. Others (2/13) simply prohibited the transfer of biological samples from their institutions to a foreign country. Reasons given for such prohibition included:

> I want everything to be done in Egypt and we raise the technical skills of people working in Egypt and technology transfer should be done in every project [from the West to Egypt] but [if] everything is going to be transferred abroad no technical support can be done here and no technology transfer [to Egypt].

Several RECs linked the transfer of biological samples with the possibility of biological warfare. Other issues regarding sample research included identifying the organization which would be in charge of the samples and the site of storage, so that research participants could request withdrawal of their samples in the future.

Discussion of Themes

This study contributes further insights to issues previously investigated regarding challenges faced by RECs in developing countries and also adds perspectives on other issues and challenges confronted by these RECs. Among previous known issues, the REC chairs (or their designees) provided further insights regarding their membership composition. For example, inadequacy of gender representation was explained to be due to underrepresentation of women on the faculty, especially in surgery. One reason that may account for unequal gender representation on the faculty is lower literacy rates among women in the developing world, and hence, a lack of competent professional women available in the university setting. Another factor affecting women faculty representation includes the cultural belief that a woman's role is primarily as a mother and a wife in a male-dominated society.

Several studies have demonstrated inadequate gender representation on RECs in European countries and in several developing world regions (Moerman et al., 2007; Moodley & Myer, 2007; Nyika et al., 2009). Commentators have suggested that adequate representation of women on RECs could enhance sensitivity to the issue of equitable representation of men and women in research (Moerman et al., 2007).

Research ethics guidelines do not mention or are not explicit regarding gender representation on RECs. For example, the European Union directives of 2001 and 2004 do not contain provisions for gender representation in RECs nor do the national regulations of EU member states (Druml et al., 2009; Moerman et al., 2007). The U.S. Code of Federal Regulations mention that IRB membership requires gender representation only to the extent that ''no IRB consists entirely of men or entirely of women'' (45 C.F.R. 46.107, rev. June 18, 1991). Several of the international guidelines merely recommend adequate gender representation (Council for International Organizations of Medical Sciences [CIOMS], 2002; World Health Organization [WHO], 2000).

Several RECs voiced concerns with a previously undocumented issue involving overrepresentation of senior professors on the RECs. This occurrence is not surprising considering the hierarchical nature of academia in Egypt. Egyptian commentators have stated that ''in Egyptian society, decision making is commonly delegated to the most powerful figure in the context within which the decision is being made'' (Rashad, Phipps, & Haith-Cooper, 2004, p. 396). Accordingly, it is commonly accepted to have mostly senior members on committees, since they are regarded as the most powerful and, therefore, are considered the best fit to make decisions. Further studies into committee dynamics could clarify the interactions between the senior and junior staff on committees.

RECs also commented on the inadequacy of community representation, which was largely due to difficulties with retaining the services of lay indivduals. Other studies have shown underrepresentation of community members in the developing world (Moodley & Myer, 2007; Nyika et al., 2009). An imbalance in membership in favor of institutional members over that of the community would bias the review process toward the interests of researchers rather than the interests of research participants (Schuppli & Fraser, 2007). Indeed, members from the community might be more knowledgeable and sensitive to the concerns of those who participate in clinical research. Also, an REC that has a membership consisting predominantly of affiliated scientists/clinicians might prevent an objective discussion of the protocol being reviewed, as lay members might feel intimidated by the power hierarchy that exists between themselves and scientists/clinicians (ibid.).

Many research ethics guidelines recommend community membership. For example, the Department of Health in South Africa issued national guidelines requiring RECs to be ''representative of the communities they serve and increasingly reflect the demographic profile of the population of South Africa … [and that there must be] at least two lay persons with no affiliations with the institution, not currently involved in medical, scientific or legal work'' (Moodley & Myer, 2007). The National Bioethics Advisory Commission in the United States recommends that nonscientists make up at least 25% of an REC membership (National Bioethics Advisory Commission [NBAC], 2001). The UK requires one-third community members on RECs and Sweden requires an equal number of scientists and community members (Schuppli & Fraser, 2007; UK Health Departments, 2011).

Respondents brought up the issue involving compensating REC members, many of whom are underpaid from their faculty position, and hence, time spent on reviewing protocols impedes them from pursuing other income-producing jobs from outside of the university. In Egypt, it is estimated that 71% of physicians working in urban areas have a second job, while 15% of them have a third job (Ferrinho et al., 2004). Accordingly, membership commitment and performance may be affected if not properly compensated.

Many participants also voiced concerns with the lack of ethics training of REC members, as well as that of investigators. Several studies revealed inadequate training of REC members in African countries, including Egypt and South Africa, and Iran (Abou-Zeid, 2010; Kirigia, Wambebe, & Baba-Moussa, 2005; Larijani et al., 2006; Moodley & Myer, 2007) . The inadequate training of REC members could compromise the efficiency, independence, and integrity of RECs.

There are several explanations for the lack of training. First, there is inadequate capacity to teach research ethics in the developing world. Second, regulations, if they do exist, do not mandate that such training is a requirement for REC members. Finally, as related by our study sample, many senior REC members resist efforts at training. To enhance ethics capacity, several organizations have established training programs for developing world

academicians. These include efforts by UNESCO (UNESCO 2012) and the Fogarty International Center of the National Institutes of Health (Fogarty International Center 2012).

A concern with ethics training involves the exportation of Western bioethics to the developing world, which has been viewed as another type of imperialism. For example, it has been argued that the principles of research ethics that originate from Western moral philosophy emphasize individuality and autonomous decision making and fail to acknowledge the web of relationships and the role of the family in decision making (Benatar, 2004). But, the host countries frequently adopt and adapt to Western ethical guidelines that are not customized to the local context (Oguz, 2003; Rashad et al., 2004). Commentators have described at length the importance of considering the local customs and culture in evaluating research and the insensitivity of only applying Western-based research ethics values (Benatar & Singer, 2000; Benatar, 2004; Rashad et al., 2004; Shapiro & Meslin, 2001). In a study of researchers' attitudes and beliefs toward U.S. regulations for the protection of human subjects in research, 83% of the respondents believed the regulations were insensitive to the local culture and traditions ''sometimes'' or ''always,'' and 37% of researchers indicated that U.S. regulations were ''never'' flexible when they needed to be (Hyder et al., 2004). Better communication among sponsors, training organizations, local health professionals, investigators, and REC members are needed to address the best ways to deliver customized research ethics training that respects local culture and traditions.

Our interview study also elicited concerns with the inadequacies of human and capital resources, which has been demonstrated in previous studies investigating RECs in the developing world (Moodley & Myer, 2007; Sleem, El-Kamary, & Silverman, 2010). Scarcity of capital resources included the unavailability of assigned rooms and the lack of equipment, such as computers and photocopy machines. These shortages hamper REC operations and directly affect their long-term sustainability due to members' frustrations. To address such shortages, there is a need for institutional commitment.

Many RECs had several concerns with informed consent. These included the length and highly technical language of the ICF, and the process by which informed consent is obtained. Many respondents voiced skepticism that investigators would explain all of the significant details in the ICFs to potential participants. Requiring the signature of research participants on the ICF was also a challenge, because many potential research participants would harbor distrust when asked to sign a document they cannot read. Our study further adds to what has been discussed regarding informed consent in the developing world (Rashad et al., 2004; Shapiro & Meslin, 2001; Tindana, Kass, & Akweongo, 2006). RECs should ensure that ICF forms are comprehensible and as short as possible to avoid intimidating potential research participants from enrolling in research. In addition, RECs should consider alternative means of obtaining consent, such as pictures and the use of local dialect to aid comprehension. RECs should also propose different ways to indicate consent other than signing an ICF, such as verbal consent or voice recording (Shapiro & Meslin, 2001; Tindana et al., 2006). To ensure the compliance of investigators, REC should monitor the process itself and confirm that investigators take the time to explain the research purpose, methods, and risks/benefits.

Another issue not previously explored included issues involving biological sample research. A major concern was the potential for stigmatizing Egyptian society through the collection of biological samples for future unspecified genetic research, which many respondents thought should not be done. Also, many respondents revealed that the Egyptian government needs to approve the transfer of biological samples to foreign countries, as such research might represent a security risk. Such approval can take 4–6 months to obtain. Judging from

the responses of the respondents, this topic is sensitive and several interviewees were reluctant to openly discuss it.

A previous survey study explored the attitudes of stakeholders in several developing regions toward biological tissue transfer (Zhang, 2010). Generally, these stakeholders strongly agreed that biological samples should be kept in the home countries, for use by local scientists engaged in current/future research, and allowing local scientists to make decisions regarding the management of samples, including veto power for future sample usage. It is worth noting that in this study by Zhang and associates, the strongest positions were held by Egyptian respondents ($> 80\%$). Finally, a survey was performed that investigated the attitudes of Egyptian patients toward the collection and storage of biological samples for future research (Abou-Zeid, 2010). In this study, 82% and 69% of the 600 surveyed participants agreed to volunteer for blood and solid tissue research, respectively. Approximately half of the participants indicated that consent forms should contain a provision to collect blood for future research, but almost half of these participants believed that such research should be restricted to the disease initially studied. Almost 66% were agreeable to the use of their samples for future genetic research and 82% wanted government approval for transferring the samples abroad. Exportation of biological samples to an Arab country was favored by 62% of respondents, whereas a smaller percentage were in favor of exporting samples to a European country and to the United States–42% and 37%, respectively.

Another previously undocumented issue involved the oversight by the national government of research in academic institutions. Specifically, the Central Agency for Public Mobilization and Statistics (CAPMAS) mandates: ''No entity in the government, public or private sector, shall be allowed to conduct any surveys except after obtaining a written decision from the CAPMAS'' (Arab Republic of Egypt, 2012). This organization issues a decision on research topics and methods, as well as the dates and manner of publishing results. Inevitably, such measures might lead to self-censorship by investigators themselves.

We acknowledge several limitations of our study. First, when carrying out the interviews online, the Internet connection was not always optimal during the interviews and several sessions had to be rescheduled. Such interruptions might have prevented the free flow of ideas. Also, many interviewees were not comfortable using the Internet conferencing software. Judging by the length of the interviews, those conducted face-to-face were longer than online ones, as face-to-face participants were more willing to elaborate and share their experience. Another limitation regards the willingness of our participants to be transparent on certain issues. For example, several were reluctant to speak openly about a ''political'' issue or be in a position that might be interpreted as being critical to a superior authority. Finally, it was problematic to reach several interviewees for follow-up questions, because of their busy schedules and the political unrest that was occurring in the country during the time of the study (i.e., the Egyptian Revolution).

Best Practices

This study uncovered several issues related to the practices of RECs in Egypt that are most likely generalizable to RECs in countries in similar stages of ethics review capacity and with similar academic cultures. Accordingly, we recommend open discussion of these issues that might lead to enhanced functioning of the RECs. Among the issues was inadequate gender and community representation on the RECs and what steps could be taken to address this concern. Another important issue regards the power hierarchy that exists between senior and junior members of the RECs. As such, the junior staff, who are probably most vocal about human rights and who are probably receiving enhanced training in research ethics, need to

have a larger voice at the REC meetings. Methods of compensating REC members need to be addressed, as this issue gains significance in an environment where faculty salaries are not equivalent to those in Western academic centers. Finally, several respondents mentioned concerns with the conduct of the informed consent process and several recommended efforts to monitor this process.

Research Agenda

Several issues uncovered in this study warrant further investigation, such as exploring the dynamics of REC meetings. Another area of focus would be to further elucidate the concerns regarding exportation of biological samples and the oversight of research by the government. Additionally, the perspectives regarding the exportation of Western philosophy should be obtained from developing country trainees who are enrolled in ethics programs developed by Western bioethicists. Finally, interviews of RECs should be conducted in other developing countries to confirm the generalizability of our results.

Educational Implications

Several of the issues explored in this study should be the focus of educational efforts. First and foremost, additional methods of REC training should be explored and could include online learning, so that a broader audience can be reached. Online learning can also serve to be a source of continuing education for REC members. Such educational efforts should include interactive components (e.g., learner-learner and learner-instructor) that are lacking in several existing self-paced online training programs in research ethics. In addition to the core concepts traditionally taught in research ethics programs, other topics should be added, such as (a) ethics of international collaborative research between developing and developed countries; (b) ethics of payments to research participants; (c) ethics of biological sample research; (d) ethics of genetic research; and (e) methods of monitoring on-site research studies.

Acknowledgments

Biographies

Amal Matar received her master's degree in the Department of Biotechnology at American University in Cairo. The research in this manuscript contributed to her thesis for the MSc degree. She graduated from Ain Shams Medical School in Cairo and worked for the Ministry of Health and Population in Egypt for seven years. She is presently serving as the academic coordinator for the Middle East Research Ethics Training Initiative (MER-ETI), which is sponsored by the Fogarty International Center at the National Institutes of Health. She generated the idea for this study, helped design the study, performed and analyzed the interviews, and contributed to the writing of the manuscript.

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TABLE 1

Characteristics of Research Ethics Committees (n=13).

Characteristic	Number
Type of REC staff interviewed	
Chair	6
Co-Chair	2
Moderators	5
Type of Research Ethics Committee	
Research Institutes	4
University	
Medical School	6
Humanities and Social Science	1
Dental School	1
Medical Department	1
Geographical Region	
Urban (Cairo and Giza)	9
Delta (Lower Egypt)	2
Rural (Upper Egypt)	2
Duration of Existence of RECs	
Less than 2 years	4
2–5 years	6
More than 5 years	3
Number of Members on REC	
From 5 to 9 members	5
From 10 to 14 members	4
More than 14 members	4
Female/Total Member Ratio in RECs	
Less than 0.40	6
Greater than 0.40	6
Decision-making Process	
Consensus	8
Majority vote	4
Both methods	1
Reviewer System	
Primary	2
Secondary	1
Both	7
Frequency of Meetings	
At least once/month	13
Less than once/month	0
Average number of protocols reviewed per meeting	
Less than 5/meeting	7

Characteristic	Number
From 5–20/meeting	1
Greater than 20/meeting	3

TABLE 2

List of Themes and Associated Subthemes.

Major Themes	Subthemes
Previously Known Themes (New Subthemes)*	
REC membership	• Inadequate gender representation
	• Over-representation of senior vs. junior staff*
	• Difficulty with maintaining community representative on REC*
	• Difficulty in compensating REC members*
Training needs of REC members	• Obstacles to training of REC members
	• Insufficient continuous training for REC members
Availability of human and capital resources	• Lack of capital resources for REC
	• Lack of administrative help
	• Negligent record keeping of REC process
Role of national government	• Lack of national regulations
	• Inadequate funding for research
Issues with informed consent	• Difficult language of the informed consent
	• Length of the informed consent form
	• High illiteracy rate of research participants leading to poor understanding of the informed consent
	• Inadequate monitoring of the informed consent process
	• Lack of consensus regarding the age of adulthood (18 vs. 21 years)*
New Themes That Emerged From the Interviews	
Government censorship of research	
Investigator-related issues	• Poor methodologies
	• Not trusting investigators to conduct research as stated in the protocol
	• Promotional research (faculty research to get promoted)
	• Requiring investigators to submit their protocols to RECs
Concerns with biological sample research	• Fear of stigmatization of Egyptian population
	• Need for security clearance for samples to be sent overseas
	• Fears associated with genetic analysis studies of Egyptian population
	• Distrust of foreign collaborators