**Research Ethics Committees in Lebanon: Current Status and Challenges**

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Abstract

Conduct of research ethics is a critical issue in the scientific community. In order to assure that the research specially the clinical trials, research ethics committees or institutional research boards were structured within most of the research-related organizations. The aim of the current study was to survey the ministry of health approved research ethics committees in Lebanon with the purpose to identify their current structure, processing and functionality. In addition, to address the limitations and constrains facing the committees. A survey-based study was conducted to indentify committees’ membership requirements, level of ethics knowledge, workload, and perceived challenges. Descriptive statistical analysis was performed to assess the obtained data.

In Lebanon, Ministry of Health accredited eighteen research ethics committees; most of them are related to the universities and hospitals. The percentile of respondent was 61.11% as eleven committees participated. The participating committees have standard operating procedures. The physicians were the most frequent member-background with the eleven committees while philosopher wasn’t presented. Mainly the committees held their meetings on monthly base. Almost eighty percent of the committee’s members had knowledge or formal training on conduct of research ethics. Moreover, physical resources such as meeting room and computers, practically, the committees use their organizations ones with a working budget. Regarding, the various challenges facing the committees to process their duties efficiently, the limitation of the national research ethics standards and lack of ethics experts, the lack of approved research proposal oversight, deficiency of research ethics experts and inadequate training on conduct of research ethics. The study results recommend to standardized the requirements of research ethic committees membership, allocate a private budget, develop a well-structures national research ethics guidelines, and empowering the committees with conduct of research ethics experts.

**Keywords:** Conduct of Research Ethics, Ethics, Institution Research Board, Lebanon, Research Committees.

**Introduction**

Animals and human recruitment as research subjects are progressing worldwide specially during preclinical and clinical studies which are carried out in the third world countries and middle east (1), particularly in Lebanon, the number of studies involved animals and humans is increasing either through the scientific research or clinical trials that are carried out in research labs or medical centres and pharmaceutical companies sported studies, respectively (2), along with the widespread awareness of research ethics issues and faults, necessitated the establishment of institutional research ethics capacity primarily functional review board and research ethical committees. Consequently, the need of ethical guidelines was evoked (3).

Historically, ethical guidelines didn’t crystallized in their current known form till the end of World War II. Prior to that, code of William Beaumont, issued in 1833, represents the oldest American document dealing with the ethics (4) Although, Nuremberg Code (1947), is the actual trial to create a national ethical codes concerned with research on human (5). This was followed by the Declaration of Helsinki (adopted, 1964; latest amendment, 2008), established by the World Medical Association (WMA), which created international regulations governing many countries (6). There are other international guidelines that were progressively established exemplified by International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982; revised, 2002) (7), prepared by the Council for International Organizations of Medical Sciences (CIOMS) and WHO, and the Guidelines for Good Clinical Practice by the ICH (8). On the other hand, till the moment, most of Middle East countries apparently adopted many of these guidelines but actual operation reflects weaker strict ethical guidelines specifically during clinical trials compared to European and North American (9).

As a response for such circumferences, National Council for Scientific Research (NCSR) developed the ‘Charter of Ethics and Guiding Principles of Scientific Research in July 2016 (10), which suffers from many limitations the main of it is that the ethical protection of clinical trials participants is only two legal protections (11), which is the lowest among the Arab world as Qatari ethical guideline has 19 protections rights and Saudi requirement guidelines has 15 protections rights (12). Moreover, The extent of adherence Lebanese research committees to the ‘Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants’, which were developed by the WHO in 2011 is still questionable and didn’t precisely determined (13).

Obviously, the growth of both is not balanced as not only the number of institutional review board (IRBs) or research ethics committees (RECs) but their proper guidelines, regulations and performance are far behind the appropriate required level (14). Currently, the implementation of REC in the Middle East is increasing but there are limited information regarding their minimal requirements, members’ backgrounds, resources, and adherence to the international guidelines and respectively the quality of their decisions (15). There are some studies concerned with the characteristics and functionality of research ethics committees in Africa and more recently in Egypt (16, 17).

Identification of the present structure, capacity, international guidelines adherence and standard procedures within the existing RECs is critical on several levels starting from self-correction and improvement through modification of their regulations till guidance of the health policy makers to development a national guideline and address the constrains challenging the RECs. Moreover, to design a strategic plan targeting the performance of local RECs to be equivalent to their international committees in Europe and North America.

Therefore, a survey-based study was carried out aiming at distinguishing the characteristics, the requirements for its membership and procedures of formally approved research ethics committees in Lebanon that haven’t been systematically studied before. In addition, the current status of the established RECs and the limitations and constrains facing and limiting their proper role and functionality will be addressed.

**Methods**

Study Design

A cross-sectional quantitative and descriptive survey-based study,

Research tool

A questioner-based survey was adopted from a previous published study evaluating the resources and needs of research ethics committees in Egypt [12]. The survey tool was categorized into different sections with the aim to gather information about; characteristics of the REC, membership, previous knowledge and training on ethics, tasks, standard procedures within the committee, and resources additionally, the challenges facing the committee to perform its role efficiently.

Participants

Chairs of ministry of health approved research ethics committees in Lebanon.

Recruitment and Distribution Process

The formally approved research ethics committees in Lebanon were recognized through the formal list provided by the ministry of health (MOH). The questionnaire was transcribed online using Google form® (Google. USA), and assessed for feasibility prior being sent to the committees chiefs. Afterwards, an email was sent separately to each chair of all accredited RECs inviting them to fill the questionnaire. The surveys were sent as a link to their emails, which illustrate the aim of the study and the informed consent. The electronic version of the survey assures anonymity of the participants. The emails were sent between late of April 2019 and early of August 2019. Follow-up telephone calls were made to the chairmen to ensure they had received the survey electronically. A pilot study was carried out in order to evaluate the research tool validity (two participants). Based on their comments, the questionnaire was modified.

Statistical Analysis

Qualitative data was statistically analyzed using SSPS.

Ethical Considerations

Informed Consent

The email contained an introduction about the study in addition; a cover letter illustrated the purpose, risks, benefits, confidentiality, and voluntary nature of the study was sent along with the survey to each participant.

Confidentiality

Anonymity and confidentiality were assured to enhance accurate reporting by the participants. Confidentiality was doubtless through the use of electronic surveys. The participants were informed that the aggregated data would be solely use for scientific publication and policy makers will receive a copy of it.

Ethics Review

The study protocol and design was examined by Institutional Review Board (IRB) at Beirut Arab University, Lebanon and according to the regulations, the current study was exempted from ethical approval.

**Results**

The survey was sent to the eighteen approved RECs in Lebanon and the percentage of response was 61.12% (11/18) of legally approved committees.

General Characteristics

The general features of Lebanese research ethics committees are shown in table I. Concerning the type of researches that are reviewed by the RECs, the responded committees are involved in the ethical review of observational studies with variable responses regarding the other types of studies specifically, master and doctoral thesis (80-90%), clinical trials (90.9%) while the least reviewed study was grants where only 36.4% of committees involved. All the participated committees reveled the existence of both standard operating procedures (SOPs) and management of conflicts of interest policies. Moreover, most of the committees (10/11) developed a well define system for complains while only four of them used a hotline receive such complains.

Highlighting the committees view towards the appropriateness of a list of international ethical guidelines to be used as an ethical guide within the committee, both Council of the International Organizations of the Medical Sciences (CIOMS) and Declaration of Helsinki were marked as 'very appropriate' resource by 90.9% of the committees while Belmont Report was considered as "very appropriate" guideline by only seven committees (Table I).

Most of RECs reported their decisions to a top official personal/body the president, vice-president, secretary general, faculty council, or the hospital administration (9/11). Only a committee reported to the Department Head and another one reported solely to the faculty dean and a committee reported to both the top officials and the dean. None of the committees communicates its decision to the research only but four committees reported to both the researcher and the top officials and

Table I: General features of Research Ethics Committees

|  |  |
| --- | --- |
| Type of researches that are reviewed | Percentage (Frequency) |
| Master's thesis | 90.9 (10/11) |
| PhD thesis | 81.1 (9/11) |
| Pharmaceutical clinical trials | 90.9 (10/11) |
| Research proposal | 90.9 (10/11) |
| Grants | 36.4 (4/11) |
| Interventional -investigator initiated study | 72.2 (8/11) |
| Observational study | 100 (11/11) |
| Existence | |
| Standard Operating Procedures for the applications and committee | 100 (11/11) |
| Policies to manage conflicts of interest | 100 (11/11) |
| System enables the participants to complain | 90.9 (10/11) |
| A ‘hot line’ to received participants’ complaints | 36.4 (4/11) |
| Research ethics guidelines rated as 'very appropriate' | |
| Council of the International Organizations of the Medical Sciences (CIOMS) | 90.9 (10/11) |
| Declaration of Helsinki | 90.9 (10/11) |
| UNESCO guideline | 72.2 (8/11) |
| Belmont Report | 63.6 (7/11) |

RECs Membership

The number of members of the studied RECs ranged between 6-15 personal (median=12, SD= 2.41) with an average of 10.36 members. The institutional research boards or RECs had a minimal of six members (Tablet II). Members are of varied backgrounds but all the committees shared the characteristic of its structure included a medical doctor (one of the committees had two), legal expert/attorney and community member. Members with scientific and medical backgrounds represented 31.2% of the membership exemplary, 6.4% of the members from all of the RECs were pharmacists, 5.6% were non-affiliated doctors, and 4.6% were nurses. Social workers as members are represented in nine of the studied committees even in the smallest one. Other members were not of scientific, medical or legal background such as ethicist (6/11) and religious leader (4/11). Only in one committee journalist was a member while none of the studied RECs had a philosopher within its structure (Table II). Moreover, a committee reported the presence of psychologist and dentist as members.

Table II: Research Ethics Committees with at least one of the listed profession

|  |  |
| --- | --- |
| Membership category | Percentage of the RECs (Number) |
| Medical Doctor | 100 (11/11) |
| Pharmacist | 72.2 (8/11) |
| Non-affiliated Doctor | 63.6 (7/11) |
| Scientist | 63.6 (7/11) |
| Nurse | 54.4 (6/11) |
| Legal Expert/attorney | 100 (11/11) |
| Journalist | 9 (1/11) |
| Ethicist | 54.4 (6/11) |
| Philosopher | Zero (0/11) |
| Religious Leader | 36.4 (4/11) |
| Administrator | 90.9 (10/11) |
| Community Member | 100 (11/11) |
| Social worker | 81.1 (9/11) |

Committee Load

The periodicity of RECs meeting was varied between once per month to once per two months, where five reported a monthly meeting, and three reported a meeting every two months, and surprisingly, 27.3% claimed that there’s no periodical scheduled meeting for the committee (Figure I). The average duration of the RECs meetings was 1.81 hour (median: 2 hours; range 0.5-5) with most of the committees meeting time is 1-3 hours as illustrated in figure I. Number of protocols reviewed by RECs ranged between 2-20 per meeting (average of 6.72 protocols) and an average of 73.9 protocols per year (range 4-250). Eight committees reported reviewing 5 or less protocols/meeting while three RECs revealed that they revise more than 100 protocol/year. Continuing reviews and expedited reviews were carried out through all the responded RECs except one committee.

|  |  |
| --- | --- |
| The committee meeting.png | The average duration of committee meeting.png |

Figure 1: Number of protocol reviewed by RECs per meeting and its duration

Proposal Review Process

Upon examining the collecting data from the respondent RECs seven committees only required the investigators to its submit protocols using its own standardized form. All the committees had a primary review system for the submitted protocols despite that, only nine of them (81.1%) tired to match proposal subject matter to primary reviewers’ expertise (Table III). Considering the adoption of the committee for a system, which enables the chair or an authorized person to approve protocols by an expedited review process, ten out of the eleven committees reported that. The notification of the committee decision in a written form is performed by all the participated RECs but only 81.1% stated the expiration date in its approval letter. Ten committees necessitated the use of their approved informed consent form. In addition a copy of REC-approved consent form was attached to the approval letter in 63.6% of the committees but only two of these seven committees attach a stamped copy with the expiration date as shown in table III. As portrayed in figure 2, the written decision letter was reported to be delivered within 2-5 days in four committees, 2-10 days in five committees, 2-20 days in one committee and it required more than 20 days for one REC. The time frame within which the RECs members have to review materials prior to meeting is between 3 and more than 15 days specifically three committees (27.3%) assigned 3-7 days while two committees assigned more than 15 days (18.2%) as illustrated in figure 2.

Table III: Ethics Review Committee process

|  |  |
| --- | --- |
| Review Process | Percentage (Frequency) |
| Investigators are required to submit protocol using an REC submission form | 63.6 (7/11) |
| A primary review system is used to review protocols | 100 (11/11) |
| Attempt to match subject matter of protocol to primary reviewer's expertise | 81.1 (9/11) |
| A system is in place whereby the chair or an authorized person is able to approve protocols by an expedited review process | 90.9 (10/11) |
| REC notifies investigators in writing of its decision | 100 (11/11) |
| Contents of Approval Letter |  |
| For studies approved for 1 year, approval letter states expiration date | 81.1 (9/11) |
| Requirement to use the REC-approved informed consent form | 90.9 (10/11) |
| Copy of REC-approved consent form is attached to the approval letter | 63.6 (7/11) |
| Attached REC-approved consent form is stamped with expiration date | 18.18 (2/11) |

|  |  |
| --- | --- |
| Count of 10. The average time interval between meeting and written notification to investigators_ (1).png | Count of 9. Number of working days that REC members have to review materials prior to meeting_.png |

Figure 2: Average time interval between meeting and written notification to investigators and the number of working days that REC members have to review materials prior to meeting and

Committee capability and ethical background

The committee self-reflection on its own ability to review international protocols was graded from limited to excellent where more than half of the participated committees reported good level (7/11), two committees indicated their abilities by being moderate while two committees assigned excellent ability for themselves (18.1%).

Concerning the prior ethics training, almost all the committees except one revealed that their chair person received such training while the percentage of their members were varied as at least 25%, 50%, 75% and 100% were trained in four, two, two and three committees, respectively but none of committees members received no previous training. The nature of the received training, none of the committees’ chief received a degree in ethics, but they have either courses or workshops or NIH training or sometimes combination of these (figure 3)

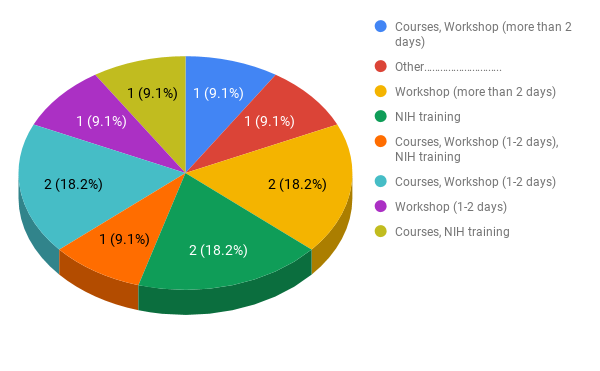


Figure 3: The nature of the prior research ethics training for the committee chair

The rating of the respondent RECs to the significance of some training topics is shown in table IV. At least 60% of the RECs rated the following topics to be "very important'; use of placebo controlled trials, determination of methods to reduce risk, determination of risks in research, assessment of benefits to participants and society, monitoring and oversight of approved studies, scientific design issues in clinical trials, assessment of understanding of informed consent, determination of appropriate subject selection in vulnerable populations, and privacy and confidentiality. Obviously, none of the training topics were thoughtful to be “not so important” by more than two committees namely; the access to benefits after the trial is over, the determination of appropriate subject selection in vulnerable populations, and privacy and confidentiality (one committee) and social and behavioural studies (two committees).

Table IV: Training topics rated as being "Very important" or "Not so important"

|  |  |  |
| --- | --- | --- |
| Topic | Very important | Not so important |
| The use of placebo controlled trials | 63.6 (7/11) | - |
| Determination of methods to reduce risk | 90.9 (10/11) | - |
| The interpretation of pre-clinical studies | 45.45 (5/11) | - |
| Determination of risks in research | 90.9 (10/11) | - |
| Assessment of benefits to participants and society | 81.1 (9/11) | - |
| Scientific design issues in clinical trials | 63.6 (7/11) | - |
| Monitoring and oversight of approved studies | 72.2 (8/11) | - |
| Assessment of cultural sensitivity for informed consent | 63.6 (7/11) | - |
| Assessment of understanding of informed consent | 63.6 (7/11) | - |
| Access to benefits after the trial is over | 45.45 (5/11) | 9 (1/11) |
| Determination of appropriate subject selection in vulnerable populations | 63.6 (7/11) | 9 (1/11) |
| Community participation | 45.45 (5/11) | 9 (1/11) |
| Social and behavioural studies | 45.45 (5/11) | 18.18 (2/11) |
| Privacy and confidentiality | 90.9 (10/11) | 9 (1/11) |

Feasibility of committee resources

Financially, more than half of the RECs reported having allocated budget (54.54%), while only three committees highlighted their members receive a financial compensation for their activities. Concerning the administrative work, only one committee office hadn’t a secretarial support and in 72.2 % of the committees, the chair performed the administrative duties. Regarding the materialistically tools of the committee, eight committees mentioned that there’s a dedicated office space for the committee while nine committees had access to use the computers but only six committees utilized an computerized data base to trace protocols. Additionally, in most of the committees (10/11), work is based on the institution shared resources.

Difficulties facing Research Ethics Committees

Challenges and constrains facing the proper functionality of RECs in Lebanon are depicted in table V. The most frequent reported challenge was that related to the development of appropriate national ethics guidelines (72.2%). Other frequent limitations were the inadequate ability to monitor the approved protocols, the lack of ongoing training for members in research ethics, and the lack of coordination between different committees. About 45.45% of the committees considered the following issues as challenges; lack of national accreditation mechanism for ethics committees, lack of national standards for operation of committees, variable use of ethical guidelines across committees in Lebanon, and difficulties adapting international guidelines to local conditions. The least reported challenge was the one related to the competence of members to review research protocols (36.36%). Moreover, a committee mentioned that lack of laws and guidelines concerned with application of genetics and biobanks and another committee was worry about the mechanism that ensuring the compliance to approved research studies.

Table V: Challenges and constrains facing the proper functionality of Research Ethics Committees

|  |  |
| --- | --- |
| Challenge | Percentage (Frequency) |
| The need to develop appropriate national ethics guidelines | 72.2 (8/11) |
| Inadequate ability to monitor approved protocols | 54.54 (6/11) |
| Lack of ongoing training for members in research ethics | 54.54 (6/11) |
| Lack of national accreditation mechanism for ethics committees | 45.45 (5/11) |
| Lack of national standards for operation of committees | 45.45 (5/11) |
| Competence of members to review research protocols | 36.36 (4/11) |
| Variable use of ethical guidelines across committees in Lebanon | 45.45 (5/11) |
| Lack of coordination between different committee | 54.54 (6/11) |
| Difficulties adapting international guidelines to local conditions | 45.45 (5/11) |

**Discussion**

Research ethics committees are being widely involved in research governance with the aim to maintain research subjects rights and welfare. Exploring the mechanism, the structure and the process of RECs is a cornerstone to detect the committees’ pitfalls thus developing solutions and alternatives to preserve research integrity and participants. The duties of RECs involve research proposal review and decision making which is influence by many factors among them; institutes policies and regulations, culture and religions, and values of committee. In addition, committee members’ experience, knowledge and ethical training, and committee dynamics may also affect its decision (18). Thus investigating the current accredited RECs in Lebanon structure, processing, load, resources, and challenges is starting point to improve their performance, which was our goal in the current study.

The results obtained from the analysis of collected data highlighted that the participated committees had the requirements to be efficiently functionalized as an ethical review board according to International Ethical Guidelines for Biomedical Research Involving Human Subjects (7) and ICH Good Clinical Practice by European Medicines Agency (19). As all the responded committees had a well-established standard operational process, conflict of interest handling policies, system for compliment and ultimate structure. In addition, the committees mostly reporting to high authorities and none of them reported directly and solely to the research which strengthen their legitimacy. Moreover, most of them followed various international guidelines (8-10 committees) namely; Council of the International Organizations of the Medical Sciences, Declaration of Helsinki, and UNESCO guideline with Belmont Report being the lowest to be noted as important reference guideline which is an analogous to reported in a study about international guidelines in Africa (16). Similar result was highlighted by Sleem *et al.* where only one committee of 12 committees denoted Belmont Report as a very appropriate guideline (17). Concerning the periodicity of committees meetings, most of them revealed a meeting a least per two months with a mean duration of 1.8 hours which is sufficient to review the average number of studies (6.7) unlike a study carried out in Egypt where a 2 hours meeting considered appropriate to examine 3.8 proposal (17). This difference may be due the difference in the nature of the proposals, number of committees’ members and their backgrounds. The average number of proposal revised per years was 73.9 that was less than that reported in Chenneville *et al.* study where REC reviewed 110-120 proposals per year and this can explained on the difference of average duration of the meeting which was 2-3 hours (20).

Lebanese RECs incorporated the international agencies proposal review processing as a reference specifically the submission process using a unified form, implementation of primary review system, matching the proposal subject to primary reviewers’ expertise, the adoption of expedited review process, written notification of the committee decision within specific short period of time, and provide sufficient time for the RECs members have to review materials prior to meeting (7, 13, 19). Almost all the committees’ chiefs had a ethical background in various forms and more than 63% of the committees, 50% of their members received ethics training. These values are greater than previously reported in Africa but less than that of Egypt (16, 17). This discrepancy can be seen from different views mainly the history of RECs in Egypt and the level of ethical education and training in Africa.

The data collected demonstrated the current structure of RECs in Lebanon justified the structure requirements in terms of members number and diversity of background and expertise. Regarding the contribution of member with medical and scientific backgrounds precisely physicians, pharmacists, nurses, and scientists didn’t exceed 31.2% which is even less than reported in a USA study (21) where in percentage of physicians, scientists and pharmacists was 46%. This difference may be a result of smaller number of committees (11 out of 18) while in their study was 87 out of 89. On the other hand, in developing countries, the percentage of medical and scientific members was higher than that reported I the current study for example 61% in South Africa (22) and 88% in Egypt (17). The observed difference can be due to the existence of a Lebanese national guideline prepared by ministry of health showed the minimal membership diversity for the committee to be approved. The community member is an essential pillar in structure of RECs in our case, in Lebanon, the studied committees had a community member and nine of them also had a social worker. That goes in parallel with the recommendation of The National Bioethics Advisory Commission in the United States. The significance of diversity is essential for adequate accurate multifaceted reviewing of the applied proposal, professional competence to review proposal of different subjects, cultural and religious considerations, social and personal impact for welfare of the study subjects, minimization of decision bias, and respect and acceptance of committee decision (23). The presence of ethicist was noticed in more than have of the committees, according to Arnason, ethicist is responsible for implementing and updating the ethical code of the committee, address and explain any ethical dilemma rose from a proposal, provide ethical training of the committee members, and contribute to public debate about ethical issues (24). Another astonishing observation was that none the committees had a philosopher as a member. The philosopher within the RECs has the ability to identify philosophical points and the presuppositions and flaws within any argument (25).

Concerning the committee resources, the case in Lebanon is slightly better when compared to South Africa and Egypt (17, 22) where half of the committees had a located budget and nine of them had a dedicated office unlike Egypt where none of the committees had a budget. Despite that better financial situation of the Lebanese committees, still most of the administrative workload is carried out by the committee chair and only small fraction of the committees used an electronic version to trace the applied proposals.

Research ethics committees reported many challenges that limit their ideal functionality. Particularly, the lack of appropriate national ethics guidelines, inadequacy to monitor approved protocols, lack of coordination between different committee and national standards for operation of committees, and the difficulties faced on adapting international guidelines to local Lebanese conditions. Comparable challenges were reported in other Mideast countries and Africa (17, 22). Moreover, the lack of ongoing training for members in research ethics was reported as a constrain with special concern about certain issues such as determination of risks in research and methods to reduce it, assessment of benefits to participants and society, the use of placebo controlled trials and the assessment of understanding of informed consent. In a study in South Africa, similar training topics were labeled to be important to research ethics committees members (22).

The strength points in the current study are; the study design and recorded rate of response, which allowed to detect the inconsistency and discrepancies between the RECs in Lebanon, and the involvement of RECs chiefs who are well orientated about the membership, organization and structure. On the other side, a major limitation of our study is the use of a self-reporting tool, which may limit the objectivity and accuracy of the responses and induce results bias.

**Conclusion**

The research protocols involving animals and human subjects, which require RECs reviewing an approval, are progressing in number in the developing countries especially in Lebanon. The current study highlighted the structure and processing within Lebanese research ethics committees which can be considered in gereanl acceptable and up to the international standards. The major committees functionality limitations revealed during this study are lack of financial resources and appropriate training of the members. Eventually, the observed gap should be bridged through the cooperation between the institutes that REC belongs to and the Ministry of Public Health to improve the RECs performance to grantee personal and social welfare.

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