



RESEARCH ARTICLE

ASSESSMENT OF READINESS OF TEACHING HOSPITALS IN LEBANON TO IRB AND IMPACT ON PRACTICE AND DOCUMENTATION

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ABSTRACT

Objective: The purpose of study was to identify the current research conduct in several teaching hospitals with an Institutional Review Board (IRB) in Lebanon regarding the application of the international codes and regulations

Methodology: Quantitative and Qualitative methods allowed an in-depth understanding of hospitals' clinical research, level of respect of safety measures, compliance with the international regulations, understanding challenges and future recommendation to improve the IRB system. A non-random sampling was used.

Result: Based on mixed method analyses, it was generally derived that there was a lack of implementation of IRB system in Lebanon with accordance to the international codes and regulations. (17% of IRB committees doesn't have a written waiving criteria nor deception policy, only 33% have an annual training program).

Conclusion: The study noticed the lack of application of international research regulations and protocols, while confirmed by the absence of IRB accreditation system. In addition to that, a weak monitoring system was mentioned in the associated hospitals. The teaching hospitals in general apply the IRB requirements partially, while confirmed by the incompleteness of document system, lack of training regarding IRB, the safety and confidentiality not as required according to ethical principles.

There are inefficient steps that were established by the MoPH. Efforts should be made to address these concerns and how effective IRBs are at protecting human research participants and to achieve a full monitoring process via clinical research conducted in healthcare organizations.

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INTRODUCTION

Research in the health care domain is certainly essential in a way similar to any other domain that needs to develop professionally and stay updated. It is essential for maintaining the public trust and support because in short, health care cannot advance in a scientific fashion without research. However, the actual priority in the research domain is to maintain an ethical standards of conduct. The worldwide concepts of ethical research were initially developed to be aligned with humanitarian standards and regulations. Here forth, the Institutional Review Board IRB is one of the challenging approaches in the health care sector. Research, principally, is an act of experimentation. According to the (Nass, Levit, & Gostin, 2009), research is defined as "a systematic investigation, including research development,

testing and evaluation, designed to develop or contribute to generalizable knowledge" (preface, 45 CFR §46.102 (e)). Based on this broad definition, health research may include biomedical, social, health service research and any type of studies of factors that are related to health. The health research includes biomedical, social, health service research and any type of studies related to factors affecting health. Perhaps the most familiar form of health research is the clinical trial, in which volunteers participate in studies to test the efficacy and safety of new medical or non-medical interventions. The Institutional Review Board IRB is hence considered a key performer or energizer tool to provide integrity and safety to any research, especially in health care organizations. Most historical reviews related to IRBs or research guidelines recognize the Nuremberg Trials (mid 1940s) (Amdur & Bankert, 2011) as its starting point. Rarely has academic research dealt with earlier cases; however, there are several incidents that were obtrusive way earlier than the famous Nuremberg trials.

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In a 1767 medical malpractice action, surgeons attempted to straighten the patient's leg after a fracture by using a device that they had developed and that was not customarily used by physicians of the time. Back then, the court held the surgeons liable for harming the patient, without consent. Thus, Slater defined experimentation as being treatment that is not standardly administered, and he established the requirement of obtaining informed consent to such experimentation. Another case in 1871, commonly known as New York case (*Carpenter v. Blake*) (Greenwald, 1982), the Supreme Court faced the situation of a patient who had been treated unsuccessfully in an unorthodox manner. That case established an approach to biomedical research to be continued until the twentieth century, i.e. reckless experimentalists must not take the place of educated, experienced practitioners.

These two previously mentioned illustrations are only examples of tens of several cases that have happened in the era before World War II, where biomedical research was rarely conducted in other than an informal and unplanned fashion. Organized efforts were rarely undertaken and were characterized by a lack of concern for the well-being or protection of the rights of the subjects of the investigation. Even in the United States, the government had a relatively minor role in regulating research conduct until the late 1950s. There were no federal regulations that required IRB approval to conduct research involving human subjects, and ethical standards for conducting research were not uniformly applied or accepted. However, it is widely recognized that the first internationally recognized code of research ethics was the Nuremberg Code issued in 1947 by the Nazi War Crimes Tribunal before Nazi physicians were tried for research cruelties performed on prisoners of war. The Nuremberg Code was a document that articulated the basic requirements for conducting research in a way that respects the fundamental rights of research subjects (Amdur & Bankert, 2011). According to them, the basic elements of the code are voluntary and informed consent, a favorable risk/benefit analysis, and the right to withdraw without penalty. The above basic elements had been incorporated into most subsequent ethical codes. This code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner (The Belmont Report, 2016).

As biomedical research efforts expanded, the international need for a more specific code of ethics was formulated in the 1964 Declaration of Helsinki. In that year, the World Medical Association met in Helsinki, Finland, to draft the Declaration of Helsinki, a document that would describe the standards of ethical research involving human subjects. Last revised in 2000, the Declaration of Helsinki added the following two key points (Amdur & Bankert, 2011): 1) the interests of the subject should always be given a higher priority than those of society 2) that every subject in clinical research should get the best known treatment. The Declaration of Helsinki was revised in 1975, 1983, 1989, and 1996, and is the basis for good clinical practices used today. In 1978, the National Commission for the Protection of Human issued the Belmont Report, a major milestone in research ethics and research regulation. The Belmont Report laid out three general ethical principles that should govern human subjects' research:

Beneficence: To maximize benefits for science, humanity, and research participants and to avoid or minimize risk or harm.

Respect: To protect the autonomy and privacy rights of participants.

Justice: To ensure the fair distribution among persons and groups of the costs and benefits of research.

In 1981, the Department of Health and Human Services (HHS) codified the Policy for the Protection of Human Subjects (45 CFR 46). Subpart A of these regulations, is also called the "Common Rule," provides for the basic foundation of the Institutional Review Boards IRBs. Henceforth, the well-established concept of IRB came to public. The origins of IRBs are explained through a series of *scandals*. In 1966, a senior member of the Department of Anesthesiology at Harvard Medical School Dr. Beecher described 22 studies that had been conducted by respected investigators and recently published in prestigious medical journals. Beecher's article is a milestone in the history of research ethics. For each of these studies (Beecher, 1966) explained why the study was unethical based on fundamental principles such as lack of informed consent and increased risk to subjects. In Dec.1971, the United State department of Health, Education, and Welfare began to require the creation of IRBs. Later in 1974, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research is established, and the National Research Act is passed by Congress. This Act prompted the establishment of IRBs and required them to review and approve all research funded by the government involving human participants (Amdur & Bankert, 2011). The critical role of the board, according to the policy of Human Research Protection Program HRPP in the United States Department of Health and Human Services (www.HHS.gov), can be summed up in maintaining and supporting the ethical integrity of research by reviewing research protocols to ensure, among other things, that research participants receive safe and ethical treatment and provide informed consent, based on patient/ volunteers right, and that the potential for a conflict of interest is well-controlled & minimized to avoid any unexpected outcomes (Policy Number: 001/ Dated: September 26, 2010 / Version #1).

Eventually, and according to (Shahnazarian, 2006), the IRB committee has gained the authority to approve, require changes to the study procedures, or disapprove proposed research projects. Henceforth, and due to this importance, IRB is almost considered a necessity in professional organizations including universities, hospitals and medical research facilities. According to (Daou & Zogheib, 2014), there is a definite increase in the number of research projects in Lebanon, though we are still far from the numbers in the US or some EU countries. Moreover, there is a parallel interest from the Ministry of Public Health in Lebanon "to regulate this field, and provide oversight at the national level", (Daou & Zogheib, 2014). In their strenuous effort to regulate clinical research and improve research ethics, the Ministry of Public Health and Lebanese hospitals are together pushing toward IRBs. However, there are still multiple challenges facing medical research in Lebanon when it comes to resources, opportunities and regulations. Per contra, Lebanon is considered to have more definite advantages compared to other countries in the region (Daou & Zogheib, 2014). According to them, the most frequent trials in Lebanon are the trials in oncology and hematology followed by infectious disease, neurology, cardiology and rheumatology. Thus, the MOPH issued memo number 1/1159, dated April 15, 2014 to regulate the

pharmaceutical trials followed by memo number 1/2286, on December 24, 2014, and 1/141 dated on 2016 enforcing the regulation of IRB committee that related to clinical trials on human subjects. The regulation of clinical trials is a priority for the Public Health sector since ensuring high standards of patient safety is one of the Lebanese Public Health Ministry's policies. Moreover, the Ministry noticed the increase in clinical trials in recent years. According to (Daou & Zogheib, 2014), there were 206 clinical research studies in Lebanon that were registered at the United States government clinical trials database in the first half of 2014 alone (www.clinicaltrials.gov). Earlier in 2012, the Ministry decided to take few steps towards having a direct role in the ethical and regulatory oversight of clinical trials while waiting for the issuance of a relevant law by the parliament. Thus, the MOPH issued memo number 27, dated April 20, 2012 followed by memo number 72, on September 14, 2012, enforcing the registration of clinical trials in the country. Nevertheless, it is important to mention that there is currently no law to regulate the clinical trials in Lebanon. More efforts are exerted in the pharmaceutical field. The Pharmacy law number 367 dated 11/8/1994 mentioned indirectly that only teaching hospitals in Lebanon are allowed to conduct clinical research involved with using medications under the article 55. Accordingly, the ministry further explained this article by a decree number 569/2 dated December 4, 1996, and limited the conduct of clinical research to teaching hospitals or hospitals affiliated with a medical school.

Aim

The primary objective of this research is to study the current practices when it comes to conducting clinical research in several teaching hospitals in Lebanon regarding the application of IRB rules and regulations. It seeks to identify problems of the IRB system in Lebanese hospitals as well as to assess the readiness of these hospitals to IRB when it comes to practice and documentation.

Methods

The study is based on quantitative and qualitative approach. The quantitative research aimed to gather an in-depth understanding of hospital behavior within the clinical research and levels of respecting safety measures and compliance rate with the international rules and regulations. The qualitative research aimed to gather information about clinical research challenges and future recommendations in order to improve the hospital behavior and system approach. The study was compelled to use all hospitals with IRB (6 teaching hospitals out of 9 having IRB) to assess the working procedures based on the ministry decrees and international regulations. A non-random sampling method (convenient and purposive sample) was used because the population under study was conveniently available and the research limitations required a specific qualification which is having IRB. Data in this study were collected through a questionnaire with closed and open-ended questions alongside interviews. The questionnaire substantially included an informative coding system with the following categories: the organizational management of IRB committee, policies and procedures, training and IRB member's development, review and consultancy system, informed consent, subject safety, monitoring process, it also had questions related to documentation process.

This questionnaire was adopted with courtesy from the Office for Human Research Protections OHRP's Quality Assessment Program of the United States Department of Health and Human Services (www.HHS.gov), it was initially tested, validated, developed and applied to assess IRB systems in American hospitals. This tool was intended to support institutions do self-assessment in order to evaluate and improve the quality of their human research protection programs and to identify strengths and areas for improvement by using this valid questionnaire. Open-ended questions allowed the possibility of discovering respondents' answers spontaneously, and thus avoiding the bias that might have resulted from suggesting answers to respondents, a bias which may occur in the case of close-ended questions. The data collected were analyzed both quantitatively and qualitatively. Tables, graphs and pie charts were used to help interpret the data according to the issues analyzed. Qualitative summaries were also generated for open-ended responses. A correlation between the standards required by the Lebanese Accreditation System (according to the reference of the Lebanese Ministry of Public Health) and the international requirements of the IRB/ clinical research committees and principles was established and studied in order to identify if they are matched and or overlapped together.

RESULTS

Based on the quantitative and qualitative analyses of the questionnaire and open-ended responses, it was generally derived that there was a lack of strict implementation of IRB system in the Lebanese context with accordance to the international rules and regulations. The compliance rates are summarized as per the followings:

- Lack of primary review system of each research proposal and protocol: 17% of hospital don't have a primary review process and 17% of them doesn't have a regular review process (Figure 1).
- No regular revision of IRB policies and procedures: 17% of hospitals doesn't have a regular revision of IRB policies and procedures (Figure 2).
- 50% of IRB committees have a regular election system to assign their members (Figure 3).
- The clinical research not observed (by internal audit program or other method) to provide quality assurance and quality improvements of research activities: only 50% of teaching hospitals has an internal audit program (Figure 4).
- The retention process of IRB records not conducted as per international policies, (17% for 3 years, 16% for 10 years, 50% not clearly identified, 17% not destroyed) (Figure 5).
- 50% of IRB committees consider that the approval of research proposals by the technical related department is not obligatory and this doesn't comply with the literature review (Figure 6).
- Elevated time period between deadline and schedule of IRB meeting, 49% of time period are within 14 days, 34% of time period are more than 28 days (Figure 7).
- 17% of IRB committee are not concerned to apply an informed consent from the subject's legally authorized representative while 33% rarely apply it (Figure 8).

- Breach of safety rules regarding volunteers: 17% of Principal Investigator Obtain Informed Consent before getting IRB Approval (Figure 9).
- Absence of link between the actual accreditation standards and the IRB requirements according to federal rules and regulations (Figure 10).
- Lack of waiving policy or criteria: 17% of IRB committees doesn't have a written waiving policy or criteria (Table 1).
- Lack of deception policy: 83% of IRB committees doesn't have a deception policy (Table 2).
- Lack of training program for IRB committee members which could lead to a lack of scientific precision when taking decisions regarding clinical research approvals and monitoring process: 83% of hospitals conduct an irregular training program while 33% have an annual training program for the IRB members and 17% doesn't have a training program (Table 3 and 4).

Feedback Hypothesis:

This study shows that the null hypothesis was not confirmed:

- **H1:** There exists a lack of IRBs organizational management regarding clinical research in the targeted hospitals: it was **confirmed**.
- **H2:** IRBs of teaching hospitals don't totally comply with MOPH policies and procedures: Based on quantitative analysis the teaching hospitals comply with the available decrees of MOPH. The qualitative analysis shows that there is a contradiction, while some teaching hospitals still do not comply with the MOPH recommendations based on Belmont report and Declaration of Helsinki and federal rules and regulations. H2 was **not confirmed**.
- **H3:** IRB members don't sustain training programs related as internationally advised: both Quantitative and Qualitative reveals that the training is still inadequate and insufficient for the IRB members to deal with clinical research as internationally recommended. H3 was **confirmed**.

Table 1. Existence of Written Waiver Criteria

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	5	83.3	83.3	83.3
	No	1	16.7	16.7	100.0
	Total	6	100.0	100.0	

Table 2. Existence of Written Policy for Research Involving Deception

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	1	16.7	16.7	16.7
	No	5	83.3	83.3	100.0
	Total	6	100.0	100.0	

Table 3. Frequency of Training Program

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Annually	2	33.3	33.3	33.3
	Every 2 years	1	16.7	16.7	50.0
	Every Three Years	1	16.7	16.7	66.7
	N/A	1	16.7	16.7	83.3
	Upon Needs	1	16.7	16.7	100.0
	Total	6	100.0	100.0	

Table 4. Existence of Training Program for IRB Members

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	5	83.3	83.3	83.3
	No	1	16.7	16.7	100.0
	Total	6	100.0	100.0	

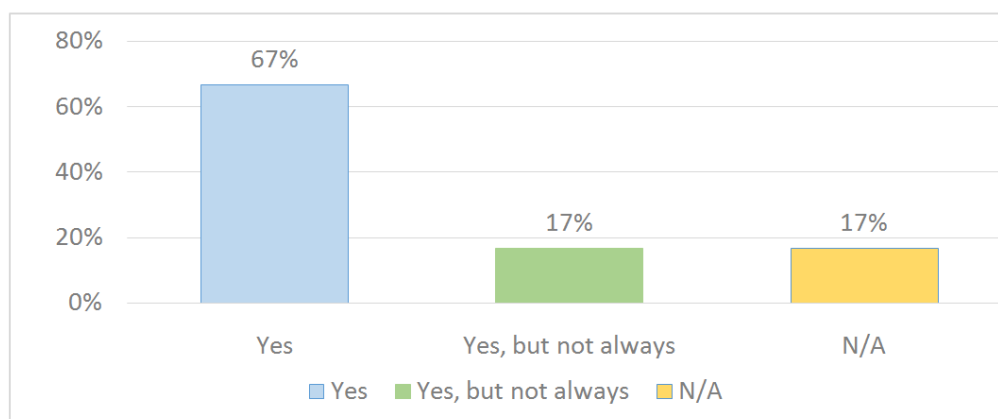


Figure 1. Existence of Primary Review Before Full Review Board for Continuing Reviews

- **H4:** lack of continuous improvement process related to absence of accreditation standards: The feedback analysis confirmed the lack of continuous monitoring and improvement processes regarding clinical research activities, there are no close monitoring via all studies at regular basis. H4 was **confirmed**.
- **H5:** IRBs are poorly committed to subjects' safety and privacy: The quantitative analysis **confirmed** a full commitment to subject' safety and privacy. A **contradiction** appeared in terms of qualitative analysis that the Lebanese hospitals partially comply with the international protocols and guidance mentioned earlier in the literature review, such as the Declaration of Helsinki. H5 was **confirmed**.
- **H6:** IRBs are not in fully monitors processes during research: The quantitative analysis was **contradicting** with the qualitative one. So the qualitative **confirmed** the lack of monitoring process during research activities compared with the total compliance with monitoring requirement according to quantitative analysis. H6 was **confirmed**.
- **H7:** IRB documentation system is not fully developed: The policies and procedures are still not totally developed according to literature review and OHRP recommendations; H7 was **confirmed**.

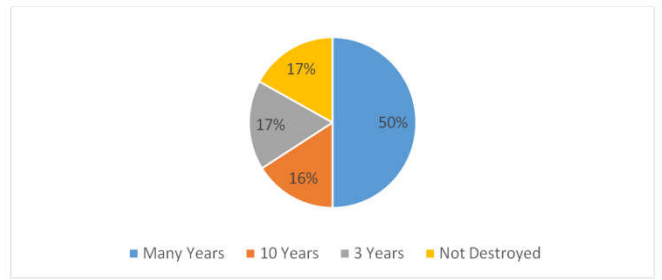


Figure 5. Retention Period of IRB records

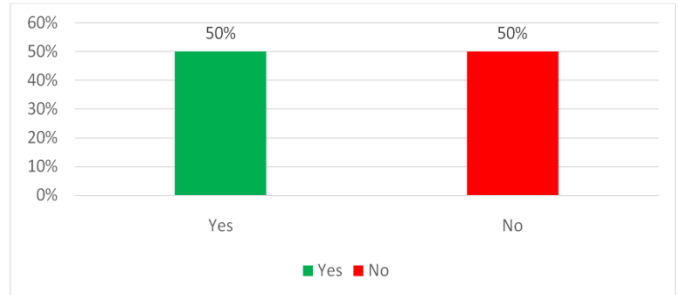


Figure 6. Approval on Submission Form by the Technical Related Departments

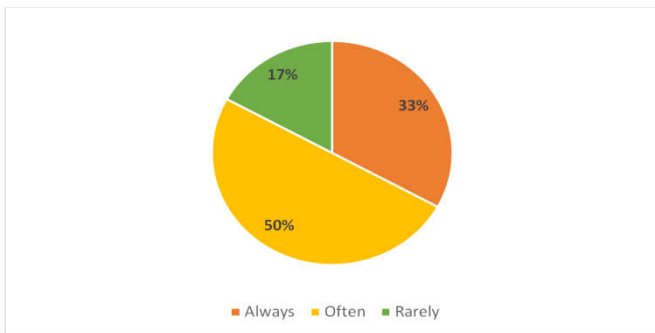


Figure 2. Revision Frequencies of SOP's



Figure 7. Time Period Between Deadline and Schedule of IRB Meeting

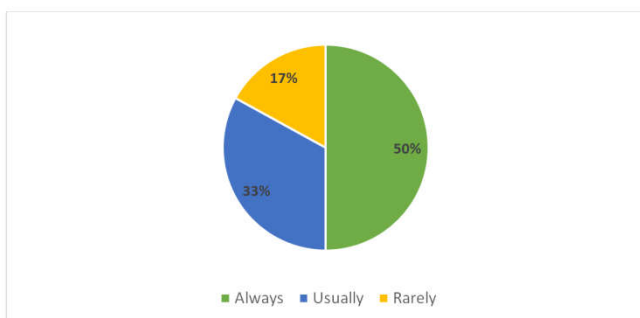


Figure 3. Existence of IRB Committee Election/ Selection Criteria

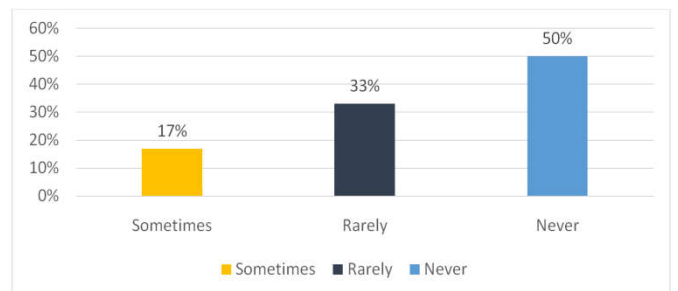


Figure 8. Waiving The Informed Consent from The Subject's Legally Authorized Representative

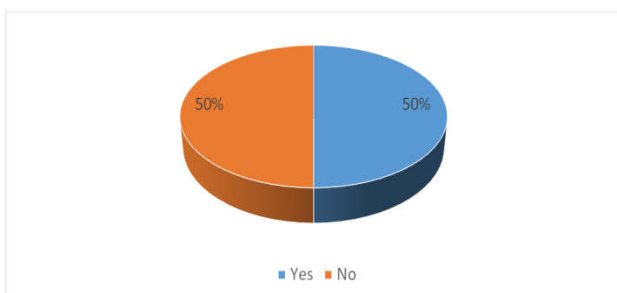


Figure 4. Existence of Internal Audit for research Activities

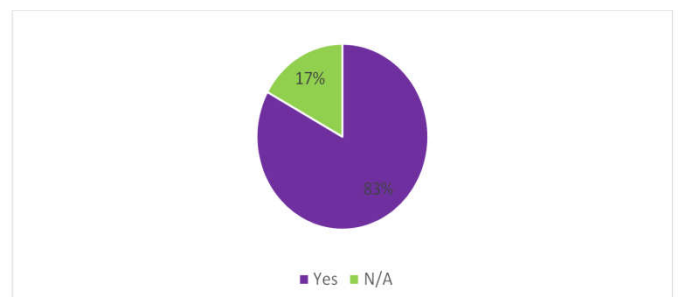


Figure 9. Obligation of Principal Investigator to Get IRB Approval Before Obtaining Informed Consent

RELATIONSHIP CHART

Plant: Lebanese University Project: Institutional Review Board.....
 Reference: Master In Healthcare Quality Management Date: 02/05/016 Charted by: Mohammed Ftouni

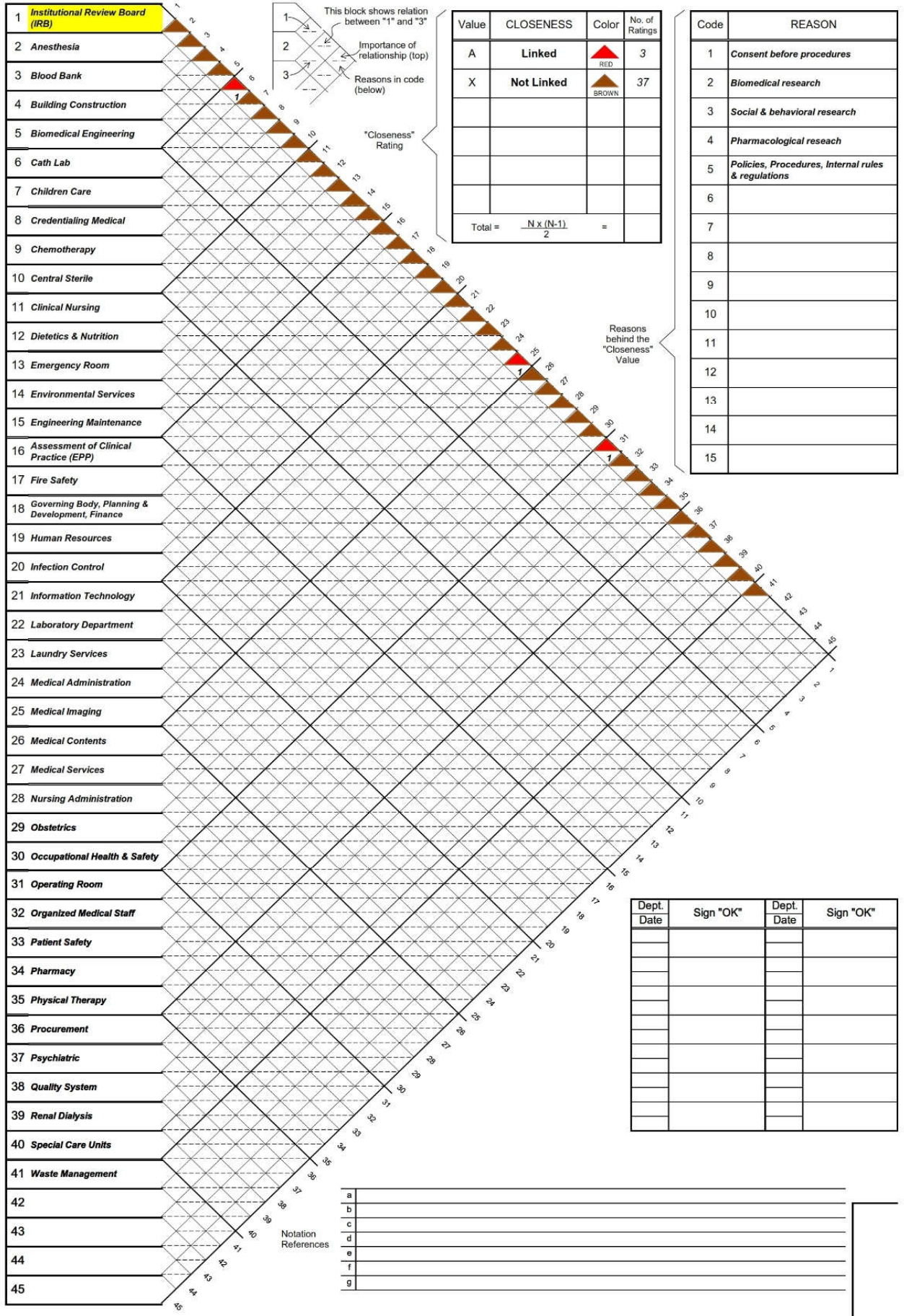


Figure 10. The actual correlation between Lebanese accreditation standards with the required criteria of IRB principles and rules

DISCUSSION

This study yielded a deeper understanding of the current situation even when it comes to related criticism. One initial critique is that the current accreditation system and the IRB requirements of clinical research on pharmaceuticals and biomedical engineering are still not firmly linked together and there is no existence of official standards issued by the Ministry of Public Health. Most IRB members do not use a systematic scientific approach of assessing the risk/benefit ratio when evaluating protocols. Some IRBs are typically made up of physicians and non-expert staff who are biased toward quantitative research ignoring qualitative aspects of research trials. There are no specific budgets for IRB activities nor sufficient support of the IRB committees by hospitals in general. In comparison to other countries, there is a lack of research publications at Lebanese level. The IRB work is still not under the full control of the hospital governing (quality control part), nor by the MOPH. There exist unjustified demands for consent in some research and an increasing interest in the content of the consent document than with the consent process. The elevated dwell time to take research approval by IRB has remarkable effects on research requirements and expected outcomes even upon this very same research. Moreover, there is no strict policy regarding documents privacy and confidentiality; records are not kept in a closed locker. Finally, it is well-noted that there is an absence of common rules between all IRBs in Lebanon and an absence of standardized measures and criteria from MOPH to check compliance level of IRB committee.

The limitations of this research are

Not all teaching hospitals had an IRB and thus the sample size was not as was expected to be in order to meet the number of available teaching hospitals in Lebanon. Some hospitals have considered this study as a human subject research, and for that a series of administrative steps were requested from their IRB to get approval from a full-review committee alongside the unreasonable demands for consent by some IRB committees.

Conclusion

The study noticed the lack of application of international research regulations and protocols, while confirmed by the absence of accreditation system specific for IRB and the absence of direct supervision by the Ministry of Public Health on the conducted clinical research. In addition to that, a weak monitoring system was mentioned in the associated hospitals. Steps already taken by the Lebanese MoPH are still inefficient and they need more time and efforts to achieve a full monitoring process via clinical research conducted in healthcare organizations. The study proved also that the teaching hospitals in general apply the IRB requirements partially, while confirmed by the incompleteness of document system, lack of training regarding IRB requirements, lack of monitoring process via clinical research and others, the safety and confidentiality not as required according to ethical principles. Efforts should be made to address these concerns and how effective IRBs are at protecting human research participants.

Recommendations for Practice

The following recommendations and future work are entirely based on work done in this research whether it was the

literature review, the questionnaire analyses or the interviews (open-ended feedback) done by the researcher. It could be realized that the later recommendations are parallel to deductions and criticism done earlier in some aspects.

1. MOPH is ought to establish a national center for clinical research in order to regulate and improve the current situation in Lebanon.
2. Establish national conferences to change the Lebanese popular cultures and to encourage volunteers to participate in clinical trials.
3. Apply the required laws and regulations related to clinical trials to avoid unfairness attraction of sponsors to conduct research.
4. Provide full protection of the safety and confidentiality of human research subject based on the Declaration of Helsinki and Belmont Report.
5. Ensure the availability of accreditation standards and a manual of policies and procedures concerning research programs approved by MOPH to regulate and improve the activities of clinical research.
6. Encourage all teaching hospitals to activate IRB committees and invest more in clinical trials for the benefits of community and patients. Encourage researchers to participate in publishing issues and provide support from MOPH to increase the number of researchers and sponsors.
7. Strengthen the role of ethics/IRB committees that have the right to monitor ongoing studies (Declaration of Helsinki)
8. Establish a process of systematic assessment of risks and benefits for research subject based on the international recommendation (HHS.gov, Belmont report).
9. Train IRB members and consider acquiring a Certification from local program (MOPH) or international program (CITI, Collaborative Institutional Training Initiative).
10. Unify the criteria of when to go for a full-board review meeting depending on the severity and sensitivity of research topic.
11. Determine a specific budget and financial resources from organizations to help IRB committees in activating the follow-up movement of clinical research.
12. Identify a logical time interval to get approvals from IRB committees and avoid delayed approvals.
13. Provide a continuous quality control system on ongoing trials by internal audit and surveillance plan.
14. Establish scientific communication with universities and institutions and teaching hospitals, all of them can be success factors that help the research system in Lebanon to be more developed and affordable to do most kinds of research (pharmaceutical, biomedical and humanistic)

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Annexes

Questionnaire

Dear Respondent,

For each item, choose the best corresponding answer that fits your case:

General Information

- Name of Institution or Organization (optional):
- Address: North Lebanon South Lebanon Mount Lebanon Beirut Bekaa, others: _____
- The organization is considered as Teaching hospital: Yes No
- The organization has an IRB/ Ethical committee: Yes No
- Year of initiation of IRB: After year of 2012 Before year of 2012

Administrative Information

- Does your organization have an organizational chart for your human subject's protection program? Yes No N/A
- How often does the organization use a clearly identified criteria to select/elect the IRB chairs and/or IRB members? Always Usually Often Sometimes Rarely None
- Does your institution/IRB organization have an internal audit (quality assurance/ quality improvement program) for research activities involving human subjects? Yes No N/A

4. Does your institution/IRB organization have a centralized hot line or number for potential/enrolled research participants to file complaints or direct questions regarding human subject's protection issues?

Yes No N/A

5. Do IRB members receive periodic specific training sessions regarding human subject protections program?

Yes No If YES, how often?

6. How often does your IRB usually convene for full committee review of research studies?

Always often Sometimes rarely Never

7. Does your IRB have written Standard Operating Procedures (SOPs)?

Yes No

8. How often are the written IRB standard operating procedures reviewed?

Always often Sometimes rarely Never

9. For how long are IRB records (e.g., protocol files, minutes) stored on site and readily accessible to the IRB members and staff?

Months _____ Years _____

10. Does your IRB require investigators to use an IRB submission form for initial review of protocols?

Yes No N/A

11. Does your IRB submission form request the approval and signature of the department chair (or supervisor) prior to submission to the IRB?

Yes No N/A

12. Does your IRB require the approval and signature of other individuals prior to submission to the IRB (e.g., pharmacy, nursing)?

Yes No N/A

Preparation for Full Committee and Continuing Review Process

13. The IRB has a deadline for investigators to submit protocols that require full committee review.

Yes No N/A

If yes, how many days usually separate between the deadline and the scheduled IRB meeting?

_____ day(s).

14. The IRB(s) use/s a primary reviewer system for full committee reviews of new protocols:

Yes No N/A

15. How often does the IRB bring in a consultant to provide scientific or other relevant expertise for the review of a particular protocol?

Always often Sometimes rarely Never

16.The IRB ensures that the informed consent documents include input by a non-medical personal [e.g., Lawyer]?
 Yes No N/A

17.The IRB requests a written status report from the investigator for continuing the review?
 Yes No N/A

If Yes, how long before the expiration of IRB approval?
__>60 days __45-59 days __30-44 days __<30days
__other: _____.

IRB review process

18.Does your IRB use a primary review system for continuing reviews that require full committee review?
 Yes No N/A

If applicable, how many days prior to the date of the IRB meeting do IRB members have to review Martials?
 Less than 2 weeks between 2_4 weeks
between 4_6 weeks more than 6 weeks, specify: _____
_____.

19.The IRB often informs the investigator of the need to obtain Assurances for performance sites engaged in the research:
 Yes No N/A

20.The IRB considers characteristics of the local setting during the review process of the research to be conducted (i.e., race, gender, cultural backgrounds, and sensitivity to issues such as community attitudes, institutional policies and commitments, as well as applicable laws and standards of professional conduct and practice)?
 Always often Sometimes rarely Never

21.Who usually determines whether a protocol submitted for IRB review is to be reviewed by full committee or expedited review?

Not applicable

22.Who is authorized by your IRB/IRB chair to approve protocols by expedited review?

Not applicable

23.The IRB determines who will be authorized to obtain informed consent from subjects
 Yes No N/A

24.The IRB requires the Principal Investigator (PI) to obtain IRB approval before delegating the responsibility to someone else to obtain informed consent from subjects
 Yes No N/A

25.Does your IRB review the process by which informed consent will be obtained (e.g., conditions under which a subject is approached for recruitment)?
 Yes No

26.Does your IRB ensure that the informed consent document is comprehensible to the subject population (e.g., appropriate reading level)?
 Yes No N/A

27.Does your IRB consider whether a translation to a foreign language is needed?
 Yes No N/A

28.Does your IRB ever waive (abandon) the requirement to obtain informed consent from each prospective subject or the subject’s legally authorized representative?
 Always often Sometimes rarely Never

29.There are documented criteria that the IRB use to waive the requirement:
 Yes No N/A

30.Does your IRB have a policy for review of research involving deception?
 Yes No N/A

31.The IRB explicitly considers how to minimize risks to subjects
 Yes No

32.The IRB considers whether risks to subjects are reasonable in relation to anticipated benefits
 Yes No

33.The IRB reviews recruitment processes to ensure that the selection of subjects will be equitable (e.g., gender, age, race/ethnicity)
 Yes No N/A

34.The IRB reviews advertisements to be used for the recruitment of subjects
 Always often Sometimes rarely Never

35.The IRB requires, when appropriate, that the research plan includes adequate provisions for monitoring the data collected to ensure the safety of subjects
 Yes No N/A

36.The IRB requires, when appropriate, that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality
 Yes No N/A

37.The IRB recommends or requires, when appropriate, submission of a Certificate of Confidentiality
 Yes No N/A

38.When some or all of the subjects are likely to be vulnerable to constraints or undue influences (such as, children, prisoners, women who are pregnant, persons with mental disabilities, or persons who are economically or educationally disadvantaged), the IRB considers and requires that additional safeguards are included in the study to protect the rights and welfare of the subjects
 Yes No N/A

39.The IRB determines at the initial review of a study the appropriate interval for continuing review based on the degree of risk

- Yes No N/A

40.The IRB considers and complies with the reporting requirements in accordance with the Code of Federal Regulations adopted by the MOPH (45 CFR 46, 21 CFR 50, 56, 312, 21 CFR 612, 812)

- Yes No N/A

IRB Minutes

41.The IRB minutes usually record the names of IRB members and consultant present

- Yes No N/A

42.The IRB members are notified of all new sponsor- or investigator-initiated modifications/amendments to protocols (i.e., not changes requested by the full committee from a prior review) that were approved by expedited review since the prior meeting

- Yes No N/A

43.The IRB members are notified of all protocols that have been approved by expedited review since the prior meeting

- Yes No N/A

44.For protocols undergoing continuing review by full committee, the convened IRB (with quorum) reviews, deliberates, and votes for each study

- Yes No N/A

45.The IRB members are notified of all protocols undergoing continuing review by the expedited review process

- Yes No N/A

46.The minutes document IRB review of adverse events and unanticipated problems

- Yes No N/A

47.The minutes include IRB review of protocol violations or deviations

- Yes No N/A

Documentation of IRB Reviews in the Minutes

48.For protocols in which your IRB waived the requirement of informed consent, the justification for waiver is documented in the minutes in accordance with the Code of Federal Regulation adopted by MOPH (e.g. 45 CFR 46.116(d)

- Yes No N/A

49.The minutes document any consideration of additional safeguards for vulnerable subjects when appropriate

- Yes No N/A

50.The minutes document all IRB actions including at least one scientist, one non-scientist and one non-institutional member (as applicable) in the review and vote

- Yes No N/A

51.The minutes record the name of IRB members who were excused from the discussion and vote due to a conflict of interest

- Yes No N/A

Post IRB Review

52.The IRB notify investigators, institution formally of its decision to approve or disapprove the proposed research activity or to require modifications in order to secure IRB approval

- Yes No N/A

53.The IRB monitors or requires monitoring of any study

- Yes No N/A

Approval Letter

54.The approval letter or approval document from your IRB includes the title of the study, protocol number, and version (or amendment) date?

- Yes No N/A

55.The IRB-approved informed consent form is stamped with an approval date

- Yes No N/A

Open Ended Questions

1. To what extent do you feel that the working mechanisms or policies and procedures in your organization can maintain the safety & confidentiality of participants in clinical research?

2.How do you assess the current control methods by your IRB on Clinical Research to assert control over the Principles Researcher and search outcome?

3.Do you think that the training sessions attended by the members of the clinical research at your organization are sufficient and raise the eligibility and skills of committee members?

If not, what do you think are the recommended training courses that are supposed to govern the members of the Committee on Clinical Research in order to upgrade their skills?

4. How do you assess the actions taken by the IRB committee at your organization to prevent conflicts of interest during the research?

5. How do you evaluate the safety measures taken to ensure the safety of participants in clinical research at your organization?

6. What is your comment on the appointment/ election criteria IRB members on the regulatory and scientific level?

7. What do you think are the steps to be adopted by the General Management of your organization for the development of clinical research?

8.What do you think are the fundamental policies and procedures that must be provided within the clinical research?

9.What do you think are the most important safety measures taken to ensure the safety of participants in clinical research?

10.How do you think that being a Teaching Hospital (University) is related to establish a Committee for Clinical Research?

11. What are the internal challenges facing the committee of clinical research at the level of research activities provided?

12.How do you assess/ reflect the actual situation in Lebanon when it comes to conducting clinical research?

13.How do you evaluate the current accreditation system compatibility with the requirements of clinical research on pharmaceuticals and medical engineering level?

14. What are the critical success factors of clinical research in the Lebanese health institutions? [Examples: availability of teaching hospital, availability of researchers, and availability of sponsors interested in research, lack of regulations...etc.]

15. How do you evaluate the future of Lebanon at the level of clinical research?

16.In your opinion, what are the future recommendations and refine processes that should be established by the ministry of public health in order to improve the IRB system in each healthcare domain?

