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Institutional Review Board Compliance with National Regulatory Body: A Successful Experience from Saudi Arabia

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Abstract

Background: The Institutional Review Board (IRB) or Research Ethics Committees (RECs) is established to review the research proposals and ensure that participants' ethical standards, scientific merit, and human rights are protected. **Purpose:** The authors report the experience of the REC at Qassim Region, Saudi Arabia over 10 years period. **Methods:** All proposals submitted to Qassim REC during the period 2008-2017 were studied using a 30 items data collection form based on The National Committee of Bioethics Regulations. Data extracted included; principal investigator characteristics, numbers of proposals reviewed, applications completeness, approval decision status, reported ethical issues, classification of the ethical review, and committee review duration. The structure, workload, and review process of Qassim REC were addressed redundant. **Results:** During 10 years, Qassim Research Ethics Committee (QREC) witnessed a progressive increase in the number of submitted proposals, from 9 to 149 proposals. Out of 508 submitted applications, 439 (86.4%) proposals were eligible for ethical review. Of these, 50 (11.4%) proposals were incomplete due to nonresponse of the principal investigators to the QREC comments. The final decision was made for 389 (88.6%) completed proposals. The approval rate was 85.4%, while the rejection rate was only 1.1%. The median time taken for ethical review was 13 days. Proposals that underwent full board review had a long review dura-

tion (Median: 19 days) in comparison to the expedited review (Median: 10 days). Incomplete Committee requirements, unclear research methodology, or possible ethical violation opportunities were the main reasons for delayed decisions. **Conclusion:** The workload of the Qassim ethics committee is high and growing progressively. However, the process indicators as per National Bioethics Committee rules were satisfactory. Rejection of proposals was rare as most of the reviewed proposals were descriptive studies with infrequent ethical matters.

Keywords

Research Ethics Committee, Institutional Review Board, Informed Consent, Ethical Approval, Qassim, Saudi Arabia

1. Introduction

Research on humans is mandatory for the development of health care services. However, it may carry serious possible risks to the research subjects and the community [1]. The research team should take all precautions to prevent or minimize any possible hazard and should always be translucent to the subject and to the community [2]. Participants, on the other side, should be well informed by the investigators about research procedures, expected benefits, and risks [3].

The research institution is held responsible for the research conducted within its vicinity or under its supervision. Research institutions are requested to form committees to regulate research and protect participant rights [4]. In 1991, the Department of Health and Human Services in the United States made it mandatory for any research institute to have an institutional review board (REC) to conduct research [5]. REC or Research Ethics Committees are requested to review, approve, and supervise research through well-established systematic methods. The main objectives of these boards are to protect the research subject and to ensure the scientific integrity of the research [6].

In the Kingdom of Saudi Arabia (KSA); all research proposals/grants involving living creatures are protected by the law released by a Royal Decree in 2001 [7]. Based on that Decree, research on humans is controlled by the National Committee of Bio-Ethics (NCBE) at King Abdul Aziz City for Science and Technology (KACST), Riyadh. The first NCBE regulations were released in 2011 [7].

The Local Research ethics committee in Qassim was established in 1991 by the Provincial Health Directorate, department of continuous education and research. It was established to fulfill the growing research province's needs. In 2011, Qassim REC received recognition from NCBE as one of the national local committees, (Registration number: H-04-Q-001) [7].

At the time of the review, Qassim REC is composed of 8 members from vari-

ous backgrounds; physicians, scientists, university academic staff, and one community representative. Occasionally, external reviewers may be consulted. Qassim REC reviews the submitted research proposals in the context of NCBE framework [7] [8] [9] [10].

Qassim REC also offers informal verbal and written advice to researchers for the improvement of their proposals. Furthermore, Qassim REC orients clinical and academic staff about research ethics and ethical application requirements through Continuous Medical Education (CME) presentations and scientific meetings. It also has administrative documents at the provincial health directorate website.

Once the researcher submits his/her proposal, REC secretary checks requirements completion. The eligible proposals are first reviewed by the REC coordinator and chairman. This initial review identifies proposals that need more extensive review and nominates a suitable reviewer. Most of the observational studies are reviewed as "exempted or expedited reviews" [11] [12]. While decisions on Randomized Control Trials (RCTs) and all rejections are taken during formal committee meetings after extensive discussion "full-board review". As of 2016, all clinical trials should further be reviewed by the Saudi Food and Drug Authority (SFDA) after they are granted REC approval [13].

We report here our QREC experience over 10 year period (2008-2017). We hope that this report is read by our client researchers and be a means of feedback and image reflection tool. Similar boards may find it interesting as well.

2. Methods

We conducted a retrospective review of all proposals submitted to the local REC in Qassim for ten years (1st January 2008 to 31st December 2017). This review aimed to assess the Qassim REC structure, workload, review process, and review outcomes, and to evaluate the REC's compliance with regulations of the NCBE.

All proposals were studied using a 30 items data collection form developed by the authors. The data collection form had three parts. The first part addressed the principal investigator's basic demographic and professional characteristics. Part two listed the essential documents needed to fulfill the REC requirements, e.g. NCBE research ethics certificate, data collection tools, and informed consent. Part three identified the study design and classification. Studies were classified into clinical, public health, and laboratory studies. It also contained the review type; exempt, expedited, or full-board review, and the final REC decision.

Finally, based on NCBE guidelines, few process performance indicators were presented. The review process duration, was defined as the time from the date of proposal submission to the date of final decision release. This duration composed of three phases; first, the initial response duration, defined as the duration from the proposal submission date to the date of sending the first response to the principal investigator (PI). This duration should not exceed 10 workings days. The PI's response to the REC queries or comments should be submitted to

the REC within 90 days, while the PI should receive the final decision within 15 working days from completion of the request [7]. These time intervals and the total number of proposals reviewed were used to measure the QREC workload. Other indicators of the committee activities included the number of committee meetings per year and the availability of a review checklist.

The data were analyzed using the Epi-info software program, version 3.5.4. Categorical data were presented as proportions using frequency distribution. The student t-test was used to compare the meantime from the submission of proposals to approval. Statistical significance was set at a p-value of < 0.5.

3. Results

3.1. Qassim REC Workload

Five hundred and eight applications were submitted to Qassim REC for review over the ten years study period. Of these, 69 (13.6%) applications were ineligible for REC review as they had no proposals or their proposals were suffering severe deficiencies. Submitting authors were advised to resubmit after fulfilling the REC requirements. All of those 69 applications had stopped at that stage as the REC secretary did not receive any response from the authors. The remaining 439 (86.4%) proposals were retrieved for this audit. Of these, 50 proposals (11.4%) were sent back to the principal investigators to complete other requirements or with some comments and suggestions for improvements. Till the time of this report, we didn't receive any response from their related principal investigators. A formal final REC decision was taken for 389 (88.6%) proposals (**Figure 1**).

Figure 2 depicts the submitted proposals frequency per year. It shows a wide range of 9 to 149 with a median of 30 proposals per year. The line graph also displayed a sharp increase in the number of submitted proposals during the last two years.

3.2. Duration of Review and Approval Rate

The median duration of the REC response, from the date of proposal submission to the first response to the investigator, was five days (0 - 114 days), but 75% of responses were sent within 13 days. Furthermore, the median duration of the total review process, defined as the duration from the date of submission to the date of the final decision, was 10 days (range 0 - 178 days). The total review duration was mainly affected by the review type. The median duration for the full board review was 19 days while expedited review had a mean of 10 days.

Most submitted proposals were approved, 375 (85.4%). Only five proposals (1.1%) were rejected. Two out of these rejected studies were interventional studies and 3 were descriptive ones. The usual reason for rejection was the research ethics principles violation. The remaining rejected nine (2.1%) proposals were submitted after the study was completed, hence our REC regretted for being unable to review them (**Table 1**).

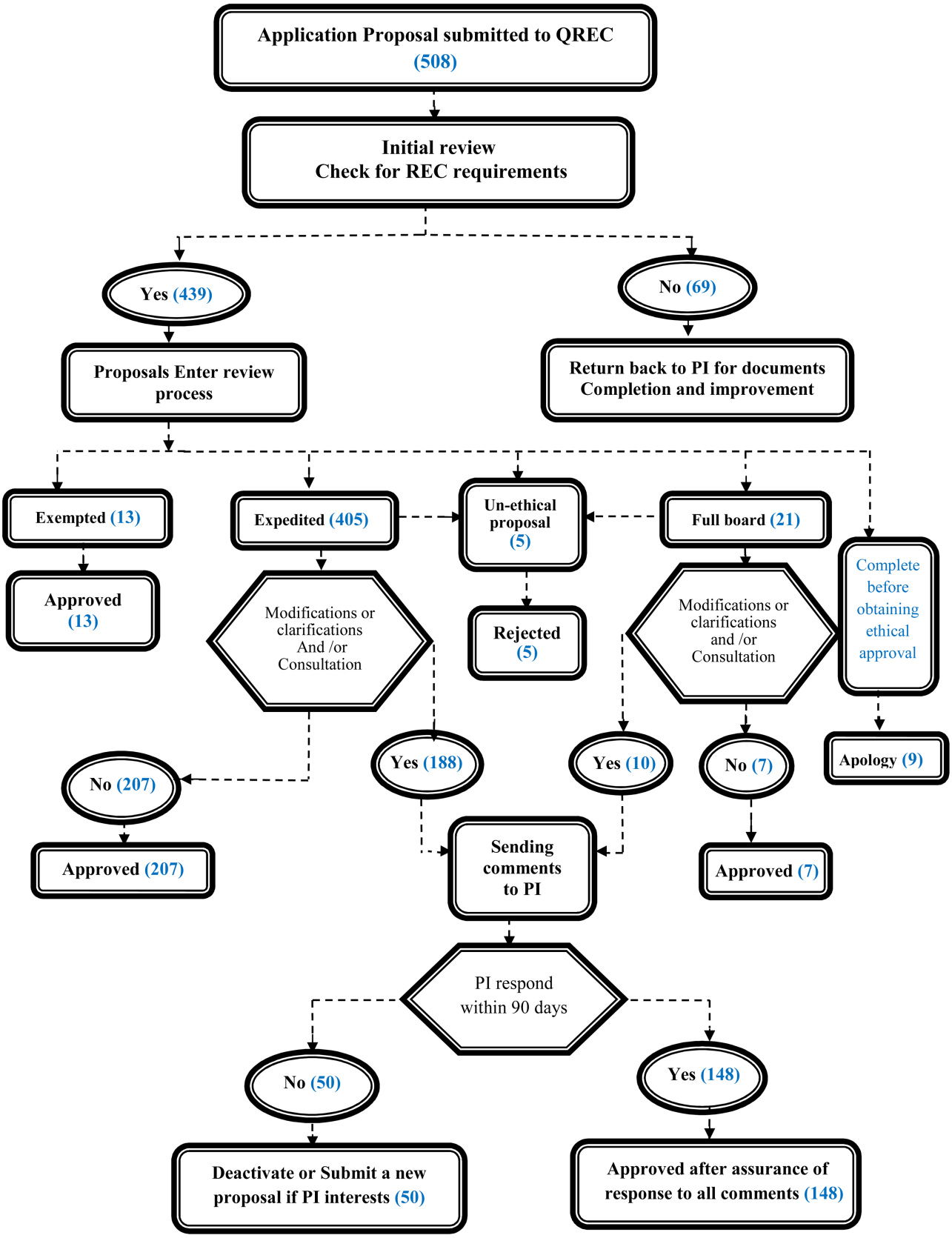

Figure 1. Qassim research ethics committee workflow and outcomes for the submitted applications during 10 years period (N = 508).

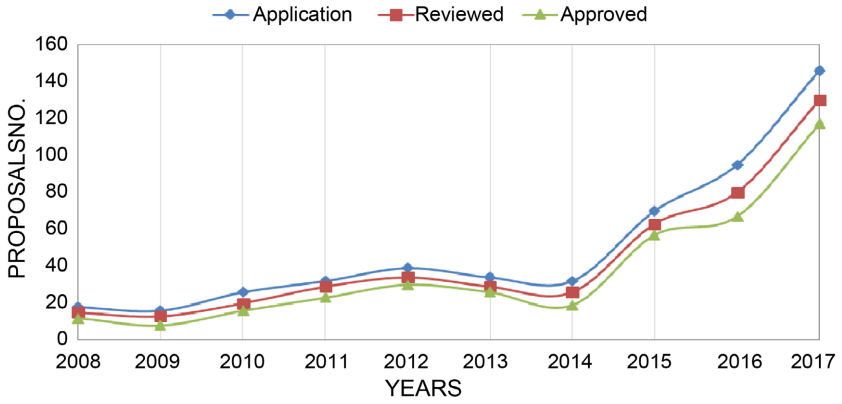

Figure 2. Qassim research ethics committee workload; trend of total applications versus reviewed and approved proposals over 10 years. *Median of submitted proposal = 38.9/year.

Table 1. Qassim research ethics committee; performance indicators and outcomes of the reviewed proposals during 10 year (N = 439).

Characteristic	Frequency (N)	Percentage (%)
Initial Review Results		
Fit for approval	290	66
Needs modification	74	16.9
Lacks of essential requirement	63	14.4
Needs modification & lacks essential requirement	12	2.7
Type of review		
Expedited	405	(92.3)
Full board	21	(4.7)
Exempted	13	(3)
Total Numbers of reviewers		
One reviewer	15	(3.4)
Two reviewers	252	(57.4)
Three reviewers	132	(30)
Four reviewers	31	(7.1)
Five reviewers	9	(2.1)
Consultation Outside QREC		
External reviewers		
Yes	21	(4.8)
No	418	(95.2)
Outcome of reviewed proposal		
Approved	375	(85.4)
Suspended*	50	(11.4)
Apologized	9	(2.1)
Rejected	5	(1.1)
Study location		
Local (Qassim Province)	406	(92.5)
Multi-centers	33	(7.5)
Vulnerable Groups		
Yes	48	(10.9)
No	391	(89.1)

*Suspended due to failure of PI to respond to the QREC comments.

3.3. Characteristics of Principal Investigators and Submitted Proposals

As shown in Table 2, majority of principal investigators (PI) were males, 316 (72%), of Saudi nationality, 295 (67.2%), academic staff, 142 (32.3%), and had MD or Ph.D 190 (43.3%).

Table 3 displays the completeness status of the submitted proposals, *i.e.* fulfillment of the REC requirements. The majority of investigators submitted their

Table 2. Qassim research ethics committee; characteristics of principal investigators of the reviewd proposals during 10 years, (N = 439).

Characteristic	Frequency (N)	Percentage (%)
Principal Investigator (PI) gender		
Male	316	72
Female	123	28
Principal Investigator (PI) Nationality		
Saudi	295	67.2
Non-Saudi	144	32.8
Principal Investigator (PI) Profession		
Academic staff	142	32.3
Undergraduate students	130	29.6
Postgraduate students	62	14.1
Physician	81	18.6
Dentist	7	1.6
Nurse	6	1.4
Pharmacist & Asst. Pharmacist	7	1.1
Radiologist	2	1.4
Others	2	1.4
Qualification and field of Principal Investigator (PI)		
Academic *field*	**332**	**76.5**
PhD	43	13
MD	76	22.9
Master	32	9.6
Bachelor	12	3.6
Postgraduate students	39	11.7
Undergraduate students	130	39.2
Service *field*	**107**	**23.5**
PhD	18	16.8
MD	53	59.5
Master	23	21.5
Bachelor	13	12.1

Table 3. Qassim research ethics committee; characteristics of the total reviewed proposals during 10 years period, (N = 439).

Characteristic		Yes		No	
		N	%	N	%
Essential documents should be submitted with the request (n = 439)	Identification letter	353	80.4	86	19.6
	Data Collection Tools	370	84.3	69	15.7
	Informed Consent	337	76.8	102	23.2
Essential documents are requesting since 2015 as per NCBE-KACT guidelines (n = 266)	Investigator's Curriculum Vitae (C.V)	232	87.2	34	12.8
	Investigator's Ethics Certificate from NCBE	228	85.7	38	14.3
Scientific characteristics of research proposals	**Characteristic**	**Frequency (N)**		**Percentage (%)**	
Sample size	Statistically calculated	352		80.2	
	Not statistically calculated	87		19.8	
Inclusion & Exclusion criteria	Provided	370		84.3	
	Not Provided	69		15.7	
Data analysis plan	Yes	356		81.1	
	No	83		18.9	
Study setting	Hospitals	308		70.2	
	Universities & Schools	60		13.7	
	PHCCs	34		7.7	
	Community	26		5.9	
	Ministry of Health	5		1.1	
	Others	6		1.4	
Classification of study design	***Interventional***	**18**		**4.1**	
	RCT	11		61.1	
	Non-RCT	7		38.9	
	Observational	**421**		**95.9**	
	Cross-sectional	316		75.1	
	Record review + Audit	74		17.6	
	Case-control	14		3.3	
	Cohort	8		1.9	
	Qualitative	9		2.1	

*Differences in date due to board requirements which was updating according to NCBE regulations.

identification letters, 353 (80.4%), ethics course certificates from NCBE website, 228 (85.7%), and data collection forms, 370 (84.3%). Majority of studies, 337 (76.8%) provided informed consent. All of the remaining studies, 102 (23.2%) were conducted on hospital records or had no risk to the participants (Table 3). Among studies intended to be conducted on vulnerable groups, 17 out of 48

(35.4%) were initially submitted without informed consent.

Majority of studies were observational, 421 (95.9%) and only 18 (4.1%) were interventional studies. Furthermore, the most frequent research sites were hospitals, 308 (70.2%), followed by teaching institutes, 60 (13.7%) (**Table 3**).

4. Discussion

The main goal of institutional research ethics is to protect research subjects. Secondary goals include ensuring the scientific integrity of research, both during planning and implementation. As the highest proportion of our research was simple surveys, ethical issues were quite limited.

The majority of QREC applicants were undergraduate or postgraduate students, ethical considerations regarding the recruitment of patients for medical research require QREC to remain vigilant in protecting research subjects and also in trying to help researchers to observe the highest ethical standards of conduct. This is especially true for research conducted on students and trainees, who may be denied consent or decline from seriously consenting to experimental research [14].

The main focus of this report is on QREC performance indicators of structure and process. However, the research outcome is expected to be indirectly positively affected by good research conduct [15] [16]. Several aspects have been suggested in the literature as indirect benefits of REC review on research quality. Examples include improving study participants understanding of the research risk-benefit, hence better-informed participant decision making and strengthening their positive attitudes toward the research. Researchers, on the other side, have better risk assessment and communication with patients. Furthermore, research methods are more likely to be better organized, more transparent, and rationalized research steps [17] [18] [19] [20] [21].

As per the national bioethics committee guidelines, the minimum number of local research ethics committee members is five [7]. Throughout its history, QREC had fulfilled this standard with a maximum number of eight members. This is similar to a previous report from REC in Thailand, where the REC is composed of at least 5 members [22].

None of the QREC members is a full-time nor even a part-time member. All members have their full duties as any other staff member in their departments. The committee workload is beyond the average load for usual technical committees or boards [23]. The impact of QREC workload on work stress and review quality should be carefully considered.

It is unclear whether expanding the number of committee members would improve QREC performance, both in timeliness and quality. Encouraging other health care institutes in the province to establish their research ethics committees is probably a more efficient option.

The NCBE regulations allow for external consultations [7]. Our experiences indicate that external consultants take a very long time to respond and occasio-

nally address issues beyond the scope of the committee. Lack of incentives and limited research experience in the province may be behind the low consultation rate.

Several RECs set timeliness targets in their standard operating procedures for proposal review, which usually ranges between 30 and 60 days [24] [25] [26] [27]. Our median time for initial review response, from proposal submission to board review for all reviewed studies was 13 days and the median time taken for the final approval was 25 days. Though quite long, it was better than the duration reported by one international committee, 25 versus 88 [22]. The overall review duration depends on multiple factors. The principal investigator's response to the committee requests or suggested modifications plays major role.

Clinical studies could not achieve NCBE duration standards. This finding was similar to a previous study in Nigeria [28]. Factors behind this delay include multiple reviewers, multi-center studies, external consultations, and the time taken by the applicants to review their proposals as per QREC requests or recommendations. Full board review duration was more than twice the duration for expedited review, 49 days vs. 22 days respectively. Many Principal Investigators or QREC factors could be behind this difference. Interventional studies are usually reviewed by all board members and external consultation is common. The researcher's response to suggested modifications usually takes a long time. Scientific and ethical approval may warrant involovement of specialized staff or assurance of suitable laboratory facilities. The provision of such requirements then modifying and updating interventional research proposals usually takes months.

Most of the submitted proposals were reviewed by 3 members of QREC. As per NCBE guidelines, the number of reviewers depends on the study type. For example, one reviewer is frequently enough to review and approve minimal risk studies, e.g. retrospective record reviews.

As most of the principal investigators were undergraduate or postgraduate students from academic institutes, the board feels responsible for protecting patient rights, assessing research risk and benefits, and critically reviewing informed consents. Although most of the studies did not carry a high risk to participants, informed consent is frequently requested as per guidelines. Nine studies failed to provide informed consent until requested by REC. There was a significant statistical relationship between the provision of informed consent and the study design Observational studies were more likely to be initially submitted without informed consent, P = 0.000. This finding was consistent with a previous study [29] [30].

Research methodology quality has a direct and indirect influence on ethical approval issuance. Every aspect of the research methodology was seriously assessed. We frequently faced researcher resistance and reluctance to discuss such issues as the committee is perceived to be concerned with participants' rights only.

Initial QREC responses to the investigators are similar to what were reported

by RECs in Africa and South America. Referral back to investigators for clarification and/or revision or provision of missing requirements was the commonest reason [31] [32].

In this report, the approval rate was 85.4%. This is similar to most of the other reviewed studies [28] [33] [34] but is higher than the study reported by the University of the Witwatersrand in South Africa [35].

About 11.4% of reviewed proposals were suspended due to the failure of PIs to respond to the board queries, requests for clarification, or amendments. In such cases, according to NCBE guidelines, REC may cancel the proposal if the principal investigator fails to respond to the REC within 90 days. If the investigator is still interested in the project, a new application should then be submitted, QREC apologized for 2.1% of the reviewed proposals only. Apologies were due to two reasons; either the research was conducted and completed before getting the ethical approval or due to an unsound research methodology.

The rejection frequency was uncommon as only 5 proposals were rejected. Our low disapproved rate of 1.1% was similar to the experience of a Brazilian study where a 1.7% disproval rate was reported [36] Different reasons were behind disapproval decisions. The most frequent reasons were risk-benefit disequilibrium, human rights violations, and failure to respond to QREC advice regarding genuine ethical or methodological modification in the study.

5. Conclusion

We reviewed QREC workload and its performance over 10 years period as per NCBE guidelines. Our REC workload is rapidly growing. However, as per NCBE process indicators, the committee performance was generally satisfactory. Clinical studies had a longer review duration in comparison to observational studies. Incomplete committee requirements, unclear research methodology, or possible ethical violation opportunities were the main reasons for delayed decisions or rejection. Good REC commitment to NCBE guidelines resulted in a high approval rate and low rejection rate. Further study for assessing the principal investigators' satisfaction with the Qassim REC process may complete the picture of Qassim REC.

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Ethical Consideration

As this review did not involve human subjects, ethical approval was not needed to conduct this study.

Authors' Contributions

Authors' contributions OA originated the idea, and AS and AA planned the analysis and prepared the draft manuscript. AM& EE participated in the study design and commented on the manuscript. SG participated in the study design, collected data, and commented on the manuscript. All authors read and approved the final manuscript.

Competing Interests

The authors declare that they have no competing interests.

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Abbreviations

IRB: Institutional Review Board

KACST: King Abdul-Aziz City for Science and Technology

MOH: Ministry of Health

NCBE: National Committee of Bioethics

OHRP: Office for Human Research Protections

PI: Principal Investigator

QREC: Qassim Institutional Review Board

SFDA: Saudi Food and Drug Authority

Appendix

Summary

- This study summarized Qassim Research Ethics Committee's performance over 10 years, as per the national bioethics guidelines.
- About 508 proposals were submitted but only 439 were eligible for review.
- Majority (85.4%) were approved and only (1.1%) were rejected, the rest were fallen short of completing the essential requirement.
- Our experience highlighted the importance of controlling research conduct and insuring participants' protection.