


Research Policy of the Institutional Review Board in Pharmacy Practice

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ABSTRACT

Objectives: This study aims to declare the Research policy of the Institutional Review Board at pharmaceutical care services as a new initiative in Saudi Arabia. **Methods:** This article is a narrative review of pharmacy research. Litterateur researched specific research policies and procedures in pharmacy practice using a variety of databases, including PubMed, Medline, and Google Scholar. The period covered for the search is from the 1960s to October 2021. The terms used are in the English language and encompasses narrative reviews, systemic reviews, meta-analyses, and guidelines. The search term includes all hospital and community pharmacy-related services. Besides, there are national and international guidelines for conducting general research in hospital practice. The pharmacy research committee was formed and comprised numerous expert members, including clinical pharmacists, pharmacists specializing in drug information, and clinical research specialists. A member drafted the policy's guidelines, which were then reviewed and corrected by another member. The research specialist made the third revision. The subject emphasizes the research policy of the Institutional Review Board in pharmacy practice. **Results:** The Institutional Review Board's definition and functions were examined. The policies and procedures have been established. In pharmacy research, there were three distinct categories of actions. That includes Exempted Research, in which no risks to patients are involved. For example, a review of a new program or service, a cost analysis, therapeutic guidelines, review articles, a systematic review, a meta-analysis, or a cross-sectional study. Expedited Research posed little risk to patients. The Complete revision Research has a high risk of adverse effects on patients, such as clinical trials. **Conclusion:** The Institutional Review Board for research policies in pharmaceutical care services is a new initiative within pharmacy departments' research and development efforts. The Institutional Review Board for research policies in pharmaceutical care services may enhance pharmacy research and the benefits of investments in pharmacy practice within a healthcare organization. Besides, prevent any adverse events associated with the investigational drug and improve patient clinical outcomes.

Key words: Research, Policy, Institutional Review Board, Pharmacy, Practice, Saudi Arabia.

INTRODUCTION

Local and international clinical practice guidelines were established several years ago.^[1-11] Additionally, non-clinical trial guidelines cover observational, case-control, and cohort studies, as well as systematic reviews and meta-analyses.^[12-15] All healthcare professionals should follow the research guidelines. Adherence to the guidelines necessitates a review of the research by the healthcare body or community within healthcare organizations to avoid human harm and patient risks. The guidelines recommended establishing an Institutional Review Board (IRB) or an Ethical Committee or a Research and Ethical Committee.^[11,16,17] The committee is responsible for various tasks, with the primary objective of protecting patients from any investigational material. There were three levels of safety in the research. One category of submissions is exempt from the committee because there is no risk to patients or no trial involving patients, such as narrative reviews or systemic reviews and meta-analyses.^[18,19] The second type of research is expedited by a committee that requires only a

few members to review and approve suspected harm or requires additional safeguards to prevent patient harm, such as blood samples being drawn from patients for any study.^[18,19] Thirdly, full committee members are required to review such clinical trials or investigation medications.^[18,19] However, various studies.^[11-11,16] discuss the committee's policy and procedures.^[17] However, pharmacy research and the institutional review board, pharmacists' roles on committees, and the relationship between the committee and pharmacy practice are rarely or inadequately written at the moment.^[18] The author is unfamiliar with the IRB-approved investigation in pharmacy practice. The current review's objective is to establish IRB and pharmacy policies and procedures.

MATERIALS AND METHODS

It's a narrative review of pharmacy research. Litterateur searched for specific topics related to research in pharmacy practice in a variety of databases, including PubMed, Medline, and Google Scholar. The time frame for the search

is from the 1960s to October 2021. The terms used were in English and included narrative review, systemic review, Meta-analysis, and guidelines. The policies were limited for the previous ten years. In a search term, all hospital or community pharmacy services are included. Inpatient pharmacy, outpatient or ambulatory care pharmacy, satellite pharmacy, extemporaneous preparation, repackaging units, pharmacy store, drug information center, and clinical pharmacy services were among the pharmacy services available. Furthermore, the National and international guidelines for general research in hospital practice.^[1-11,20-22] The Saudi Food and Drug Authority (SFDA),^[2,11] European Medicine Agency,^[9] the American Society of Health-System Pharmacist (ASHP),^[10] and World Health Organization (WHO),^[7] and other literature.^[23,24] The pharmacy research committee was formed and comprised of numerous expert members. That includes clinical pharmacists, pharmacists specializing in drug information, and clinical research specialists. One member drafted the policy guidelines, another member reviewed and corrected them, and a research specialist revised them three times. The topic covered various areas, including pharmacy research practice, research and ethical committees, data collection and organization in pharmacy practice, the quality of pharmacy research services, pharmacy research competency, and pharmacy research education and training. The current reviews were reported following the internationally adopted Appraisal of Guidelines, Research, and Evaluation (AGREE) standard.^[25]

The search term methodology was done as follows

Search: research policy[Title/Abstract]
Filters: **Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English**

("research policy"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research policy[MeSH Terms] Filters: **Full text, Guideline, Practice Guideline, in the last 10 years, Humans, English**

(("research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research s"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher s"[All Fields] OR

"researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]) AND "policy"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR practiceguideline[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research: «research personnel»[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research's"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher's"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]

policy[MeSH Terms]: «policy»[MeSH Terms]

Search: research procedures[Title/Abstract]
Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English**

("research procedures"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research procedures [MeSH Terms]
Filters: **Full text, Guideline, Practice Guideline, in the last 10 years, Humans, English**

(("research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research s"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher s"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]) AND "methods"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR practiceguideline[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research: «research personnel»[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research's"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher's"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]

procedures [MeSH Terms]: «methods»[MeSH Terms]

Search: research report[Title/Abstract]
Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English**

("research report"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research reporting[Title/Abstract]
Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English**

("research reporting"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research report[MeSH Terms]
Filters: **Full text, Guideline, Practice Guideline, in the last 10 years, Humans, English**

("research report"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR practiceguideline[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research report[MeSH Terms]: «research report»[MeSH Terms]

Search: clinical trial policy[Title/Abstract]
Filters: **Full text, Humans, English**

("clinical trial policy"[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: clinical trial policy[MeSH Terms]
Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

(("clinical trial"[Publication Type] OR "clinical trials as topic"[MeSH Terms] OR "clinical trial"[All Fields] AND "policy"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

clinical trial: «clinical trial»[Publication Type] .or. "clinical trials as topic"[MeSH Terms] .or. "clinical trial"[All Fields]

policy[MeSH Terms]: «policy»[MeSH Terms]

Search: clinical trial reporting[Title/Abstract]
Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English**

(“clinical trial reporting”[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: **clinical trial report**[MeSH Terms]
Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

((“clinical trial”[Publication Type] OR “clinical trials as topic”[MeSH Terms] OR “clinical trial”[All Fields]) AND “research report”[MeSH Terms]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

clinical trial: «clinical trial»[Publication Type] .or. “clinical trials as topic”[MeSH Terms] .or. “clinical trial”[All Fields]

report[MeSH Terms]: «research report» [MeSH Terms]

Search: **Institutional Review Board**[Title]
Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

(“institutional review board”[Title]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Search: **Institutional Review Board**[MeSH Terms] **Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

(“ethics committees, research”[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

Institutional Review Board[MeSH Terms]: «ethics committees, research»[MeSH Terms]

Search: **pharmacy Institutional Review Board** [Title/Abstract] **Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

((“pharmacie”[All Fields] OR “pharmacies” [MeSH Terms] OR “pharmacies”[All Fields] OR “pharmacy”[MeSH Terms] OR “pharmacy”[All Fields] OR “pharmacy s”[All Fields]) AND “institutional review board”[Title/Abstract]) AND ((y_10[Filter]) AND (guideline[Filter]

OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

pharmacy: «pharmacie”[All Fields] OR “pharmacies”[MeSH Terms] OR “pharmacies” [All Fields] OR “pharmacy”[MeSH Terms] OR “pharmacy”[All Fields] OR “pharmacy’s”[All Fields]

Search: **pharmacy Institutional Review Board** [MeSH Terms] **Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

((“pharmacie”[All Fields] OR “pharmacies” [MeSH Terms] OR “pharmacies”[All Fields] OR “pharmacy”[MeSH Terms] OR “pharmacy”[All Fields] OR “pharmacy s”[All Fields]) AND “ethics committees, research”[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

pharmacy: «pharmacie”[All Fields] OR “pharmacies”[MeSH Terms] OR “pharmacies” [All Fields] OR “pharmacy”[MeSH Terms] OR “pharmacy”[All Fields] OR “pharmacy’s”[All Fields]

Institutional Review Board[MeSH Terms]: «ethics committees, research»[MeSH Terms]

Search: **pharmaceutical Institutional Review Board**[Title/Abstract] **Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

((“biopharmaceutics”[MeSH Terms] OR “biopharmaceutics”[All Fields] OR “pharmaceutic”[All Fields] OR “pharmaceutics” [All Fields] OR “pharmaceutical preparations” [MeSH Terms] OR (“pharmaceutical”[All Fields] AND “preparations”[All Fields]) OR “pharmaceutical preparations”[All Fields] OR “pharmaceutical”[All Fields] OR “pharmaceutics” [All Fields] OR “pharmaceutically”[All Fields]) AND “institutional review board”[Title/Abstract]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

pharmaceutical: «biopharmaceutics»[MeSH Terms] OR “biopharmaceutics”[All Fields] OR “pharmaceutic”[All Fields] OR “pharmaceutics”

[All Fields] OR “pharmaceutical preparations” [MeSH Terms] OR (“pharmaceutical”[All Fields] AND “preparations”[All Fields]) OR “pharmaceutical preparations”[All Fields] OR “pharmaceutical”[All Fields] OR “pharmaceutics” [All Fields] OR “pharmaceutically”[All Fields]

Search: **pharmaceutical Institutional Review Board**[MeSH Terms] **Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

((“biopharmaceutics”[MeSH Terms] OR “biopharmaceutics”[All Fields] OR “pharmaceutic”[All Fields] OR “pharmaceutics” [All Fields] OR “pharmaceutical preparations” [MeSH Terms] OR (“pharmaceutical”[All Fields] AND “preparations”[All Fields]) OR “pharmaceutical preparations”[All Fields] OR “pharmaceutical”[All Fields] OR “pharmaceutics”[All Fields] OR “pharmaceutically”[All Fields] AND “ethics committees, research”[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

pharmaceutical: «biopharmaceutics»[MeSH Terms] OR “biopharmaceutics”[All Fields] OR “pharmaceutic”[All Fields] OR “pharmaceutics” [All Fields] OR “pharmaceutical preparations” [MeSH Terms] OR (“pharmaceutical”[All Fields] AND “preparations”[All Fields]) OR “pharmaceutical preparations”[All Fields] OR “pharmaceutical”[All Fields] OR “pharmaceutics” [All Fields] OR “pharmaceutically”[All Fields] OR “pharmaceutically”[All Fields]

Institutional Review Board[MeSH Terms]: «ethics committees, research»[MeSH Terms]

Search: **pharmacist Institutional Review Board** [Title/Abstract] **Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

((“pharmacist s”[All Fields] OR “pharmacists” [MeSH Terms] OR “pharmacists”[All Fields] OR “pharmacist”[All Fields]) AND “institutional reviewboard”[Title/Abstract]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis [Filter] OR practiceguideline[Filter] OR review [Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

pharmacist: «pharmacists»[All Fields] OR «pharmacists»[MeSH Terms] OR “pharmacists” [All Fields] OR “pharmacist”[All Fields]

Search: pharmacist Institutional Review Board [MeSH Terms] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

((“pharmacist s”[All Fields] OR “pharmacists” [MeSH Terms] OR “pharmacists”[All Fields] OR “pharmacist”[All Fields]) AND “ethics committees, research”[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline [Filter] OR review[Filter] OR systematicreview [Filter]) AND (ff[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

pharmacist: «pharmacists»[All Fields] OR «pharmacists»[MeSH Terms] OR “pharmacists” [All Fields] OR “pharmacist”[All Fields]

Institutional Review Board[MeSH Terms]: «ethics committees, research»[MeSH Terms]

RESULTS AND DISCUSSION

The pharmacist may adhere to the following suggested pharmacy policies and procedures.^[1-11]

The Institutional Review Board is defined as a committee comprised of at least five members drawn from the healthcare organization’s scientific community with certain functions about research.

The function of the Institutional Review Board

1. Conduct a review of human research and communicate to investigators and healthcare organizations whether an action is approved, disapproved, or requires revision.
 - a. Exempted Research: This type of research does not require IRB approval (discovery studies, review of novel ideas, review of new programs, review of new services, cost analysis, therapeutic guidelines). The review article, the systematic review, the meta-analysis, the observational study, and the cross-sectional study).
 - b. Expedited Research; this refers to human research subject to review by a member of the IRB committee with the least amount of risk to patients.
 - c. Comprehensive revision Human research must be thoroughly reviewed by all IRB members, including research that involves a high risk of harm to patients, such as a clinical trial.

2. Ensure that the human research project is adhered to after approval.
3. Accept the donation to conduct research.
4. Approval of the research project’s financial support.
5. Oversee the cost analysis and payment for all human clinical trials.

Policy and Procedures

1. The researcher should review their work, which falls into three categories. If the category is Exempt, the research proposal does not need to be submitted to the committee. Otherwise, the investigator submits the research project to the research department’s responsible person for segregation.
2. If the research is exempt, it may begin outside healthcare organizations. If the research is conducted within hospitals, it must obtain approval from healthcare organizations.
3. If the research project falls under the category of Expedited. The IRB reviews the research proposal.
4. If possible, the chair or secretary of the IRB invites three members with expertise in the research project to review it.
5. If the research project is approved, the IRB’s secretary will send a letter or email confirming the committee’s approval.
6. The IRB sends a copy of the approval letter to the healthcare administration, emphasizing the importance of allowing the research to begin.
7. If a research project requires extensive revision, the chairman or secretary of the IRB should invite all committee members to review it.
8. If more than 60% of the community approves the research project, the secretary will send an approval letter or email to the investigator, copying healthcare administration and all relevant departments, authorizing the researcher to begin the research.
9. Revise the research project following patient rights and welfare, applicable local laws and regulations, institutional commitments, and professional standards.
10. The investigators should submit a certificate of good clinical practice or research training, informed consent for clinical trials, and a conflict of interest letter.
11. All investigators should adhere to the Saudi Food and Drug Authority’s guidelines for conducting clinical trials at all stages.

12. The committee will determine the cost of human clinical trials that will take place in healthcare organizations.
13. The researcher should submit a progress report on the research project every quarter in an expedited and complete revision.
14. The monitoring report for clinical trials should include the following.
 - The total number of subjects.
 - A summary of any unexpected problems and available data on adverse events.
 - A summary of any subjects withdrawn from the study since the most recent institutional review board (IRB) review.
 - A summary of all complaints received regarding the research since the most recent IRB review.
 - A review of recent literature that may be pertinent to the research.
 - Any multicentre trial reports that are pertinent.
 - Any additional pertinent information, particularly information regarding the risks associated with the research.
 - A copy of the current informed consent document and any new consent being proposed.
15. The researcher should submit a final letter indicating the completion of the research project, along with a summary of the findings.
16. Upon receiving the investigator’s final letter, the committee will send the investigator a closing letter regarding the research project.
17. If clinical trials are extended beyond the period approved, the chairperson or secretary of the committee invites all members to a meeting to make final decisions. Either extend the duration of the research project or send a letter concluding the project.
18. If serious problems or non-compliance with research methodology occur during the clinical trial, the committee will write to the investigator requesting that the research be terminated.
19. The selected committee member will regularly monitor all approved human research projects and communicate the current state of affairs to all committee members for action.

CONCLUSION

The international review board is a critical committee for clinical trials of investigational medications conducted by healthcare organizations. The committee evaluated,

approved, and monitored clinical research involving known risks to patients. All pharmacy research is undertaken not to endanger or jeopardize patients, their disclosure, or their welfare; therefore, such observational studies related to pharmacy practice were exempt from the committee. However, the committee can focus on significant research that poses a risk to patients and encourage observational studies conducted by young researchers or students. All IRB committees should conduct an audit of their activities and revise the types of research required to enhance the quality and quantity of performance committees in healthcare organizations.

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ACKNOWLEDGEMENT

None.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

IRB: Institutional Review Board; **KSA:** Kingdom of Saudi; **SFDA:** Saudi Food and Drug Authority; **WHO:** World Health Organization; **EMA:** European Medicine Agency; **ASHP:** American Society of Health-System Pharmacists; **AGREE:** Appraisal of Guidelines, Research, and Evaluation.

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