# Research Policy on Pharmacy Investigational Medication

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## ABSTRACT

**Objectives:** This study aims to demonstrate the Research Policy of Pharmacy Investigational Medication 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 time 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 settings. 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 Pharmacy Research's policy on Investigational Medication. **Results:** The Pharmacy Research policy for Investigational Medication consisted of a number of components, including the administration of pharmacies, the procurement of investigational drugs, and the storage of investigational drugs. Additionally, the investigative drug prescription, the preparation of investigative drugs, the dispensing of investigative drugs, the administration of investigative drugs, and the monitoring of investigative drugs. There were a number of essential policy items, including the safety of investigational medications, the cost of investigational drugs, and the sponsors of investigational drug research. **Conclusion:** The Pharmacy Research policy for Investigational Medication is a new initiative as part of pharmacy practice research and development. Investigational Medication Pharmacy Research policy helps healthcare organizations improve patient safety and prevent drug-related morbidity and mortality. It is a component of Saudi Arabia's pharmacy strategic plan for Vision 2030 and pharmacy reimbursement initiatives.
**Key words:** Research, Policy, Pharmacy, Investigational, Drug, Medication, Saudi Arabia.

## INTRODUCTION

In practice, pharmacy services in healthcare organizations cover a wide range of topics.[1] It was divided into different sections, departments, and programs. The pharmacy's performance and activities must be organized by the pharmacy services.[2,3] In addition, the pharmacy services dispense thousands of medications across hundreds of prescriptions.[4] These medications should be delivered to patients on time, along with appropriate education and counseling.[5] These things require organization, and pharmacy policies and procedures are required. Pharmacy policies and procedures are part of local or international pharmacy standards.[1,6-8] It also has accreditation requirements for pharmacies and healthcare organizations.[1,9] The policy calls for better clinical outcomes for patients and the prevention of drug-related problems.[2,3] Furthermore, medication safety is closely monitored during procurement, storage, preparation, and dispensing.[2,3,6] The pharmacy policy and procedures cover all hospital medications that have been approved for dispensing by hospital leaders. Those medications could be registered in local or international countries, or they could be in the process of being registered, or they could be in clinical trials. Until the investigational drugs were fully registered in each country, they were temporarily used in healthcare organizations. As a result, they require specific policies and procedures to cover all aspects of medication preparation, prescription, and dispensing.[10] There were discrepancies in the performance of clinical trial medications according to investigational drug services and policy or procedures, according to some studies.[11-13] There have been few studies or discussions about the pharmacy policy of research medications.[10] The author is unaware of any publications on the subject,[14-16] and the goal of the recent review is to declare the investigational drug policy and procedures in pharmacy practice.

## 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.[10,17-29] The Saudi Food and Drug Authority (SFDA),[17,18] the European Medicine Agency,[29] the American Society of Health-System Pharmacists (ASHP),[10] and the World Health Organization (WHO),[27] as well as pharmacy literature,[30-43] and other literature.[14-16] Aside from that, the Equator Network is a library of health research guidelines based on randomized trials. That includes the Consolidated Standards of Reporting Trials (CONSORT); the Guidelines for Reporting Parallel Group Randomized Trials, which are guided by writing policy and procedures,[44-46] which were developed by a committee of pharmacy researchers. Clinical pharmacists, drug information pharmacists, and clinical research specialists are among those who work in this field. One member's policy draft guidelines were reviewed and corrected by a second member, and the research specialist completed the third revision. Pharmacy research practice, research and ethical committee, data collection and organizations, quality of pharmacy research services, competency of pharmacy research services, and pharmacy research education and training were among the topics covered. The current reviews were reported in accordance with the adopted international Appraisal of Guidelines, Research, and Evaluation (AGREE).[47]

## The search term methodology was done as follows

Search: **pharmacy research policy[Title/Abstract]** Filters: **Full text, 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 "research policy"[Title/Abstract]) 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 research policy[MeSH Terms]** Filters: **Full text, Guideline, Meta-Analysis,** Practice **Guideline, Review, Systematic Review, Humans, English**

(("pharmacy research"[MeSH Terms] OR ("pharmacy"[All Fields] AND "research"[All Fields]) OR "pharmacy research"[All Fields]) AND "policy"[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

**pharmacy research:** «pharmacy research»[MeSH Terms] OR («pharmacy»[All Fields] AND «research»[All Fields]) OR «pharmacy research»[All Fields]

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

Search: **pharmaceutical research policy[Title/Abstract]** Filters: **Full text, 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 "pharmaceuticals"[All Fields] OR "pharmaceutical s"[All Fields] OR "pharmaceutically"[All Fields]) AND "research policy"[Title/Abstract]) 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 «pharmaceuticals»[All Fields] OR «pharmaceutical›s»[All Fields] OR «pharmaceutically»[All Fields]

Search: **pharmaceutical research policy[MeSH Terms]** Filters: **Full text, Guideline, Meta-Analysis,** Practice **Guideline, Review, Systematic Review, Humans, English**

(("pharmaceutical research"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "research"[All Fields]) OR "pharmaceutical research"[All Fields]) AND "policy"[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

**pharmaceutical research:** «pharmaceutical research»[MeSH Terms] OR («pharmaceutical»[All Fields] AND «research»[All Fields]) OR «pharmaceutical research»[All Fields]

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

Search: **investigational drug policy[Title/Abstract]** Filters: **Full text, Humans, English**

("investigational"[All Fields] AND "drug policy"[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: **investigational drug policy[MeSH Terms]** Filters: **Full text, Guideline, Meta-Analysis,** Practice **Guideline, Review, Systematic Review, Humans, English**

(("drugs, investigational"[MeSH Terms] OR ("drugs"[All Fields] AND "investigational"[All Fields]) OR "investigational drugs"[All Fields] OR ("investigational"[All Fields] AND "drug"[All Fields]) OR "investigational drug"[All Fields]) AND "policy"[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

**investigational drug:** «drugs, investigational»[MeSH Terms] OR («drugs»[All Fields] AND «investigational»[All Fields]) OR «investigational drugs»[All Fields] OR («investigational»[All Fields] AND «drug»[All Fields]) OR «investigational drug»[All Fields]

**policy[MeSH Terms]:** «policy»[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]

## RESULTS AND DISCUSSIONS

The policy and procedures for investigational medications were divided into several sections. Starting with pharmacy administration, procurement of investigational drugs, and storage of investigational medicines. It is followed by prescribing investigative drugs, preparing and dispensing, administering, and monitoring them. Additionally, the following information pertains to the investigational medication's safety, the investigational drug's cost, and the investigational drug's research sponsor:

The policy for Pharmacy Investigational Medication.[10,14,17-19,27-29,34,44-46]

### Pharmacy administration

1. Pharmacy departments should receive protocols for investigational medications from the healthcare organization's IRB. That includes the acquisition, storage, prescription, preparation, dispensing, and administration of medications.
2. The pharmacy departments should receive additional documentation. For instance, the letter from the IRB approving the investigational medications or the investigational drug sheet. Additionally, pharmacy departments should provide a summary of the investigational drug sheet. The drug sheet included the name and common synonyms, the dosage forms and strengths, the usual dosage range, the dosage schedule and route of administration, and the indications for this study. Apart from the anticipated therapeutic effect, the anticipated and potential adverse effects, including toxicity symptoms and their treatment, drug-drug and drug-food interactions, contraindications, and storage requirements, must be considered. Additionally, instructions for dosage preparation and administration, including stability and handling guidelines, instructions for disposal of unused doses, and the names and telephone numbers of the principal investigator, authorized sub-investigators, and study coordinators, are included.
3. The distribution sheet for investigational drugs should be kept confidential by the appropriate pharmacy staff. Additionally, all facets of the health system. For example, the health care computer system may have access to all drug sheets.
4. Pharmacy departments place the research pharmacist or investigational drug pharmacist in any location within the pharmacy capable of handling clinical trial activities.
5. Principal investigators should educate and train members of the reach team and research pharmacy staff about the protocol for investigational medications.

### Investigational drug Procurement

1. If the investigational drug is supported by the manufacturer, it should have a manufacture lot number and bar code with blinded names and sufficient quantities to last until the end of the clinical trial.
2. If the clinical trial is conducted using the formulary medication, the pharmacy department assigns some quantities of medication until the clinical trial is completed and the medication is funded by the healthcare organization in accordance with the drug protocol approved by the institutional review board.

### Investigational drug Storage

1. When possible, the pharmacy should have a separate location for investigational medications, such as a satellite research pharmacy.
2. The investigational drug storehouses all medications currently undergoing clinical trials.
3. All investigational drugs should be stored following the protocol for the clinical trial.
4. All investigational drug stores should be maintained at the required temperature and location and labeled or have blinding labels.
5. All investigational medications are labeled with a barcode and the manufacturer's batch number.
6. The pharmacist should keep track of the investigational medicines' inventory and maintain documentation records.
7. If the medication is kept in a location other than pharmacy departments, such small quantities. The pharmacist should conduct an audit to ensure that proper storage, accountability, and dispensing are occurring in accordance with the institution's regulations and local pharmacy law.
8. Records for investigational medications should include the drug's name, dosage form, strength, lot number, and expiration date. Additionally, the sponsor's name, telephone number, and address. The protocol number and any other data required for dispensing. Another recorder shall include the number of drugs received, wasted, or dispensed, as well as the dates associated with those quantities. Additionally, the record of the names or codes of individuals received and prescribers, the quantity on hand, the minimum stock and reorder levels, and the recorder's initials.
9. All investigational medications should be quantified based on the therapeutic doses specified in the protocol.
10. All investigational medications that are not administered should be returned to the pharmacy investigational drug store with documentation.
11. A sponsor or the SFDA may audit all investigational drug records.
12. After the clinical study, the pharmacist shall return all unused investigational medications following sponsor instructions and applicable local regulations.

### Investigational drug Prescribing

1. All investigational medications must be prescribed in accordance with the protocol and methodology for the investigational drug.
2. The investigational drugs are restricted only to physicians with prescribing privileges.
3. Detailed information about investigational drugs, including patient information, dosing, frequency, route of administration, and information about prescribing procedures.

4. According to the drug protocol, investigational drugs should be prescribed under generic or blinding names.

## Investigational drug Preparation and dispensing

1. The pharmacist prepared the investigational drug following the manufacturer's protocol.
2. The pharmacist dispenses medications in accordance with medication management and usage guidelines, which may include, but are not limited to reviewing the order, maintaining the patient profile, packaging, labeling, and delivery following quality management procedures.
3. Investigational medications are only dispensed by authorized pharmacists upon prescription by authorized investigators following the drug protocol.
4. The labeling of investigational drugs should include the drug's name, strength, dose, frequency, and route of administration. Additionally, investigational drug labeling is distinct from non-investigational drug labeling. That could be accomplished using a unit dose drug distribution system or the provision of ambulatory care services.
    - The labeling of investigational drugs should include any warnings about potential hazards.
    - A method for obtaining a valid and signed convent had been established.
5. The research pharmacist or investigational nurses should educate patients receiving investigational medications and non-investigational.
6. All investigational medications should be accompanied by educational materials and dispensed through inpatient or outpatient pharmacies.

## Investigational drug Administration

The investigational drug administration procedures should be discussed with patients. The nurses follow the approved investigational drug protocol, and medication should be administered appropriately.

## Investigational drug Monitoring

Research pharmacists, investigators, and research teams should monitor the investigational drug and all patient drug therapy. To begin, it must monitor the drug's safety and efficacy. Any drug-related complications (medication errors, adverse drug reactions, non-compliance, excessive compliance, overdose, and poisoning) should be documented following the investigational drug protocol.

## Investigational medication safety

1. All investigational medications should adhere to local and international medication safety guidelines and regulations (CBAHI, ISMP, and Joint Commission) throughout the medication management process. From procurement to administration.
2. The investigational drug should be stored under appropriate control in a pharmacy store with restricted access and a separate location.
3. Prior to initiating the clinical trial, the research or investigational drug pharmacist should review all medication management processes and follow them consistently.
4. The research or investigational drug pharmacist should ensure that the blinding system is adequately implemented to administer the correct drug to patients.
5. The reach team, including the investigator, the sponsor, and a research or investigational drug pharmacist, must establish a procedure for emergency unbinding treatment.
6. The pharmacist responsible for research or investigational drugs may assign some pharmacists to assist with clinical trial work. In addition, the responsible pharmacist is responsible for educating and training the new pharmacist regarding drug protocol studies.
7. The research or investigational drug pharmacist should monitor patients for medication adherence by dispensing medications that were not taken or administered to them. In addition, the pharmacist should inform the patient about the research team's dedication.
8. The research or investigational drug pharmacist should counsel patients about medications and encourage them to adhere to drug protocol requirements.

## Investigational drug cost

1. Prior to conducting the study, the research or investigational drug pharmacist should estimate the cost of the clinical trial in order to determine the study's cost-effectiveness.
2. The research or investigational drug pharmacist should prepare an annual report about the clinical trial conducted. It emphasizes the investigational medications used and cost-related issues to the pharmacy director and the pharmacy and therapeutic committee. In addition, the information should include past and current studies and financial statements.
3. All drug direct and indirect costs and other expenses should be calculated and allocated appropriately by the healthcare organization's budget, sponsor reimbursement, or healthcare insurance.
4. Regardless, no healthcare organization should charge patients for investigational medications.
5. The informed consent form should include a breakdown of all anticipated drug costs. Additionally, patients should be informed of the cost of coverage by their health insurance company, sponsor, or healthcare organization, as well as the amount they pay for each visit.

## Investigational drug Research Sponsors

1. The manufacturer or sponsor should obtain reliable and validated data from healthcare organizations that have conducted clinical trials.
2. The manufacturer or sponsor should adhere to guidelines to ensure the study is conducted effectively, efficiently, and safely. That includes packaging medications properly following national and international drug registration agencies (SFDA, FDA, USP-NF, B-NF). In addition, medicines must be labeled following applicable regulations, standards, and local laws. Besides, the expiration date and lot number should be clearly marked on investigational medications, and the sponsor representative's (handling the investigational drugs) telephone number should be available 24 hr a day.
3. The sponsor or manufacturer should provide the pharmacist with the following information, emphasizing the drug sheet. That includes the storage conditions required prior to and subsequent preparation. The diluents used in reconstitution and administration, as well as the final concentration of the active ingredient, the prepared product's stability, compatibility with drug delivery systems, diluents or intravenous fluids, containers, intravenous tubing, and filters, and the product's known compatibility or incompatibility with other products. Apart from that, light sensitivity, filtration requirements, expiration dates or retest dates, special preparation and administration instructions, routes and methods of administration, including infusion rates for injectable products. Additionally, to Be aware of adverse effects occurring during or following administration and how to avoid or treat

them. The usual dosage regimens and the maximum dose have been tested for specific disease states. That includes prescribing and labeling dosage expressions, contraindications, drug interactions, and special precautions for storage, handling, and disposal of cytotoxic and hazardous drugs. The pharmacy department must provide material safety data sheets for all hazardous drugs. Additionally, information about pharmacology, including mechanism of action, pharmacokinetic characteristics, and the return of unused drugs to the sponsor, should be provided to the pharmacist and information regarding storage and return procedures. Contaminated, outdated, or unsuitable medications should be returned to the sponsor or destroyed following the institution's policies, practices, and applicable laws and regulations.

4. All information pertaining to investigational medications should be accessible during any emergency, including adverse drug reaction and management, emergency protocol management, and supply under the emergency use protocol. During clinical trials, the research or investigational drug pharmacist should contact the sponsor in the event of an emergency.
5. The research or investigational drug pharmacist should have the following information about investigational medications on hand: the study monitor's name and telephone number, the estimated time of receiving the medications, the quantities for each shipment, the procedures for ordering investigational drugs, and the drug receipt invoice.
6. The sponsor should cover the following financial expenses for personal, storage, equipment, and an ancillary product such as needles or diluents, syringes, computers, and data processing software, as well as the pharmacy costs associated with the study.
7. The sponsor of research or investigational medications should provide final closure details within six months of the clinical trial's conclusion. That includes study closure notifications, drug disposition directives, and the final audit of all study records.
8. The final report of the research should be written following the Consolidated Standards of Reporting Trials (CONSORT) and the Guidelines for Reporting Parallel Group Randomized Trials.[44-46]

## CONCLUSION

Drug research or investigational medication policies and procedures are fundamental aspects of pharmaceutical care services' research and development units. The policies and procedures are necessary to establish an excellent clinical practice foundation and promote pharmacy incidents reports in pharmacy research services. Additionally, the policy will safeguard patients against any drug-related complications and improve patient outcomes in clinical trials. Therefore, the investigational drugs policy is strongly recommended for Saudi Arabian pharmacy practice implementation.

## ACKNOWLEDGEMENT

None.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

### Funding

None

### Consent for Publications

Informed consent was obtained from all the participants

### Ethical Approval

This research was exempted from research and ethical committee or an institutional review board (IRB) approval.

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

## ABBREVIATIONS

**KSA:** Kingdom of Saudi; **SFDA:** Saudi Food and Drug Authority (SFDA); **EMEA:** European Medicine Agency; **WHO:** World Health Organization; **ASHP:** American Society of Health-System Pharmacists; **CONSORT:** Consolidated Standards of Reporting Trials; **AGREE:** Appraisal of Guidelines, Research, and Evaluation.

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