

Kingdom of Saudi Arabia

Ministry of National Guard

Health Affairs



المملكة العربية السعودية  
وزارة الحرس الوطني  
الشؤون الصحية

# APP

## MINISTRY OF NATIONAL GUARD - HEALTH AFFAIRS ADMINISTRATIVE POLICY AND PROCEDURES

NUMBER : 1433-37  
TITLE : CONDUCTING RESEARCH STUDIES  
ORIGINATING DEPT. : KING ABDULLAH INTERNATIONAL MEDICAL  
RESEARCH CENTER (KAIMRC) (417780)  
ORIGINAL DATE : DECEMBER 2012  
REVISED DATE : SEPTEMBER 2015

### 1. PURPOSE

To provide a process for conducting research studies approved by the Institutional Review Board (IRB).

### 2. APPLICABILITY

To all research studies conducted within Ministry of National Guard - Health Affairs (MNG-HA) facilities.

### 3. RELATED REFERENCES

- 3.1 APP 1419-05: Research Proposal Submission, Processing and Approval
- 3.2 APP 1426-02: Institutional Review Board (IRB)
- 3.3 APP 1432-04: Appeal Process for Rejected Research Proposal or Suspended Ongoing Research Study
- 3.4 APP 1432-20: Monitoring Research Studies
- 3.5 International Conference of Harmonisation (ICH): ICH Harmonised Tripartite Guideline - Guideline for Good Clinical Practice E6(R1)
- 3.6 Joint Commission International Accreditation Standards for Hospitals, 5th Edition (2014) – HRP.7, ME.1-6 and HRP.7.1, ME.1-3

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#### 4. DEFINITIONS

- 4.1 Adverse Event (AE)** refers to any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product research studies.
- 4.2 Audit** refers to a systematic and independent examination of research study-related activities and documents to determine whether the evaluated study-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's Standard Operating Procedures (SOP), Good Clinical Practice (GCP), and the applicable regulatory requirements.
- 4.3 Case Report Form (CRF)** is a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.
- 4.4 Chief Principal Investigator (Chief PI)** refers to an individual who has the responsibilities of the principal investigator and is responsible for submitting the research protocol for multi-center studies and overall conduct of the research in other sites.
- 4.5 Clinical Research** refers to a branch of medical research that determines the safety and effectiveness of medications, medical devices, diagnostic products and/or treatment regimens intended for human use.
- 4.6 Clinical Research Associates (CRA)** work closely with the Principal Investigator (PI) to perform various responsibilities for conducting research studies as directed by the PI.
- 4.7 Clinical Trials** refers to a set of tests in medical research and drug development that generate safety and efficacy data for health interventions, e.g., drugs, diagnostics, devices and protocols).
- 4.8 Essential Documents** are documents that allow on individual and collective bases to evaluate the conduct of a study and the quality of the data produced.
- 4.9 Externally Sponsored Research Studies** refer to studies sponsored and/or funded by any non-MNG-HA organization.
- 4.10 Informed Consent** refers to the process by which a subject voluntarily confirms their willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated Informed Consent Form (ICF).
- 4.11 Informed Consent Form (ICF)** refers to a form used for documenting informed consent from a subject of a research study.

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trial, at the sponsor's and/or contract research organizations' (CRO's) facilities or at other establishments deemed appropriate by the regulatory authority(ies).

- 4.13 Institutional Review Board (IRB)** refers to an independent body composed of medical, scientific, and non scientific members whose responsibility is to ensure the protection of the rights, safety and well being of human subjects involved a research studies.
- 4.14 International Conference of Harmonisation/Good Clinical Practice (ICH/GCP)** is a standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.
- 4.15 Investigational Drug Services Unit** refers to a subunit of the Research Office composed of licensed pharmacists which provides support and guidance for the safe and efficient management of investigational products used in clinical trials. It provides services on dispensing, accountability, handling, storage and control of investigational drugs in compliance with the research study protocol, KAIMRC/MNG-HA, external sponsor policies, ICH/GCP guidelines and applicable regulatory requirements.
- 4.16 Investigational Product** refers to a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
- 4.17 Monitoring** refers to the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the research study protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements.
- 4.18 Monitoring Report** refers to a written report from the monitor to the Research Office after each site visit and/or other trial-related communication.
- 4.19 MNG-HA Sponsored Research Studies** refers to the research studies sponsored and funded by MNG-HA.
- 4.20 Principal Investigator (PI)** refers to a person responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at the trial site, the PI is the responsible leader of the team.
- 4.21 Protocol Amendment** refers to a written description of a change(s) or formal clarification of an approved protocol.
- 4.22 Regulatory Authorities** refers to bodies having the power to regulate and review the submitted clinical data and those conducting inspections.
- 4.23 Research Committee (RC)** is a body composed of medical practitioners/clinicians whose responsibility is to review all research proposals for MNG-HA services, make recommendations for amendment and/or approval on scientific basis and forward them to IRB for ethical point of view.

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- 4.24 Research Office (RO)** is a section of KAIMRC which manages all research studies conducted within MNG-HA.
- 4.25 Research Funding Committee (RFC)** refers to a committee responsible for review and approval of fund requests for conducting research projects per Committee Formation Order-KAIMRC-01-011.
- 4.26 Research Study Protocol** refers to a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The research study protocol usually gives the background and rationale for the trial, however, these may be provided in other protocol referenced documents.
- 4.27 Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (SADR)** refers to an untoward medical occurrence that at any dose: results in death, a life-threatening situation, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or a congenital anomaly/birth defect.
- 4.28 Site Principal Investigator (Site PI)** refers to an individual who has the responsibilities of the principal investigator and is responsible for conducting the research study for a particular center of multi-center studies.
- 4.29 Source Documents** refers to Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
- 4.30 Standard Operating Procedure (SOP)** is a document that specifies all operational steps, acceptance criteria, personnel responsibilities, and materials required to accomplish a task.
- 4.31 Sponsor** refers to an individual, company, institution or organization who takes responsibility for the initiation, management and/or financing of a research study.
- 4.32 Study Close Out** refers to the procedures undertaken to fulfill administrative, regulatory, and human participant requirements either after completion of study related requirements or if the study is prematurely terminated for any reason.
- 4.33 Sub-Investigator:** Any individual member of the research team designated and supervised by the PI at a study site to perform critical research project-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
- 4.34 Subject/Trial Subject** refers to an individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
- 4.35 Suspected Unexpected Serious Adverse Reaction (SUSAR)** refers to a serious adverse event or serious adverse drug reaction considered "unexpected". An event is

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considered unexpected if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere as applicable.

## 5. POLICY

**5.1** Patients and families must be identified and informed about how to gain access to clinical research, investigations or trials relevant to their treatment needs in accordance with KAIMRC SOPs. The following measures must be adopted as applicable:

**5.1.1** Publication of relevant information about all ongoing trials in the KAIMRC website.

**5.1.2** Display of posters/screens containing relevant information about trials in the outpatient & inpatient clinics.

**5.1.3** Distribution of leaflets in the outpatient clinics and inpatient areas.

**5.1.4** Any advertisement that may be used for the recruitment of research subjects, whether in the form of posters, emails, telephone calls and/or other materials must receive IRB approval prior to their application.

**5.2** The PI is primarily responsible for overall conduct of the research study and is responsible for ensuring proper protection of research subject' rights, safety and wellbeing.

**5.2.1** The PI must not initiate any research study related procedures and/or recruit any research subjects without obtaining the final IRB approval on the research protocol and other study documents, as applicable, unless the research proposal has been exempted from IRB approval. For more information refer to APP 1419-05 and APP 1426-02.

**5.2.2** The PI must conduct the research study in a systematic and orderly manner, ensuring compliance to the following:

**5.2.2.1** Research protocol, ICH/GCP guidelines, Institutional Review Board (IRB) policies and regulations

**5.2.2.2** Saudi Food and Drug Authority (SFDA)

**5.2.2.3** Standard Operation Procedures (SOPs) as stated in this APP (Appendix A)

**5.2.2.4** MNG-HA research-related policies and procedures

**5.2.2.5** Other national and/or international regulations, as applicable.

**5.3** The PI/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

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- 5.4 The PI and other research team members are responsible for protecting the confidentiality and privacy of all screened and enrolled research subjects.
- 5.4.1 The PI must record efforts regarding research subject screening and enrollment.
- 5.4.2 The PI must ensure that study procedures are performed only on those subjects enrolled in the research study that have given their voluntary consent to be part of the research study.
- 5.4.3 The PI must ensure that all arrangements are made to protect confidential information related to screened and enrolled research subjects during and after the completion of the research study, refer SOP SM 404 Protecting Confidential Information (**Appendix A**) for details.
- 5.5 Any deviation/violation from the research protocol must be reported to the IRB and Research Office within five (5) working days.
- 5.6 The PI is responsible for reporting Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reaction (SUSAR) to the IRB and Adverse Events (AEs) in the Case Report Form in timely manner as per KAIMRC policies and procedures.
- 5.7 The research study must be conducted within the specified duration stated in the research protocol.
- 5.8 The PI is responsible for selecting and identifying their research team members.
- 5.8.1 The PI must select an adequate number of research team members to allow him/her to adequately conduct the research procedures.
- 5.8.2 The PI must make sure that any member of the research team plays a role in the research study.
- 5.9 The PI must perform specific research study procedures in accordance with the proposed work plan stated in the research protocol.
- 5.9.1 The PI must initiate study procedures no later than ninety (90) days from IRB approval, or ninety (90) days from the release of funds, if applicable.
- 5.9.2 The PI must inform the Monitoring Unit and IRB regarding the initiation of the first study procedure(s) or the recruitment of the first research study subject.
- 5.9.3 The PI must inform the Research Office, IRB and Funding Committee in the event of failure to conduct the research study within the specified duration.
- 5.9.4 Any changes to the IRB approved protocol must be reported to the IRB for approval.
- 5.9.4.1 PI must obtain IRB approval prior to the implementation of any protocol amendments. The PI can follow the existing protocol until the new amendments are approved (refer to APP 1426-02: Institutional Review Board).

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- 5.10** The PI must ascertain the validity of the IRB approval, as IRB approval is typically valid for one (1) year, refer to APP 1426-02 for more information.
- 5.10.1** PI must submit the request for extension two (2) month prior to the expiry date, elaborate the status of the study till date and the plan for the next year. For more information, refer to APP 1426-02.
- 5.11** The IRB has the right to terminate or suspend the research study based on ethical grounds, violation of patient rights or safety.
- 5.12** Upon completion, or premature termination of the research study, the PI must notify the IRB and Monitoring Unit.
- 5.13** For all Investigator initiated clinical studies subject to Saudi Food and Drug Association (SFDA) regulations, the PI must obtain SFDA approval for the conduct of the research study prior to the implementation of any research related activities. For more information see SFDA Regulations (**Appendix B**).
- 5.13.1** For all externally sponsored clinical studies subject to SFDA regulations, the PI is responsible for ensuring the sponsor has fulfilled all SFDA requirements, and that the sponsor obtained SFDA approval for the research study prior to implementation of any research related activities.
- 5.14** All research studies are subject to monitoring by the Monitoring Unit, KAIMRC. The PI is requested to fully comply with the monitoring process requirements as per APP 1432-20.
- 5.14.1** The PI is responsible for reviewing and responding to all data queries generated by the Monitoring Unit.
- 5.15** **In case of non-compliance with MNG-HA research-related policies and procedures and SOPs, the IRB and/or RFC has the final authority to terminate or suspend any research study as per APP 1426 -02.**
- 5.15.1** The PI has the right to appeal against any decision taken by the IRB and/or RFC to terminate or suspend a research study as per APP 1432 -04.
- 5.16** The PI may delegate some or all of their responsibilities to one (1) or more Sub-Investigators and/or other research team members; where:
- 5.16.1** The delegated Sub-Investigators must be qualified by training, education and experience to perform the delegated task.
- 5.16.2** Delegation of responsibilities must be documented in writing, and signed by both the PI and the delegated individual in the delegation log.
- 5.16.3** The start and end dates of delegation must also be documented in writing.
- 5.17** During temporary absence of the PI all of their responsibilities must be delegated to a Sub-Investigator.
- 5.17.1** The delegated individual must possess the equivalent qualification and experience as the study PI.

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- 5.17.2 The delegated individual must be part of the research team previously approved by the IRB.
- 5.18 All investigational drugs must be dispensed, handled and managed by the KAIMRC Investigational Drug Services Unit.
- 5.19 The PI must comply with the retention period of the research study related documents after study closure.
- 5.19.1 Research study related documents, files and/or records must be retained at the investigational site for at least three (3) years after completion of the study; after which these documentations must be retained in a secure archival facility for at least five (5) years.
- 5.20 In the event of any conflict of interest arising during the conduct of a research study, action must be taken according to SOP RA 204 Conflict of Interest (**Appendix A**).
- 5.21 If the PI is resigning from MNG-HA or withdrawing from the project, the IRB must be notified and withhold the project until a new PI is assigned and resume responsibilities. The resigned/withdrawn PI may still continue in the project as Sub-Investigator.

## 6. PROCEDURES

- 6.1 Once the research proposal is IRB approved, the following pre-initiation activities must be carried out:
- 6.1.1 The IRB, Research Office and Research Funding Committee (as applicable) will send a request to the PI for submitting the documents as described in SOP RA 202 Initial and On-going Submissions and SOP RA 203 Reporting Requirements (**Appendix A**).
- 6.1.2 The PI will compile all essential documents generated before, during and at the completion of the study as required by SOP RA 201 Essential Documents (**Appendix A**) and as directed by SOP GA 105 Records Management, Accountability and Retention/Documentation of Communication (**Appendix A**).
- 6.1.3 For all clinical trials and for some non-clinical trials as applicable, the Monitoring Unit will conduct an initial monitoring visit once the monitoring unit is notified that the research protocol has been approved by the IRB, funding committee and/or the research grant fund is being released by MNG-HA, in order to ensure readiness of the PI and research team to carry out the research study procedures, as per APP 1432-20.
- 6.2 For all clinical trials and for some non-clinical trials as applicable, the PI initiates the study upon obtaining the recommendation for study initiation from the Monitoring Unit, or after conducting and completing the initiation visit by the sponsor's CRA for externally sponsored studies.

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- 6.2.1 The PI will refer to SOP PM 302 Study Start Up (**Appendix A**) for general information and guidelines on study start up activities.
- 6.2.2 For all clinical trials and for some non-clinical trials as applicable, once the monitoring unit has recommended initiation of the study, the PI will start subject screening and enrollment. The PI will refer to SOP "SM 401 subject recruitment and screening" for information and guidance.
- 6.2.3 The PI will obtain informed consent and document the process in the medical chart for each subject recruited by following SOP "SM 402: Informed Consent (**Appendix A**). The template of informed consent is available in the Appendices C, G-J of APP 1419-05 Research Proposal Submission, Processing and Approval.
- 6.2.4 If the PI decides to amend the protocol, Informed Consent form (ICF), and any other document pertaining to the research study, then they will change them according to the IRB policies and procedures.
  - 6.2.4.1 Once the Protocol is re-approved, the PI will train the study team members on the amended protocol and this will be documented in the training log.
  - 6.2.4.2 For ICF amendments, all research subjects and/or their legally acceptable representatives/Impartial Witness who are actively enrolled in the research study will be re-consented by reading and signing the modified ICF and the process should be documented in the medical charts of subjects.
- 6.2.5 The PI will strictly comply with the eligibility and enrollment criteria for each enrolled and consented research subject. For the policy and procedures on subject eligibility and enrollment, refer to SOP SM 403: Eligibility and Enrollment (**Appendix A**).
- 6.2.6 The PI will make all possible efforts to protect confidential information in research studies as per SOP SM 404 Protecting Confidential Information (**Appendix A**).
- 6.2.7 Deviations from research protocol will be as per SOP PM 307 Protocol Compliance - Waivers, Deviations, Memos to File (**Appendix A**).
- 6.2.8 All research subject visits and assessments will be organized as per SOP SM 405 Subject Visits and Assessment (**Appendix A**).
- 6.2.9 The PI will ensure that source documents, such as patient charts (hard and/or electronic format), are in compliance with the policy and procedures of SOP PM 304 Source Documentation (**Appendix A**).
  - 6.2.9.1 The PI will ensure that all collected data documented on the data collection sheet and/or case report form have their origin and may be verified from the research subject's source documents, such as laboratory reports, physicians notes, patient files etc.

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- 6.2.10 Where applicable, the Investigational Drug Services Unit will follow the guidelines of SOP PM 303 Investigational Product Management (**Appendix A**).
- 6.2.11 Adverse Events (AEs) and Serious Adverse Events (SAEs) may be experienced by research subjects as a result of their direct or indirect participation in the study, should be managed in accordance with SOP SM 406 AE Management (**Appendix A**).
- 6.2.12 Collection of research data will follow the policy and procedures as per SOP DM 501 Clinical Data Management (**Appendix A**).
- 6.2.13 In cases where an electronic data management system is utilized for research data collection, the PI will comply with the policy and procedures as per SOP DM 502 Use of Electronic Data Management Systems (**Appendix A**).
- 6.2.14 The PI is expected to comply with all routine monitoring activities performed by the KAIMRC Monitoring Unit during the course of the study. The PI will utilize SOP PM 305 Monitoring Visits (**Appendix A**) for the preparation of monitoring visits.
- 6.2.15 The research study may also be audited by the following bodies:
  - 6.2.15.1 KAIMRC for assuring compliance to quality standards. The PI will refer to the SOP QA 601 Quality Assurance Audits (**Appendix A**) for details.
  - 6.2.15.2 Applicable regulatory authorities (SFDA) may conduct inspections for assuring compliance to the regulatory requirements. Refer to SOP QA 602 Inspections and Regulatory Authorities (**Appendix A**) for details.
- 6.2.16 During the temporary absence of the PI, the PI will submit a memorandum will be submitted to the Research Office stating the period of absence and the identity of the delegated Sub-Investigator.
- 6.2.17 The PI may request an extension of approval by submitting a memorandum, together with the annual progress report of the research study, to the IRB and Research Office (APP 1426-02, **Appendix A**). For more information about ongoing review and extension of approved research studies, refer to APP 1426-02.
- 6.3 The PI closes out the study upon completion or premature termination of the research study.
  - 6.3.1 The PI submits the final study report to the IRB and Research Office.
  - 6.3.2 The Monitoring Unit conducts the close out visit as per APP 1432-20.
  - 6.3.3 If the Monitoring Unit recommends study closeout, the PI will follow SOP PM 306: Study Completion (**Appendix A**).

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6.3.4 For management of records during and on completion of the research study, the PI will refer to SOP GA 105: Record Management, Accountability and Retention and Documentation of Communication (**Appendix A**).

6.4 The PI must submit a copy of the publication to the Research Office.

## 7. RESPONSIBILITY

7.1 It is the responsibility of the KAIMRC and all other concerned departments to implement and comply with the policies and procedures as stated in this APP.

7.2 Internal Audit and Organizational Development will randomly monitor implementation of the provisions within this APP.

## 8. APPROVAL

### PREPARED BY:



DR. AHMED AL ASKAR  
Executive Director, KAIMRC

19 OCT 2015

DATE

### REVIEWED BY:

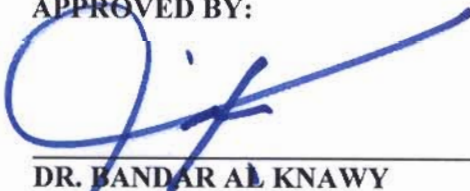


SAAD AL OTAIBI  
Executive Director  
Internal Audit and Organizational Development, MNG-HA

27 OCT 2015

DATE

### APPROVED BY:



DR. BANDAR AL KAWAY  
Chief Executive Officer, MNG-HA  
President, KSAU-HS

11/11/2015

EFFECTIVE DATE

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KAIMRC Standard Operation Procedures for the Conduct of Clinical Research; Adapted from Center Watch, ISBN 1-930624-56-5	SOP Table of Contents
Page 1 of 1	2011-09-15

## TABLE OF CONTENTS (number of pages)

### **GLOBAL GUIDELINES (1)**

### **GLOSSARY (17)**

### **LIST OF ABBREVIATIONS (1)**

### **LIST OF ATTACHMENTS (3)**

### **GENERAL ADMINISTRATION (GA)**

105 Record Management, Accountability, Retention and Documentation of Communication (11)

### **REGULATORY AFFAIRS (RA)**

201 Essential Documents (Volumes 1-4) (10)

202 Initial and On-going Submissions (8)

203 Reporting Requirements (2)

204 Conflict of Interest (7)

### **PROJECT MANAGEMENT (PM)**

301 Assessing Study Feasibility (Scientific & Financial) (16)

302 Study Start Up (13)

303 Investigational Product Management (5)

304 Source Documentation (4)

305 Monitoring Visits (7)

306 Study Completion (4)

307 Protocol Compliance – Waivers, Deviations, Memos to File (7)

### **SUBJECT MANAGEMENT (SM)**

401 Subject Recruitment and Screening (8)

402 Informed Consent (17)

403 Eligibility and Enrollment (9)

404 Protecting Confidential Information (14)

405 Subject Visits and Assessments (24)

406 AE Management (13)

### **DATA MANAGEMENT (DM)**

501 Clinical Data Management (3)

502 Use of Electronic Data Management Systems (5)

### **QUALITY ASSURANCE (QA)**

601 Quality Assurance Audits (9)

602 Inspections and Regulatory Authorities (4)

M  
JA  
42



Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
Drug Sector (255)



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
(٢٥٥)  
قطاع الدواء

تمميم عاجل جداً بالفاكس

الموضوع: الدراسات السريرية على الأدوية

رقم التعميم: ١٧٩٤ وتاريخ: ١٤٣٢/١/٢٥

معالي المدير العام التنفيذي للشؤون الصحية بالحرس الوطني  
معالي المدير العام التنفيذي للمنظمة العامة لمستشفى الملك فيصل التخصصي ومركز الأبحاث بالرياض  
سعادة وكيل وزارة الصحة للشؤون التنفيذية  
سعادة وكيل وزارة الصحة للطب العلاجي  
سعادة المدير العام التنفيذي لمستشفى الملك فيصل التخصصي ومركز الأبحاث بجدة  
سعادة مدير عام الخدمات الطبية بوزارة الداخلية  
سعادة مدير عام الخدمات الطبية بالقوات المسلحة  
سعادة مدير عام الخدمات الطبية برئاسة الاستخبارات العامة  
سعادة مدير عام الإدارة العامة للخدمات الطبية بوزارة الشؤون الاجتماعية  
سعادة مدير عام الصحة المدرسية بوزارة التربية والتعليم  
سعادة المدير التنفيذي لبرنامج الخدمات الصحية بالهيئة الملكية بالجبريل  
سعادة المدير التنفيذي لبرنامج الخدمات الصحية بالهيئة الملكية ببنبع  
سعادة نائب رئيس شركة أرامكو السعودية للخدمات الطبية  
سعادة عميد كلية الطب بجامعة الملك سعود والمشرف العام على المستشفيات الجامعية  
سعادة عميد كلية الطب بجامعة الملك عبدالعزيز والمشرف العام على مستشفى الملك عبدالعزيز بجدة  
سعادة المشرف العام على مستشفى الأمير فيصل بن فهد بن عبدالعزيز للطب الرياضي  
سعادة المشرف العام على مستشفى الملك فهد للتطعيم بالخبر  
سعادة عميد كلية الطب بجامعة الملك خالد  
سعادة عميد كلية الطب بجامعة أم القرى بمكة المكرمة  
سعادة عميد كلية الطب بجامعة طيبة بالمدينة المنورة  
سعادة عميد كلية الطب بجامعة القصيم  
سعادة عميد كلية الطب بجامعة الجوف  
سعادة عميد كلية الطب بجامعة جازان  
سعادة مدير عام مدينة الأمير سلطان للخدمات الإنسانية  
سعادة المدير العام التنفيذي على مدينة الملك فهد الطبية  
سعادة المدير العام التنفيذي لمستشفى الملك خالد التخصصي للعيون  
سعادة المدير العام التنفيذي لمستشفى الملك فهد التخصصي بالدمام  
سعادة المشرف العام على مجمع الملك سعود الطبي  
سعادة مدير عام الشؤون الصحية بمنطقة الرياض / مكة المكرمة / المدينة المنورة / القصيم / الشرقية / صبر/حائل/ الحدود الشمالية/الباحة/نجران/جازان/الجوف/تبوك  
سعادة مدير الشؤون الصحية بمحافظة الطائف /جدة / الأحساء/ بيشه/ حفر الباطن / القريات/ القنفذة

السلام عليكم ورحمة الله وبركاته ، ، ،

استناداً إلى نظام الهيئة العامة للغذاء والدواء الصادر بالمرسوم الملكي رقم (م/٦) وتاريخ

١٤٢٨/١/٢٥ هـ ونظام المنشآت والمستحضرات الصيدلانية الصادر بالمرسوم الملكي رقم م/٣١ وتاريخ

١٤٢٥/٦/١ هـ ، نود إفادتكم بما يلي:

لإجراء فحص بالمناسم  
لإجراء فحص بالمناسم

مدير عام الفحص

لإجراء فحص / محمد بن محمد  
لإجراء فحص / عبد الله بن محمد

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المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
قطاع الدواء (٢٥٥)

**أولاً:** يجب تسجيل جميع الدراسات السريرية في الهيئة العامة للغذاء والدواء - قطاع الدواء  
- إدارة الدراسات السريرية بناء على التعميم الصادر برقم ٣٤٧٦ و تاريخ ١٤٣١/٢/١٣ هـ  
بخصوص الدراسات السريرية على الأدوية.

### ثانياً: الموافقة على طلب إجراء الدراسات السريرية.

١. يقوم الباحث أو الجهة الراعية للدراسة أو مركز متابعة دراسات سريرية بتسجيل جميع الدراسات السريرية لدى الهيئة العامة للغذاء والدواء وفقاً لمتطلبات الهيئة الموضحة في المرفق رقم (١) علماً بأن التسجيل لا يعني الموافقة.
٢. يجب على الباحث أو الجهة الراعية للدراسة أو مركز متابعة دراسات سريرية الالتزام بنظام أخلاقيات البحث على المخلوقات الحية وفقاً لما ورد بالمرسوم الملكي الكريم رقم (م/٥٩) وتاريخ ١٤٣١/٩/١٤ هـ.
٣. تقوم الشركة الراعية للدراسة السريرية أو مركز متابعة دراسات سريرية بدفع المقابل المادي لتقييم الدراسة السريرية وقدره خمسة عشر ألف ريال (١٥ ألف ريال) للهيئة العامة للغذاء والدواء عن كل بروتوكول دراسة سريرية يتم تقييمه من قبل الهيئة بحسب ما جاء في التعميم رقم ٣٩٩٣/ع وتاريخ ١٤٣٠/١٠/١٥ هـ.

### ٤. الدراسات السريرية التي تستخدم فيها الأدوية المسجلة لدى الهيئة العامة للغذاء والدواء:

- لا يتطلب الحصول على موافقة خطية من الهيئة العامة للغذاء والدواء إلا في الحالات الثلاث التالية:

- ✓ استخدام الدواء بغير دواعي الاستخدام الذي سجل من أجله.
- ✓ تغيير نظام الجرعة أو خيارات العلاج. (Change in dosage regimen or Treatment options)
- ✓ استخدام غير مقنن (Off label indication)



Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
Drug Sector (255)



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
قطاع الدواء (٢٥٥)

- يكتفى بإبلاغ الهيئة بالدراسة السريرية و تقديم ملف متطلبات إجراء الدراسات السريرية للأدوية المسجلة بحسب المرفق رقم (١).
- يستطيع الباحث البدء بالدراسة بعد الحصول على موافقة لجنة الأخلاقيات IRB/IC في موقع إجراء الدراسة السريرية إلا في الحالات الثلاث المستثناة أعلاه.
- ٥. الدراسات السريرية التي تستخدم فيها الأدوية الغير مسجلة لدى الهيئة العامة للغذاء و

#### الدواء:

- جميع هذه الدراسات تتطلب الحصول على موافقة خطية من الهيئة العامة للغذاء و الدواء لكل موقع إجراء دراسة سريرية على حدة.
- يجب الالتزام بمتطلبات الهيئة العامة للغذاء و الدواء بحسب المرفق رقم (١).
- في حالة الدراسات السريرية التي تستخدم فيها أدوية مسجلة من قبل إدارة الغذاء و الدواء الأمريكية (FDA) أو الوكالة الأوروبية للأدوية (EMA) فإن الهيئة تلزم الشركة المنتجة للدواء بتقديم طلب تسجيل الدواء للهيئة خلال ٦ أشهر من تاريخ الموافقة على إجراء الدراسة السريرية.
- في حالة الدراسات السريرية التي تستخدم فيها أدوية غير مسجلة من قبل إدارة الغذاء و الدواء الأمريكية (FDA) أو الوكالة الأوروبية للأدوية (EMA) فإن الهيئة تلزم الشركة المنتجة للدواء بتقديم طلب تسجيل دواء بحثي (IND) بناء على متطلبات التسجيل في الهيئة العامة للغذاء و الدواء مع مراعاة أن الهيئة لا تستقبل طلبات تسجيل دواء بحثي (IND) إلا في الحالات التالية:
- ✓ أن يكون طلب التسجيل مقدم من شركة محلية.
- ✓ أن تكون الدراسة السريرية المقدمة متعددة المراكز (Multi-center) و قد وصلت إلى المرحلتين الثانية أو الثالثة (Phase II or Phase III) و أن يكون هدف

Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
Drug Sector (255)



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
قطاع الدواء (٢٥٥)

الدراسة إجراء دراسات على أدوية ستستخدم في علاج مرض نقص المناعة المكتسبة  
الإيدز أو مرض السرطان أو أمراض وبائية.

٦. الفترة الزمنية اللازمة للدرد على الباحث أو الشركة الداعمة للدراسة السريرية في حال

إكمال ملف التقديم ستكون حسب التقسيم التالي:

- ١٠ أيام عمل للدراسات السريرية التي تستخدم فيها الأدوية المسجلة لدى الهيئة العامة للغذاء والدواء.
- ٢٠ يوم عمل للدراسات السريرية التي تستخدم فيها الأدوية غير المسجلة لدى الهيئة العامة للغذاء والدواء و مسجلة من قبل إدارة الغذاء والدواء الأمريكية (FDA) أو الوكالة الأوروبية للأدوية (EMA).
- ١٨٠ يوم عمل للدراسات السريرية التي تستخدم فيها الأدوية غير المسجلة لدى الهيئة العامة للغذاء والدواء و غير مسجلة من قبل إدارة الغذاء والدواء الأمريكية (FDA) أو الوكالة الأوروبية للأدوية (EMA).

#### ثالثاً: استيراد الأدوية المستخدمة في الدراسات السريرية.

١. يجب تقديم طلب استيراد لعينات الدواء المستخدم في الدراسة السريرية بعد أخذ الموافقة على إجرائها إلى وحدة الفسخ المركزي- بقطاع الدواء وفقاً لمتطلبات الاستيراد في الهيئة العامة للغذاء والدواء.

#### رابعاً: إرسال العينات الحيوية إلى خارج مقرات إجراء الدراسات السريرية.

١. يجب على الباحث أو الجهة الراعية للدراسة أو مركز متابعة دراسات سريرية الالتزام بنظام أخلاقيات البحث على المخلوقات الحية وفقاً لما ورد بالمرسوم الملكي الكريم رقم (م/٥٩) و تاريخ ١٤٣١/٩/١٤ هـ و الذي ينظم التعامل مع العينات الحيوية.



Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
Drug Sector (255)



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
(٢٥٥)  
قطاع الدواء

٢. يجب على الباحث أو الجهة الراعية للدراسة أو مركز متابعة دراسات سريرية أخذ موافقة الهيئة العامة للغذاء والدواء في حال نص بروتوكول الدراسة السريرية على إرسال العينات الحيوية إلى مختبرات خارج المملكة العربية السعودية على أن يتم تقديم طلب من الباحث الرئيسي يوضح ما يلي:
- عدد العينات الحيوية المراد إرسالها و التاريخ المتوقع للإرسالية.
  - الجهة المراد إرسال العينات الحيوية إليها على ألا تتعارض مع ما ذكر في بروتوكول الدراسة.
  - تمهد بأن العينات الحيوية المرسله سوف تستخدم لغرض البحث كما هو مذكور في بروتوكول الدراسة.

#### خامساً: التعامل مع الأعراض الجانبية.

١. ضرورة إبلاغ الهيئة عن جميع الأعراض الجانبية المتوقعة و غير المتوقعة (غير الخطرة) للمستحضرات التي تخضع للدراسة بصورة مستعجلة خلال خمسة عشر يوماً (١٥ يوم) ، أما في حال حدوث أي عرض جانبي خطير (Serious side effects) يؤدي إلى أحد النتائج التالية: (الوفاة، تهديد الحياة، دخول المستشفى للمعالجة، حدوث المعجز أو الإعاقة، أو ظهور عيب خلقي) فيلزم إبلاغ الهيئة على الفور خلال مدة أقصاها سبعة أيام (٧ أيام).

#### سادساً: التعامل مع إيقاف الدراسة من قبل الهيئة.

١. يجب على الباحث أو الجهة الراعية للدراسة أو مركز متابعة دراسات سريرية الالتزام بمتطلبات الهيئة العامة للغذاء والدواء بحسب المرفق رقم (٢) .

Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
Drug Sector (255)



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
(٢٥٥)  
قطاع الدواء

### سابعاً: التعامل مع انتهاء الدراسة.

يجب على الباحث أو الجهة الراعية للدراسة أو مركز متابعة دراسات سريرية الالتزام بمتطلبات الهيئة العامة للغذاء والدواء بحسب المرفق رقم (٢).

### ثامناً: كفاءة الباحثين في الدراسات السريرية.

١. للرفع من كفاءة الباحثين في الدراسات السريرية فإن الهيئة ستقوم ابتداء من تاريخ ١٤٣٢/١/١هـ بإلزام الباحثين بتقديم ما يثبت حصولهم على تدريب مناسب على أسس الممارسة الإكلينيكية الجيدة (GCP) لكل من يرغب في المشاركة بالدراسات السريرية.

يُرجى وفي حال وجود أي استفسارات فيمكنكم التواصل عن طريق البريد الإلكتروني: CT.Drug@sFDA.gov.sa أو الاتصال على هاتف ٢٧٥٩٢٢٢ - ٠١ تحويلة ٢٢١٨ أو ٢٣٣٩ وحدة الدراسات السريرية.

وتقبلوا خالص التحية والتقدير ،،،

نائب الرئيس لشئون الدواء

  
الد. عبدالله بن عبدالعزيز



Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
(255)  
Drug Sector



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
(٢٥٥)  
قطاع الدواء

After completion or termination of the trial, all of the documents identified in section 8.3 should be in the file together with the following:

	Title of Document	Purpose	Located in Files of Investigator/ Sponsor Institution	
8.4.1	Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol . To document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	X	X
8.4.2	Documentation of investigational product(s) destruction	To document destruction of unused investigational product(s) by sponsor or at site	X (if destroyed at site)	X
8.4.3	Completed subject identification code list	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	
8.4.4	Audit certificate (if required)	To document that audit was performed (if required) (see section 5.19.3(e))		X
8.4.5	Final trial close-out monitoring report	To document that all activities required for trial close-out are completed, and copies of essential document are held in the appropriate files		X
8.4.6	Treatment allocation and decoding documentation	Returned to sponsor to document any decoding that may have occurred		X
8.4.7	Final report by investigator/institution to IRB/IEC where required, and where applicable, to the SFDA (see section 4.13)	To document completion of the trial	X	
8.4.8	Clinical study report (see section 5.22)	To document results and interpretation of trial	X (if applicable)	X

Kingdom of Saudi Arabia  
Saudi Food & Drug Authority  
Drug Sector (255)



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء  
(٢٥٥) قطاع الدواء

### مرفق رقم (١)

متطلبات الهيئة العامة للغذاء والدواء للموافقة على إجراء الدراسات السريرية

### SFDA requirements for clinical trial approval

Requirement	Registered Drug	Unregistered Drug	
		Registered in FDA/EMA	Unregistered in FDA/EMA
Headed Letter to SFDA.	✓	✓	✓
Bank Transfer Payment.	✓	✓	✓
Confidentiality Agreement.	✓	✓	✓
Trial Application Form.	✓	✓	✓
Trial Protocol.	✓	✓	✓
Informed Consent Form.	✓	✓	✓
IRB/EC Approval.	✓	✓	✓
Investigator Brochure.	✓	✓	✓
Financial Disclosure of Principal Investigator.	✓	✓	✓
GMP Certificate.	x	✓	✓
Certificate of Analysis of Study Drug.	x	✓	✓
Sample of Label of Study Drug.	✓	✓	✓
IMP Labeling & Packaging	x	✓	✓
Samples of drug	x	✓	✓
Clinical Trial Agreement.	✓	✓	✓
CVs of Principal Investigator & Coordinator.	✓	✓	✓
IND application	x	x	✓
Saudi Drug Registration application	x	✓	x