

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 : 1432-04  
TITLE : APPEAL PROCESS FOR REJECTED RESEARCH PROPOSAL  
OR SUSPENDED ONGOING RESEARCH STUDY  
ORIGINATING DEPT. : KING ABDULLAH INTERNATIONAL MEDICAL RESEARCH  
CENTER (417780)  
ORIGINAL DATE : FEBRUARY 2011  
REVISED DATE : APRIL 2015

### 1. PURPOSE

To govern the process of appealing against a decision made by the Institutional Review Board (IRB), Research Committee (RC) and/or Research Funding Committee (RFC) to reject a research proposal.

### 2. APPLICABILITY

To all research professionals and staff involved in the process of appealing against the decision made by the IRB, RC and/or RFC.

### 3. RELATED REFERENCES

- 3.1 APP 1419-05: Research Proposal Submission, Processing & Approval
- 3.2 APP 1426-02: Institutional Review Board (IRB)
- 3.3 APP 1433-37: Conducting Research Studies

### 4. DEFINITIONS

- 4.1 **Appeal** refers to a formal request made by the principal investigator against the decision made by the Research Committee /Institutional Review Board/Research Funding Committee that resulted in the rejection of a research proposal.

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- 4.2 **Appropriate Committee** refers to Research Committee, Institutional Review Board or Research Funding Committee.
- 4.3 **Institutional Review Board (IRB)** refers to an independent body composed of medical, scientific and non-scientific members whose responsibility is to ensure protection of the rights, safety and well being of human subjects involved in a research study.
- 4.4 **Principal Investigator (PI)** refers to an individual or group of individuals who prepares, develop and submit research proposals for review by the research committee.
- 4.5 **Program** refers to Ministry of National Guard-Health Affairs (MNG-HA) and all affiliated facilities.
- 4.6 **Proposal Processing & Protocol Development Unit (PPDU)** refers to the the unit that receives and facilitates the review and approval for submitted proposals to KAIMRC central region.
- 4.7 **Research Office (RO)** is a section of King Abdullah International Medical Reserch Center (KAIMRC) which manages all clinical researches conducted by KAIMRC.
- 4.8 **Research Committee (RC)** refers to a committee composed of medical practitioners / clinicians whose responsibility is to review all research proposals for the Program services and make recommendations for amendment and / or approval on scientific basis, and forward them to IRB for ethical point of view.
- 4.9 **Research Funding Committee (RFC)** refers to a committee which reviews all fund requests for conducting research studies.
- 4.10 **Research Proposal** refers to a document describing the plan of a proposed research study including the methodology, method of analyzing the results, and the budget.
- 4.11 **Turn around time** is the period between receipt of appeal and dispatch of final decision to the PI.

## 5. POLICY

- 5.1 Appeals may be made for research proposals that were rejected or suspended by the RC, IRB, RFC.
- 5.2 All appeals must be submitted by the Principal Investigator (PI) of the proposed research study.
  - 5.2.1 An appeal can be submitted within thirty (30) days from the date of rejection of a research proposal.
  - 5.2.2 Only two (2) appeals are allowed per research project.
    - 5.2.2.1 Appeal must be sent to the respective committee which rejected the research proposal.
    - 5.2.2.2 The PI can re-appeal to the respective committee upon rejection of the first appeal.

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5.2.2.3 Re-appeals must be considered only if new arguments supporting the proposal are presented. Resubmission of the previous appeal is not allowed.

5.3 The maximum turn around time for appeals review process must be fifteen (15) working days.

## 6. PROCEDURES

6.1 The PI completes the **Appeal Request Registration Form (Appendix A)**.

6.1.1 The PI will justify the reason for appealing the initial decision taken by the appropriate committee.

6.1.2 Adequate supporting information (literature reviews, published statistical reports, etc) will be provided when justifying the reason for the appeal.

6.2 Submission of appeals against the decision by the Research Committee or Research Funding Committee:

6.2.1 PI submits the completed, signed appeal to the Proposal Processing & Protocol Development Unit (PPDU) of RO.

6.2.2 The PPDU will send a letter of acknowledgement to the PI confirming receipt of the appeal.

6.2.3 PPDU will state the document number and the date of receipt of the appeal in the appeal request form.

6.2.4 The PPDU submits the appeal to the appropriate committee for review (either RC or RFC as applicable).

6.2.5 Review of appeals submitted to the RC:

6.2.5.1 The RC Chairman submits the proposal to the RC committee for review.

6.2.5.2 If all RC members unanimously suggest accepting or rejecting the appeal, the RC Chairman is bound by the decision. However, if there is no unanimous agreement between the RC members, the RC Chairman will call for voting on the appeal request. The majority decision will determine whether the appeal will/will not be accepted.

6.2.5.3 The RC Chairman submits the committee decision on the appeal to the Executive Director, KAIMRC for final approval.

6.2.6 Review of appeals submitted to the RFC:

6.2.6.1 The RFC Chairman forwards the appeal to the RFC members for review and discussion.

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6.2.6.2 A majority vote by the RFC members to decide whether the appeal will be accepted or not.

6.2.6.3 The RFC Chairman forwards the decision to the Executive Director, KAIMRC for approval.

6.3 Submission of appeal against the decision by the IRB:

6.3.1 The PI submits the appeal to the IRB committee.

6.3.2 The IRB Chairman, forwards the appeal to the IRB committee members for review.

6.3.3 A majority vote by the IRB committee members will decide whether the appeal will be accepted or not.

6.3.4 The IRB Chairman forwards the committee decision on the appeal to the Chief Executive Officer, MNG-HA for final approval.

6.3.5 A copy of committee decision will be sent to the Executive Director of KAIMRC and Research Office.

6.4 The chairman of the respective committee notifies the PI of the final decision on the appeal.

6.5 If the initial appeal was rejected, the PI may re-appeal to the respective committee, the second appeal will be evaluated as explained from 6.2 onwards.

6.6 Copies of the final decision will be retained by the respective committees.

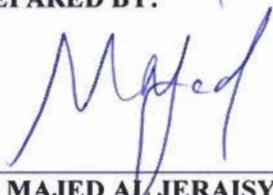
## 7. RESPONSIBILITY

7.1 It is the responsibility of KAIMRC, RFC, IRB, RC and all other concerned departments to implement provisions of this APP.

7.2 Internal Audit and Organisational Development will be responsible for monitoring compliance to the provisions as stipulated herein.

## 8. APPROVALS

PREPARED BY:



**DR. MAJED AL JERAISY**  
Chairman, Research Office  
King Abdullah International Medical Research Center

13/4/15

DATE

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CONCURRED BY:



**DR. AMIN KASHMEERY**

Chairman, Institutional Review Board  
& Head, Bioethics Section  
King Abdullah International Medical Research Center

16-4-2015

DATE



**DR. AHMED AL ASKAR**

Executive Director  
King Abdullah International Medical Research Center

21 Apr 2015

DATE

REVIEWED BY:



**SAAD AL OTAIBI**

Executive Director  
Internal Audit & Organizational Development, MNG-HA

01 JUL 2015

DATE

APPROVED BY:



**H.E. DR. BANDAR AL KAWY**

Chief Executive Officer  
Ministry of National Guard - Health Affairs

09 JUL 2015

EFFECTIVE DATE

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## Appeal Request Registration Form

**Part I - To be completed by the Principal Investigator (PI)**

## 1. Principal Investigator Details

PI Name	
Department	
Extension No.	
E-mail	

## 2. Research Study Proposal Details

Protocol Number	
Title of Proposal	
Date of Initial Submission	

### 3. Details of Appeal Being Submitted

Appealing to (state the committee to which appeal is submitted):

- ☐ *Institutional Review Board*      ☐ *Research Committee*      ☐ *Research Funding Committee*

Justification for Appeal (State why your proposal should be reconsidered for approval)

List of enclosures (include any information supporting the appeal)

#### 4. Declaration

I certify that the information I have provided in connection with this appeal is true to the best of my knowledge

\_\_\_\_\_  
**Principal Investigator**  
(Name & Signature)

\_\_\_\_\_  
Date

#### Part II - To be completed by the Research Office

Document No. : \_\_\_\_\_

**Received by :**

\_\_\_\_\_  
Name & Signature

\_\_\_\_\_  
Date

**Response sent by:**

\_\_\_\_\_  
Name & Signature

\_\_\_\_\_  
Date