

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 (419801)  
**ORIGINAL DATE** : FEBRUARY 2011  
**REVISED DATE** : FEBRUARY 2019

### 1. PURPOSE

To establish the process for appealing rejected research proposal or suspended ongoing research study by the Institutional Review Board (IRB), Research Office (RO) and/or Research Funding Committee (RFC).

### 2. APPLICABILITY

To all staff involved in the process of appealing rejected research proposal or suspended ongoing research study by the IRB.

### 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 formal request by the Principal Investigator to change or reconsider the decision of rejection of a research proposal and/or suspending ongoing research by the Research Office/Institutional Review Board /Research Funding Committee.
- 4.2 **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 studies.

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- 4.3 **Principal Investigator (PI)** refers to an individual or group of individuals who prepares, develops and submits research proposals for review by the relevant Research Committee and is responsible for conducting the approved research study.
- 4.4 **Program** refers to the Ministry of National Guard-Health Affairs (MNG-HA) and all its affiliated facilities.
- 4.5 **Proposal Processing & Protocol Development Unit (PPDU)** refers to the unit under the Research Office that is responsible in receiving and facilitating the review and approval of submitted proposals to KAIMRC.
- 4.6 **Research Office (RO)** refers to a section of KAIMRC which is responsible for processing, scientific reviewing and approval of all research studies conducted by or within MNG-HA.

## 5. POLICY

- 5.1 The Principal Investigator has the right to appeal against research proposals rejected or suspended by the Research Office (RO), Institutional Review Board (IRB) or Research Funding Committee (RFC), within thirty (30) days from the date of rejection or suspension of a research proposal/study.
- 5.2 Only two (2) appeals are allowed per research project.
- 5.2.1 An appeal must be sent to the committee that rejected the research proposal.
- 5.2.2 The PI can re-appeal to the committee upon rejection of the first appeal.
- 5.2.3 Re-appeals can be considered only when new arguments supporting the proposal are presented. Resubmission of the previous appeal is not allowed.
- 5.3 The maximum turnaround time for appeals review process is not more than fifteen (15) working days.

## 6. PROCEDURES

- 6.1 The PI will complete the Appeal Request Form (**Appendix A**).
- 6.1.1 The PI will:
- 6.1.1.1 Justify the appeal against the initial decision and support it with sufficient information (literature reviews, published statistical reports, etc.)
- 6.1.1.2 Submit the Appeal Request Form (**Appendix A**) to the Proposal Processing & Protocol Development Unit (PPDU).
- 6.2 The PPDU will send a letter of acknowledgement to the PI confirming receipt of the appeal and ensure the following:
- 6.2.1 Inclusion of the document number and the date of receipt of the appeal on the Appeal Request Form (**Appendix A**)

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**6.2.2** Submission of the completed and duly signed Appeal Request Form (**Appendix A**) to the appropriate committee for review.

**6.3 Submission of appeals against the decision by the RO or RFC**

**6.3.1 Review of appeals submitted to the RO**

**6.3.1.1** The Chairman, RO will review the appeal and decide if it needs peer review.

**6.3.1.2** If it needs for peer review, the Scientific Review Officer will send the appeal with the supporting documents to reviewers.

**6.3.1.2.1** The decision will be taken by Chairman, RO according to the reviewer's comments.

**6.3.1.3** If it does not need peer review, the Chairman, RO will decide to accept or reject the appeal.

**6.3.1.3.1** The Chairman, RO will provide justification for the decision.

**6.3.2 Review of appeals submitted to the RFC**

**6.3.2.1** The Chairman, RFC will forward the appeal to the members for review and discussion.

**6.3.2.2** A majority vote by the members will decide whether the appeal will be accepted or not.

**6.3.2.3** The Chairman, RFC will forward the decision to the Executive Director, KAIMRC for approval.

**6.4 Submission of appeal against the decision by the IRB**

**6.4.1** The PI will submit the appeal to the IRB.

**6.4.2** The Chairman, IRB will forward the appeal to the Board members for review.

**6.4.3** A majority vote by the Board members will decide whether the appeal will be accepted or not.

**6.4.4** The Chairman, IRB will forward the Board's decision on the appeal to His Excellency Chief Executive Officer for final approval.

**6.4.5** A copy of the Board's decision will be sent to the Executive Director, KAIMRC and the Chairman, Research Office.

**6.5** The Chairman of the relevant committee/board will notify the PI of the final decision on the appeal.

**6.6** If the initial appeal was rejected, the PI can file for re-appeal through re-submission of the Appeal Request Form (**Appendix A**) to the PPDU. The second appeal will be processed and evaluated accordingly.

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

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7. **RESPONSIBILITY**

7.1 It is the responsibility of King Abdullah International Medical Research Center and all other concerned departments to implement provisions of this APP.

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

8. **APPROVALS**

**PREPARED BY:**

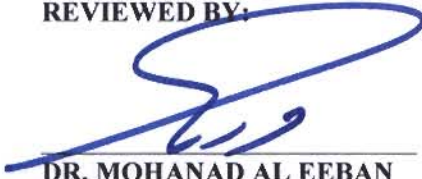


**DR. AHMED AL ASKAR**  
Executive Director  
King Abdullah International Medical Research Center

27 FEB 2019

DATE

**REVIEWED BY:**



**DR. MOHANAD AL EEBAN**  
General Director  
Corporate Planning and Regulatory Affairs, MNG-HA

27/2/19

DATE

**APPROVED BY:**



**H.E. DR. BANDAR AL KRAWY**  
Chief Executive Officer  
Ministry of National Guard - Health Affairs and  
President  
King Saudi Bin Abdulaziz University for Health Sciences

04 MAR 2019

EFFECTIVE DATE

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