

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** : 1435-10  
**TITLE** : BUDGET APPROVAL FOR INTRAMURAL RESEARCH GRANT  
**ORIGINATING DEPT.** : KING ABDULLAH INTERNATIONAL MEDICAL RESEARCH CENTER (419810)  
**ORIGINAL DATE** : OCTOBER 2014  
**REVISION DATE** : DECEMBER 2015

### 1. PURPOSE

To provide guidelines for the process and approval of fund requests for intramural research projects funded by the Ministry of National Guard – Health Affairs (MNG-HA)/King Abdullah International Medical Research Center (KAIMRC)/King Saud bin Abdulaziz University for Health Sciences (KSAU-HS).

### 2. APPLICABILITY

To all research studies/projects approved by KAIMRC and the Institutional Review Board (IRB) intended to be conducted at MNG-HA and all affiliated facilities.

### 3. RELATED REFERENCES

- 3.1 APP 1426-02: Institutional Review Board (IRB)
- 3.2 APP 1419-05: Research Proposal, Submission, Processing and Approval
- 3.3 APP 1432-04: Appeal Process for Rejected Research Proposal or Suspended Ongoing Research Study
- 3.4 APP 1429-19: Conflict of Interest
- 3.5 Committee Formation Order (CFO) BK/NG 12 Institutional Review Board, December 2010
- 3.6 CFO dated 10<sup>th</sup> January 2010 Research Funding Committee

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- 3.7 CFO dated 21<sup>st</sup> September 2005 Research Committee
- 3.8 International Conference of Harmonisation (ICH): ICH Harmonised Tripartite Guideline - Guideline for Good Clinical Practice E6(R1)
- 3.9 Joint Commission International Accreditation Standards for Hospitals, 5<sup>th</sup> Edition (2014) HRP.1.1, ME.1-3

#### 4. DEFINITIONS

- 4.1 **Budget** refers to the financial resources allocated by MNG-HA for funding research projects.
- 4.2 **Consultant** refers to the individual who provides professional advice to the Research Team in the area of expertise either statistical consultation like study design or scientific consultation like technology, engineering, medicine or food production.
- 4.3 **International Conference on Harmonization/Good Clinical Practice (ICH/GCP)** is an international ethical and scientific quality standard for designing, conducting, recording and reporting research involving the participation of human subjects.
- 4.4 **Data Collection** refers to the process of extracting data from subject, charts or medical records by research professional or highly specialized personnel.
- 4.5 **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.
- 4.6 **Intramural Fund** refers to the fund originating within MNG-HA, KAIMRC or KSAU-HS.
- 4.7 **Principal Investigator (PI)** refers to an individual or a group of individuals who prepare, develop and submit research proposal(s) for approval, and are responsible for conducting the research study according to the research proposal/protocol, ICH/GCP guidelines and other applicable regulatory authority requirements.
- 4.8 **Research Assistant** refers to research professional who assists the PI in conducting the study.
- 4.9 **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.
- 4.10 **Research Funding Committee (RFC)** refers to a committee responsible for review and approval of fund requests for conducting research projects per CFO-KAIMRC-01-011.
- 4.11 **Research Grant** refers to the funds allocated to an approved research project through KAIMRC.

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- 4.12 Research Scientists** include Senior Research Scientist, Research Scientist and Associate Research Scientist working in KAIMRC and/or KSAU-HS.
- 4.13 Research Support Team** refers to support personnel other than the Research Team such as Research Coordinator, Consultants, Data Entry Clerk, etc.
- 4.14 Research Team** refers to the PI and Sub-Investigators.
- 4.15 Sub-Investigator** is 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).

## 5. POLICY

- 5.1** Annual research budget must be designated, prepared and allocated by KAIMRC/MNG-HA to fund research projects.
- 5.2** All research projects must be reviewed and approved by KAIMRC and IRB to be eligible for KAIMRC/MNG-HA funding.
- 5.2.1** All submitted research proposals must be in compliance with the standards and regulations of the local regulatory authorities, the institutional regulations of KAIMRC/KSAU-HS/MNG-HA, ICH/GCP and any other applicable regulatory requirements as per APP 1426-02.
- 5.3** Approved funding requests are allocated from MNG-HA research budget by RFC.
- 5.4** All proposed budget must be reviewed and discussed at RFC meeting for approval. The decision of RFC must be communicated to PI within ninety (90) days following the submission of a complete and valid budget.
- 5.5** The RFC must evaluate the proposed budget under the following criteria:
- 5.5.1** Availability of funds for research projects
- 5.5.2** Meets the current KAIMRC research priorities
- 5.5.3** Allocation of funds for different categories described in Proposed Budget Guidelines (**Appendix A**).
- 5.5.4** PI's achievements for previous or on-going research projects.
- 5.6** Proposed budgets must not be discussed in RFC unless approved by IRB.
- 5.7** The PI must disclose to KAIMRC and seek its approval before soliciting funds from other sources. Non-compliance **will** result in suspension or cancellation of funds.

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- 5.8** The PI has full responsibility in managing their research fund, ensuring the following:
- 5.8.1** Completion of proposed budget for research project and submission of relevant e-form
  - 5.8.2** Provide clear justification and explanation of all budgetary items with supporting official documents to facilitate approval process
  - 5.8.3** Fulfillment of the requirements stated by RFC in a timely manner not exceeding a total of thirty (30) working days.
    - 5.8.3.1** Failure of PI to comply within above time frame must be considered by RFC as withdrawal of funding proposal.
    - 5.8.3.2** RFC must decide whether to reject, suspend or resume funding based on PI's clear justification for the delay.
- 5.9** Proposed budgets must include the personnel involved in the research study, supplies and equipment, patient compensation and other costs and must comply with the Proposed Budget Guidelines (**Appendix A**).
- 5.10** An adequate indemnity insurance statement must be submitted for all clinical trials.
- 5.10.1** Such insurance must cover all adverse events experienced by any or all of the research subjects except in cases of malpractices by the investigator.
  - 5.10.2** Indemnity insurance is covered by MNG-HA for all its sponsored clinical studies conducted within its facilities. For more details, see APP 1419-05: Research Proposal Submission, Processing and Approval.
- 5.11** Personnel involved in the research study must be paid based on the justification of their role and involvement.
- 5.11.1** PI must be paid based on the significance of the study, their involvement in the research work and the magnitude of work illustrated in a work plan including detailed responsibilities.
- 5.12** Fees for educational course/training and incentives for Research Team in Retrospective studies and cross-sectional surveys are items not generally covered by the grant. However, incentives may be given depending on the following:
- Complexity of the project
  - Complexity of the Case Report Form (CRF) (number of variables, amount of data to be collected)
  - Sample Size
  - Anticipated time spent in completing the project
- 5.13** Twenty five percent (25%) of the budget for the project must be allocated as Operational Services other than the Research Team who helped in the logistics and administration of the

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project. Distribution of this fund must be under the discretion of the Research Funding Committee according to the overtime per hour rate.

- 5.14** KAIMRC Operations Director is authorized to approve budget modification up to ten percent (10%) of the total approved budget or up to ten thousand Saudi Riyals (SAR10,000) for small grants.

**5.14.1** The KAIMRC Operations Director must report to the RFC regarding the changes.

**5.14.2** In case of disapproval, PI has the right to appeal as per APP 1432-04.

## **6. PROCEDURES**

- 6.1** The PI will access the proposal electronic submission (E-submission) system through <http://esubmission.kaimrc.med> or <http://esubmission.kaimrc.med.sa> as per APP 1419-05.
- 6.2** The PI will complete the proposed budget component on the e-Forms.
- 6.3** The Research Office will forward the research proposal including the proposed budget to IRB for further approval and send copy to RFC and Operations-Research Grant Management Unit, KAIMRC.
- 6.4** The Operations-Research Grant Management Unit, KAIMRC will do a preliminary check to ensure the completion of budget and supporting documents and will initiate communication with the PI.
- 6.5** Upon approval of research proposal by IRB and without modification needed, the budget will be discussed by RFC. Otherwise, PI will make the required modification and ensure its re-submission to be discussed at RFC meeting.
- 6.6** Notification together with the research contract will be sent to PI for signature after approval by RFC.
- 6.7** The grant approval will be valid for one (1) month upon receipt of the notification from RFC. The Research Contract will be signed by the Principal Investigator within this period otherwise the grant will be cancelled.
- 6.8** The signed research contract will be sent to the Executive Director, KAIMRC for final approval and subsequently forwarded to Operations-Research Grant Management Unit, KAIMRC for processing.
- 6.9** The study will start within three (3) months upon signing the Research Contract otherwise the grant will be cancelled.
- 6.10** The Principal Investigator will notify Operations-Research Grant Management Unit, KAIMRC once the project starts.
- 6.11** Any request for extension will be subject to evaluation by the RFC based on the Principal Investigator's justification.

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6.12 Re-allocation of budget for supplies and equipment and other costs to personnel is not allowed.

6.13 Modification of budget for incentives to Research Team will not be allowed.

## 7. RESPONSIBILITY

7.1 It is the responsibility of KAIMRC, KSAU-HS and all other concerned departments at MNG-HA to implement the provisions of this APP.

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

## 8. APPROVALS

### PREPARED BY:

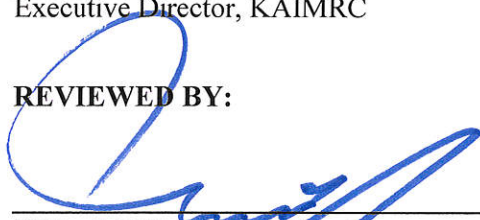


DR. AHMED AL ASKAR  
Executive Director, KAIMRC

16 FEB 2016

DATE

### REVIEWED BY:



COL. SAMI AL AJLAN  
Executive Director  
Internal Audit and Organizational Development, MNG-HA

21 FEB 2016

DATE

### APPROVED BY:



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

22/FEB/2016

EFFECTIVE DATE

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## Appendix A

### Proposed Budget Guidelines

Proposed budget must include the following items:

#### 1. Personnel

##### 1.1 Research Team

##### 1.1.1 Principal Investigator (PI)

**1.1.1.1** For each research project the PI may be eligible for incentives not exceeding two thousand Saudi riyals (SAR2,000) per month for a maximum of ten (10) months, which is twenty thousand Saudi riyals (SAR20,000) per year per individual. Maximum period of the project must be two (2) years, that is, total incentives to be paid to the PI must not exceed forty thousand Saudi riyals (SAR40,000) per project.

**1.1.1.1.1** The incentives will be released as follows: 50% upon completion of the project, 50% upon publication of the final study results.

**1.1.1.1.2** Extra Incentives may be paid to the researcher based on the discretion of the RFC depending on the following:

- Merit of the study
- Productivity of the Researcher
- Whether the researcher has an extramural grant

**1.1.1.1.3** The extra incentives to be allocated shall be between 5,000SR to 10,000SR per project.

**1.1.1.2** PIs acting as supervisor/mentor in research projects for KSAU-HS students, including those in the Doctoral (PhD) / Masteral (MS) Degree Program might be eligible for incentives not exceeding five thousand Saudi riyals (SAR5,000) per project.

**1.1.1.2.1** If the PI is acting as supervisor/mentor in more than one (1) ongoing research project, the total accumulative incentive to be paid must not exceed twenty thousand Saudi riyals (SAR20,000) per year.

##### 1.1.2 Sub-Investigator (SI)

**1.1.2.1** For each research project, SI may be eligible for incentives not exceeding one thousand five hundred Saudi riyals (SAR1,500) per month for a maximum of ten (10) months, which is fifteen thousand Saudi riyals

(SAR15,000) per year per individual. Maximum period of the project must be two (2) years, that is, total incentives must not exceed thirty thousand Saudi riyals (SAR30,000) per project. If the number of SIs exceeds three (3), the total amount to be given to them must not exceed fifty thousand Saudi riyals (SAR50,000) annually with a maximum of one hundred thousand Saudi riyals (SAR100,000) per project.

**1.1.3** If a member of the Research Team is involved in more than one (1) on-going research project, the total accumulative incentives to be paid to an individual must not exceed thirty thousand Saudi riyals (SAR30,000) per year unless they are acting as PI in two (2) of the research projects where the incentives per individual must be a maximum of forty thousand Saudi riyals (SAR40,000) per year.

**1.1.4** Research Team members except supervisors/mentors with research projects that are part of their requirements for completion of training, whether undergraduate or postgraduate, research are not eligible for payment of incentives. However, support may be provided otherwise.

**1.1.5** The Research Team from non-MNG-HA participating sites for KAIMRC sponsored multi-center studies is not eligible for incentives. Instead, payment for patient recruitment inclusive of all expenses incurred at the study site based on the location and complexities of the study will be provided as follows:

**1.1.5.1** A maximum of one thousand Saudi riyals (SAR1,000) per subject for national sites

**1.1.5.2** A maximum of three thousand Saudi riyals (SAR3,000) per subject for international sites.

## **1.2 Research Support Team**

### **1.2.1 Consultants**

**1.2.1.1** They must be eligible for a fee only if they are not members of the Research Team. Based on the type of consultation, the fund will be allocated as follows:

**1.2.1.1.1** For scientific consultation, the amount must not exceed two thousand Saudi riyals (SAR2,000) per day, maximum of twenty thousand Saudi riyals (SAR20,000) per year; maximum of forty thousand Saudi riyals (SAR40,000) per project. In addition, a business class ticket per year, maximum of 2 tickets per project.

**1.2.1.1.2** For statistical consultation, the amount must not exceed ten thousand Saudi riyals (SAR10,000) per project and must be allocated for KAIMRC Bioinformatics and Research Consulting Services. If the required services cannot be provided by KAIMRC, the money may be allocated to other consultants with the approval of RFC.

### **1.2.2 Research Assistant**



**1.2.2.1** The amount must not exceed seventy-five Saudi riyals (SAR75) per patient per hour, maximum of three thousand Saudi riyals (SAR3,000) per month for a part time job, or in accordance to the MGHA basic salary catalogue for a full time job.

**1.2.3** Research Coordinator

**1.2.3.1** The amount must not exceed fifty Saudi riyals (SAR50) per patient, maximum of two thousand Saudi riyals (SAR2,000) per month for a part time job, or in accordance to the MGHA basic salary catalogue for a full time job.

**1.2.4** Data Collection may be done by physicians, pharmacists, nurses, medical technicians, interviewers, etc. and fees must not exceed one hundred Saudi riyals (SAR100) per patient for a maximum of three thousand Saudi riyals (SAR3,000) per individual for a part time job, or in accordance to the MGHA basic salary catalogue per individual for a full time job. PI must provide sufficient justification when proposing the cost. The amount will be based on:

**1.2.4.1** The information provided

**1.2.4.2** The time spent for data collection

**1.2.4.3** The educational qualification and expertise.

**1.2.5** Data Entry Personnel

**1.2.5.1** The amount will be ten Saudi riyals (SAR10) per subject, not to exceed twenty Saudi riyals (SAR20) per hour with a maximum of one thousand five hundred Saudi riyals (SAR1,500) per month for a part time job, or in accordance to the MGHA basic salary catalogue for a full time job.

**1.2.6** Administrative Assistant

**1.2.6.1** The amount must not exceed twenty Saudi riyals (SAR20) per hour, maximum of one thousand five hundred Saudi riyals (SAR1,500) per month for a part time job, or in accordance to the MGHA basic salary catalogue for a full time job.

**1.2.7** Fees for other members of the Research Support Team must not exceed the maximum allowed for an equivalent job.

**2.** Supplies and Equipment

**2.1** A detailed list with full description of each item will be provided including copy of valid quotations to support fund request. For requested equipment, the PI will be given the following options:

**2.1.1** Find out the availability of equipment within MNG-HA or alternative resources within the hospital. PI must communicate with the owner department and provide feedback to RFC on the possibility of using the same resources for the research project.

**2.1.2** Whenever the first (1<sup>st</sup>) option is not feasible, the equipment may be rented or purchased depending upon its cost effectiveness. PI must provide feedback to RFC regarding the equipment's benefits and/or possibility of future use.

**2.2** If the equipment will be purchased, PI must advise RFC of its disposition upon completion of the project, which may be any of the following:

**2.2.1** Return to KAIMRC

**2.2.2** Re-utilize by the PI for another project

**2.2.3** Re-utilize by another department within MNG-HA.

### **3. Patient Compensation**

**3.1** This includes indemnity insurance and compensation in the form of monetary gifts, food and beverages during the study. All compensation allocated for subject should be clearly defined in the Research Proposal and Informed Consent Form approved by IRB, as well as in the proposed budget in relevant e-form.

### **4. Other Costs**

#### **4.1 Publication cost**

**4.1.1** The amount must be fixed at five thousand Saudi riyals (SAR5,000) per publication. This includes costs of reports, editing, reprints, page changes, or journal. This cost will be handled and paid by KAIMRC.

**4.1.2** Monetary incentives will be granted to the Research Team based on the Impact Factor of the journal where the study is published:

JIF	Incentives
2 – 4	SAR 2,000
4 – 8	SAR 5,000
8 – 12	SAR 10,000
>12	SAR 15,000

**4.1.2.1** This will apply to publication of KAIMRC approved original research proposals, whether grant or non-grant.

**4.1.2.2** The distribution of the incentives to the Research Team will be as follows:

- 25% to the 1<sup>st</sup> author regardless whether the 1<sup>st</sup> author is the Principal Investigator or not
- 25% to the correspondent author (total of 50% if the correspondent author is also the 1<sup>st</sup> author)



- 50% distributed to KAIMRC affiliated co-authors provided that incentive to each co-author will not exceed 25%

**4.1.2.3** The authors' affiliation to KAIMRC must be clearly stated in the published article. The incentives will only be distributed to authors who indicated their affiliation to KAIMRC and according to the approved affiliation statement as follows:

Author's Name  
King Abdullah International Medical Research Center/King Saud bin Abdulaziz University for Health Sciences  
Author's Department – Hospital - MNGHA

## **4.2 Shipping cost**

- 4.2.1** Estimated cost must be supported by quotations from carriers; otherwise the same company which has a contract with MNG-HA will be utilized.

## **4.3 Traveling cost**

- 4.3.1** Cost incurred by international experts who are members of Research Team and includes fees for visa, health insurance, accommodation, and transportation. The amount must not exceed fifty thousand Saudi riyals (SAR50,000) per project.

## **4.4 Study site visit**

- 4.4.1** The amount to be paid includes transportation and accommodation costs related to the study site visit for multi-center studies. The amount must not exceed fifteen thousand Saudi riyals (SAR15,000) per year for national sites and thirty thousand Saudi riyals (SAR30,000) per year for international sites. This amount will be released prior to the visit and upon submission of the required documents and information.

## **4.5 Miscellaneous**

- 4.5.1** The amount granted must not exceed ten percent (10%) of the total budget. Generally, this covers consumable items which may include, but is not limited to the following:
- 4.5.1.1** Transportation (taxi fare, train ticket, gasoline, etc.)
  - 4.5.1.2** Catering (meals/snacks/refreshments for properly identified team meetings) – not for patients/participants/subjects for the study
  - 4.5.1.3** Communication expenses (telephone calls, fax charge, internet charge, courier charge, etc.)
  - 4.5.1.4** Computer supplies (ink cartridge, CD, etc.)
  - 4.5.1.5** Stationery supplies (paper, clips, pens, folders, etc.)
  - 4.5.1.6** Copying and printing expenses (in case MNG-HA Printing Press cannot accommodate requests)

#### **4.6 Intellectual Property/Protection Cost**

- 4.6.1** Cost associated with or spent to safeguard intellectual property in a research project such as patent, copyright and trademark. The cost ranges from lawyer fees to government fees which include registration expenses. The amount must not exceed one hundred thousand Saudi riyals (SAR100,000) per project.
- 4.6.2** Cost associated with prototyping is estimated based on the best of 3 quotes provided by the PI.