بسم الله الرحمن الرحيم

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	:	**1419-05**
TITLE	:	**RESEARCH PROPOSAL SUBMISSION, PROCESSING AND APPROVAL**
ORIGINATING DEPT.	:	**KING ABDULLAH INTERNATIONAL MEDICAL RESEARCH CENTER (KAIMRC) (417780)**
ORIGINAL DATE	:	**JULY 1998**
REVISION DATE	:	**SEPTEMBER 2015**

1. PURPOSE

To provide a process for the submission, processing and approval of research proposals for clinical and non-clinical research studies at Ministry of National Guard – Health Affairs (MNG-HA) and all affiliated facilities.

2. APPLICABILITY

To all employees involved in research studies conducted at MNG-HA, KAIMRC and affiliated facilities and research studies proposed by their affiliated professionals and staff involved in the development, processing, and approval of research studies.

3. RELATED REFERENCES

3.1 APP 1433-37: Conducting Research Studies

3.2 APP 1426-02: Institutional Review Board (IRB)

3.3 APP 1432-20: Monitoring Research Studies

3.4 APP 1429-19: Conflict of Interest

3.5 APP 1419-08: Patient Informed Consent

JA MJ

P.O. Box: 22490
Riyadh 11426
KINGDOM OF SAUDI ARABIA
(109349)

Fax: 011 - 8011000

فاكس: ٠١١-٨٠١١٠٠٠

ص.ب. ٢٢٤٩٠
الرياض ١١٤٢٦
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3.6 APP 1436-01: Authorship and Publication Conduct

3.7 APP 1432-04: Appeal Process for Rejected Research Proposals or Suspended Ongoing Research Study

3.8 APP 1435-10 Budget Approval for Intramural Research Grant

3.9 King Abdullah International Medical Research Center (KAIMRC) rules and regulations

3.10 International Conference of Harmonisation (ICH): ICH Harmonised Tripartite Guideline - Guideline for Good Clinical Practice E6(R1)

3.11 Saudi Food and Drug Authority (SFDA) rules and regulations

3.12 Joint Commission International Accreditation Standards for Hospitals, 5th Edition (2014) – HRP.7.1, ME.1-4; HRP.1.1, ME.3; PFR.5, ME.3 and 5.1, ME.1-5

4. DEFINITIONS

4.1 **Applied Research** is a form of systematic inquiry involving the practical application of science. It accesses and uses some part of the research communities' (the academia's) accumulated theories, knowledge, methods and techniques, for a specific, often state, business, or client-driven purpose. Applied research deals with solving practical problems and generally employs empirical methodologies.

4.2 **Basic Research** (also called pure research or fundamental research) is a systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena without specific applications or products in mind. It includes all branches of science and engineering.

4.3 **Chief Principal Investigator (Chief PI)** refers to an individual who has the responsibilities of the principal investigator and is responsible for submitting the research proposal for multi-center studies.

4.4 **Clinical Employee** refers to employees who are involved in patient care and occupying clinical positions.

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 Trials** are a set of tests in medical research and drug development that generate safety and efficacy data for health interventions, (e.g. drugs, diagnostics, devises treatment regimens and protocols).

4.7 **Collaborative Research** refers to a process in which individual researchers, universities and other organizations work together to undertake research to achieve a common aim and benefits the community.

4.8 **Disease Registries** refers to public health surveillance system that collects and maintains structured records on the new cases of a specific disease or condition for a specified time period and population; it analyzes and interprets data for those with a common illness or adverse health condition.

4.9 **E-Submission** refers to a web based system used to submit research proposals electronically to KAIMRC.

4.10 **External Multicenter Study (EMS)** refers to a study designed & written by any non-MNG-HA organization.

4.11 **Expedited Proposal Approval** refers to the approval of research proposal by the chairman of either Research Committee or Institutional Review Board (IRB).

4.12 **Full board Proposal Approval** refers to the approval of research proposal by the research committee /IRB.

4.13 **International Conference on Harmonization/Good Clinical Practice (ICH/GCP)** which is an international ethical and scientific quality standard for designing, conducting, recording and reporting research involving the participation of human subjects.

4.14 **Informed Consent** refers to a process by which a subject voluntarily confirms their willingness to participate in a clinical trial or research study, after having been informed of *all* aspects of the research relevant to the subject's decision to participate.

4.15 **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 wellbeing of human subjects involved in research studies.

4.16 **Investigator Initiated Research Study** refers to a study designed, written and submitted by an MNG-HA staff.

4.17 **Minimal Risk** refers to the level of risk not greater than ordinarily encountered in daily life or a routine physical/physiological examination or a test.

4.18 **Non-Clinical Employees** refers to employees appointed to positions providing general office, administrative and support services as well as specialized clerical jobs.

4.19 **Non-Clinical Research** refers to type of studies which does not involve participation of human subjects, including but not limited to, in-vivo or in-vitro experiments and animal studies.

4.20 **Principal Investigator (PI)** refers to an individual or group of individuals who prepare, develop and submit Research Proposal(s) for review by the Research Committee.

4.21 **Prospective Research** refers to an analytic study designed to determine the relationship between a condition and a characteristic shared by some members of a group. The researcher follows the population group over a defined period of time to observe the pre-defined condition.

4.22 **Research Committee (RC)** refers to a body composed of medical practitioners/clinicians whose responsibility is to review research proposals for MNG-HA and make recommendations for amendments and/or approval/disapproval on a scientific basis.

4.23 **Research Funding Committee (RFC)** refers to a committee responsible for review and approval of fund requests submitted for conducting research projects according to the committee formation order (CFO-KAIMRC-01-011).

4.24 **Research Grant** refers to the funds allocated to an approved research project through KAIMRC.

4.25 **Research Office (RO)** is a section of KAIRMC which manages all review and approval processes for all research studies originated and conducted within MNG-HA.

4.26 **Research Proposal** refers to a standard document that describes the general plan of a proposed research study submitted to KAIMRC for obtaining approval.

4.27 **Retrospective Research** refers to a study that looks back and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study, and includes case-control studies, investigations and cross sectional study.

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 **Sponsor** refers to an individual, company, institution or organization who takes responsibility for the initiation, management and/or financing of a research study.

4.30 **Study Protocol** refers to a document that describes the detailed objective(s), design, methodology, statistical considerations and organization of a clinical trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

4.31 **Study Subject** refers to an individual who participates in a clinical research study.

4.32 **Sub-Investigator** refers to any individual member of the research team designated and delegated by the PI for the research project to perform critical certain assigned procedures and/or to make important project-related decisions

4.33 **Track Record** refers to the past achievements or performance of a person in research and it means at least one (1) publication in a national/international journal as a Co-Author.

4.34 **Translational Research** is a scientific research that helps to make findings from basic science useful for practical applications that enhance human health and well-being.

5. POLICY

5.1 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.

5.2 MNG-HA, KAIMRC, King Saud Bin Abdul-Aziz University for Health Sciences (KSAU-HS) staff are encouraged to participate in collaborative research projects with national and international researchers or institutions.

5.3 KAIMRC must accept the following types of research proposals:

5.3.1 Applied research studies

5.3.2 Basic science studies

5.3.3 Translational studies

5.3.4 Experimental studies (except for Phase I clinical trials)

5.3.5 Quasi experimental studies

5.3.6 Observational studies

5.4 KAIMRC must ensure that all research studies conducted at MNG-HA adhere to all national and international scientific and ethical standards.

5.5 Research studies can be carried out in any MNG-HA department, including medical, paramedical and administrative departments, KSAU-HS facilities and KAIMRC facilities.

5.5.1 MNG-HA Chief Principal Investigators may choose to conduct their investigator initiated studies in non-MNG-HA affiliated institutions. The selection of the Site PI in such studies must comply with ICH/GCP guidelines.

5.6 All research studies involving humans as subjects or human material conducted at MNG-HA facilities or planned to be conducted outside the MNG-HA facilities by MNG-HA staff must be approved by MNG-HA IRB.

5.6.1 IRB may review proposals that are not involving human subjects.

5.7 The PI qualified by education and training must have the ultimate responsibility for the research study.

5.8 Any MNG-HA staff serving as PI in a research study must:

5.8.1 Be qualified by education, training and experience and be legally allowed to practice in their field of specialty when they are involved in clinical research study

5.8.2 Be thoroughly familiar with the research study protocol and/or investigational medicinal product(s)

5.8.3 Have valid ICH-GCP certification

5.8.4 For clinical research, have one (1) or more of the following designations and qualifications:

5.8.4.1 KAIMRC staff holding a research position of associate scientist or above, or any other positions holding a PhD in addition to a track record in research and must have a qualified consultant physician who has the responsibility for the medical care of the research study subjects as a sub-investigator, and who meets the criteria as stated in article 5.8.5.2

5.8.4.2 KSAU-HS staff holding an academic position of assistant professor or above, and must have a qualified consultant physician who has the responsibility for the medical care of the research study subjects as a sub-investigator, and who meets the criteria as stated in article 5.8.5.2

5.8.4.3 KAMC clinical staff holding a position of associate consultant physicians or above

5.8.4.4 Clinical employees who are non-physicians must hold a minimum PhD or equivalent with four (4) years experience in their field, and in addition, have a qualified consultant physician who has the responsibility for the medical care of research study subjects as a sub-investigator who meets the criteria stated in article 5.8.5.2.

5.8.5 Have one (1) or more of the following titles and qualifications, if they are conducting a non-clinical study:

5.8.5.1 Faculty member of KSAU-HS as a lecturer at a minimum and a track record of research.

5.8.5.2 Assistant consultant, staff physician, and medical fellows

5.8.5.3 MNG-HA non-clinical & clinical staff (non-physicians) working in their field of specialty for a minimum of four (4) years and/or based on the Research Committee's decision

5.8.5.4 PI who meets one of the criteria under article 5.8.4.

5.9 The PI is responsible for ensuring that all sub-investigators (including non-MNG-HA employees) have a clear and relevant role in the research study, and meet the following criteria:

5.9.1 Be qualified by education, training and experience and be legally allowed to practice in their field of specialty when they are involved in clinical research

5.9.2 Be delegated from the PI to perform study specific activities for a specific time

5.9.3 Be thoroughly familiar with the study protocol, aware of and compliant with ICH/GCP and any applicable regulatory requirements pertaining to the conduction of research studies.

5.10 Research proposals must be submitted through the KAIMRC research proposal electronic submission system (e-Submission).

5.10.1 The PI must notify the department where the study is going to be conducted and obtain the proof of notification before submitting the proposal.

5.10.2 The PI must protect the privacy of their e-Submission access credentials.

5.10.3 The following must be submitted along with the study proposal.

5.10.3.1 Any approvals from either external IRBs and/or external regulatory authorities other than the Saudi Food and Drug Authority (SFDA) if applicable.

5.10.3.2 Informed consent forms must be acquired in Arabic and English for all studies involving the participation of human subject, as explained under article 6.3.1 herein. Detailed guidelines for developing informed consent forms are given in the **Appendix M**.

5.10.3.3 Other essential documents, as applicable, under the list of essential documents **(Appendix A)**.

5.10.4 An adequate indemnity insurance statement must be submitted for all clinical trials:

5.10.4.1 Such insurance must cover all adverse events experienced by any or all of the research subjects, except in cases of malpractice from the investigator's side

5.10.4.2 Indemnity insurance is covered by MNG-HA for all MNG-HA sponsored clinical studies conducted within MNG-HA facilities

5.10.4.2.1 KAIMRC must provide indemnity insurance for the participants from the Business Center, if they are included in the research study.

5.10.4.3 For MNG-HA investigator initiated clinical trials sponsored by an external sponsor, the indemnity insurance must be covered by the sponsor, unless stated otherwise in the clinical trial agreement

5.10.4.4 For External Multicenter Studies (EMS), the external sponsor must cover the indemnity insurance.

5.10.5 Upon the submission of the proposal a declaration of any financial conflict of interest must be provided by the PI using **(Appendix B).**

5.11 The PI of a study cannot include a first relative as a sub-investigator in their study in accordance with APP 1429-19.

5.12 In the case of submitting an investigator initiated multicenter study within MNG-HA (i.e. the study must be conducted in two (2) or more MNG-HA regions Riyadh, Jeddah, Al Madinah, Al Ahsa/Al Dammam); the study must have a Chief PI and one (1) or more site PIs in each investigational site.

5.12.1 The Chief PI is responsible for:

5.12.1.1 The overall management of the research study as well as conducting the research study at their own investigational site in accordance with APP 1433-37.

5.12.1.2 All the required submissions of reports to the research committee, IRB and RFC.

5.12.1.3 The Chief PI is responsible for selecting site PIs.

5.12.2 Site PIs are responsible for:

5.12.2.1 Conducting the research study within their own research site in accordance with APP 1433-37.

5.12.2.2 Reporting the difficulties, progress and updates on the research study to the Chief PI.

5.13 All research proposals must be reviewed by the RO, and forwarded to the appropriate committee, refer to article 5.15 herein for review and approval.

5.13.1 The RO is responsible for conducting the preliminary review on the submitted research proposals/protocols and to request any clarifications and/or additional submission as required.

5.13.2 The PI is required to respond to any clarifications requested by the RO within ten (10) days of the clarifications request date.

5.13.3 Failing to meet the above deadline under article 5.14.2 herein without a valid justification must result in the cancellation of the submission.

5.14 All research proposals must be reviewed and approved by the following bodies as applicable:

5.14.1 The RC is responsible to review the quality, scientific validity, integrity and originality of the research studies.

5.14.1.1 RC has the authority to recommend for approval, reject or request modifications on the research studies.

5.14.1.2 The PI is required to respond to any modifications requested by the RC within twenty (20) working days of the modification being requested.

5.14.1.3 Failing to meet the above deadline under article 5.15.1.2 herein without a valid justification must result in the termination/suspension of the approval process.

5.14.2 The IRB is responsible to review the research study and ensure that the rights, safety and welfare of human participants are protected as per APP 1426-02, including those participants the IRB considers vulnerable participants.

5.14.2.1 No research study can be initiated before IRB approval.

5.14.2.2 All research proposals must meet the criteria for approval before granting the approval. The criteria for ethical approval of the research study are given in **Appendix L**.

5.14.2.3 Research proposal meeting the criteria for exemption may be exempt from IRB review and approved by the IRB Chairman. Determination of exemption must be based on regulatory and institutional criteria and documented.

5.14.2.1.1 In the case where the IRB Chairman is the Principal Investigator or Sub-Investigator of a research proposal that potentially qualifies for approval as exempt from review or expedited review pathway (as given below), another member of the committee will be assigned to review the proposal by the IRB Chairman.

5.14.2.1.2 The IRB Chairman will provide a quarterly report to the Executive Director, KAIMRC and IRB of all projects approved as exempt research or which were reviewed through the expedited review pathway.

5.14.2.4 No research proposal should be rejected by the IRB without full board IRB review.

5.14.2.5 The IRB members/ external specialists assigned by IRB for reviewing research studies shall be compensated based on approved scale for reviewing research proposals.

5.14.3 The Disease Registry Committee is responsible to review all disease registry proposals and recommend for approval.

5.14.4 The RFC must review approve/disapprove the fund requests of the proposed research studies submitted to KAIMRC.

5.14.5 The SFDA: All clinical trials that involve the administration of investigational products on human subjects must be reviewed and approved by the SFDA as per their policy and procedures.

5.15 All approved studies must be conducted within the time frame which is specified in the research proposal starting from the date of approval. Any extension of the study after its date of expiry must be reviewed by the RC and approved by IRB.

5.15.1 The PI must justify and explain the following to the IRB and RC:

5.15.1.1 Reasons for extension

5.15.1.2 Difficulties which led them to fall behind the study timeframe

5.15.1.3 Justification for the requested additional time period.

5.16 The PI must provide the RO with the progress report on an annual basis at a minimum or as requested by RC and/or IRB.

5.17 If the RC discovers that the submitted research proposal is plagiarized or it is discovered the PI is committing robbery of intellectual property or any other misconduct, the RC must decide on an appropriate punishment which matches the degree of the offense committed, refer APP 1436-01.

5.18 The final approval for any research study must be granted from the IRB.

5.19 Once the research proposal is approved by the required committees and regulatory authorities, the PI must conduct the research study in accordance with APP 1433-37.

6. PROCEDURES

6.1 The PI will access the proposed electronic submission (e-Submission) system through http://esubmission.kaimrc.med or http://esubmission.kaimrc.med.sa.

6.2 The PI will create a user account referring to the e-Submission user manual **(Appendix D)** to allow access to the system and upload the respective documents of the research study.

6.3 Once all components of the research proposal have been completed, the PI will complete the proposal submittal form on the KAIMRC e-Submission system.

6.3.1 The following documents will be attached to the research proposal submittal form through the e-Submission system:

6.3.1.1 Informed consent forms will be required (in Arabic and English) for all studies that involve the participation of human subject, as follows:

6.3.1.1.3 For interventional studies, use Arabic Consent form **(Appendix G)** and English Consent form **(Appendix C)**

6.3.1.1.3 For non-interventional studies, use Arabic Consent form **(Appendix H)** and English Consent form **(Appendix I)**.

6.3.1.1.3 For Cross-sectional surveys, use Consent Form **(Appendix J)**

6.3.1.2 Case report form (CRF)/Data Collection Sheet/instrument, if applicable

6.3.1.3 Up-to-date curriculum vitae (including a list of publications) of the PI and sub-investigators.

6.3.1.4 For all clinical trials, the PI will submit, along with the research study protocol, any essential document that is applicable to the clinical trial as per the list of Essential Documents Checklist **(Appendix A).**

6.3.2 The PI may suggest two (2) or more scientific peer reviewers who have extensive education, experience and previous record of research activities and publications in the same field of expertise.

6.3.3 The research proposal that includes a request for a fund from KAIMRC will contain full and clear discussion on budget considerations.

6.3.3.1 All financial aspects of the study will be clearly enclosed in the e-submitted proposal. This will include information about the sources of funding support, payment to subjects, payments to the investigators or other members of the research team. A statement on conflict of interest, if any, will also be included, refer to APP 1435-10.

6.4 Proposal Receipt and Preliminary Review

6.4.1 The PI submits the research proposal to the RO through the e-Submission system.

6.4.2 The scientific reviewer notifies PI's head of department/chairman of the receipt of the proposal.

6.4.2.1 The department head/chairman may raise a valid concern (if any) regarding the submitted proposal within three (3) working days of *receipt of notification. If the* chairman does not respond within three (3) working days, the research office will assume that the section head/chairman has no objection on the proposal submission.

6.4.3 The scientific reviewer completes a preliminary review on the research proposals.

6.4.3.1 If the proposal is found to be incomplete, the scientific reviewer will communicate all the items missing from the research proposal application to the PI and request to complete and re-submit the items within ten (10) working days.

6.4.4 Upon receipt of the complete proposal, the assigned scientific reviewer checks the proposal and decides if the proposal will be reviewed by the RC on an expedited or full board review basis.

6.4.4.1 The scientific reviewer will classify proposals on an expedited review basis according to the following criteria:

6.4.4.1.3 Studies that are part of PhD dissertations, Master's thesis or KSAU-HS student's projects that have already passed the scientific review process, studies that are retrospective in nature or a cross-sectional survey.

6.4.4.1.3 External Multicenter Studies (EMS).

6.4.4.2 All other prospective studies initiated by MNG-HA staff will be processed on a full board review basis.

6.4.4.2.3 The RC Chairman may waive the expert review process for selected research studies and expedite the approval process based on the complexity and nature of the research study.

6.4.5 Expedited Scientific Committee Review Process

6.4.5.1 The scientific reviewer submits the proposal to the RC chairman for review and approval. The RC Chairman may forward the proposal to one (1) or two (2) research committee members for review.

6.4.5.2 If the proposal requires modification, it will be dealt as described in article 6.5.2 below.

6.4.5.3 If the proposal does not require modifications, it will be recommended for approval by the RC as described in article 6.5.3 below.

6.4.6 Full Board Review Process

6.4.6.1 The scientific reviewer identifies suitable reviewer/s to conduct an expert peer review on the research proposal.

6.4.6.2 The scientific reviewer will obtain a confidentiality agreement **(Appendix E)** from each peer reviewer prior to sending the research proposal to them.

6.4.6.3 Once the reviewer's reports are completed the scientific reviewer forwards the proposal to the RC for review and recommendation for approval.

6.5 Scientific Committee Review

6.5.1 RC members discuss the research proposal in the RC meeting and decide whether to approve, reject or require modifications on the research proposal.

6.5.2 If the proposal requires modification, a memo will be sent to the PI addressing the required modifications.

6.5.2.1 The PI is required to reply to the RC request for the modifications within twenty (20) working days.

6.5.2.2 If the PI fails to meet the requested modifications or if the PI does not provide a valid justification not to implement the suggested modifications by the RC, the scientific reviewer will re-send the proposal back to the PI.

6.5.2.2.1 The PI will be given one (1) opportunity to comply with the requested modifications by the RC within five (5) working days.

6.5.2.2.2 Failure to comply with the RC requirements will result in termination of the approval process and closure of the study application.

6.5.2.3 If the suggested modifications are appropriately reflected on the modified proposal (or the PI has provided a valid justifications not to implement the requested modifications from the RC), the scientific reviewer recommends scientific approval of the research proposal, and communicates their decision to the RC chairman.

6.5.2.3.1 If scientific reviewer cannot make a decision on the submitted modified research proposal, the proposal will be sent back to the initial peer reviewers for their feedback.

6.5.2.4 The RC Chairman reviews and takes the appropriate decision on the modified proposal.

6.5.3 If the proposal doesn't require further modifications, the RO prepares a memo of recommendation for approval, which is addressed to the IRB chairman and copied to Research Funding Committee (RFC), if applicable.

6.5.4 If the proposal is rejected, the RC will send a letter of rejection to the PI with a justification for the rejection.

6.5.4.1 The PI has the right to appeal the decision of the committee within thirty (30) calendar days from the date of rejection in accordance with APP 1432-04.

6.6 Ethical Approval

6.6.1 The IRB reviews all research involving human subjects in order to assure compliance to the ethical standards.

6.6.1.1 The IRB administration staff will review the documents submitted for completeness, refer to **Appendix A** for the list of the essential items to be submitted by the PI.

6.6.1.1.1 Any missing documents will be documented. The PI will be asked to complete and submit all missing documents before processing the proposal further.

6.6.1.2 When all documents are complete, the IRB administration staff will send acknowledgement to the PI indicating date of review and if their presence is required.

6.6.1.3 The IRB officer performs the initial review of all research proposals involving human subjects. The IRB officer will determine whether the proposal:

6.6.1.3.1 Meets the criteria for exempt human studies research. This applies to projects that fall into one of the following categories:

6.6.1.3.1.1 Research with non-human contact.

6.6.1.3.1.2 Research studies in which the information about subjects is obtained in a manner that human subjects cannot be identified, directly or through identifiers linked to subjects.

6.6.1.3.1.3 Research with no risk involved to the subjects.

6.6.1.3.1.4 The IRB officer submits the proposals that are exempt from review proposals to the IRB chairman for approval.

6.6.1.3.2 Qualifies for review through the expedited review pathway. This applies to projects that meet the criteria for 'minimal risk' to human subjects and do not fall into one of the exception categories (research involving private identifiable data that has previously been collected and most or all case reports or retrospective studies fall into this category). See **Appendix K** for further details.

6.6.1.3.2.1 The IRB officer submits the proposal to one (1) or two (2) IRB members or external specialist for review, if required.

6.6.1.3.2.2 Wherever applicable, the IRB members review the proposal against the criteria of ethical approval of research (**Appendix L**).

6.6.1.3.2.3 If the proposal requires modification, the IRB officer sends the memo of modification to the PI addressing the required changes.

6.6.1.3.2.4 If the proposal does not require modifications, it will be recommended for approval by the IRB Chairman.

6.6.1.3.3 All projects that do not meet the requirements for exempt human studies research or expedited review undergoes full IRB Committee review.

6.6.1.3.3.1 The IRB Committee meets on scheduled date and reviews each proposal against the criteria of ethical approval of research (**Appendix L**). The IRB may request the presence of the PI in the discussion if necessary.

6.6.1.3.3.2 If the proposal requires modification, the IRB officer sends the memo of modification to the PI addressing the required changes.

6.6.1.3.3.3 If the proposal meets all criteria of ethical approval by majority vote in the motion, the IRB committee recommends approval of the proposal.

6.6.2 The IRB chairman approves the proposal by signing a memo of approval, if the proposal meets the minimal criteria for approval, see **Appendix L**.

6.6.3 The IRB administration staff sends the memo of approval to the PI.

6.7 Financial Approval

6.7.1 RFC reviews the fund requests for research studies as per APP 1435-10.

6.8 Final Approval and Contracting

6.8.1 Once the approval from the RC chairman and other applicable committees are obtained, the proposal will be forwarded to KAIMRC Executive Director, then to the MNG-HA CEO for their final approval.

7. RESPONSIBILITY

7.1 KAIMRC, KSAU-HS and all other relevant departments at MNG-HA will be responsible for the implementation of 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

29 OCT 2015
DATE

REVIEWED BY:

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

09 NOV 2015
DATE

APPROVED BY:

H.E. DR. BANDAR AL KNAWY
Chief Executive Officer, MNG-HA
President, KSAU-HS

19/11/2015
EFFECTIVE DATE