Standard Operating Procedures

of

Ethics Committee

College of Applied Medical Sciences, King Khalid University, Abha, KSA

October 2018

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1. Preamble:

King Khalid University (KKU) is a rapidly growing institution of higher education in Saudi Arabia. It is one of the biggest centers of learning in the Middle East with about 70,000 students controlled and reputation of major provider of higher education in all the disciplines. College of Applied Medical Sciences (CAMS) of this university has contributed to various leading innovations and discoveries, which has led to improvements in medical science. In keeping with the advances in research and developments in realm of medical ethics, and to provide impetus to research, the Ethics Committee (EC) was formed as structured below:

	Members
1	Dr. Ayed Awad Dera, **(Chairman)** Assistant Professor Department of Clinical Laboratory Science, College of Applied Medical Sciences, King Khalid University, Abha.
2	Dr. Gaffar Sarwar Zaman, **(Member)** Assistant Professor, Department of Clinical Laboratory Science, College of Applied Medical Sciences, King Khalid University, Abha.
3	Dr. Omer Loaz, **(Member)** Assistant Professor, Department of Radiology, College of Applied Medical Sciences, King Khalid University, Abha.
4	Dr. Ravi Shankar Reddy, **(Member)** Assistant Professor, Department of Physical Therapy, Collage of Applied Medical Sciences, King Khalid University, Abha.
5	Dr. Ahmed Mohammed Saif, **(Member)** Assistant Professor, Department of Clinical Laboratory Science, College of Applied Medical Sciences, Najran University, Najran.

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Purpose of Ethics Committee and Standard Operating Procedures (SOP): The main work of EC is to protect the interest of the patient and to ensure that no harm in done. Other purposes of SOP of EC are to define the process for writing, reviewing, distributing and amending SOPs. EC should facilitate and promote work of researchers. EC has a major role for giving impetus to research so that all conflicts of interest must be shared by appropriate declaration.

2. Standard Operating Procedures for Ethics Committee

Following aspects have been incorporated in the standard operating procedures of EC:

SOP-1. Responsibility of Chairman regarding SOP:

One of the foremost responsibilities of the Chairman is to appoint an SOP team, to formulate a new SOP or to revise existing SOP. Also, it is the responsibility of the Chairman to:

i. Appoint one or more SOP Teams as he thinks adequate
ii. Approve the SOPs: The final version should be presented to the Chairman for review and approval.
iii. Sign and date the approved SOPs: The Chairman will sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from which the SOP will be implemented. The face page may also contain signature of Dean of the Institution as having accepted the document (as per the institutional policy).

SOP-2. Responsibility of the Ethics Committee regarding SOP:

- Evaluate the request(s) for SOP/s revision in negotiation with the Chairman. The EC members should review the SOPs at least once in every 3 years.
- Suggest and initiate new / modified SOP/ s as needed
- Draft the SOP/s
- Evaluate and appraise the draft SOP

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- Submit the draft SOP for approval to Chairman
- Implement, distribute and file SOPs
- Verify and corroborate that all the EC members and involved staff are working according to current version of SOPs
- Maintain a recent distribution list for each SOP.
- Maintain a file of all current and previous SOPs

SOP-3. Roles and Responsibilities of Members of the EC

Chairman:

- The Chairman will be responsible for conducting the committee meetings, leading deliberations concerned with the review of research proposals.
- The Chairman will preside over all elections as well as administrative and financial matters concerning the committee's functions.
- The representation at various meetings and forums will be made by the Chairman
- The Chairman will sign all types of documents and communications related to EC functioning.

Members

- The members will comprise of medical, non-medical and scientific persons to represent the various points of view; it will also help to promote complete and adequate review of research proposals.
- A brief Curriculum Vitae (CV) of all members will be maintained at the institutional office. The CV should contain: name, address, professional qualification, area of expertise, current affiliation, if any.
- Must possess the required qualifications as given by applicable guidelines and regulations from time to time.
- Should have the time, expertise and commitment to perform all functions
- It is required that the committee should include at least one member who is a

clinician.

- EC may invite member(s) of specific special interest groups for an EC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for elucidating their views. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have right to vote.
- Each EC member, reviewing research project or attending EC meetings, must sign the agreement which is contained in the confidentiality Form. After appointment, member must submit a signed recent CV.
- A member may be disqualified from continuance should the Chairman decide that the member's work and conduct has been inappropriate of an EC member.
- Members must attend all EC Meetings and participate in discussions and deliberation.
- All members must review, discuss and consider research Proposals submitted for evaluation.
- A member must review the progress reports and monitor ongoing studies.
- They must visit research sites wherever needed, and whenever instructed by the Chairman.
- All members must assess and gauge final reports and outcomes.
- They must maintain confidentiality of the documents and deliberations of EC meetings.
- Any conflict of interest by any member should be submitted to the Chairman in writing.
- All members should participate in continuing education activities in biomedical ethics and biomedical research.
- Carry out the work entrusted by Chairman.
- Members should have updated information on relevant laws and regulations pertaining to medical ethics.

Independent consultants:

It is the responsibility of the Chairperson to nominate the name of one or more independent consultants (if he feels it is necessary), to establish the process of calling/consulting independent consultants to provide special expertise on case to case basis. The independent consultant can belong to medical, medicolegal or special interest groups (***Annexure-4***)

SOP-4. Frequency of meetings, and Quorum requirement:

EC will meet about once in 1 month.

Quorum requirement:

- Quorum should consist of a minimum of 4 persons at any time, including the Chairman. Regarding the minimum number of persons, the Chairman's decision will be final.
- The full board meeting will be held as scheduled provided there is quorum.
- In absence of the Chairman, Co-Chairman (chosen by the Chairman) will chair the meeting.

SOP-5. Categorization of Research Study Protocols Received for Initial Review:

It is the responsibility of the Co-Chairman [in consultation with Chairman (as applicable)] to categorize the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants:

i. Full board review.
ii. Expedited review.
iii. Exemption from review.

New research study proposals received by the 20th of the month will be considered for review in the next monthly meeting of the EC.

Full Board Review:

When any new research proposals and other related documents are tabled in a formally convened meeting of the Ethics Committee for detailed discussion and decision, this is called Full Board Review.

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- Research studies involving more than minimal risk to human study participants are required by national and international regulations to be reviewed by the Ethics Committee full board.
- Research that is considered minimal risk but involves vulnerable populations may be referred for Full Board Review.
- Research proposals that have undergone expedited review, but when no decisions can be reached, are referred to Full Board Review.

EC members will be responsible for reviewing the research protocols and related documents within the given time frames. It is the responsibility of all the EC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol. The Chairman is responsible to sign and date the decision in the EC Decision Form.

Expedited Review:

Expedited review can be done by circulation of the research proposal among the committee members, followed by an immediate response within 7 days. Time factor for review process must be minimum. Whether all or few members can do the review, will depend on the subject and at the discretion of the Chairman. One or two members of committee along with Chairman can do expedited review.

Exemption from review:

When research fulfils the following criteria, the EC may grant an exemption from review:

- Research does not involve live human participants, is on data in the public domain or is on anonymized data derived from participants and the research has less than minimal risk to participants, an exemption from EC review may be considered.
- Examples that may be eligible for exemption from review include:
  1. Audits of educational practices
  2. Research on microbes cultured in the laboratory
  3. Research on immortalized cell lines

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4. Research on cadavers or death certificates provided such research reveals no identifying personal data
5. Analysis of data freely available in public domain

- A PI may also apply to EC for exemption from review if he or she finds that the proposed research study satisfies the criteria for exemption.

Waiver:

The Chairman will decide about the waiver, if needed. All projects to be done in the institution should come to ethical committee for review, who will decide whether it is a "non-research work" that qualifies eligibility for waiver.

SOP-6. Appointment of primary reviewers and elements of review:

Primary reviewers

The Chairman will appoint two or more primary reviewers for each study based on his expertise in the related field and experience. More than two may be appointed if necessary.

Elements of Review

1. Review of the project should be based on scientific design and conduct of the study; to ensure care, dignity, integrity, of research participants, protection of research participant's confidentiality; consideration of community values and communication of consent process in both English and Arabic language. (***Annexure –1***).
2. It should be clarified in the proposal that while the primary purpose of the medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
3. The Research is conducted in a manner that minimizes possible harm to the environment.
4. Appropriate compensation and treatment for subjects who are harmed, because of participating in research must be ensured.
5. Medical research involving human subjects must conform to generally accepted

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scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

6. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed because of participation in the research study. In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.
7. For a potential research subject who is incapable of giving informed consent, the researcher must seek informed consent from the legally authorised representative.
8. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, researcher must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of the EC.

SOP-7. Reviewing proposals involving vulnerable populations:

It is the responsibility of the EC Chairman to ensure that EC members are well-versed in new and evolving regulations and guidelines relating to vulnerable populations, through regular training programmes. Chairman is responsible for selecting primary reviewers who have appropriate expertise to carry out the reviews of such research and for securing consulting expert opinion as and when required for such reviews.

Who are vulnerable subjects?

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a

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retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, pregnant women, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Reviewing studies with vulnerable participants:

The study should be reviewed as per SOP-5. Additionally, the protocol should be reviewed to assess if the following points are addressed:

- Can the research be performed in any other non-vulnerable participants?
- Is there justification to use vulnerable population?
- Do the benefits justify the risks?
- Are the participants selected equitably?
- Have the measures to protect Autonomy of the vulnerable population been described?
- EC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study. (***Annexure-3***)

SOP-8. Reviewing proposals involving animal research:

It is the responsibility of the EC Chairman to ensure that EC members are well versed in new and evolving regulations and guidelines relating to animal research, through regular training programmes. Chairman is responsible for selecting primary reviewers who have appropriate expertise to carry out the reviews of such research and for securing consulting expert opinion as and when required for such reviews. Humane consideration for the well-being of the animal should be incorporated into the design and conduct of all procedures involving animals.

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Reviewing studies with animal research should see to

- The scientific purpose of the research should be of sufficient potential significance to justify the use of animals.
- There should be a reasonable expectation that the research will result in increasing scientific knowledge in different aspects of biomedicine and also will increase understanding of the species under study or provide results that could improve the quality of health or welfare of humans or other animals.
- Good experimental design is required reducing the number of animals used in research since they allow scientists to collect data using the minimum number of animals required.
- Scientists should ensure that all individuals who use animals under their supervision receive explicit instruction in experimental methods and in the care, maintenance, and handling of the species being studied.
- The researchers should handle the animals carefully and administer appropriate anaesthetics and analgesics during the experiments.
- Responsibilities for the conditions under which animals are kept, both within and outside of the context of active experimentation or teaching, rests with the researcher under the supervision of the animal care committee and with individuals appointed by the institution to oversee animal care.
- Surgical procedures require close supervision and attention to humane considerations by the scientist.
- If the surgical procedure is likely to cause greater discomfort than that attending anesthetization, and, unless there is specific justification for acting otherwise, animals should be maintained under anesthesia until the procedure is ended. Animals cannot be subjected to successive surgical procedures unless these are required by the nature of the research, the nature of the surgery, or for the well-being of the animal.

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SOP-9. Suggested decisions made by committee:

During the discussion at the next subsequent meeting, the primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided on the assessment form. The comments of an independent consultant (if applicable) will be discussed by a member chosen by the Chairman. The other EC members shall give their comments right after the presentation. The investigator/sub-investigator may be contacted/called in to provide clarifications on the study protocol that he/she has submitted for review to the EC, as per requirement. The EC members will discuss and clarify the comments and suggestions.

For all the new reviewed proposals, the committee will reach to one of the following decisions:

i. Approval as submitted
ii. Withheld approval contingent upon specific revisions - *Chair alone will approve the revisions.*
iii. Tabled for substantive change - *Full EC will approve changes.*
iv. Disapproval - *If a proposal has been disapproved then the same could be resubmitted to the committee for review.*

Decision process:

All the proposals will be approved by consensus (among all the members). In case of disagreement, decision will be based on the Chairman’s decision only.

Communicating decision:

- *Process of communicating:* Minutes documented by a secretary from amongst the members (Chosen by the Chairman) will be distributed in form of hardcopy to each member. Each member must give his comments/suggestions within a stipulated time frame of 7 days in writing.
- Suggestions/comments on minutes by each member will be incorporated in the

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final copy as such or after discussion, or after final approval by the Chairman, if required.

- Chairman will sign the final minutes.
- Communication to researchers will be done by Co-Chairman.

(***Annexure-5***)

SOP-10. Follow-up and Distribution of review work:

Approved projects will be followed for

- Adverse drug reaction report: Adverse drug reactions, if any, during the project should be reported.
- Annual progress report should be reported in a standard format. **(Annexure–1)**

Distribution of review work:

Revised Proposal:

In case of minor amendment, the investigator will state the changes that have been made and will subsequently be subjected to approval by the Chair. If there are major modifications the Chairman may refer the proposal to full committee for approval.

Expert Consultation:

Depending on the specialized area of the proposal, the Chair may direct the Co-chairman to obtain review by an expert prior to consideration for ethical approval by the EC. The reviewer must give comments in writing on scientific merit and feasibility to assist in the decision by the EC. Chairman will identify the name of the external reviewer from the list suggested by the members of EC.

Special cases:

- If any member is unable to attend the meeting, he/she can send his/her written comments in absentia.

- To adjourn meeting in absence of Chairman/vice-chairman, no documenter needed amongst ethical committee members.

SOP-11. Agenda Preparation, Meeting Procedures and Recording of Minutes

It is the responsibility of the Co-Chairman assisted by the EC members to prepare the agenda for the EC meeting. The Chairman will review and approve the agenda. It is the responsibility of the Chairman to ensure proper recording and dissemination of the minutes after the meeting is over. It is the responsibility of all members to read and approve the minutes sent to him. The Chairman will review and finally approve the minutes

SOP-12. Standard format for submission of proposals.

a. Protocol must have all necessary sections to give a complete and holistic view. The proposal must be submitted in a format.
b. If legal advice is needed, the Co-chairman will flag relevant sections in proposal.
c. Summary: Each proposal must be accompanied by a summary in a specified format.

Salient features for proposals:

i. Under usual circumstances the EC will not take up more than 15 new proposals for clearance in one sitting. To avoid inconvenience to researchers, additional meeting/s can be held by the Chair within a fortnight.
ii. Under usual circumstances the EC will not take up proposals that are not listed in the agenda for review under "Other matters" with permission of the Chair.

Chairman will give a dead line for responses to the proponents for modifications recommended in new/modified proposals by the committee. He will ensure with reasonable certainly that the proponents have received communications from the committee within the stipulated time.

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Non-adherence to dead line will result in dropping of the proposal from the agenda.

- The members of EC must maintain confidentiality with regarding deliberations during the meeting. Only the final and approved minutes will be made public.
- The committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence.

SOP-13. Review of Study Completion Reports:

1. The Co-Chairman will present the report and members can discuss as needed. Following the discussion, the Chairman may take one of the following decisions:
    1. noted / approved
    2. request for additional information / clarification
2. One of the members chosen for this purpose by the Chairman will draft a letter to the PI conveying decision on the study completion report.
3. The study shall be considered as closed if the decision by EC is “Noted” or “Approved”.
4. The Study Completion Report Form will be signed by the Chairman.
5. The final report will be placed in the master file and kept in the archival area.
6. Members will sign to confirm their participation in all meetings including the past and current one.
7. EC will only consider proposals submitted with a budget justification.
8. EC is neither responsible for any rights claimed by the patients or investigators nor it is liable to be contacted. This information along with the letter of approval should be be circulated to all faculty members in written. Investigators of projects approved by the EC, since inception, must be informed accordingly.
9. Investigators must sign an undertaking stating they are responsible to ensure safety and best available care to patients enrolled for the duration of the research study.
10. Any information received by the EC should be communicated to Chairman. along with his signature, at the time of the meeting. If the member cannot attend the meeting, the comments can be sent in advance to EC to be reviewed in his absence.

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11. Any ethical clearance given by the committee shall be valid for a period of one year. After which the principal investigator will be responsible for renewal of the ethical clearance.

SOP-14. Dealing with Participants' Requests and/or Complaints to Institutional Ethics

In case of a complaint received from a research participant:

- The Chairman will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairman will:
  i. Appoint a subcommittee of two or more EC members for enquiry to resolve the matter.
  ii. Call an emergency meeting of two or more EC members for discussion or Consider the matter for discussion at the next full board meeting.
- The Chairman will assess the situation and mediate a dialogue between the research participant and PI to resolve the matter.
- The EC will insist on factual details to determine gap, if any, between truth and individual perception.
  i. The final decision will be taken by the Chairman
  ii. The information including any action taken or follow-up and final decision will be recorded in a form and the form is signed and dated.

SOP-15. Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents

It is the responsibility of Chairman with assistance of a member chosen by him to ensure that all active study files and EC records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the EC office.

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B. All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of:
   - **i.** All original research proposals reviewed and approved,
   - **ii.** Reviewer's assessment forms
   - **iii.** Study approval letter
   - **iv.** Reviewed and approved consent documents,
   - **v.** Amendments and any other correspondence
   - **vi.** Study progress reports and interim reports,
   - **vii.** Serious adverse event report forms submitted by investigators,
   - **viii.** Any other reports
   - **ix.** EC correspondence

C. Strict confidentiality will be maintained for the contents of the files

D. All active files will be kept secured in a file cabinet with controlled access.

E. A log book for accessing the files by authorized staff & members will be maintained.

F. At the end of the archival period, the closed files will be shredded and disposed of by authorized EC personnel.

SOP-16. Training and Assessment of Ethics Committee Members:

Topics for training

EC members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and Responsibilities of EC members
- Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- Recent Developments in relevant health science specialties
- SOPs of the EC

It is the responsibility of the EC Chairman to ensure that there is adequate

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initial and continued training of the EC members. The Chairman is responsible for assessment of all EC members and complete a self-assessment exercise at prescribed intervals. Ethics committee shall be available in accordance with the Helsinki declaration as revised 2013.

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