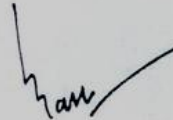


KHYBER MEDICAL UNIVERSITY RESEARCH & ETHICS STATUTES 2008 (Amended June 2013)

REVISION POINTS

1. University **Syndicate** is replaced by University **Senate**.
2. **Section 27** is replaced by **Section 28**
3. **Khyber Medial University Act (NWFP Act No 1 of 2007** is replaced by **Khyber Pakhtunkhwa Universities Act 2012**.
4. **Council** is replaced by **Board**
5. **Graduate and Research Management Council (GRMC)** is replaced by **Advanced Studies & Research Board (AS&RB)**.
6. **Regional Director of College of Physicians & Surgeons Pakistan** is replaced by **Director: Office of Research Innovation & Commercialization (ORIC) KMU**.
7. **Meeting frequency of the board and powers of the board have been added under section 3.**
8. **Functions of the board** have been updated starting from **g to l** under **section 4**.
9. The **KMU-REB** has been replaced by **KMU-EB**. Details of the rules/regulations and code of conduct start from **section 5 (5.1 to 5.7)**.



**KHYBER MEDICAL UNIVERSITY RESEARCH & ETHICS STATUTES 2008 (Amended June 2013)**

WHEREAS it is expedient to, stimulate, support, sustain and regulate quality research and ethics, the following statutes are framed by the University Senate under Section 28 of the **Khyber Pukhtunkhwa Universities Act 2012**.

1. Short Title, Commencement and Application: - (1) These statutes may be called the Khyber Medical University Research & Ethics Statutes, 2008. **(Revised June 2013)** (2) They shall come into force at once.

2. Definitions: - (1) In these statutes, unless the context otherwise requires:-

- (a) "Board" means **Advanced Studies & Research Board (AS&RB)** established under these Statutes;
- (b) "Commission" Means Higher Education Commission of Pakistan.
- (c) "Faculty" means a faculty constituted under the Clause 1 of the 1<sup>st</sup> Statutes of the KMU or as amended/revised/updated from time to time;
- (d) "Research Proposal" means a proposal submitted by students -/ staff alone or with their collaborators, for approval to Board ;
- (e) "Staff" mean employees of the University.
- (f) "KMU-EB" means Khyber Medical University-Ethics Board.
- (g) "Secretariat" means **Staff of ORIC Office**

3. **Composition of Board:**

(1) The **Board** shall consist of:

- i) The Vice-Chancellor (Chairman)
  - ii) The Deans,
  - iii) Three University Professors other than Deans to be appointed by the Syndicate, and
  - iv) Three University Teachers having research qualifications and experience to be appointed by the Academic Council.
  - v) The Director Office of Research Innovation Commercialization (ORIC), Khyber Medical University as member-cum-secretary.
  - vi) Regional Director of Pakistan Medical & Research Council.
  - vii) **Secretary of Board can identify and request technical research specialists as co-opted members whenever required.**
- (2) The term of office of members of the **AS&RB** other than ex-officio members shall be three years.
- (3) **Meeting of the Board is to be called upon as and when required but the call period should not exceed three months.**
- (4) **The quorum for the meeting will be one third of its members and fraction will be counted as one**

**Functions of the Board:**

The functions of the **Board** shall be:-

- a) To advise the Authorities on all matters concerned with the promotion of Advanced Studies and Research in the University and all its constituent and affiliated colleges;
- b) to consider and report to the Authorities on the institution of research degrees in the University,
- c) To propose regulations to the Academic Council regarding the award of research degrees;
- d) To appoint supervisors for research students and determine the subjects of their thesis;
- e) To recommend panels of names of paper setters and examiners for research examinations after considering the proposals of the Board of Studies; and
- f) To perform such other functions as may be prescribed with the approval of the Syndicate.
- g) The board (after detailed review of the proposals/thesis) shall be competent to approve/reject/revise on technical grounds of KMU students of Masters or above level.**
- h) The Board shall be competent to review/amend the project on a later stage after request from the supervisor or can make the decision independently.**
- i) The Board develop/modify the proposal and thesis format/guideline and should ensure the uniformity of research guidelines in the university.
- j) The Board can recommend research proposals to ORIC fund Management Committee (MC) for possible funding.
- k) The board should ensure that ORIC Office should check and make necessary scrutiny of all the proposals and supporting documents to be complete before presenting them to the Board meeting.

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## 5. Constitution of Khyber Medical University- Ethics Board (KMU-EB)

In suppression of previously notified "KMU-REB", KMU-EB is constituted to provide a platform for ethical consideration of all the research work conducted in KMU or elsewhere, in the light of the available national and international guidelines and principals.

5.1: The KMU-EB is guided in its work by the World Medical Association "Declaration of Helsinki (1964)" last updated in 2008 as well as the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2002) and the World Health Organization research ethics guidelines of ethical justification, individual informed consent, inducement to participate, extra measure dealing with vulnerable groups of children, pregnant ladies, disadvantaged communities and safeguarding confidentiality.

5.2: The board shall consists of;

- i) Chairman Deans Committee (Chairman)
- ii) Director Academics Administration & Quality Control
- iii) Director Institute of Basic Medical Sciences (IBMS)
- iv) Director Institute of Public Health and Social sciences (IPH&SS)
- v) One eminent teacher form each faculty of the University having relevant higher qualifications and well established experience in the field of research, to be appointed by the Academic Council;
- vi) The Director ORIC of the University, who shall be secretary cum member of the Board;
- vii) Lawyer of Good reputation selected from the three nominees of High Court Bar Association by the Vice Chancellor
- viii) One eminent scientist/Researcher, other than employees of the University, to be nominated by the Vice Chancellor.
- ix) One representative from the community to be nominated by the Vice Chancellor.
- x) One representative from Higher Education Commission.
- xi) Co-opted member(s) [subject specialist and others] as and when required by the Chairman at the recommendation of Secretary of KMU-EB.

5.3: The terms of office of members of the KMU-EB other than Ex-office members shall be three years.

5.4: The quorum for a meeting KMU-EB shall be one half of the total number, fraction being counted as one. **Meeting of the KMU-EB is to be called upon as and when required but the call period should not exceed three months.**

5.5: **Function of the KMU-EB:**

The function of the University KMU-EB shall be:

- a. Keep current on ethical issues related to research involving human participants, to educate the University, community on these issues and to formulate policies on these matters;
- b. Review, approve, reject, propose modifications to, or terminate any proposed or ongoing non-medical research involving human participants or animals conducted at Khyber Medical University or by members of Khyber Medical University, including anyone affiliated with the University conducting such research at or under the auspices of University;

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- c. Assess and limit the risks to participants in research involving humans; and where there is more than minimal risk is identified, the KMU EB shall satisfy itself that the design of a research project is capable of addressing the questions being asked in the research;
- d. Monitor ongoing projects and to determine guidelines for the review of ongoing research projects and guidelines for reviewing requests for changes in previously approved research;
- e. Develop policies and procedures for assessing and approving student research;
- f. Act as the Appeal Board for appeals of decisions rendered regarding research by the institutions ethics committees;
- g. Serve as a resource to the research community, communicating and advising researchers on guidelines, procedures and other matters relating to the conduct of research on humans and animals;
- h. Meet regularly to discharge their responsibilities, and to keep and maintain minutes of such meetings. The documentation will be accessible to researchers pertaining to their application, and to "authorized" representatives of the institution and funding agencies;
- i. Liaise with of affiliated institutions to optimize efficiencies, co-ordinate activities and to ensure consistency of decisions;
- j. Implement and monitor the final decision of the Appeal Panel on behalf of the Ethics Board.

**3. Powers of the KMU-EB:** The Board shall have the powers to;

- i) Approve of all research proposals on ethical grounds
- ii) Reject a "Research Proposal" on ethical grounds, which shall not be considered by any other authority of the university.
- iii) Develop rules for conduct of its business.
- iv) Develop regulations for conduct of its functions.

**4. The Review Process of KMU-EB**

**a) Proposal Submission:**

All research proposals involving human participants need to be submitted through the KMU-EB Secretariat, using the "KMU-EB review application form". Each proposal undergoes a preliminary screening by the secretariat to confirm that all necessary documentation has been submitted. This includes checking that all documents ticked on the coversheet are attached i.e. the study protocol, informed consent forms, study instruments.

Once the KMU-EB is in possession of all the necessary documentation and satisfactory desk review and correspondence the study is triaged for review purposes. Based on certain set of criteria, a proposal is submitted for one of the following types of review:

• **Full Board Review of Proposals**

All research proposals that present more than minimal risk to human subjects are reviewed by two primary reviewers who present the proposal to the Board followed by a general discussion and a consensus decision. The researcher/s responsible for the proposal under review are invited to respond to queries raised and to provide clarifications and/or justifications.

• **Expedited Review of Proposals**

A proposal is circulated for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case, the proposal is sent to two reviewers who are required to provide their feedback to the secretariat within 5

working days. As appropriate, the proposal is then either approved or returned to the applicant for further action.

- **Exempt from Review**

Proposals are exempt from review if there is no possibility of harm arising as a result of the conduct of the research project or if the information being evaluated is already available in the public domain. However, the exemption will be based upon criteria developed by the university.

- **Continuing Review**

The ethics approval is provided to a proposal only for a limited time period, usually for a period of one year. In order to renew approval the applicant is required to request for a Continuing Review of the proposal.

**b) KMU-EB meeting**

One of the 2 primary reviewers makes a brief presentation of the proposal under review, highlighting the ethical and other issues raised by the study and the documentation provided for review. The second primary reviewer supplements the presentation by his/her own review. After the presentation by the primary reviewers, the discussion is opened to the rest of the KMU-EB members, who may raise additional questions. The Secretariat may invite the applicant to attend the segment of the KMU-EB meeting when discussions on his/her proposal are taking place. The applicant is given the opportunity to respond to all the queries and comments, and there is often a lively discussion on the proposal. When all the queries have been answered, the applicant will leave the meeting so as to enable the Primary Reviewers to make their overall recommendations, which the rest of the Committee may or may not endorse. In the event of the latter, a debate will take place until the KMU-EB agrees in unison what the final recommendation should be.

"A KMU-EB decision on a research proposal shall be made by consensus. Where consensus cannot be reached, consideration of the proposal shall be postponed to a subsequent meeting in order to seek additional information or expert advice if so decided by a majority of members present and voting, or the proposal shall be considered not approved."

**c) Communication of the outcome**

Whether a proposal has been submitted to a full KMU-EB or for an Expedited Review, the outcome of the review will be communicated within one week. The secretariat will provide a KMU-EB Summary Review Form (ANNEX 2) to the applicant outlining the concerns, if any, raised by the KMU-EB at the meeting. The KMU-EB may give any one of the following recommendations on a proposal: The final authority of approval/rejection/revision will be done by the chairman of the KMU-EB

- **Approved conditionally, subject to amendments:** means that the proposal is approved subject to the incorporation into the proposal of the required amendments, to the satisfaction of the members of the KMU-EB. The applicant shall provide the Secretariat with a copy of the amended proposal, which shall be considered Approved when the KMU-EB finds that the changes made fulfill the KMU-EB's request.

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- **Approved conditionally, subject to clarification:** means that the proposal is approved if the clarifications requested by the KMU-EB are provided by the responsible Applicant in writing to the Secretariat, and the KMU-EB finds that the clarifications are acceptable.
- **Approved conditionally, subject to submission of further documentation:** means that the proposal is approved subject to receipt of some specific documents such as approval by another ethics KMU-EB, submission of translated informed consent forms, etc.
- **Decision deferred:** means that the proposal is not approved as submitted either because there is insufficient information to make a decision or the proposal is not ethically sound. However the proposal can be re-submitted after revision to address the reasons for the deferment and this should be reviewed by the KMU-EB as a whole.
- **Not Approved:** means that the proposal is ethically unacceptable and may not be resubmitted to the KMU-EB.

d) **Time frame**

The initial screening is done on the first day of receipt of the proposal to ensure that all the documentation has been submitted. A more detailed technical screening at the Secretariat level is then carried out within 5 working days.

*Expedited review* - Once submitted for expedited review, the proposal is reviewed within 10 days. Consequently, An applicant can expect a response from the Secretariat within two-three weeks of the initial submission.

*Full KMU-EB review* - If a proposal is sent for regular review, it will be discussed at the next meeting to the date of receipt of a satisfactory submission. As a general rule KMU-EB meetings take place on a quarterly basis. The cut-off date for receiving a proposal for discussion at a particular meeting is 3 weeks earlier.

The length of time for approval, with both expedited and regular reviews, depends on the promptness of the response from the applicant to KMU-EB concerns.

e) **Follow Up**

KMU-EB will require progress report of research proposal approved by them either at predetermined interval or at any stage.

f) **Notification**

KMU-EB will require researchers to keep the KMU-EBs informed of:

- All cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study);
- Serious and unexpected adverse events related to the conduct of the study, for example adverse effects of drugs, and the response taken by the investigator; and any new information that may affect the risk/benefit ratio of the study.

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