**KHYBER MEDICAL UNIVERSITY RESEARCH & ETHICS REGULATIONS**

WHEREAS it is expedient to, stimulate, support, sustain and regulate quality research and ethics, the following regulations are framed by the Academic Council under Section 25 (2)(b) of the THE KHYBER PAKHTUNKHWA UNIVERSITIES ACT, 2012 (amended 2016).

**Preamble**

The mission of the relevant concerned bodies, committees and faculty is to encourage and support quality research across all disciplines of medical and allied health sciences at Khyber Medical University of Pakistan.

Promoting basic, innovative and applied research; inter-and multi-disciplinary research; production of scholarly and creative works in accordance with the mission of the University and supporting research that addresses the multiple challenges faced by the region.

 Recognising the crucial importance of freedom of thought and expression in achieving research excellence by adhering to high standards of research ethics, integrity and conduct.

**1. Short Title, Commencement and Application**: -

(i) These regulations may be called the Khyber Medical University Research & Ethics Regulations 2017

(ii) They shall come into force at once.

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

1. “Board” means Advanced Studies and Research Board (ASRB) Board established under these regulations;
2. “UEC” means University Ethics Committee (UEC)(established under these Regulations;
3. “IBC”: means Institutional biosafety committee (IBC)
4. “GSC”: Graduate studies committee (GSC) at institutional /departmental level
5. “Commission” Means Higher Education Commission of Pakistan.
6. “Faculty” means a faculty constituted under the Clause 1 of the 1st Statutes of the KMU or as amended/revised/updated from time to time;
7. “Research Proposal” means a proposal submitted by students / staff or with their collaboration
8. “Staff” mean employees of the University.

**3. Working of ASRB**

i. **Presiding over the Meeting**

1. In the absence of the Chairperson, meeting of the AS&RB shall be presided over by the Convener delegated by the Vice-Chancellor
2. In the absence of the Secretary the senior most official of ORIC, shall act as Secretary of the AS&RB.

**ii. Absenteeism**

Any member other than EX-Officio member(s), after two consecutive absentees from the meetings of AS&RB shall be notified by the Chairperson and will be disqualified after three consecutive absentees or a total of four or more absentees in one academic year.

**iii. Meetings and Agenda of the AS&RB**

Meeting of the Advanced Studies and Research Board:

The ordinary meeting of the Advanced Studies and Research Board shall be held on the date, time and place as may be approved by the Vice Chancellor provided that the AS&RB shall have a meeting at least once a month.

All meetings of AS&RB shall be scheduled by the first week of January for the proceeding calendar year by the Secretary.

The Secretary shall prepare the agenda in consultation with the Chairperson keeping in view the aim and function of the AS&RB and circulate it among the members (preferably via email) at least 10 days before the meeting and the approved agenda and working papers (all synopses to be reviewed) shall be sent to the members.

Any member/scholar/supervisor may propose an item/research proposal which may be included as supplementary agenda with the approval of the Vice-Chancellor provided that it is received at least 4 days before the date of meeting and further that the item is admissible.

Items included in the agenda or supplementary agenda may be taken up for consideration in such order as may be deemed fit by the Chairperson.

A special meeting of the AS&RB may be convened with the approval of the Vice Chancellor at the request of one-third of the members to discuss a particular issue. Agenda for such a meeting shall be circulated at least three days before the meeting.

**iv. Code of Conduct of the AS&RB**

1. The Chairperson or his nominated Convener shall control the order in which members of the AS&RB may address the meeting and the manner in which the business of the house may be conducted.
2. Members when speaking, shall address the Chair, No member shall without special leave from the Chairperson, speak more than once on the same proposition. The final decision on all matters of research review shall be made by the Presiding Chairperson in consultation with the subject specialist of the particular area of research.
3. All members shall keep in consideration that their critique should be objective, flexible, acceptable, comprehensive, constructive, organized, thoughtful and specific to provide the scholars something constructive to raise their quality of research.
4. Scholars and their supervisors shall comment upon their own research and shall address the chair only if and when invited to on other areas of research.
5. The Supervisor shall not answer questions on the students behalf, until and unless asked by the 'Chair' for clarifications on the Synopsis
6. The Secretary shall explain the following ground rules before proceeding;
	* + - 1. Timings allowed to the students for presentation
				2. Address the Chair at all times and avoid cross-talk
				3. Announce to keep Mobiles on silent

**v. Procedure for Re-consideration of Previous Decisions:**

* 1. Any previous decision of the AS&RB shall not ordinarily be re-considered without the permission of the Vice-Chancellor, or unless a written request is received from two thirds of the total number of members of the AS&RB for re-consideration.
	2. Keeping in view the main function of the AS&RB the board shall review the research synopses presented to it and categorise all the synopses into four main groups,

**Group A**: Approved without any corrections

**Group B**: Approved but with minor corrections[[1]](#footnote-1)

**Group C**: Major changes to present before the board at their next meeting.[[2]](#footnote-2)

**Group D**: Rejected and sent back to the Graduate Studies Committee[[3]](#footnote-3)

* 1. The AS&RB shall at the end formulate an overall feedback to the authorities on all matters connected with the promotion of advanced studies and research publication in the University in view of the research proposals scrutinised on the day.
	2. They shall in addition provide feedback, and areas for improvement to the Graduate Studies Committees of each Institute (constituent and affiliated).
	3. They shall also recommend faculty development courses and continuing professional development courses to the scholars to improve the quality of research.
	4. The presence of the supervisor, invited guests or ad-hoc members shall be at the discretion of the Chairperson.

**vi. Validation of Proceedings**

* 1. The Secretary shall record the proceedings and shall submit them to the Vice- Chancellor for further necessary action.
	2. The proceedings of the AS&RB meeting shall be circulated among all the members as well as concerned scholars and supervisors.
	3. If any member of the AS&RB draws the attention of the Secretary or the Chairperson to any discrepancy between a decision taken and its record in the proceedings, the views of the member shall be placed before the Chairperson whose judgment shall be forwarded to the member concerned. If the member is still not satisfied, the matter shall be placed before the AS&RB at its next meeting, without prejudice to the action taken.
	4. The record of the relevant extract of the proceedings along with relevant working papers / files shall be maintained and forwarded by the Secretary to the respective sections/persons for information and necessary action.
	5. The secretary AS&RB shall issue a letter of approval of research proposal/synopsis to the concerned scholar copied to his/her supervisor and head of the institute within 3 days.
	6. The proceedings of the AS&RB shall not be invalidated on the grounds that; either any member did not receive the notice or agenda and working papers, or both for the meeting of AS&RB, or the availability of a vacancy in the AS&RB due to expiry of the term of office of any member.
	7. The AS&RB may, at its discretion change / amend, from time to time these regulations.

**4. Khyber Medical University Ethics Committee (UEC):**

**i. KMU Code of Conduct for undertaking Research**

1. All the staff, students of the University are required to understand adopt and practice code of research conduct in compliance with national and international good practice and laws.
2. The three basic principles of ethics; respect for persons autonomy and rights, justice and beneficence/non-maleficence has to be followed in all the research work.
3. The University is committed to conduct research in accordance with the above principals and is expecting all academic, research and relevant support staff, students and their supervisors and other individuals conducting research or involved in the peer review of research process to set standards.
4. They all have to be honest in terms of their actions including conflict of interest, ensure openness by sharing their findings, follow professional guidance and legislation, and avoid research misconduct at the steps of research process.

**ii. Constitution of Khyber Medical University- Ethics Committee (UEC)**

The previously notified “KMU-REB” will be replaced by UEC and will seek guidance from the national and international principals.

* 1. The UEC 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 Organisation 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 condidentaility.
	2. **The Committee shall consists of;**
1. Senior most Dean (Chairman)
2. 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 Vice Chancellor;
3. The Director ORIC or his/her representative of the University, who shall be secretary cum member of the Committee;
4. Assistant Registrar (Legal) / Legal Advisor of the University
5. One eminent scientist/Researcher, other than employees of the University, to be nominated by the Vice Chancellor.
6. Co-opted member(s) [subject specialist and others] as and when required.
	1. The terms of office of members of the KMU Ethics Committee other than Ex-officio members shall be three years.
	2. The quorum for a meeting KMU Ethics Committee shall be 50% of the total number, fraction being counted as one.

**iii. Function of the KMU Ethics Committee:**

 The function of the University KMU Ethics Committee shall be:

* + - * 1. 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;
				2. 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 the University;
				3. Assess and limit the risks to participants in research involving humans; and where there is more than minimal risk is identified, the KMU EC shall satisfy itself that the design of a research project is capable of addressing the questions being asked in the research;
				4. 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;
				5. Develop policies and procedures for assessing and approving student research;
				6. 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;
				7. Meet (at least once in a month) 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;
				8. Liaise with constituent / affiliated institutions to optimize efficiencies, co-ordinate activities and to ensure consistency of decisions;

**iv. Powers of the KMU Ethical Committee:**

 The Committee shall have the powers to;

1. Approve of all research proposals on ethical grounds
2. Reject a “Research Proposal” on ethical grounds, which shall not be considered by any other authority of the university.

**v. The Review Process**

1. **Proposal Submission:**

All research proposals involving human participants need to be submitted through the ORIC, using the “UEC ethical review application form”. Each proposal undergoes a preliminary screening by the ORIC 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 UEC is in possession of all the necessary documentation and satisfactory desk review and correspondence the study is triaged for review purposes.

1. **Communication of the outcome**

The ORIC shall provide a UEC Summary Review Form to the applicant outlining the concerns, if any, raised by the UEC at the meeting. The UEC may give any one of the following recommendations on a proposal:

1. 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 UEC. The applicant shall provide the Secretariat with a copy of the amended proposal, which shall be considered Approved when the UEC finds that the changes made fulfill the UEC’s request.
2. Approved conditionally, subject to clarification: means that the proposal is approved if the clarifications requested by the UEC are provided by the responsible Applicant in writing to the Secretariat, and the UEC finds that the clarifications are acceptable.
3. 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 UEC, submission of translated informed consent forms, etc.
4. 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 UEC as a whole.
5. Not Approved: means that the proposal is ethically unacceptable and may not be resubmitted to the UEC.

A UEC decision on a research proposal shall be made by majority.

1. **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 ORIC level is then to be carried out within 5 working days.

1. **Notification**

UEC will require researchers to keep the UECs informed of all cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study);

**5. Institutional biosafety committee (IBC):**

i) The Institutional Biosafety Committee (IBC) is a formal expert committee of KMU with approval from relevant statutory bodies. This committee is established to ensure research, diagnostic and clinical work in KMU and its affiliated institutes is performed in a safe, risk-free environment. It provides guidance in cases of breach of safety and advises corrective action when such happens. The scope of KMU IBC may be extended as deemed necessary after formal approval from the aforementioned bodies. The IBC is chaired by appointee of the VC of KMU.

KMU IBC shall ensure safe laboratory practices, and safeguard human life and the environment in research, teaching, clinical and diagnostic work in KMU laboratories, constituent and affiliated institutions’ premises or in the field. The responsibilities of the IBC include, but are not limited to the following:

a. Provide guidance to PI/supervisor on biosafety policies and issues in the use of hazards in research, including safety of laboratory personnel and other members of the organisation.

b. Recommend approval of research projects that includes use of potentially biohazardous and periodically reviewing these research projects.

c. Assess and monitor the facilities, procedures, practices, training and expertise of personnel involved in potentially hazardous research.

d. Notify the PI of the results of the IBC’s review, approval, or rejection of their application for approval and notification of all activities involving the use of potentially hazardous material.

e. Assess and set containment levels for potentially hazardous material research and modify containment levels as necessary.

f. Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.

g. Adopt and implement emergency response plan covering accidental spills and personnel contamination, resulting from potentially biohazardous materials research.

h. Ensure the information provided in the relevant application form (Approval/Notification) is correct and complete.

i. Recommend suspension of project approval for the possession or use of potentially hazardous material. including research, where the IBC finds non-compliance or that such use or possession poses a threat to the health and safety of the community.

**ii. Other related responsibilities**

a. Advocate formation of institutional biosafety committees in other institutions.

b. Advocate national legislations towards establishment of a national biosafety Committee.

c. Provide training to IBC members from other institutions.

d. Routinely review the policies and procedures of the IBC and modify them as necessary to ensure appropriate biosafety measures

**6. Graduate Studies Committee (GSC):**

The Graduate Studies Committee is a sub-committee of the Institutional Committee of Graduate Studies (IBOS), and has delegated decision-making powers for operational graduate research matters. It also provides advice to the Insttitutional Committee of Graduate Studies (IBOS)on policy and regulations regarding graduate research.

1. **The Mission Statement of GSC**
2. To encourage and support quality research through positive feedback.
3. To promote basic, innovative and applied research; inter-and multi-disciplinary.
4. To recognize the crucial importance of freedom of thought and expression in achieving research excellence by adhering to high standards of research ethics, integrity and conduct.
5. **The Role of GSC**
6. To judge the scientific quality of research projects through positive feedback.
7. Formal assessment of research potential of institutes through, the type and quality of research generated at the institutes based on the available facilities.
8. Availability of current facilities at the institutes vs. expectations
9. To provide recommendations to the Director of Institute on improving the research potentials through,
	1. ***Training Need Assessment*** of faculty, staff and students.
	2. Improvement of laboratory and other facilities for quality research.
	3. Equipment, lab consumables, staffing, softwares.
10. **The Members of GSC to be appointed by the Vice Chancellor**
11. The Director of Institute
12. One member from each department (Subject experts with research experience.)
13. Conflict of interest (in case a student of a member is presenting) Co-opted members shall be subject specialists appointed for a particular meeting
14. A clinician interested in research (from Tertiary Care Hospital). Duration=1 Year,
15. An academician from an affiliated / constituent institute, Duration=1 Year
16. Incase serial No ii has less than 4 members then, A minimum of at least 4 members who have a research experience from other than the institute as nominated by the dean/head of the institute
17. The quorum for a meeting of Graduate Studies Committee shall be Fifty percent of the total number of members.

**Note:** Membership will be terminated if any member fails to attend 3 consecutive meetings.

**7. Guidelines for Thesis Writing**

1. **A thesis should comprise of the following components**
	1. Title pages 1&2
	2. Dedication (optional)
	3. Certificate
	4. Declaration
	5. Acknowledgements (One page only)
	6. Abstract
	7. Table of contents
	8. List of tables (if there)
	9. List of figures (if there)
	10. List of abbreviations
	11. Chapter 1: Introduction/Review of literature
	12. Chapter 2: Materials and Methods
	13. Chapter 3: Results
	14. Chapter 4: Discussion
	15. Conclusion (One page only)
	16. References (Harvard style)
	17. Appendices (Optional)
2. **General guidelines for thesis writing and binding**

Word count should be between 30,000 to 80,000 words for the PhD and 10,000 minimum words for MS/MPhil or equivalent degrees. Where 10,000 words equals 20 pages single spaced or 30 pages 1.5 spaced.

1. **Margins:**

Page size should be A4, with 1inch margins on the top, bottom and right side while 1.5 inches on left side. Higher or lower margins will only be acceptable in special circumstances.

1. **Numbering:**
2. All the pages from abstract to dedication should be numbered as in lower case Roman numerals (i, ii, iii…). Do not number the copyright page, signature page, title page, but do include each of them in the pretext page count.
3. All pages starting from introduction to the end of the thesis should be numbered in Arabic numeral (1, 2, 3…).
4. Page numbers should appear on the center bottom of the page.
5. The first page of every major section (chapters, appendices, bibliography, etc.) must begin on a new page
6. **Font:**
7. Time New Roman or Calibri script should be used for writing thesis.
8. All the headings should be written in bold face.
9. Chapter number and respective chapter title should be written on the page header in the center for example 1-Introduction
10. Major headings should appear centered all in capitals (16pt).
11. First order headings should be left aligned (14pt).
12. Second order headings should be left aligned (12pt).
13. Third order headings should be left aligned and italicized (12pt)
14. Font size should be 12pt in main body text and 10pt for table & figure legends.
15. Line spacing should be 1.5 and 6pt (before and after) between the paragraphs. Single spacing may be used only in the Table of Contents, footnotes and endnotes, charts, graphs, tables, quotations, captions, glossary and appendices. Prose quotations over three lines long should be in block quote, double or single-spaced, and indented on the left. Do not use quotation marks in the block quote except when indicating quotations within the block quote
16. **Tables and Illustrations**
17. Pages carrying illustrative material must be given page numbers appropriate to their place in the document.
18. All tables, figures, illustrations, and other types of examples included and referenced in the text of the dissertation should be numbered for identification. Figures should be numbered to include chapter number so that illustrations’ numbers reflect their locations in the document.
19. Captions and legends should either be placed on the same page with the figure, graph, table or illustration they describe. Incase these illustrations are too large to fit then the caption /legend should be placed on the facing page side-by-side in continuous view. Figures, captions, and page numbers must be easily readable when the electronic document is viewed at 100 percent.
20. **Printing**
21. Thesis should be printed on one side of a good quality paper at least 70g and bound in soft (strip binding) to be sent for external review.
22. All prints should be taken on portrait format and use of landscape format should be avoided but if used should not be numbered though the number shall be counted.
23. At the time of submission for review the thesis must be final in all aspects except the hard binding and incorporation of any amendments as required by the examiner(s).
24. Final hard bound copy (3 copies) should be in black in case of MPhil and Maroon in case of PhD with golden writing. The contents in covering front board should be the same as presented in the covering page of thesis in soft binding.
25. The spine of the thesis should carry name of the scholar, name of the degree and year.
26. The title of the thesis should be exactly the same in all aspects as approved and notified by the AS&RB.
27. The final copy of thesis (after viva examination) should be duly signed by all the concerned and submitted to the university library and supervisor.

**8. Research Thesis submission pathway**

IBOS

GSC

AS&RB

UEC

IBC

Academic council

1. along with the Synopsis review sheet, to be submitted to ORIC with no need to resubmit to the board. [↑](#footnote-ref-1)
2. as detailed in the synopsis review .Secretary shall intimate the scholar and provide the Synopsis review sheet with queries and corrections as well as a guide to the presentation. The supervisor shall have to be present for the presentation [↑](#footnote-ref-2)
3. with the synopsis review sheet detailing all reasons for the rejection. [↑](#footnote-ref-3)