

BAQAI MEDICAL UNIVERSITY

**POLICY & TERMS OF
REFERENCES (ToRs) ON
RESEARCH ETHICS**

Version 1

2020



Baqai Medical University

CONTENTS

1. INTRODUCTION	3
2. PURPOSE	3
3. IMPLEMENTATION TIMELINE	3
4. POLICY STATEMENT	3
5. RESPONSIBILITIES OF THE FACULTY, STUDENTS & THE ETHICS COMMITTEE	4
6. ETHICS COMMITTEE MANDATE	5
7. PROCESS OF OBTAINING ETHICAL APPROVAL	5
8. EXTERNAL RESEARCHERS WISHING TO CONDUCT RESEARCH INVOLVING UNIVERSITY FACULTY, STAFF OR STUDENTS AS PARTICIPANTS	5
9. WORKING OF ETHICS COMMITTEE	6
10. MEETINGS	6
11. POWERS OF THE COMMITTEE	7
12. RESPONSIBILITIES OF THE APPLICANT AFTER APPROVAL	7
13. CONFIDENTIALITY	8
14. INDEMNITY	8

1. INTRODUCTION

The Baqai Medical University (BMU) recognizes its obligation to maintain high ethical standards across the breadth of its activities including the research activities. BMU seeks to achieve this through raising awareness of ethical issues, particularly those related to research, through debate and by formulating codes, guidelines, and procedures which are necessary to ensure that high standards are achieved as far as ethical, social, and environmental issues are concerned. This should be an ongoing process as definitions of manifestations of ethical issues are subject to change. The policy should be read in conjunction with the WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects. This has also been recommended by the Higher Education Commission (HEC), Pakistan.

The Ethics Committee of BMU shall be the sole authority to grant ethical approvals.

2. PURPOSE

This policy provides a framework for decision making on ethical issues that aims to safeguard and protect the rights of the university and its constituent institutions, university researchers, and research participants.

3. IMPLEMENTATION TIMELINE

This policy and ToRs shall be implemented immediately and will last till the constitution of any other approved policy or directives by the Academic Council in this regard.

4. POLICY STATEMENT

- 4.1. This policy applies to all research involving human participants conducted by researchers under the auspices of the university. It also includes other types of research that may raise ethical issues or concerns regarding animals, the environment, etc.
- 4.2. Human participants are defined as human beings, human tissue and bodily fluids, and human data and records (for example medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements). Human data includes photographs and videos of individuals.
- 4.3. This policy applies to all university employees engaged in research, students of the university, and other individuals who are undertaking research using university premises or facilities and/or in the university's name.
- 4.4. Where ethical approval has been obtained from another Pakistani recognized university or DAI for a collaborative project, approval from BMU shall also be required if BMU staff or students are recruited as participants.
- 4.5. It is mandatory to obtain the approval of the Ethics Committee of BMU before the start of any research or part of it.

5. RESPONSIBILITIES OF THE FACULTY, STUDENTS & THE ETHICS COMMITTEE OF BMU

- 5.1. It is the responsibility of all faculty, staff, and students engaged in research to adhere to the highest standards of research integrity and to conduct their research following the ethical requirements of professional and regulatory bodies.
- 5.2. It is the responsibility of the research supervisors and the Ethics Committee to promote an environment that fosters and supports the research of high ethical standards, cooperation, and the open and honest exchange of ideas.
- 5.3. The Ethics Committee of BMU (EC) has the responsibility to consider the ethical implications of proposed human research studies conducted at the University, or any other site by staff or students of the university and determine whether or not they are acceptable on ethical grounds.
- 5.4. The researchers should avoid, prevent, or minimize harm to others in the widest sense. Participants should not be subjected to unnecessary risks or discomfort and their participation in the project must be essential to achieving aims that could not be fulfilled without their participation.
- 5.5. The physical, mental, and social well-being of the participant should be promoted. The protection of the participant is the most important responsibility of the researcher.
- 5.6. Ethics concerns the minimization of risk and weighing risk against benefit. All researchers should be aware of the ethical issues that may arise in the course of their work and should be encouraged to take responsibility for their own ethical actions.
- 5.7. Everyone involved in a project should be treated fairly. There should be equality in the distribution of benefits and risks among the population group(s) likely to benefit from the research.
- 5.8. Projects are approved for a stated time. Any extensions for an additional period or any major divergence from the approved project must be subjected to further ethical approval.
- 5.9. Participants must give their informed consent before taking part in a study. Valid consent must be given voluntarily by participants who are competent and given sufficient information to make the judgment.
- 5.10. The EC should review and approve (with or without modification) or withhold approval of proposals for research on human tissue, products, fetus, or genetic material from human subjects, whether dead or alive by the University's faculty members, students, or visiting scholars, based on ethical considerations.
- 5.11. The EC should also advocate, encourage, and monitor "best practice" ethical standards in research; protect subjects of research from unnecessary harm; preserve the rights of the subjects.
- 5.12. The EC undertakes a regular review of the ongoing research for any unethical practices.

- 5.13. The EC should record information of all research proposals including name, address, and qualifications of the Principal Investigator(s), the financial sponsor, title of the project, research methodology, and the research objectives.

6. ETHICS COMMITTEE MANDATE

All research taking place at BMU or by its faculty, staff, or students at any site, which involves human or animal subjects, tissue, products, fetus, or genetic material from human or animal subjects, whether dead or alive or use of any kind of data will need approval by the ETHICS COMMITTEE before the research can commence.

7. PROCESS OF OBTAINING ETHICAL APPROVAL

- 7.1. All faculty, staff, and research students should submit applications along with their proposed synopsis for ethics approval to the Secretary Ethics Committee through proper channel i.e. Head of Department, Head of Institution, and Dean of the concerned faculty.
- 7.2. The proposals will then be sent to all the members of the EC before a meeting to discuss the same. The EC may:
- Approve the submission without amendment.
 - Approve the submission conditionally upon amendments.
 - Request changes or revisions that will require a resubmission to the University EC.
 - Decline/Reject the submission.
- 7.3. Students enrolled in the university's academic programs should follow the process for obtaining the ethics approval outlined for their courses.
- 7.4. Following approval, any significant change to the design or methodology during the project will require an amendment to the original submission which will need approval by the EC of the University.
- 7.5. Approval is awarded for data collection within specified dates. Any extension to this period should be requested from the EC of the University.
- 7.6. The letter should be issued by the Secretary EC informing the concerned researcher about the decision of the EC.

8. EXTERNAL RESEARCHERS WISHING TO CONDUCT RESEARCH INVOLVING UNIVERSITY FACULTY, STAFF OR STUDENTS AS PARTICIPANTS

- 8.1. Researchers based at another Pakistani recognized University wishing to recruit faculty, staff, or students from BMU will need ethical approval for the proposed research from their institution, including approval for participant recruitment at other universities. They do not need to re-apply for ethical approval at BMU for

the original project but do need to request approval to recruit participants from BMU through the Ethics Committee of BMU.

- 8.2. Evidence of ethical approval from their institution and details of their proposed research should be sent to the EC Secretary (registrar@baqai.edu.pk). The request to recruit participants will be examined at the next University EC meeting.

9. WORKING OF ETHICS COMMITTEE

9.1. Administrative Structure

Chairman, Vice Chancellor who heads the committee and calls the meetings.

Secretary, who will be a full member and will be responsible for taking the minutes and keeping the record of the same.

9.2. Membership

Mechanism of Appointment: The Vice Chancellor shall appoint the members of the EC. At least one faculty member from each faculty shall be appointed that is actively involved in the research especially postgraduate level research.

9.3. Tenure of Membership

The tenure shall be of three years, extendable for a further 3 years by the competent authority.

9.4. Number of Ethics Committee Members

There is no fixed number for the members of EC. However, at least one University academic staff member from each faculty with the knowledge and current experience in research shall be appointed.

9.5. Mechanism of Appointment of New Member

New members will be appointed by the Chairman of the EC.

9.6. Lay Members

At least one lay member (non-medical person of good standing) shall also be the part of the EC of BMU.

9.7. Revocation of Membership

If a member is absent for three (3) consecutive meetings without assigning a reason, despite being informed of the meeting, he/she will have her membership revoked.

10. MEETINGS

10.1. Responsibility: The Secretary with the approval of the Chairman.

10.2. Quorum: The quorum for a meeting of the Committee is:

- Where there is an odd number of members, a majority of members; or
- Where there is an even number of members, half of the members plus one.

10.3. Frequency of Meetings: At least twice in a year and all the researchers are required to submit their research proposal/projects at least one month prior to the scheduled meeting notification.

10.4. Minutes of the Meeting: Responsibility of the Secretary. The decision of the committee shall be communicated to the concerned within a month from the meeting date.

10.5. Appeal Process: Faculty, staff, and students who do not receive approval for their study to go ahead can appeal to the Chair of the EC. Appeals should be made in writing and should comprise a covering letter with sufficient information to allow the grounds for appeal to be understood, including documentation on which the original decision was based.

10.6. Duration of Approval of a Project: As per the duration of the program or case to case basis, at the end of which the PI should submit a progress report following which the approval may be extended if required.

10.7. Cancellation of Approval: The EC will have the authority to cancel the approval if a progress report is not submitted even after it is sought. The approval may also be withdrawn if new risks/side effects are revealed. The approval may also be withdrawn if the EC comes to know of misconduct by the PI, breaching the contract of trust between the PI and the EC. In such circumstances, the EC will have the right to inform the funding agency of the withdrawal of approval.

11. POWERS OF THE COMMITTEE

The Committee may:

- The BMU Ethics Committee is the sole authority to execute the following powers
- Revoke approval if dissatisfied with the conduct of the research or of the researcher.
- Reject the research proposal in whole or in part if the proposal is against any ethical principle and/or the requirements for the said proposal are not fulfilled.
- Defer consideration of a research proposal to a subsequent meeting if substantial modification is required or where significant additional information is needed.
- Authorize the research to proceed without requiring any amendment.
- Require clarification or modification of parts of the research submission. The Chair will normally be granted authority to approve the amendments without requiring further deliberations by the full Committee.

12. RESPONSIBILITIES OF THE APPLICANT AFTER APPROVAL

The applicant is responsible for:

- Reporting any adverse incident during a study to the Committee, even if the incident

is not directly related to the study (e.g., a complaint by a subject, etc.).

- Notifying the EC of any change in protocol and obtaining further ethical approval as appropriate.

13. CONFIDENTIALITY

Proceedings of the meetings, the minutes, and the archives are considered highly confidential and shall be maintained as such.

14. INDEMNITY

All decisions of the EC will have the complete support of the University.