Baqai Medical University

INSTITUTIONAL REVIEW & ETHICS BOARD (IREB) POLICY & TERMS OF REFERENCES (ToRs)

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BAQAI MEDICAL UNIVERSITY

INSTITUTIONAL REVIEW & ETHICS BOARD (IREB)

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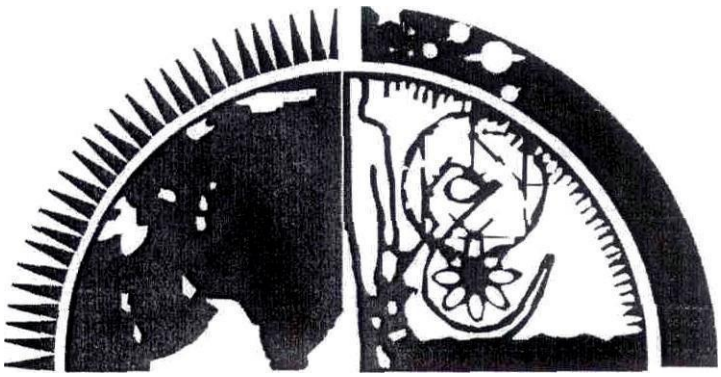

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1. INTRODUCTION:

The Baqai Medical University (BMU) recognizes its obligation to maintain high ethical standards across the breadth of its activities, including its research activities. BMU seeks to achieve this by raising awareness of ethical issues, particularly those related to research, through debate and by formulating codes, guidelines, and procedures that 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 subjectto change. The policy should be read in conjunction with the WMA Declaration of Helsinki- Ethical Principles for Medical Research Involving Human and Animal Subjects. This has also been recommended by the Higher Education Commission (HEC), Pakistan.

The Institutional Review & Ethics Board (IREB) of BMU shall be the sole authority to grant ethical approvals.

2. PURPOSE:

This policy provides a framework for decision-making on overall review particularly ethical issues that aim 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.

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, audio recordings with or without photographs, video, and test results, including scholastic achievements).

4.3. This policy applies to all university employees engaged in research, students at the university, and other individuals who are undertaking research using university premises or facilities and/or in the university's name.

4.4. The scope of IREB approval is not limited to members of the Baqai Medical University, outsiders are also encouraged to apply for approval from the BMU IREB.

4.5. 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.

4.6. It is mandatory to obtain the approval of the IREB of BMU before the start of any research or part of it.

5. RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW & ETHICS BOARD 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 IREB to promote an environment that fosters and supports research with high ethical standards, cooperation, and the open and honest exchange of ideas.

5.3. The IREB of BMU is responsible for considering the ethical implications of proposed human research studies conducted at the University, or any other site by staff or students at the university and determining whether they are acceptable on ethical grounds.

5.4. Researchers should avoid, prevent, or minimize harm to others in the widest sense. Calculated risks if deemed necessary under the supervision of expert researcher.

5.5. The Bio-psycho social and economic well-being of participants should be promoted. The costs and expenses of research topics incurred as a result of being a participant are the responsibility of the researcher.

5.6. IREB 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 theresearch.

5.8. Projects shall be approved within a specified period. Any extension of the period for which the project has been agreed or any material divergence from it shall be subject to further IREB approval.

5.9. The IREB ensures that the animals maintained by the University are used exclusively for research or teaching.

5.10. Participants must be properly instructed to complete the questionnaire and provide information after informed consent. In the case of minors' consent of a guardian or parent must

be added. Methods for removing language barriers when collecting data must be validated and reported.

5.11. The IREB 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 visitingscholars, based on ethical considerations.

5.12. The IREB should also advocate, encourage, and monitor "best practice" ethical standards in research to protect subjects from unnecessary harm and preserve their rights.

5.13. The IREB undertakes a regular review of the ongoing research for any unethical practices.

5.14. The IREB should record information on all research proposals, including the names, addresses, and qualifications of the Principal Investigator(s), the financial sponsor, the title of the project, the research methodology, and the research objectives.

5.15. PI(s) involvement in meetings, when needed, PI(s) can be invited to the meeting.

6. INSTITUTIONAL REVIEW &ETHICTIC BOARD (IREB) MANDATE

The IREB of BMU will grant approval based on research synopsis. Consistently, IREB BMU approvals should be taken priorly if the research is taking place at BMU and its constitutional institute or by its faculty, staff, or students at any site that involves human or animal subjects, tissue, products, fetus, or genetic material from human or animal subjects, whether dead or alive or the use of any kind of data. The synopsis must clearly reflect the outcome of the studysubjects during and after the study. The profile must clearly reflect sample and subject conditionand storage, handling, consultation, animal husbandry, and sample storage.

7. PROCESS OF OBTAINING IREB APPROVAL

7.1. All faculty, staff, and research students should submit applications along with their proposed synopsis for IREB approval to the Secretary of IREB through the proper channel, i.e., the 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 IREB before a meeting to discuss them. The IREB may

- Approve the submission without amendment.
- Approve the submission conditionally upon amendments duly approved and referred by the Dean.
- Request changes or revisions that will require a resubmission to the university's IREB.
- Decline or 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. 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 IREB of the University.

7.4. Approval is awarded for data collection within specified dates. Any extension to this period should be requested from the IREB of the University.

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

8.1. Researchers based at another Pakistani-recognized University wishing to recruit faculty, staff, or students from BMU and its constitutional institutions 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 IREB approval at BMU for the original project, but they do need to request approval to recruit participants from BMU through the FRRC of the concerned faculty under the supervision of the Dean, and subsequently, it will be reported in IREB.

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

9. WORKING OF INSTITUTIONAL REVIEW & ETHICS BOARD

9.1. Administrative Structure

Chairman, Vice Chancellor of the University, who presides over the IREB meetings.

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

9.2. Composition of IREB Membership

The Ethical Review Board shall consist of at least nine members. One from each faculty, including both men and women, of whom at least:

i. Two members have expertise in relevant research disciplines, fields, and methodologies covered by the Ethical Review Board.

ii. One member is knowledgeable in ethics and preferably has a degree.

iii. One member is knowledgeable about the relevant law. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research.

iv. One community member has no affiliation with the institution.

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

vi. For animal studies, A suitably qualified person with substantial recent experience in the use of animals for scientific purposes as following standard guidelines.

9.3. Tenure of Membership

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

9.4. Number of IREB Members

There is no fixed number for the members of IREB. 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 IREB.

9.6. Revocation of Membership

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

9.7. Training

In their duties as members of IREB, appointed members shall attend or take part in training courses related to research ethics review, ethical aspects of research methodology, and any additional relevant skills that may be required to fulfill this role. Induction and orientation training shall be carried out for all the members of the board. Topics for induction and orientation training shall include, but not be limited to, the following:

- Moral Philosophy
- Ethical Principles
- Animal sentience
- Value of Animal Research
- Overview of animal use at BMU
- Institutional policy, National Standards, Laws, and Compliance
- Creating a Culture of Care
- Compassion fatigue
- Occupational wellness

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
- When there is an even number of members, half of the members plus one

10.3. Frequency of Meetings: At least 3–4 meetings in a year, and all the researchers must submit their research proposals or projects at least one month before the scheduled directing notification.

10.4. Minutes of the Meeting: Responsibility of the Secretary The decision of the board shall be communicated to the concerned within a month of 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 IREB. Appeals should be made in writing and should comprise a cover 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 on a case-to- case basis, at the end of which the PI should submit a progress report, following which the approval may be extended if

10.7. Cancellation of Approval: The IREB 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 or side effects are revealed. The approval may also be withdrawn if the board comes toknow of misconduct by the PI, breaching the contract of trust between the PI and the IREB. In such circumstances, the board will have the right to inform the funding agency of the withdrawalof approval.

11. POWERS OF THE IREB

The Institutional Review & Ethics Board (IREB) is the sole authority to execute the following powers:

- Revoke ethical approval if you are dissatisfied with the conduct of the research or 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 Board.

12. RESPONSIBILITIES OF THE APPLICANT AFTER APPROVAL

The applicant is responsible for:

- Reporting any adverse incident during a study to the Board, even if the incident is not directly related to the study (e.g., a complaint by a subject, etc.),
- Notifying the IREB of any change in protocol and obtaining further ethical approval as appropriate.

13. CONFIDENTIALITY

The 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 IREB will have the complete support of the University.