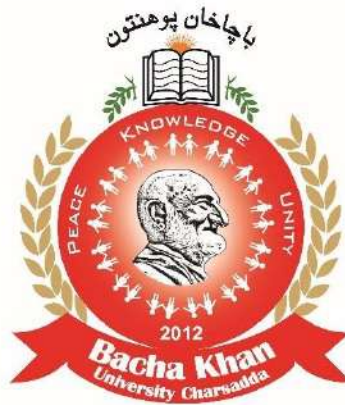


Research Ethics Policy



Directorate of ORIC
Bacha Khan University,
Charsadda, KP Pakistan



www.bkuc.edu.pk



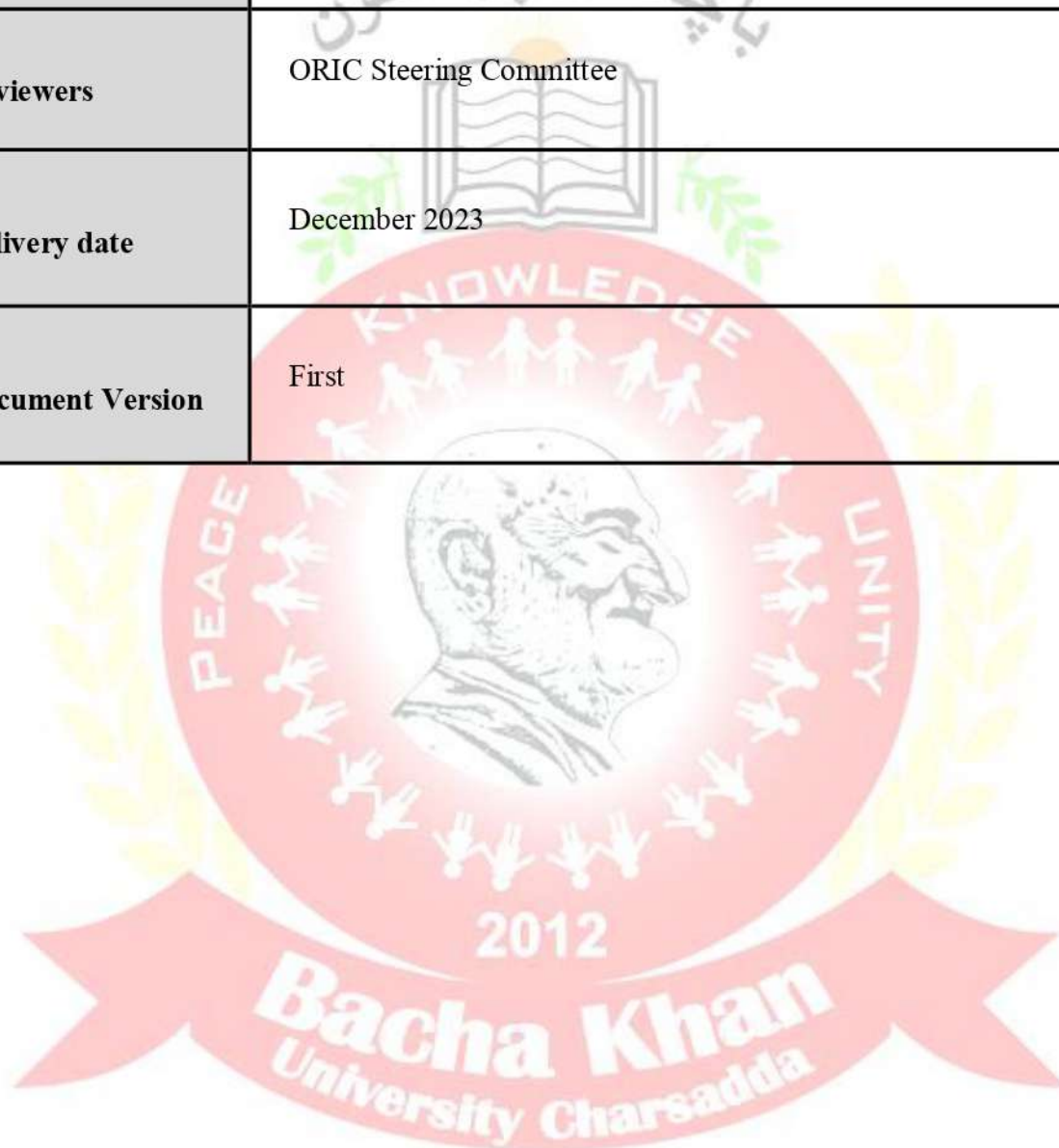
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1. Introduction

The specific guidelines for conducting an ethical evaluation of every research project at Bacha Khan University Charsadda are outlined in the research ethics policy. An integral component of a long-lasting research culture is research integrity and ethical behavior, both of which are crucial components of research at the University. Through its interaction with external research partners and stakeholders, BKUC is completely dedicated to guarantee the ethical conduct of every research project carried out by its faculty members, researchers and students. All faculty members, researchers and students engaged in research activities have a responsibility to maintain the highest possible standards of professionalism and honesty. Researchers (including faculty and students) at the University have an obligation to take personal responsibility for the quality of their research work and those working under their supervision, and to ensure that public and private funds are used effectively in the best interest of university, society and country as a whole.

The Higher Education Commission mandated the establishment of the Directorate of ORIC at BKUC. The Office of Research, Innovation and Commercialization (ORIC) is committed to assist the institution in conducting and commercializing of high-quality research. Using methods including research training (for faculty members, researchers and students), project planning, execution, support, and technology transfer, ORIC aims to facilitate collaboration between industry and other academic institutes.

2. Objective of Research Ethics Policy

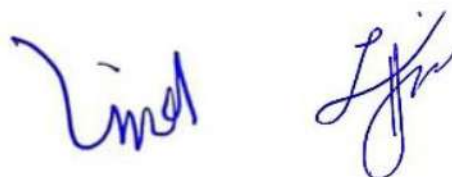
To establish and promote research culture at BKUC that is based on ethics, integrity, and academic honesty. To help researchers, build their ethical skills, and make sure they follow the rules and regulations of the University.

3. Scope of Research Ethics Policy

The purpose of the Research Ethics Policy is to assist BKUC faculty members, researchers and students in upholding high ethical standards throughout their research process.

4. General Principles

The ideas and methods guiding research participants are the foundation of the research ethics policy. The core components are:



- i. Minimizing the harmful effects to participants and researchers involved in the research study.
- ii. Maintaining the participants' dignity.
- iii. Participants' free and informed consent, or specific protections in cases where this is not practicable.
- iv. Hiding the identity of the responders and confidentiality of information provided by the research participants.
- v. Properly disseminating and publishing research findings.
- vi. Researcher independence and objectivity.

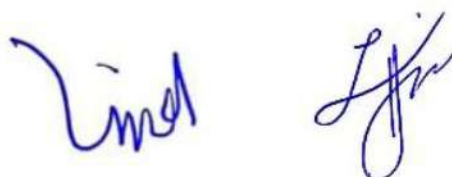
5. Ethical Institution Review Board (EIRB)

In order to verify that the research process carried out at BKUC complies with ethical norms, legal considerations, and professional standards, Directorate of ORIC has constituted an independent Ethical Institution Review Board (EIRB) of the University.

The BKUC Ethical Institution Review Board (EIRB) supports initiatives that preserve the rights and dignity of human and animal participants as well as research that adheres to the highest ethical standards. Before commencement of a research study the EIRB approves all research proposals/research projects involving human and/or animals, whether they are individuals or communities. For a research to proceed, every modification suggested by EIRB should be incorporated to make sure that the participant's basic rights are protected. Written instructions on ethical issues for research involving human and animal subjects are provided by the EIRB. EIRB might audit research studies to make sure it complies with regulations of research ethics policy of the university while it is being conducted. It has the right to revoke permission if at any step the rules are violated.

5.1.Role of Ethical Institution Review Board (EIRB)

The Ethical Institution Review Board (EIRB) of Bacha Khan University Charsadda must approve all research projects and research proposals/synopsis involving human or animal subjects before they may begin. Research, testing, and survey procedures in the field of education are all good examples of situations where subjects won't be personally identifiable in any way and where disclosure of the data wouldn't put the subjects at risk of criminal or civil liability or harm their economic security, professional prospects, or public image. EIRB may give exemption contingent upon:

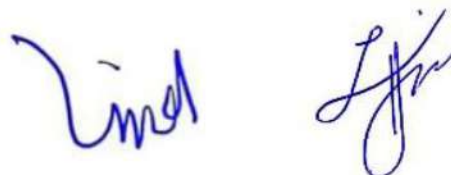


- i. The research participant will be asked for their informed consent.
- ii. The proposal contains strategies for informing the research subject as well as plans for communicating study results with the research subject(s) and the relevant communities.
- iii. Existing data, papers, and specimens that may not include any information that can be used to connect individuals to the data are also excluded, for example the Review of literature and theoretical analysis. Analysis of data, papers, and samples irrespective of the major/field.
- iv. Researchers may provide an option of sharing the findings of the study with the subject participants with proper procedure they will opt for this purpose.

5.2. Informed consent must include

Any research study involving human subjects are required to be engaged on voluntarily basis and should be properly informed/addressed about the research study. Regardless of the subjects' age, gender, or literacy level all the information regarding the study may be communicated to all the participants in a language that is easily understandable for the participants. The researcher should make it clear why it is vital to use certain/vulnerable populations as research subjects, such as convicts, children, or people with mental disabilities etc. and why there is need to have informed consent duly signed by them or their guardians.

1. The researcher must make sure that the subject or legal guardian understands the informed consent.
2. The goal of the study must be very clear to the participants.
3. Describe the method that the participants will be asked to go through.
4. List any techniques that are unconventional, experimental, or investigative.
5. Specify the kind and quantity of monitoring that will be done both during and after the research.
6. The duration of the subject's involvement in research study must be clearly mentioned.
7. Describe how documents containing personal information about the subject will be kept secret.



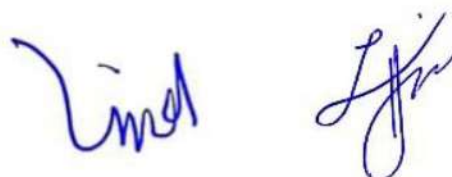
8. Indication that participation is optional and purely on voluntary basis and declining to participate would not subject the individual to any penalties or deprive them of advantages to which they are otherwise entitled.
9. The consent form may be written in easily understandable official language (English) with the translation (if required) in national language/local language and must be explained verbally to the participants (preferably in local language if the participants are not highly educated). Technical, Scientific, or medical concepts must be described in a clear and easy manner. The PI is in charge of making sure the consent process is done properly.
10. Research participants' right to protect their integrity must always be respected. Every effort should be made to protect the subject's personal information's confidentiality and privacy. Every effort should be made to reduce the study's negative effects (if any) on the subject's social, mental, and physical integrity.
11. The researcher shall always respect the individuality, rights, desires, ideas, consent, and autonomy of each individual subject while conducting research.

5.3.Application Method/Process

The PI/Supervisor/In-charge of research project should submit an application stating the reason and highlighting the portion for which ethical approval is required from Ethical Institution Review Board (EIRB) for review and ethical approval on prescribed proforma/format.

Furthermore,

1. The application must be submitted 15 days before the subsequent meeting.
2. Supervisors/Researchers will submit their cases for ethical approval to the Directorate of ORIC through Head of Department & Concerned Dean and if there is any deficiency, it is communicated to the concerned supervisor to provide the relevant documents before the agenda is finalized for the meeting. If the relevant documents are not provided within due time, the case will be dropped from the coming meeting and may be included in the next meeting (if the deficiency has been fulfilled). Within a week of the EIRB meeting, all the concerned supervisors/researchers will be informed about the decisions made during EIRB meeting regarding their cases.
3. The applicant/PI/Supervisor should provide additional information or modifications as suggested by the EIRB. If any PI/Supervisor/researcher is asked to explain/answer



questions raised by EIRB and he/she fails to communicate the respective information within 15 days, the EIRB will issue a reminder and will give them another 15 days to respond. The file will be closed if the PI/Supervisor/Researcher fails to respond within a month (initial 15 days plus 15 days after reminder)

4. When the research study includes an item (pharmaceutical or device under investigative process), an appropriate summarization of all security, pharmaceutical, pharmacological, and the toxicological information on the study product must be provided, along with a brief overview of clinical experience to date with the study product (e.g., a recent investigator's booklet, published data, an overview of the product's quality).
5. Form of informed consent from participants (and its translation if required by the participants for easy understanding)

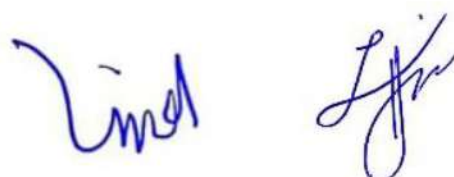
5.4. Conditions of approval

1. Permission is granted for a certain time (normal duration of the research project). A proposal for an extension of the ethical clearance must be made if the research project takes much longer than the approved time duration.
2. Acceptance is subject to the requirement that any suggested changes to the approved procedure be presented to the Committee for their approval prior to the changes being implemented.
3. The approval is granted subject to the incorporation of all suggested changes suggested by EIRB.
4. EIRB might audit research to make sure it complies with regulations while it is being conducted.

6. Research Ethics Policy

6.1. Coverage

- i. The BKUC's Research Ethics Policy applies to all of the university's research projects as well as those of its external partners who work on studies involving BKUC Faculty/Researchers and students including surveys, focus groups, lab experiments, field tests, and other types of research.
- ii. The policy applies to all research projects carried out by BKUC employees including faculty, researchers and students.



- iii. The policy includes research projects dealing with people, animals, and objects of BKUC.
- iv. The Directorate of ORIC Bacha Khan University Charsadda should be consulted for guidance regarding ethical concerns in research projects.

6.2.Principles

- i. Research interventions may not have any negative effects on people, animals, or public infrastructure.
- ii. In any study endeavors participants' physiological, psychological spiritual, economical, or any other kinds of safety should be guaranteed.
- iii. No research project may result in the destruction of public property, the deterioration of natural resources, or the introduction of any harmful objects to the health or safety of humans or other creatures.
- iv. Individuals who volunteer their time and information for study should not have their identities revealed or publicized without their permission.
- v. The humans, animals, and public property must be treated with respect and honesty at all times.
- vi. Regarding issues related to race, religion, sexual orientation, and other potentially divisive factors, we must take a neutral and objective stance.
- vii. Any individual should not be subjected to any kind of pressure or threat in order to participate in the study.
- viii. Participation in research requires informed consents and comprehension of the study's purpose.
- ix. Before commencement of any research study, researchers must first get informed consent from the individuals who will participate in that research study.
- x. Participants in research must understand the potential advantages and risks of taking part and provide their informed consent willingly.
- xi. In order to conduct any kind of research, permission must first be obtained from the property owner/ manager/In-Charge of any public or privately owned animals or land that may be involved.
- xii. In order to conduct research, it is necessary to get informed permission from the guardian of children, individuals with disabilities, or anybody or anything else



- engaged in the study who lacks the mental capacity to understand and provide such consent.
- xiii. Humans and animals from other cooperating organizations need authorization to participate.
 - xiv. The Director QEC at BKUC must sign the plagiarism report before submission to the ASRB for further approval.
 - xv. Finally, the Ethical Institution Review Board (EIRB) has to provide its approval certificate to ensure that research study is according to the ethical guidelines of the University.
 - xvi. The duty of ensuring ethical compliance and providing direction throughout the study is sole responsibility of Supervisor/PI.

6.3.Perspectives from the Law

- i. It is important to note that the laws currently in effect in Pakistan supersede any research ethics policy that may conflict with those laws.
- ii. Human and the animal participants' authorization is covered by the research ethics policy and will require approval from EIRB.
- iii. All of the committee's recommendations and the university's research ethics policy are in line with institutional norms.
- iv. The researcher must obey by all applicable local, state, and federal laws.
- v. To conduct research ethically, a researcher must follow the guidelines set forth by all research collaborators.

6.4.The Legal Framework

- i. All research endeavors, whether academic, commercial, or otherwise, must adhere to the statutory standards of Pakistani law.
- ii. Each field's individual research ethics requirements should be followed by researchers within that area.
- iii. Most of the time, grant applicants must attest that their study plans involving human/animal participants have been authorized by the Ethical Institution Review Board (EIRB).
- iv. This is a requirement of Research Councils, charity trusts, and other research funding agencies.

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6.5.Human-Related Research

Any study involving human/animal participants must pass an adequate ethical review in order to proceed.

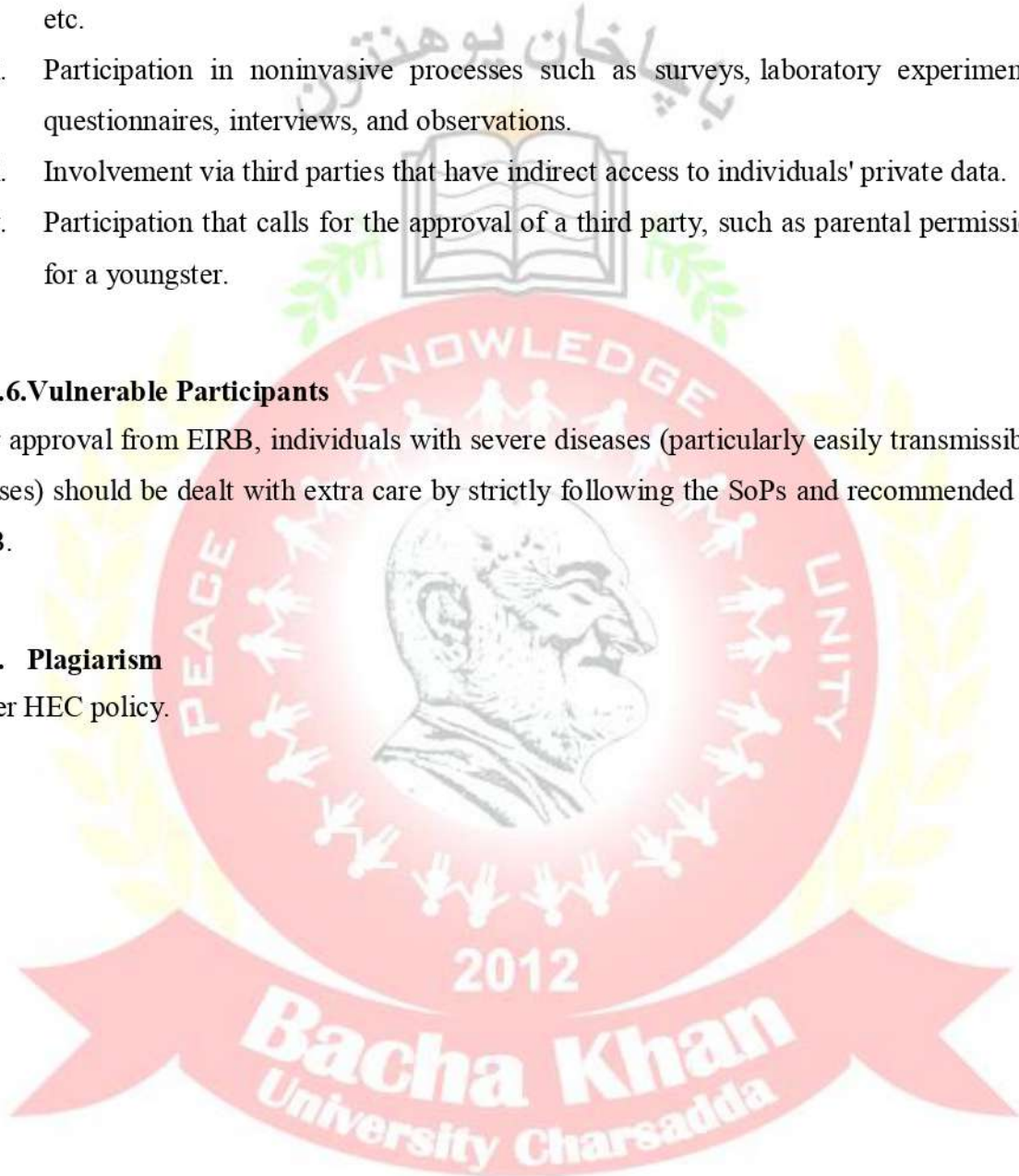
- i. Involvement in a direct way, using intrusive procedures like taking sample of blood etc.
- ii. Participation in noninvasive processes such as surveys, laboratory experiments, questionnaires, interviews, and observations.
- iii. Involvement via third parties that have indirect access to individuals' private data.
- iv. Participation that calls for the approval of a third party, such as parental permission for a youngster.

6.6.Vulnerable Participants

After approval from EIRB, individuals with severe diseases (particularly easily transmissible diseases) should be dealt with extra care by strictly following the SoPs and recommended of EIRB.

7. Plagiarism

As per HEC policy.



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