ETHICAL REVIEW COMMITTEE

Ethical Review Committee

The Ethical Review Committee (ERC) at Kinnaird College for Women facilitates research of highest ethical standard and the projects that protect the dignity and rights of human/animal participants. The ERC at Kinnaird College reviews all research projects involving human/animals, whether as individuals or communities before a study can begin. Any change in conditions that could affect the rights of subjects during a study must be approved for the study to continue. The ERC provides written guidelines on ethical considerations for research involving human subject. Research could be audited by ERC during the research period to ensure compliance with guidelines. It may withdraw approval if dissatisfied with the conduct of the investigation.

Guideline

All research projects/ research reports/ theses/ synopsis involving human/animal subjects, whether as individuals or communities, shall be reviewed by the Ethical Review Committee (ERC) of Kinnaird College before the study begins.

Some research that involves human subjects may be exempted from the regulations requiring ERC approval. Examples include educational research, testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects financial standing, employability, or reputation. Such exemption would be conditional to:

• The informed consent is taken from the research subject.

• The information gathered being relevant/beneficial to the research subject and his/her community.

• Proposal includes planning for sharing study findings with the research subject/s and the relevant communities planned, as well as mechanisms for informing the research subject.

• Also exempted are the uses of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data. Examples:

• Literature review; and theoretical analysis. In such cases the only ethical Concern would be acknowledgement of sources.

• Analysis of data, documents, specimen, not linked to individual subjects.

• All researchers must give the subject participants the option of sharing the results and specify how this will be done.

Essentials of informed consent are:

The human subjects in the research study must participate willingly, having been informed about the research. Please provide all information that is likely to affect the person irrespective of age, sex, or literacy level of the subjects. If the human subjects in your project are part of a vulnerable population, such as prisoners, children or mentally handicapped then the researcher should clearly state why is it necessary to have such groups as their research subjects and how do they plan to administer the informed consent.

1. Investigator must ensure that the informed consent is clearly comprehended by the subject / guardian

2. Purpose of research must be clearly explained.

3. In simple word describe the procedure that the subjects would be expected to undergo. Identify any procedures that are experimental/ investigational/ non-therapeutic. Indicate type and frequency of monitoring during and after the study.

4. Length of time subject is expected to participate, if subject's participation is expected to continue over a long period of time.

5. Describe the extent to which confidentiality of records identifying the subject will be maintained.

6. Statement that participation is voluntary and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.

7. Consent document must be clearly written and/or verbally explained so as to be understandable to subjects (local language wherever applicable). The language must be non-technical (comparable to the language in a newspaper or general circulation magazine), and scientific, technical or medical terms must be plainly defined. It is PI's responsibility to ensure quality of consent procedure.

8. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy and confidentiality of the patient's information. Minimize the impact of the study on the subject's physical, mental and social integrity.

9. In the conduct of research, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject.

Application Process

• The researcher responsible for the ethical and scientific conduct of the research/ life sciences should submit an application (on provided application form) for review of the ethics of proposed

biomedical/nonmedical/life sciences research to the Ethical Review Committee- Kinnaird College for Women. The procedure is as follows:

• ERC meets once a month.

• The deadline for submission of the application is 2 weeks prior to the next meeting.

• Applications will be acknowledged and researchers shall be informed of the review date. The researchers shall also be communicated regarding the incompleteness of an application.

• The outcome of review shall be communicated to the researchers within a week after the ERC meeting.

• In cases where the ERC requests supplementary information or changes to documents from the applicant, such information should be provided at least a week before the next meeting.

• In cases where clarification is sought and researchers fail to respond within 3 weeks, ERC will send a reminder and allow a further 3 weeks period for response. Beyond these 3 weeks, the file will be closed.

• Application along with research report/thesis (synopsis) must be submitted in first Friday of the month to the Office of Research to forward to the Chairman Ethical Committee.

• Two copies of research report/theses/synopsis (clearly identified and dated), together with supporting documents and annexes. This should always include description of the ethical considerations involved in the research.

• Questionnaire (if applicable) intended for research participants should be included.

• When the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, a summary of the product's characteristics).

• Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required in other languages.

Approval Conditions

• Approval is given for a specified period. If the research study takes longer than the specified period to complete, a request for an extension of the ethics clearance should be sought.

• Approval is given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being effected.

• Approval is given on condition that a copy of the research project final report is lodged with the Ethics Committee for its information.

• Approval is given subject to researchers notifying the Ethics Committee if and when a project is curtailed, terminated or completed.

• Research could be audited by ERC during the research period to ensure compliance with guidelines.

Committee Members

Following are the members of the Ethical Review Committee at Kinnaird College for Women, Lahore.

i.	Dr Shahnaz Chaudhry	Chairperson
ii.	Dr Ghazala Yaqub	Member
iii.	Dr Urusa Fahim	Member
iv.	Dr Hooria Younas	Member
v.	Dr Irum Anjum	Member

Review Process

The Committee shall meet once a month with administrative assistance from the Office of Research. ERC applications submitted each month are reviewed by the committee on the third week of the following month. The outcome of review is communicated to the researchers within two weeks after the ERC meeting. In cases where clarification is sought, ERC will notify the Principal Investigator to respond within three weeks. If the PI fails to respond in the given time, ERC will close the file and the PI will be required to start a new ERC application.