

**SOCIAL SCIENCES, LAW
AND
HUMANITIES RESEARCH ETHICS**

Social Sciences, Law and Humanities Research Ethics

The University is committed to promoting a quality research culture by ensuring high standards of research management, administration and governance. In practice this means that no research can take place until all of the required approvals have been given from the appropriate institutions.

Definition of 'human participants' in The British Psychological Society's Code of Human Research Ethics: "including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids and human data and records (such as but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements."

A Disclosure and certificate must also be obtained if you will come into contact with children or vulnerable adults.

Departments will be responsible for ensuring the ethical review of all M.phil Ph.d and faculty members research.

Any research which is deemed by the Head of Department/Nominated Ethics Representative to require full ethics committee approval should be sent to the committee. Any research which falls within the circumstances under which ethical approval is required will need to go through the Approval again after prescribed corrections..

If in doubt, researchers or student supervisors should discuss their research with Dr. Iqbal Azher, Convener, or any member of Institutional Bioethics Committee. Applicants who wish to discuss their application before submission should, in the first instance, contact: deanpharm@uok.edu.pk

Accountability

The Institutional Bioethics Committee is accountable to the University's Vice Chancellor and is required to report to the University through this Committee.

Application process

- The Institutional Bioethics Committee will normally only accept applications for ethical approval after funding has been awarded (in the instances where external funding is sought), except when ethics approval forms part of the requirements of a grant application or where it is helpful to the applicant for the review to take place earlier. Applications relating to internally funded or own account research may be submitted at any time but must be before the commencement of any research.
- Principal Investigators should apply (applications for students must be made by the supervisor who acts as Principal Investigator) using the [application form](#) and all applications must be supported by the signature of the Head of Department. Principal Investigators are advised to read the [Guidelines](#) before completing the application form.
- Fully completed applications should be sent in email format to deanpharm@uok.edu.pk Please ensure the signature page on the application form is complete, i.e. contains the wet signatures of all relevant parties. Applications must be submitted **at least 3 weeks in advance** of the next Committee meeting to allow members appropriate time to review applications.

Review Procedure

- a) Applications will be sent to all Institutional Bioethics Committee members prior to the meeting and comments will be collected, discussed and recorded at the meeting.
- b) Applicants will be notified of the Institutional Bioethics Committee's decision as soon as possible after the meeting in writing. The Institutional Bioethics Committee's decision will be one of the following and details of any amendments required will be included:
 - Approved – no amendment.
 - Conditionally Approved – minor amendments required.
 - Resubmit – needs to be resubmitted with substantial amendments.
 - Rejected – ethically unsound.
- c) Applicants have a right to appeal the Committee's decision to **reject** an application. The appeal process is carried out by the University Vice Chancellor.

Convener's Action

Convener's action may be taken (with the advice of other Committee members if appropriate) to:

- determine whether or not an application falls within the remit of the committee;
- confirm the approval of conditionally-approved protocols when the conditions have been met;
- approve protocol amendments which are typographical corrections, minor redrafting or administrative points;
- note correspondence received for information only.
- Approve expedited review applications according to approved process.

Changes to research projects

The Institutional Bioethics Committee's approval must be sought for any substantial change that is made to a project. If you are in any doubt about whether the change you are making is sufficiently substantial to require further ethics committee review please contact deanpharm@uok.edu.pk in the first instance.

The following are examples, though not an exhaustive list, of substantial changes that *would* require the Committee's approval:

- Recruitment strategies
- Sample frames
- Rewording of any documentation including letters or information sheets
- Change to Principal Investigator.

How to Apply to Institutional Bioethics Committee

Submission of Applications

Fully completed and signed application forms should be sent via email to deanpharm@uok.edu.pk. Applications must be submitted **at least 3 weeks in advance** of the next Committee meeting to allow members appropriate time to review applications.

Applications Checklist

Applications should include the following documents which should display the full title as given in Question A1 of the Application Form:

- IBC application form
- Participant Information Sheet
- Consent Form

If applicable:

- Copies of any relevant authorizations/ permissions to use the tests/Instrument/Questionnaire etc.
- Copies of any questionnaires/surveys/interview schedules/Psychological Tests
- Copies of any draft recruitment material, e.g. draft email for email recruitment method, recruitment poster, text for social media post/s

The following information should be included on the participant information sheet:

“Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below,

Prof. Dr. Iqbal Azher

Convener, Institutional Bioethics Committee

University of Karachi.

deampharm@uok.edu.pk

SOCIAL SCIENCES, LAW & HUMANITIES RESEARCH ETHICS

Application for Approval of Research Project Involving Human Participants

SECTION A. GENERAL INFORMATION

1. Applicant's Details

a. Title:

b. Full Name:

c. Email:

d. Telephone:

e. Department:

2. Project Title:

3. Other Investigator(s):

4. Project Start Date:

5. Project End Date:

6. Funding Body (if any):

Yes No

a. Are there any potential conflicts of interest?

b. If yes, please specify

7. Is this a Student Project?

Yes No

a. Student name

b. Student email address

Section B: PROJECT DETAILS

1. Please give a brief summary of the project (in lay terms) including the scientific benefit:

2. Please summarise the methodology to be used:

3. Please describe briefly any ethical issues and / or sensitive topics that will be covered during the course of the project:

4. How do you intend to handle these areas?

5. What possible risks are there for the researcher?

6. Will you, or any of the research team, who will come into contact with participants be required to obtain criminal record clearance?

Yes No

7. If answered 'yes' to 6, please confirm that such clearance will be obtained:

Yes No

SECTION C: PARTICIPANTS

1. How will participants be recruited?

2. How many participants will be recruited?

3. How will informed consent be obtained from the participants (please provide a consent form and participant information sheets to be used)? If no consent will be obtained please explain why:

4. Will deception be used during the course of the research?

Yes No

5. If yes, why is it deemed necessary?

6. Will the participant group include any children or vulnerable adults?

Yes No

7. If yes, please explain the necessity of these individuals:

8. If yes, please also explain how and from whom fully informed consent will be obtained:

9. Will participants be given payment and/or incentives for participating in the research?

Yes No

10. If yes, please specify level of compensation and source of the funds or incentives. Please also explain the necessity of such compensation:

11. What possible benefits and/or risks to participants are there to this research?

12. What arrangements have been made for reporting the results of the research to and/or debriefing the participants:

13. What qualified personnel will be available to deal with possible adverse consequences/reactions to those participating in this research?

SECTION D: DATA

1. How will you ensure confidentiality? *(Please give details of how and at what stage in the project you will anonymise the data):*

2. Who will have access to the data?

3. Where will consent forms, information sheets and project data be stored?

4. For how long will the above data be kept and how and when will data then be destroyed?

5. Is it anticipated that there will be any future use of the data and have the participants been informed of this use?

Yes No

6. Will any interviews be audio or video taped? If yes, please attach a copy of the consent/authorisation form.

Yes No

SECTION E: PUBLICATIONS

- 1. How will publications of research findings recognise the contributions of all researchers engaged in the study?**

SECTION F: FURTHER INFORMATION

- 1. Please give any additional information you believe to be relevant to this project:**

SECTION G: DECLARATION

The information in this form together with any accompanying information is complete and correct to the best of my knowledge and belief and I take full responsibility for it.

If the research is approved, I undertake to adhere to the study protocol without deviation.

I undertake to inform the IBC of any changes in the protocol that would have ethical implications for my research.

I am aware of my responsibility to be up to date and to comply with requirements of the law and the appropriate guidelines relating to security and confidentiality of participants' personal data.

Signature of Principal Investigator Date:

Signature of Student (If Applicable)..... Date:

Signature of Head of DepartmentDate:.....

Please send an electronic copy of the application to deanpharm@uok.edu.pk Your electronic submission should contain wet signatures of all relevant parties.

GUIDELINES FOR COMPLETING IBC APPLICATION FORM:

Please read through these guidelines carefully before completing your form as inadequate information may delay your project.

Please ensure your form is completed in a language that is comprehensible to a lay person.

Ref: This will be completed by the IBC Secretary on submission

SECTION A:

2. Applicant

- This should be the Principal Investigator and therefore the supervisor must be this on an application for a student project.

3. Other Investigators

- Please mention all other investigators involved regardless of their host institution.

7. Conflicts of Interest

- You must identify all financial/personal and any other conflicts of interest that are relevant to this project and disclose any prior relationships which could affect this research.

SECTION B:

1. Summary of Project

- Please highlight the nature of the project (e.g. pilot, evaluation).
- When justifying the scientific benefit please include any hypothesis to be tested and any specific objectives of the project.
- If the project is for an educational purpose please specify the qualification sought.

2. Methodology

- Please justify the overall design of your project and the methodology you have chosen highlighting any samples/measurements to be taken and what may have influenced your choice of methodology.
- Identify any steps taken to consult with the concerned communities during the course of designing the research.
- Summarise the nature of the participants involvement (e.g. what will happen to the participant – how will it happen, when will it happen).

3. Ethical Issues

- **Please note that all research projects involving human participants do have some ethical considerations. Please ensure you complete this section.**
- You may like to consider issues such as dependant relationships between researcher and subject; protection from harm; rights to withdraw.
- The IBC will need to see evidence that the applicant is aware of relevant issues and how they have planned to address them.

4. Risks to researcher?

- If any risks are identified please explain how you intend to minimise and/or monitor these risks.

SECTION C:

1. Recruitment of Participants

- How will potential participants be identified?
- Please identify inclusion and exclusion criteria and explain the purpose behind such criteria.
- When designing an advertisement, care should be taken to be restrained in tone and not to overstress payments or other inducements to take part. You should also state who would be the first contact point of potential respondents to adverts.

3. Informed consent

- Written consent from participants will normally be required for all projects (except questionnaires where returning a completed questionnaire is considered to be consent)
- Obtaining informed consent is vital to the ethical conduct of research involving human participants. Fully informed consent is a process by which a participant in research understands the nature and consequences of participating in research and is free to choose to consent to participating.
- Please indicate what process you intend to enact to ensure that fully informed consent is obtained and detail any additional assent procedures where children may be involved.
- If an influential relationship exists between the recruiter and potential participant please explain how you will deal with problems of informed consent for these participants.

5. Vulnerable participants

- Important considerations apply to projects involving vulnerable participants. Please identify why it is necessary for the research to include these participants and any additional requirements you have taken into account to protect these participants' rights.

6. Incentives/compensation

- Payments may be made to participants to reimburse their travel/out of pocket expenses and must be noted here but any other payment must be fully justified in this section. Financial inducements should not be offered as method of recruiting participants and should not be set at a level of inducement that would encourage people to take part in studies against their better judgement.
- If it is not possible to recompense out of pocket expenses to participants this should be explained before a participant agrees to take part in a study. A clear statement should be included in the information sheet.

7. Participant Benefit/Risk

- Please highlight any possible benefits to the participant of being part of this study (if none please highlight any benefits to future members of this group of participants)
- Please also highlight any potential harm/risks that the participant may suffer as being part of this study. This should include any physical, psychological or social discomfort or harm that may result from their participation in this project.
- Where risks/harms are identified please indicate what steps will be taken to minimise and monitor these risks or harm.

SECTION D

It is the researcher's responsibility to ensure compliance with legal requirements of the Data Protection Act.

1. Confidentiality

Your application should refer to the need to obtain permission if confidential information is to be used in a way which would identify particular participants. You must also indicate what action may be taken should information be discovered that would cause concern.

3 Storage

Original data including signed consent forms and copies of relevant documentation must be kept in a secure locked location.

4 Length of Storage

Data should be accessible for inspection if required for at least 10 years after the work is completed. Responsibility will rest with the Principal Investigator to produce, when required, evidence that informed consent has been obtained.

6 Audio/Video Recording

The IBC will expect that fully informed consent is obtained from the research participants involved

**INSTITUTIONAL BIOETHICS COMMITTEE
(IBC)
UNIVERSITY OF KARACHI**

GUIDELINES FOR RESEARCHERS

GENERAL PRINCIPLES

- All research projects involving human subjects, whether as individuals or communities, including the use of human material, and tissues from the recently dead, supported and undertaken by faculty, staff or students of **University of Karachi** wherever conducted, shall be reviewed by the IBC before the study begins.
- Some research that involves human subjects may be exempted from the regulations requiring IBC 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. Also exempted are the use of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data. All researchers must give the subject participants the option of sharing the results and specify how this will be done.
- Every research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others.
- The human subjects in your project must participate willingly, having adequately informed about the research. 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.

Essentials of informed consent are:

- **Purpose** of research
- **Benefits** of the research to the society and, possibly, to the individual human subject plus person(s) undergoing research.
- All **foreseeable risks or discomforts** to the subjects. Note this not only includes physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- **Length of time** subject is expected to participate.
- **Person to contact** for answers to questions, or in event of research related injury or emergency.
- 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.
- Subjects **right to withdraw** from the study at any time
- How sharing of results with subjects will occur.
- No abbreviations will be used.

Consent document must be clearly written and understandable to subjects (local language as well 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.

- The researcher should also submit to the committee, for review, information regarding funding sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
- The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles of Helsinki Declaration.
- The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- 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

- A qualified researcher responsible for the ethical and scientific conduct of the research should submit an application for review of the ethics of proposed biomedical research.

The procedure is as follows:

- All information and application forms are available from:
Office of the Dean, Faculty of Pharmacy & Pharmaceutical Sciences
University of Karachi
Karachi
Pakistan. **Tel: (9221) 99261367**
- IBC meets thrice a year.
- 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. This will obviously delay the review process.
- The outcome of review shall be communicated to the researchers within a week after the IBC meeting.
- In cases where the IBC requests supplementary information or changes to documents from the applicant, such information should be provided at least a week before the next meeting.
- Researcher may be asked to present the case in the meeting if required.
 - Follow-up (of the researcher)
 - At the end-report

DOCUMENTS FOR SUBMISSION

- Three copies of research protocol (clearly identified and dated), together with supporting documents and annexes. This should always include description of the ethical considerations involved in the research.
- 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).
- A description of the process to be used to obtain and document consent.
- Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required in other languages.
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
- A statement of agreement to comply with ethical principles set out in relevant guidelines.
- All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other IBC or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

APPROVAL CONDITIONS

- 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.
Approval is given for therapeutic trials subject to the principal investigator notifying the Ethics Committee within seven (7) days (14 in case of unforeseen circumstances) of any adverse event or occurrence that takes place during that trial.

CHECKLIST FOR IBC APPLICATION

This checklist was prepared in order to aid investigation in preparing a complete application and to help expedite review by the IBC. Your cooperation in completing it will be greatly appreciated.

**PRINCIPAL INVESTIGATOR'S
NAME:** _____

DEPARTMENT: _____

- Copy of drug brochure or any supplementary information enclosed (if applicable)?
- Three copies of informed consent both in English and Urdu or any other local language of the population study.
- Three copies of any Questionnaire being administered during the study (if applicable).
- Copy of Project

I have made a copy of this entire application for my files.

Signature: Principal Investigator

Date

**INSTITUTIONAL BIOETHICS COMMITTEE (IBC)
UNIVERSITY OF KARACHI**

INTRODUCTORY QUESTIONNAIRE

Title of protocol: _____

Principal Investigator and Co-Investigators: _____

NAME	DESIGNATION	DEPARTMENT
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

1. Project involves the use of
Check all pertinent ones

- a) Experimental drug(s)
- b) Radioactive agents
- c) Non-therapeutic research
- d) Non-approved use or non-approved dose for approved drugs
- e) Experimental surgical procedures
- f) Behavioral research
- g) Other (please specify):

1. What is the purpose of the study?

2. Enumerate the objectives of the study

3. Description of methods used in protocol.

4. a. Expected duration of the study period

5. Subject information.

a) Types & number of subjects to be studied (give details of patients and controls)

b) Age range: _____

c) Sex: Male Female Both

d) If subjects are either children, pregnant women, mentally retarded, or prisoners, give brief explanation of need to use these particular individuals.

7. Compensation (to research subject):

Monetary: No Yes Amount Rs. _____

Reimbursement of expenses: No Yes
_____ Type and amount _____

8. What are the adverse effects expected by the subjects involved in the investigation during the study and what is the provision for managing these effects and who will pay for them?

9. What are potential benefits, if any, to be obtained by participants or society as a result of this study?

10. Location of study:

11. Laboratory studies:

- a) Will any tests be performed which are not routinely included as part of the work-up for these types of patients?
- b) Who or what agency will pay for these tests?