INSTITUTE OF HEALTH ECONOMICS
UNIVERSITY OF DHAKA

Institutional Review Board (IRB)

Application form for research activity requiring human research ethics consideration or approval

☐ Regular

☐ Fast track

Note: For fast-track application decision/comments on approval will be given within 10 days. For the regular one, it will take 30 days.

1. **Title of the Research Project:**

2. **Title of the Study (*if study title is different from the title of the research project*):**

3. **Brief description of proposed activity and its objectives:**

4. **Name of the Principal Investigators or Team Leader with contact information and relevant experience to conduct the research:**

5. **Name of the Co-investigators (if applicable):**

6. **Funding Source:**

7. Has the research proposal identified any of the following research procedures?

Please put '√' mark in the research procedures covered by he study

1.	Gathering information from or/and about human beings through: Interviewing, Surveying, Questionnaires, Observation of human behaviour	☐
2.	Using archived data in which individuals are identifiable	☐
3.	Researching into illegal activities, activities at the margins of the law or activities that have a risk of personal injury	☐
4.	Supporting innovation that might impact on human behaviour e.g., Behavioural Studies	☐
5.	Another category (please specify……..)	☐

8. Research Ethics Checklist

Please answer each question by circling the appropriate response.

1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g., children, people with learning disabilities, your own students)
   YES / NO
2. Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (e.g., students at school, members of voluntary group, residents of a nursing home)
   YES / NO
3. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places)
   YES / NO
4. Will the study involve discussion of sensitive topics (e.g., sexual activity, drug use)?
   YES / NO
5. Are drugs, placebos or other substances (e.g., food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?
   YES / NO
6. Will blood or tissue samples be obtained from participants?
   YES / NO
7. Is pain or more than mild discomfort likely to result from the study?
   YES / NO
8. Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?
   YES / NO
9. Will the study involve prolonged or repetitive testing?
   YES / NO
10. Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?
    YES / NO
11. Will the study involve recruitment of patients?
    YES / NO
12. Have measures been taken to ensure confidentiality, privacy and data protection where appropriate?
    YES / NO

13. Do the respondents have freedom to withdraw?
    YES / NO
14. Is the participation voluntary?
    YES / NO
15. Are you providing participants with full details of the objectives of the research?
    YES / NO

For the question no. 1 to 11 if you have answered 'yes'; or for the question no. 12 to 15 if you have answered 'NO' implies that that your study has an ethical issue. In that case, please describe in detail how you plan to deal with the ethical issues raised by your research. Answering 'yes' (to the question no. 1 to 11) or 'no' (to question no. 12 to 15) does not mean that you cannot do the research, only that your proposal raises significant ethical issues, which will need careful consideration. Any significant change in the question, design or conduct over the course of the research should be notified to the ethics committee for approval.

9. Please list the potential ethical issues identified (in section 8) and how these will be addressed

Ethical issue identified	How these will be addressed

10. Contact Person Details

Name	
Designation	
Email	
Mobile No:	

Signatures and date of the applicant

Please use this form for an application if your research involves:

1. Gathering information from or/and about individual human beings (and organisations) through:
    a. interviewing
    b. surveying
    c. questionnaire
    d. observation of human behaviour
    e. modifying/disturbing human behaviour
    f. interfering in normal physiological and/or psychological processes
    g. making any discomfort (physically/mentally/socially) to the individual
    h. collecting substantial personal level data which may pose risk on individuals if data are not kept confidential or
    i. any other ethical issues related to human beings

2. Using archived data in which individuals are identifiable.

3. Researching into activities which involves direct observation of or contact with those who are or who might reasonably be supposed to be engaged in or have engaged in criminal activities or activities which are related to criminal activity

4. Research which involves a risk of physical or psychological injury to the researcher or any other person involved in the research

5. Supporting innovation that might impact on human behaviour e.g., Behavioural Studies

Please submit the following documents to support the application:

1. A copy of the research proposal
2. The details of arrangements for participation of human subjects (including recruitment, consent and confidentiality procedures and documentation as appropriate)
3. A copy of all data collection instruments
4. A statement of your competence to carry out this research as a researcher or a brief one-page curriculum vitae for each applicant, including recent publications
5. Other documentation as advised necessary

There are normally four possible outcomes from reviewing the activity against the procedures in place:

1. No ethical issues
2. Minor ethical issues which have been addressed and concerns resolved
3. Major ethical issues which have been addressed and concerns resolved
4. Ethical issues that have not been resolved/addressed

FAILURE TO GAIN THE APPROVAL FOR YOUR RESEARCH MEANS THAT YOUR PROJECT MAY BE FAILED, OR YOU MAY NEED TO MAKE A SUBSTANTIAL REVISION BEFORE YOU START YOUR PROJECT