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 decisions/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 the study title is different from the title of the research project*):**

3. **Brief description of the proposed activities 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 on the research procedures covered by the study

1. Gathering information from or/and about human beings through Interviewing, Surveying, Questionnaires, and Observation of human behavior ☐

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 human behavior 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 students)
   YES / NO
2. Will the study require the cooperation of a gatekeeper for initial access to the groups or individuals to be recruited? (e.g., students at school, members of voluntary groups, residents of anursing 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 a 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 tothe 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 the recruitment of patients?YES / NO
12. Have measures been taken to ensure confidentiality, privacy, and data protection whereappropriate?
    YES / NO

13. Do the respondents have the 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 questions no. 1 to 11 if you have answered 'yes'; or for questions no. 12 to 15 if you have answered 'NO', it implies that that your study has ethical issue/issues. In that case, please describe in detail (in section 9) how you plan to deal with the ethical issues raised by your research. Answering'yes' (to questions no. 1 to 11) or 'no' (to questions 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 explain how these will beaddressed

Ethical issue identified	How these will be addressed

10. Contact Person Details

Name	
Designation	
Email	
Mobile No:	

11. Application checklist
(Please fill up the checklist. This will help submit the application more accurately.)

SL	Indicators	Response Yes/No
1.	Explained the measures to address ethical issues raised in Section 8 of the IRB application form	
2.	Submitted the final Technical Proposal/Inception Report	
3.	Submitted all the data collection instruments in English	
4.	Submitted all the data collection instruments in Bangla	
5.	Thoroughly checked the Bangla translation of all the data collection instruments	
6.	Consent form for each of the data collection instruments in English	
7.	Consent form for each of the data collection instruments in Bangla	
8.	Thoroughly checked the Bangla translation of all the consent forms	
9.	Consent form had information on the objective of data collection	
10.	Consent form indicated the duration of interview	
11.	Consent form declared whether there were any incentives for the respondents	
12.	Consent included information on the confidentiality of the data collected	
13.	Consent form included the option of voluntary withdrawal from the interview	
14.	Consent form had local contact information (phone no, email address, etc.) of investigator or researcher to whom respondents may communicate for further queries	
15.	Asked for consent explicitly (either verbal or written) in the consent form	

Note: If any of your responses to the IRB application checklist is 'No' then your application will be considered INCOMPLETE and may not be reviewed for ethical clearance. The timeline of IRB review starts from the complete application submission date.

Signature and date of the applicant

Submission Guidelines

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

1. Gathering information from or/and about individual human beings (and organizations) through:
    a. interviewing
    b. surveying
    c. questionnaire
    d. observation of human behavior
    e. modifying/disturbing human behavior
    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 that involve 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 that 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 human behaviour e.g., Behavioural Studies.

Please submit the following documents to support the application:

1. A copy of the research proposal which includes background of the study, objectives, detailed methodology, funding sources, ethical consideration, etc.
2. The details of arrangements for the participation of human subjects (including recruitment, consent and confidentiality procedures, and documentation as appropriate). The consent form should include the following contents: objective of data collection, duration of interview, whether any incentives for the respondents, withdrawal option from the interview, asking the consent explicitly
3. A copy of all data collection instruments (both Bangla and English versions)
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 is 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

Submission (Whom to submit?)

Please fill up the application form and send it to Professor Syed Abdul Hamid (s.a.hamid73@gmail.com) and Nafiz Ifteakhar (nafiz.ihe@du.ac.bd)

Contract persons

For further queries please contact:

Nafiz Ifteakhar
Assistant Professor, Institute of Health Economics
Cell: +88 01675915701
E-mail: nafizifteakharecodu@gmail.com, nafiz.ihe@du.ac.bd

Syed Abdul Hamid, PhD
Professor, Institute of Health Economics
Phone: +88-01711-441437
E-mail: s.a.hamid73@gmail.com, s.a.hamid.ihe@du.ac.bd

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