Independent University, Bangladesh

Institutional Review Board (IRB)

Policy

Contents

1. Scope and Purpose:

Like any world class university, Independent University, Bangladesh (IUB) is determined to ensure research integrity and ethical clearing of the research. It is in the interests of both the institution and all researchers that research projects are reviewed and conducted ethically, both to protect the rights and welfare of research subjects, as well as to enable recognition of international standard procedures in the conduct of research at IUB. Thus, the Institutional Review Board (IRB) is set forth to ensure that the rights and welfare of human subjects are protected during their participation in the research projects.

IUB is guided by the ethical principles set forth in the Belmont Report. The Belmont Report consists of three principles: respect for persons, beneficence, and justice, which are accepted as the three quintessential requirements for the ethical conduct of research involving human subjects. IRB focuses on research procedures to minimize the risks of harm and maximize the possible benefits to the participants and to society. All individuals involved in conducting research have obligations to respect the dignity and integrity of the people being studied, including their right not to be the subject of potentially harmful research. Researchers should ensure informed participation and promised confidentiality should be maintained. Furthermore, researchers must exercise special care when the participants of research are especially vulnerable to harm because they cannot understand the risks or because they are not in a position to refuse their participation in the research.

The IRB reviews all research projects that involve human participants, checking for compliance with the two broad standards:

1) Participants are not placed at undue risk;

2) Participants provide informed consent to their participation.

IRB is responsible for conducting reviews and providing ethics-related oversight for all research activities involving researchers of IUB or for which IUB is engaged. All research requires approval regardless of the location of the research activity (i.e., conducted on or off campus) and source of funding (i.e., IUB sponsored, externally funded or non-funded).

It is the researcher's responsibility to seek and obtain prior IUB-IRB approval before initiating the research. It is the policy that the final decision regarding approval or disapproval of all research proposals subject to the IRB review are final and binding. Any investigator who has a proposal rejected by the IRB must make appropriate modifications and submit a new proposal for review. All research on human participants conducted by faculty members, staff and/or students must conform to these ethical principles. Researchers that

proceed with research in violation of this policy are subject to disciplinary action by the University.

2. Institutional Review Board (IRB)

An Institutional Review Board (IRB) is the entity created to review proposed research in order to protect the rights and safeguard the welfare of human subjects.

2.1 IRB Composition

The composition of IRB is as follows:

a) The Vice Chancellor- Chairperson

b) The Pro-Vice Chancellor- Member;

c) Deans of Schools;

d) One external member (a non-scientist community representative) nominated by the Academic Council and approved by the Syndicate;

e) One external member (a non-IUB-affiliated scientist) nominated by the Academic Council and approved by the Syndicate.

External members are nominated for a period of two years, after which they might be reappointed for one more term. Administrative support for the IRB will be provided by the Senior Officer –Sponsored Research, in the Office of the Pro-Vice Chancellor (henceforth: IRB Secretariat).

2.1.1 External Reviewers

At the discretion of the IRB Chairperson, non-voting External Reviewers may be used to supplement or provide expertise not available on the IRB. In addition, the IRB may vote to defer action on a protocol and may require an expert in the scientific area or discipline to review the research and provide consultation to the IRB.

2.1.2 Membership Term of Appointment

Members (other than the Vice-Chancellor and Pro-Vice Chancellor) are appointed for a term of 2 years. Subject to reappointment, each IRB member is eligible to be appointed to the Board for 2 consecutive terms (4 years).

2.1.3 Members Non-Disclosure and Conflict of Interest

IRB Members and External Reviewers respect the confidentiality of the IRB deliberations and findings and do not disclose these until the Principal Investigators are formally notified by the IRB of their decision. Furthermore, IRB activities must remain confidential and confined to the board itself.

All members of the IRB are responsible for informing any potential or perceived conflict of interest with regard to membership on the board and concerning any projects reviewed by the board. They are required to self-identify conflicts of interest and refrain themselves from participating in the discussion and abstain from the vote on research activities. An IRB member may have conflict of interest if they are:

- Listed on the project, or will be included (or reasonably may be expected under academic standards to be included) as a co-author on a publication of the project's results;
- Receiving funding from the project as listed in the budget;
- Family member or relative of the Principal Investigator or any researcher involved;
- Having financial interests in a business that is supporting or facilitating the project under review, or the interest is in a business that is known for an IRB member to own or have license rights to the technology.

A member of the Board who makes a disclosure under this section must not:

- Take part, after the disclosure in any deliberation or decision of the board relating to the research project;
- Be included in the quorum when a vote on the decision is to be taken; or
- Sign any document related to the research project.

Any IRB member who becomes aware of a conflict of interest of another IRB member and the other IRB member did not self identify such conflict of interest, is required to bring the issue up in the next IRB meeting.

Abstaining from voting must be documented in the Minutes of the Meeting.

2.2 IRB's Roles and Responsibilities

- Conducting review of all the research.
- Determining whether an activity meets the definition of human subject research.
- Determining exempt status of research involving human subjects.
- Restrict, suspend or terminate an approval of a research project that is not in compliance or that has been associated with an unexpected serious adverse event to the subjects.
- Reviewing and approving, or approving with modification of any research project submission.
- Reviewing required documentation of Informed Consent from human subjects except to the extent waived in accordance with the relevant policies and procedures.
- Notify the Principal Investigator in writing of its decision with regards to a submitted research project or of modification required to obtain its final approval.
- Providing feedback in the development of IRB policy and procedures.
- Attending conferences, workshops, online courses, seminars, or lectures pertaining to human subjects' research for development.

3. Research Ethics Training:

All investigator (faculty members, students, and research staff) conducting research with human subjects must complete Collaborative Institutional Training Initiative (CITI) online training modules prior to submitting their IRB application. These modules provide researchers with an opportunity to improve their working knowledge of research integrity issues. A certificate of completion of the nominated CITI modules is a compulsory requirement for all researchers submitting ethical clearance applications or renewals.

All IRB members and administrators are required to complete training in protecting human research participants. All IRB members shall complete the "IRB Members" module of the CITI Program.

4. IRB Review

4.1 Determination of 'Human Subject Research'

Not every research involves human subjects. So, the first criterion for review is the determination of Human Subject Research. A human subject can be identified as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information. Secondary analysis of existing datasets where participants are individually identifiable should be reviewed by the IRB. The definition of human subject focuses on what information or material is obtained from people. So, if either of the following is true, the research activity involves human subjects:

- They will be actively involved in the research process, such as responding to surveys or being interviewed or examined.
- Individually identifiable data about human subjects may be gathered from other sources, such as public records, existing datasets, medical records, or other sources.

4.2 Proposals and Documents to be submitted

The Primary Investigator must complete the Application for Ethical Clearance with self assessment of Exempt or Full Review and attach all required documents. The application requires the researcher to describe their proposed research in detail, and provide sufficient information for the IRB to make their determination. All applications must be done on the prescribed Application Forms. The application forms have the following components:

1. Details of the Investigators
2. Project Funding, Purpose and Research Design
3. Criteria based on which the Exempt status if given (for Exempt Review Research only)
4. Information regarding possible conflict of Interest
5. Informed consent details along with Consent form
6. Confidentiality and data storage mechanism
7. Data Analysis and outcomes
8. The proposal (for exempt or full review).
9. Documents relevant to the Research proposal
10. CITI Certificate

Additional documents may also be required depending on the nature of the proposal.

4.3 IRB Criteria for Review

All research projects will be evaluated using the criteria specified in this policy. In addition to subject specific-scrutiny, the IRB will consider the following guidelines in reviewing proposals:

- The proposed research applies sound research design and recognized data collection techniques.
- Risks to participants are acceptable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.
- The research reflects an awareness of cultural sensitivity and traditions.
- Informed consent is obtained from all participants or their legal guardians.
- There are adequate provisions to maintain the privacy and confidentiality of participants.
- Selection of participants is appropriate and equitable.
- Research Assistants and other supporting staff are adequately trained for the tasks and possess the necessary skills, experiences and professional maturity to undertake all required tasks.
- There are planned processes for the handling of potentially sensitive data, highly personal information, and observations of criminal acts or dealing with dangerous or emergency situations (this is particularly relevant where researchers are interviewing children, visiting family homes or discussing topics of a personal nature).

Committee members follow these guidelines in the evaluation process. All efforts are made to ensure a speedy and transparent approval process.

4.3 Types of Review

Investigators make an initial determination of which type of review is appropriate for their (No Review, Exempt Review and Full Board Review) and submit the required number of copies of the protocol and supporting documentation. Research proposals should be screened by the IRB secretariat for their completeness.

For proposals where the investigator suggests No Review (because the research does not involve human subjects) or Exempt Review (where there is a minimal risk for human subjects) the IRB secretariat, in consultation with the Chairperson assigns the proposal to one IRB member to verify the Principal Investigator's initial determination. Based on IRB member's suggestion the Chairperson or his/her designee, makes the final determination of the type of the review required. All the decisions regarding the proposals for No Review and Exempt Review are then reported in the next IRB meeting.

Research proposals that do not involve human subjects may apply for No Review status. Application must be done through appropriate "No Review" Application Form (Appendix A-I). Depending on the risk involved IRB utilizes two classes of review of human subject research:

4.3.1 Exempt Review

Proposals which do not have human subjects or present less than minimal risk fall under the category of 'Exempt Review' and will be administratively reviewed. Applications must be done through the Exempt Review Application Form (Appendix A-II).

Minimal Risk: A risk is minimal where the probability of harm or discomfort anticipated in the proposed research is not greater than what is ordinarily encountered in daily life—or during the performance of routine physical, psychological or educational examinations or tests.

Exemption waives only the need for full IRB review and does not negate the need for the informed consent of subjects where applicable. The authority to determine and confirm exempt status rests with the IRB and not with the investigator.

Exemption is only awarded where the proposed research meets one or more of the exemption criteria below:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the collection or of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

4. Research is primarily focused on quality assurance or process improvement. Such projects are generally studied within an institution, comparing reality/practice to established standards, and are carried out and applicable only within the institution, and not intended for publication.

5. Research conducted as part of an in-class assignment is to be considered generally exempt from IRB review. The purpose of an IRB is to review research conducted using human subjects. Most in-class projects where research is conducted using

human subjects are not systematic or generalizable. Systematic research includes research development, testing, and evaluation, and it is designed to create generalizable knowledge. Generalizable knowledge involves the creation of new knowledge that may be the basis for scholarly publication. In general, if the project is meant to complete an assignment for a class and will not be published, it does not require IRB review.

4.3.2 Full Board Review

All research presenting more than minimal risk or those proposals which do not qualify for exemption from review and/or proposals that involve vulnerable population and special groups fall under 'Full Board review' and are subjected to review by all members of the IRB. The IRB is responsible for evaluating the potential risks and the forms it may take (Appendix B) and weighing the probability of the risk occurring and the magnitude of harm that may result. It must then judge whether the anticipated benefit, either in the form of new knowledge or research results is reasonable compared to the risk undertaken.

Applications for Full Board Review must be submitted in the Full Board Review Application Form (Appendix A-III). Researchers with research proposals that require a Full Board Review should allow ample time to complete the review process as this review type may take longer than the other review processes. The following categories of research always require full IRB approval:

1. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
2. Projects that involve sensitive or protected populations (such as children, prisoners cognitively disabled individuals etc.).
3. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

4.4 Risk/Benefit Analysis

IRB must also determine that the risks will be minimized to the extent possible. The IRB cannot approve research in which the risks are judged unreasonable in relation to the anticipated benefits. IRB must assure that potential subjects will be provided with an

accurate and fair description (during consent) of the risks or discomforts and the anticipated benefits.

4.4.1 Informed Consent

Ethical research requires that research participants, to the degree that they are capable, be given the opportunity to consent to participating in the research. This is called “Informed Consent”. Any informed consent process should include these three main components:

1. **Information:** This includes information about the research procedure, its purposes, risks and anticipated benefits, and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Many informed consent processes also include information about the organization or institution conducting the research.

2. **Comprehension:** The way in which informed consent and research information is shared is as important as the information itself. Researchers are responsible for making sure the potential research participant has comprehended the information before giving informed consent, has been provided information in a way that allows time for consideration or questioning, has been presented information in the preferred language, and makes sure that it doesn’t require high-level literacy skills.

3. **Consent is voluntary:** Consent to participate in research is valid only if voluntarily given, without coercion, undue influence, or pressure.

The consent can be obtained in the form of a “Consent Form”. An appropriate informed consent form would include:

1. A statement that the research involves, an explanation of the purposes of the research and the expected duration of the subjects' participation, and a description of the procedures to be followed.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others that may reasonably be expected from the research.

4. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

5. An explanation of whom to contact for answers to pertinent questions about the research and about research subjects' rights (Contact information of both the Principal Investigator and the IRB).

6. A statement that participation is voluntary; that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

7. The consent form may not include any language that releases, or appears to release, the investigator or his/her institution from liability, or that waives, or appears to waive any of the subject's legal rights.

Other considerations in obtaining informed consent may be appropriate in certain cases. The following must be included in the Form in the following cases:

- If the participant cannot read or understand written or spoken English, then the consent form must be translated in an alternate Language (e.g. Bangla), then a translated version of the Informed Consent Form and all accompanying information should be given to that individual.

- If the participants cannot read or understand written or spoken English, and also cannot read the alternate language (e.g. Bangla), but understands it orally, then the translated version of the Informed Consent Form should be read for that individual and the use of the alternative language orally should be documented. In this instance a witness should also sign the form along with the subject and the person acquiring informed consent.

- When children (<14 years of age) are involved in research, it is required to have the assent of the child or minor and the permission of the parent(s)/guardian(s), in place of the consent of the subjects.

- Compensation is meant to offset the time and inconvenience of participation, as well as to serve as an incentive to participate. Along with providing information to the IRB, research subjects should be accurately informed through the consent process about any compensation for participation. The consent form should clearly state what form of compensation will be provided, the amount or value of the compensation, and the timing of compensation.

- The relationship of teacher and student is inherently one that raises the issue of ‘voluntariness’. No matter how well intentioned the teacher is, students may feel compelled to participate, in the belief that failure to do so will negatively affect their grades and the attitude of the teacher (and perhaps other students) toward them. It is

therefore strongly recommended that teachers should not use their own students as subjects in their research, unless the necessity of this is clearly argued for a particular project. In such a case students should be offered an alternative activity if the activity is conducted during the class time, if they opt not to participate. Furthermore, if any extra marks are offered for participation in the research, an alternative activity for those who choose not to participate shall result in the same number of marks.

- The Principal Investigator shall discuss issues regarding special cases (e.g. people with cognitive or physical disability as participants) with the IRB and take necessary actions regarding informed consent.

A copy of the consent form must be given to the person signing the form. A Sample Consent Form is attached for reference (Appendix B-I).

4.4.2 Waiver of Informed Consent

A waiver of informed consent completely waives the requirement to obtain informed consent. The IRB may approve a consent procedure that doesn't include or which alters some or all of the consent requirements, or waive the requirement to obtain informed consent provided that:

- The research involves no risk to subjects
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
- Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study
- The research could not be carried out without the waiver or alteration. Alteration may include a simplified or waived documentation of consent.

4.4.3 Data Protection

There is an expectation for researchers to access the minimal amount of personal data to conduct the research, and to include collection of personal identifiers only where necessary. All research requires protecting privacy and maintaining confidentiality of the data collected. Maintaining human subject data securely with the appropriate level of anonymity, confidentiality, or de-identification is a key factor in ensuring a low risk threshold for the participants, the researchers, and the university. Research projects with sensitive data must have research specific strategies for privacy and confidentiality. As such, principal investigators (PIs) and their research teams are required to outline the data storage and confidentiality plan in the application for IRB review. The plan must include:

- Identifying who has access to the data
- Identifying who is maintaining the confidentiality of the data
- Describing the measures for protecting the security of the data
- Ensuring all data collection and storage devices are password protected with a strong password.
- Ensuring all sensitive research information on portable devices is encrypted.
- Limiting access to identifiable data to members of the research team.
- Ensuring identifiers, data, and keys are placed in separate, password protected/encrypted files and each file is stored in a different secure location.
- Ensuring that authentication and authorization are required for those who have access to sensitive data by providing firewalls, data encryption, and password protection.
- Developing a contingency plan for dealing with any breach of confidentiality.

5. Renewal of IRB Review

If the approved proposal exceeds the initially approved timeframe, the research must be renewed with the IRB before the expiration of the approval as indicated on the initial approval letter. The Principal Investigator should complete the Extension Request form (Appendix A-IV) and submit it to the IRB.

6. Principal Investigator Responsibilities

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable University IRB policies and procedures, for the oversight of the research and the informed consent process. Principal Investigator's responsibilities include:

- Completing the required CITI training.
- Ensuring that other investigators complete the required CITI training.
- Ensuring appropriately qualified and trained co-investigators, research assistants and data collectors (if applicable) are involved in the project.
- Submitting the complete document for review. Providing additional documents if requested by the IRB.

- Ensuring appropriate human subject protection while conducting research.
- Once the IRB has approved the research, the investigator will need to interact with the IRB if there are changes in the research protocol, adverse events (should any occur), and/or project renewals.

6.1 Project Changes

If a project changes in such a way that subjects are treated differently than outlined or described in the original proposal, a Research Project Amendment form (Appendix A-V) describing such changes must be submitted to the IRB for approval. Once the change has been approved, the researcher(s) may proceed with the research.

A change in a proposal might require a change in the consent form(s). When consent forms are submitted for review with a change form, two different consent forms must be submitted:

1. The original consent form
2. The proposed new consent form(s) with all the changes noted (boldfaced, shaded, etc.).

6.2 Adverse Events

Unanticipated problems or serious adverse events involving risk to human subjects must be reported to the IRB immediately.

All such events must be reported to the IRB using the appropriate Adverse Events Reporting Form (Appendix A-VI). The IRB will determine if the event meets the criteria.

The following events meet the IRB's definition of "any unanticipated problems involving risk to subjects or others" and should be reported within the 10-day time frame:

- Any event that was unanticipated and involved new or increased risk to subjects or others, and is related to the research procedures.
- Any accidental or unintentional change to the IRB-approved project that increases risk or has the potential to recur.
- Any deviation from the project taken without prior IRB review to eliminate apparent immediate hazard to a research subject.
- Any event that indicates an unexpected change to the risk/benefit ratio of the research.
- Any breach in confidentiality that may involve risk to the subject or others.

- Any complaint of a subject that cannot be resolved by the researcher.
- Any other event which constitutes an unanticipated risk.

6.3 Addition or Deletion of Investigator(s)

The IRB must be notified if investigators are added or removed from the research. Submission of a Research Project Amendment Form (Appendix A-V) is a requirement in such cases. If deemed necessary, additional documentation may be requested from the investigator(s). Approval of deletion or addition of personnel or investigators will be provided to the principal investigator.

7. Meeting Proceedings

IRB meetings are to occur at least thrice a year or more regularly upon the call of the IRB Chairperson, at such times and places as the IRB Chairperson may designate.

Quorum: To vote on a proposal, more than half of the members of the board must be present.

All IRB members shall be informed about the research projects that have been categorized under the No Review and Exempt Review procedures, a list of such research projects will be distributed to all IRB members attending each convened meeting.

Decisions taken during IRB meetings occur by voting and in most cases, comprise one of the following:

 Approval

 Approval with Modification

 Denial

 Deferral

 Termination or Suspension of an already approved research project

Minutes of each IRB meeting must be recorded in writing. The IRB approves the previous meeting minutes at the subsequent IRB meeting; however, a quorum is not required for such approval. If the Board requests revisions, changes are made after the meeting. The final version of the approved minutes is signed by the IRB Chairperson and filed (hardcopy) within the IRB Secretariat. Minutes must include:

-Attendance

-A list of full board reviews with the respective information: Actions taken, and decisions made by the Board, including denials; Vote on these actions (including the number of members voting for, against, and abstaining); Basis for requiring modifications to the research proposal or consent documents or for disapproving the research proposals.

-A list of all No Review and Exempt Review approvals that were taken.

8. Committee Records

Documentation of IRB activities is maintained by the IRB Secretariat for at least three years following the completion of research and includes the following:

1. Copies of all Research proposals reviewed, Informed Consent documents, etc.

2. Documentation of actions taken through procedures of No Review and Exempt Review.

3. Minutes of meetings in sufficient detail to show attendance; actions taken; vote on these actions for, against, and abstaining; basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

4. Records of renewals of review activities.

5. A list of IRB members as well as a copy of each member's professional vita.

9. Review of the Guidelines

The Terms of References shall receive feedback every year from the IRB members, Researchers and all other users of the document and shall be reviewed as appropriate by the Office of the Pro-Vice Chancellor.

Appendix A-I

"No Review" Application Form

If your research involves no human subjects[1], please complete this form. Completed forms must be submitted to the Institutional Review Board (IRB) for final decision regarding determination of a "no review" status.

SECTION A

Project Title:				
Principal Investigator (PI):	Name:		School:	
	Title:		Department:	
	Telephone:		Email:	

List all Co-Investigators below, including those from other institutions:				
Name	Responsibility on Research Project	Designation	University/ School	Email
1.				
2.				
3.				

SECTION B - Project funding, purpose and research design

1. Current or planned funding source (internal or external)	
Is project funding sought/achieved?	☐ Yes (provide the information below) ☐ No
PI of Grant or Contract:	
Funding Source:	
Time period of Grant Funding:	

2. Possible conflict of interest
Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this project or otherwise have a potential conflict of interest regarding the conduct of this project?
☐ Yes (Provide the information below) ☐ No
If yes, please provide details:

[1] A human subject can be identified as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

3. Purpose of Research Project Provide a brief summary below (i.e. maximum 300 words) of the purpose of the project in general terms, including background information as necessary, research question(s), and importantly, an explanation of why this research is needed. NOTE that a guiding ethical principle for research includes 'non-maleficence', or the duty to prevent unnecessary risks of harm for subjects, and the verification that their participation in research must be essential to achieving scientifically or socially important aims. Human subjects research must be justified by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing.
Please provide summary:

4. Description of the research design, methods and procedures (A copy of all data collection instruments must be attached with this application) Provide a description below of the research design (including steps and methodology), what kinds of data will be collected, details on the primary outcome measurements, and follow-up procedures or actions anticipated. Note: It must be designed or developed using methods appropriate to achieving the aims of the research proposal.
Please provide description:

SECTION C

I, the undersigned Principal Investigator of this research proposal hereby state that the proposed research does not involve human subjects nor it creates any situation in which individuals might be endangered.

Signature of the PI | Date

OFFICE USE ONLY

Date received		Date PI notified
Date checked and accepted		Date of change notification
Date(s) of committee review		

Is the research proposal given no review status?	☐ Yes ☐ No ☐ Revisions required	Remarks	
Detail any revisions or additional information required:			
Name of reviewer(s):		Date:	

Appendix A-II

Exempt Review Application Form

If your research involves human subjects*, please read the Institutional Review Board Policy before completing this form to determine whether you should complete this form. Exemption is only awarded where the proposed research meets one or more of the categories mentioned in the Institutional Review Board Policy.

Completed forms must be submitted to the Institutional Review Board (IRB) for final decision regarding exemption.

SECTION A

Project Title:				
Principal Investigator (PI):	Name:		School:	
	Title:		Department:	
	Telephone:		Email:	

List all Co-Investigators below, including those from other institutions:				
Name	Responsibility on Research Project	Designation	University/ School	Email
1.				
2.				
3.				

SECTION B - Project funding, purpose and research design

1. Current or planned funding source (internal or external)	
Is project funding sought/achieved?	☐ Yes (provide the information below) ☐ No
PI of Grant or Contract:	
Funding Source:	
Time period of Grant Funding:	

2. Possible conflict of interest
Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this project or otherwise have a potential conflict of interest regarding the conduct of this project?
☐ Yes (Provide the information below) ☐ No
If yes, Please provide details:

*A human subject can be identified as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

3. Purpose of Research Project Provide a brief summary below (i.e. maximum 300 words) of the purpose of the project in general terms, including background information as necessary, research question(s), and importantly, an explanation of why this research is needed. NOTE that a guiding ethical principle for research includes 'non-maleficence', or the duty to prevent unnecessary risks of harm for subjects, and the verification that their participation in research must be essential to achieving scientifically or socially important aims. Human subjects research must be justified by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing.
Please provide summary:

4. Description of the research design, methods and procedures (A copy of all data collection instruments must be attached with this application) Provide a description below of the research design (including steps and methodology), what kinds of data will be collected, details on the primary outcome measurements, and follow-up procedures or actions anticipated. Note: It must be designed or developed using methods appropriate to achieving the aims of the research proposal.
Please provide description:

SECTION C- Exemption Criteria

The proposed research is exempt from the full ethical clearance process based on the following criteria:	
1. Research will be conducted in established or commonly accepted educational settings, involving normal education practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	☐ YES
2. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public	☐

behavior, and will not: (a) record information obtained in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and will refrain from (b) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	YES
3. Research will involve the collection or of existing data, documents, records, pathological specimens, or diagnostic specimens, and these sources are either publicly available or the information will be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.	☐ YES
4. Research is primarily focused on quality assurance or process improvement. This project is generally studied within an institution, comparing reality/practice to established standards, and are carried out and applicable only within the institution, and not intended for publication.	☐ YES
5. Research conducted as part of an in-class assignment. Research that will be conducted using human subjects are not systematic or generalizable. Systematic research includes research development, testing, and evaluation, and it is designed to create generalizable knowledge. Generalizable knowledge involves the creation of new knowledge that may be the basis for scholarly publication. In general, the project is meant to complete an assignment for a class and will not be published.	☐ YES

SECTION D-Proposed Research Subjects

Describe (maximum 300 words) **who are the research subjects**, and in what ways the research will or will not present more than minimal risk to human subject.
Please provide details:

SECTION E

Complete the following questions in relation to this research project, if applicable:	
Research does NOT involve children as participants, or participants who are known to be prisoners. *Children* are defined as those under 14 years old.	☐ TRUE
Research activities do not present more than minimal risk to human subjects Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (According to the Institutional Review	☐ TRUE

Board Policy)	
If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data	☐ TRUE
If there are interactions with subjects, there will be a voluntary consent process (including some type of documentation) that will disclose such information as: • That the activities involve research • The procedures/activities in which subjects will be involved • That participation is voluntary • Name and contact information for the Principal Investigator and the IRB It is strongly recommended that teachers do not use their own students as subjects in their research, as student may feel undue pressure to participate. In principle all subjects must give consent, however **such consent or documentation of consent may be waived** as specified in the IRB Policy. ☐ I request the consent requirement is waived ☐ I request that documentation of the consent process is waived	☐ TRUE
There are adequate provisions to maintain the privacy interests of subjects.	☐ TRUE
I have completed the required CITI human subjects research online training modules.	☐ TRUE
I agree to a continuing exchange of information with the IUB- Institutional Review Board (IRB) and to obtain approval before making any changes or additions to the project.	☐ TRUE
I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.	☐ TRUE

SECTION F- Required documents

Attach all relevant documentation:	
Copies of all data collection instruments, including surveys, interview questions, etc.	☐ YES
Copies of all consent and information forms, including translated forms, as appropriate.	☐ YES
Copy of any wording, advertisement or script etc. intended to use when recruiting subjects.	☐ YES ☐ N/A
Copy of any ethical approval for co-investigators external to IUB, or collaborative institutions.	☐ YES ☐ N/A
Copy of CITI human subjects research completion report.	☐ YES

Signature of PI: _____ Date: _____

OFFICE USE ONLY

Date received		Date PI notified
Date checked and accepted		Date of change notification
Date(s) of committee review		

Is the consent requirement waived?	☐ Yes ☐ No ☐ N/A
Is documentation of the consent process waived?	☐ Yes ☐ No ☐ N/A
Is demographic information collected with cultural sensitivity?	☐ Yes ☐ No ☐ N/A
Has the PI (and Co-PI) completed CITI training?	☐ Yes ☐ No

Is the research proposal exempt from Full Board Review?	☐ Yes ☐ No ☐ Revisions required	Remarks		
Detail any revisions or additional information required:				
Name of reviewer(s):			Date:	

Appendix A-III

Full Board Ethical Clearance Application Form

If your research involves human subjects[2], please read the Institutional Review Board Policy. Complete ALL sections of this form. An incomplete application will not be reviewed, and may delay the approval process.

Completed forms must be submitted to the Institutional Review Board (IRB) for review.

SECTION A

Project Title:				
Principal Investigator (PI):	Name:		School:	
	Title:		Department:	
	Telephone:		Email:	

List all Co-Investigators below, including those from other institutions:				
Name	Responsibility on Research Project	Designation	University/ School	Email
1.				
2.				
3.				

SECTION B - Project funding, purpose and research design

1. Current or planned funding source (internal or external)	
Is project funding sought/achieved?	☐ Yes (provide information below) ☐ No
PI of Grant or Contract:	
Funding Source:	
Time period of Grant Funding:	

2. Possible conflict of interest
Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this research or otherwise have a potential conflict of interest regarding the conduct of this research? ☐ Yes (provide information below) ☐ No

[2] A human subject can be identified as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

3. Purpose of Research Project Provide a brief summary below (i.e. 300 words or less) of the purpose of the project in general terms, including background information as necessary, research question(s), and importantly, an explanation of why this research is needed. NOTE that a guiding ethical principle for research includes 'non-maleficence', or the duty to prevent unnecessary risks of harm for subjects, and the verification that their participation in research must be essential to achieving scientifically or socially important aims. Human subjects research must be justified by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing.
Please provide summary:

4. Description of the research design, methods and procedures (A copy of all data collection instruments must be attached with this application) Provide a description below of the research design (including steps and methodology), what kinds of data will be collected, details on the primary outcome measurements, and follow-up procedures or actions anticipated. Note: It must be designed or developed using methods appropriate to achieving the aims of the research proposal.
Please provide description:

SECTION C - Obtaining free and informed consent

Individuals have the right to make free and informed decisions about their consent to participate in a research project. This consent includes having an understanding (in an appropriate language, at an appropriate language level) of what they are being asked to do and why, and that they willingly agree to participate without coercion or undue enticement to do so.

Copies of any intended consent or information forms should be attached to this application. Guidelines for the Informed Consent Form are included in the IRB Policy.

1. Vulnerable populations

If you are planning to involve any of the following population groups in this project, please detail below:

Non-Bangla speakers	☐YES ☐ NO	People in prison or detention	☐YES ☐ NO
People with a cognitive disability	☐YES ☐ NO	Children (under 14 years)	☐YES ☐ NO
People with a physical disability	☐YES ☐ NO	People who are illiterate	☐YES ☐ NO
Investigators' own students	☐YES ☐ NO	Other IUB students	☐YES ☐ NO

Please provide details

2. Risk mitigation

Detail below any possible risk factors for subject involvement, including emotional distress, personal or cultural embarrassment, breach of confidentiality, economic harm, legal jeopardy, physical pain or injury, and intended method of mitigating such possible risks.

Please provide details:

3. Informed Consent

☐ Informed consent will be obtained and documented

(Attach any consent forms proposed. If non-Bangla speakers or poor levels of Bangla language understanding are anticipated, then consent information should also be attached in the language of the proposed subjects.)

☐Informed consent will be obtained but I am applying for a waiver for documentation of informed consent.

☐I am applying for a waiver of informed consent.

Please provide details:

4. Are there any anticipated inducements for participation (e.g. monetary payment), or costs to be borne by subjects (e.g. travel costs)?
Please provide details:

SECTION D - Confidentiality and data storage

1. Confidentiality How you will protect the confidentiality of the data collected, and protect against risks of breach of confidentiality or invasion of privacy. (For example, where will paper files and/or electronic data be stored? What security measures will be applied in each situation?; Specify your plans for de-identifying or maintaining anonymity of the data, especially if audio/video recordings or images will be collected; Specify procedures for data sharing with entities external to IUB; Provide a timetable and methods for destroying the data)
Please provide details:

2. Data security for storage and transmission. Select all that apply:			
For electronic data:		For hardcopy data (including specimens, tapes etc.)	
Secure network:	☐YES ☐ NO	Data de-identified by research team:	☐YES ☐ NO
Password access:	☐YES ☐ NO	Locked office:	☐YES ☐ NO
Encryption:	☐YES ☐ NO	Locked cabinet:	☐YES ☐ NO
Portable storage: (e.g. laptop, flash drive)	☐YES ☐ NO	Data coded by research team with master list secured and kept separately:	☐YES ☐ NO
Other: (provide detail below)	☐YES ☐ NO	Other: (provide detail below)	☐YES ☐ NO
Please provide details:			

SECTION E - Data analysis and outcomes

1. How will the data be evaluated? Where and by whom will data analysis be performed? Are research assistants adequately trained and experienced to manage the type of data being collected?
Please provide details:

2. Detail the projected outcomes for this research project Are there specific populations, organizations or locations likely to derive greatest benefit from the results of this project? What are the intended publication and dissemination vehicles and timelines?
Please provide details:

SECTION F - Attach all relevant documentation

Copies of all data collection instruments, including surveys, interview questions, etc	☐ YES
Copy of all consent and information forms, including translated forms, as appropriate	☐ YES
Copy of any ethical approval for co-investigators external to IUB, or collaborative institutions	☐ YES ☐ N/A
Copy of CITI human subjects research completion reports	☐ YES
Any other relevant documentation	☐ YES ☐ N/A

SECTION G

I certify that all investigators involved in this research project have completed the required ethical clearance training, and that each of the co-investigators has accepted their role in this project.

I agree to a continuing exchange of information with the IUB IRB and to obtain approval before making any changes or additions to the project.

I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.

Signature of PI: _____ Date:

OFFICE USE ONLY

Date received		Date PI notified	
Date checked and accepted		Date of change notification	
Date(s) of committee review		Date committee approved	

Is demographic information collected with cultural sensitivity?	Yes No N/A
Is the consent requirement waived?	Yes No N/A
Is documentation of the consent process waived?	Yes No N/A
Has the Principal Investigator and Co-Investigators completed CITI training?	Yes No
Does the application meet ethical clearance requirements?	Yes No

Detail of any additional information required?	Yes No
Revisions required	Yes No

Type of Approval:
□ Approval □ Approval with Modification □ Denial □ Deferral

Appendix A-IV

Extension Request for Approved Research

IRB approves a project for the time period initially mentioned with the expiration date indicated on the investigator's approval letter. Investigators wishing to collect data beyond the IRB approval expiration date must file an extension request before the initial approval expires.

Research Project #:_____IRB #_____Date of Approval: _____

Project Title:				
Principal Investigator (PI):	Name:		School:	
	Title:		Department:	
	Telephone:		Email:	

Date of expiry of IRB approval:

Previously proposed period for the Research Proposal:

Please mention reason for extension:

Attach Recent progress report of the research:

Extension requested:

Any other comments:

Signature of Principal Investigator: ……

Date:

(Please attach a copy of the initial approval letter)

Appendix A-V

Research project Amendment Form

Investigators are required to inform the IRB in writing, of project changes prior to their initiation.

IRB#:_____

Project Title:				
Principal Investigator (PI):	Name:		School:	
	Title:		Department:	
	Telephone:		Email:	

Please submit a copy of supporting documentation (i.e., project revision summaries, consent form). Changes must be highlighted.

1. Amendment in research design or method ☐Yes ☐No (If yes, summarize below)

2. Other changes in the Project ☐Yes ☐No (If yes, summarize below)

3. Consent form amendment: ☐Yes ☐No (If yes, submit copy. Changes must be highlighted.)

4. Change of the principal investigator or co-investigator: ☐Yes ☐No (If yes, complete information below)

☐Addition*

Name	Responsibility on Research Project	Designation	University/ School	Email
1.				

Please provide copy of the individual's CV. New individual(s) must sign below.

- Signature:

  _____

☐Deletion

Name	Responsibility on Research Project	Designation	University/ School	Email
1.				

Deleted individual(s) must sign below

Signature: _____

*Investigators must have the required CITI training.

Signature of Principal Investigator: _____

Date: _____

Appendix A-VI

Adverse Events Reporting Form

IRB Number:	
Principal Investigator:	
Research Title:	

Provide the following information for each unanticipated problem/event that reflects new or increased risk and is possibly related to the research procedures. Attach any summary or report.

Date of Event:	
Details of the Event	

Does this problem/event alter risk to past, present or future subjects?

Yes ☐ No ☐ Don't Know (Insufficient Information) ☐

Based on your judgment, should this problem/event be added to the consent form as a potential risk?

Yes ☐ Provide revised consent form with changes highlighted.

No ☐ Explain why not:

Based on your analysis of this problem/event,

should currently enrolled subjects be notified? Yes ☐ No ☐

should subjects who have completed their participation be notified? ☐ Yes ☐ No

Explain:

_____ _____

Principal Investigator's Signature Date

Appendix B-I

Sample Consent Form*

Title of the Research Project: Student-centered teaching strategies from students' perspectives

Name of the Principal Investigator: Dr. Yunus Ahmed

This consent form, a copy of which will be given to you, is only part of the process of informed consent required by the IUB- Institutional Review Board (IRB) Committee. You are invited to take part in a project called 'Student-centered teaching strategies from students' perspectives'. The Purpose of this Project is to have a deeper understanding of how you believe different teaching strategies can be best used to help you reach your learning objectives.

Please read the form carefully. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. This will not affect your grade or academic standing if you decide to not take part in the study or if you quit later.

If you agree to participate in this research project, you will be asked to respond to a set of questions in an interview that can take place either in person or over the phone. In addition you will be invited to share your reflections during online discussion.

There is no direct benefit to you from being in this study. However, if you take a part in this project, you might help in providing a deeper understanding of how to improve the learning experience for you and other students. There are no known risks associated with your participation in this research beyond those of everyday life.

Confidentiality of your research records will be strictly maintained by assigning unique, confidential identification numbers codes to your responses and electronic data will be password protected. The data from the study will be kept until at least 5 years after publication and then destroyed by shredding and deletion of computer data.

There will be no costs to you for taking part in this project. As a token of appreciation, you will receive 10 marks towards your final grade in this course. Should you decide not to participate in this, you will be offered an alternative activity that will result in the same number of marks.

If there is anything about the study or taking part in it that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact the principal investigator:

Name of the Principal Investigator: Dr. Yunus Ahmed

Designation: Professor

School: School of Life Sciences

Independent University, Bangladesh

Bashundhara, Dhaka

Telephone:

Email:

You may also contact Md. Hasan Saimum Wahab, Institutional Review Board, Independent University, Bangladesh (IUB); Email: sponsoredresearch@iub.edu.bd ; Contact No: 01720105738.

Statement of consent:

☐ I give my voluntary consent to take part in this project. I will be given a copy of this consent document for my records.

☐ I decline to take part in this project and opt for an alternative activity.

_____ _____

Signature of Participant Date

_____

Name of Participant

∗This is a **sample** consent form. Underlined areas will change according to the specific Research project.

Appendix C

Types of Risk to Research Subjects

Risk: The probability of harm occurring as a result of participation in a research. The risks to which research subjects may be exposed can be classified as physical, psychological, social, and/or economic. These risks may take the following forms:

Physical Harms:

Physical harms could occur either by or against the research participant if exploring sensitive topics—such as domestic violence or illegal activities such as drugs, gangs or other crimes. Some medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs.

Psychological Harms:

Participation in research may result in undesired changes in thought processes and emotion (depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but some research has the potential for causing serious psychological harm. More frequently, however, is the possibility of psychological harm when behavioral research involves an element of deception.

Psychological harms can be done in the form of Invasion of Privacy. Invasion of privacy concerns access to a person's body or behavior without consent; in the research context, it usually involves either covert observation or "participant" observation of behavior that the subject consider private. Another risk associated with confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another. The IRB must also consider whether the research design could be modified so that it can be conducted without invading the privacy of the subjects.

Social Risks:

Some invasions of privacy and breaches of confidentiality may result in embarrassment within one's business or social group, loss of employment, or criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Sometimes disclosure of personal or group attitudes, preferences or behaviors may lead to stigmatization, discrimination or prejudice.

Economic Risks:

Economic risks include disclosure of an individual’s personal information that may, if revealed to others, negatively impact employment, insurance coverage, or academic status. Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective subjects during the consent process.

All of these should be considered "risks" for purposes of IRB review.