Institutional Research Ethics Board (IREB) Policy

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Scope and Objective

The motivation of IREB is to regulate all research activities involving human subjects on the campus of United International University, ensuring that people who participate in research are treated ethically and in compliance with all national laws and regulations to assure the rights and welfare of research subjects, as well as to enable recognition of international standard procedures.

According to the Bangladesh Medical Research Council (BMRC) ethical guidelines stipulate in Section 1.2[1], the objectives of IREB are,

a. To safeguard the dignity, rights, safety, and well-being of all potential research participants.
b. To protect the rights of a researcher to carry out a legitimate investigation, as well as the reputation of the institution.
c. To minimize the potential for claims of negligence made against the researchers, the institution concerned, and any collaborating individual or organization.
d. To require evidence of ethical approval in refereed journals.
e. To influence the research design with ethical consideration.
f. To avoid potential problems [later] on, by [trial] to ensure that the main ethical issues are addressed before the research starts.

The secondary vision of IREB is to ensure that the University, affiliate institutions, and the investigators that it serves are compliant with the ethical standards and regulations governing human subject research. The IREB also serves to assist investigators in the design of ethical and regulatory compliant human subject research studies.

1. Institutional Research Ethics Board (IREB)

An Institutional Research Ethics Board (IREB) also known as an ethics committee or ethical review board is the entity created to review proposed biomedical and behavioral research in order to protect the rights and safeguard the welfare of human subjects.

1.1. Composition of IREB:

The composition of IREB should follow some regulations followed by National and International guidelines-

1. (a) The IREB must have at least five members, with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the institution.
   (b) The IREB must be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
2. The IREB must include one scientist and one non-scientist member.
3. The IREB must include at least one person who is not affiliated with the institution or in the immediate family of a person affiliated with the institution. These are commonly called "Community Members."
4. IREB members may not participate in the IREB's initial or continuing review of any project in which the member has a conflicting interest, except to provide the information requested by the IREB.
5. An IREB may include individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IREB. These individuals may not vote with the IREB.
6. For any proposal approval from IREB, the corresponding proposal must be reviewed by at least three members for approval.

Name	Highest education level	Research specialty	Institution name	Designation	IREB Membership Status
Rezwan Khan	PhD	Renewable Energy, Electrical & Electronic Engineering	Institute of Advanced Research (IAR), UIU	Professor & Executive Director	Chair
Hafiza Sultana	MBBS, M-Phil (Nutrition)	Health Education	Department of Health Education National Institute of Preventive and Social Medicine	Professor	Member

			(NIPSOM)		
Hasin Anupama Azhari	MBBS, PhD	Biomedical Engineering, Medical Physics	Director, Centre of Biomedical Science and Engineering, United Internation University	Professor	Member
Khandoker Mahmudur Rahman	PhD	Business and Economics, Marketing	United International University	Professor	Member
Khondaker A. Mamun	PhD	Public & Digital Health, Intelligent system, Research design	United International University	Professor	Member Secretary

1.2. Additional Members (Invitation Only):

1. Representative of Directorate General of Health Services (DGHS) of Bangladesh
2. Representative of Directorate General of Drug Administration (DGDA) of Bangladesh
3. Representative of Directorate General Medical Education (DGME) of Bangladesh
4. Representative of Bangladesh Medical Research Council (BMRC)

1.3. Term of appointment:

Three years (Change may happen based on requirment)

1.4. Membership Disclosure & Conflict of Interest:

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

IREB members who are considered unaffiliated with the institution will not be required to complete the standard conflict of interest form. These members will be required to sign a statement at the time of their orientation indicating that the conflict of interest policy has been provided to them.

A member with a conflict is 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. They will be allowed to receive funding from the project as listed in the budget. They could be a family member or relative of the Principal Investigator or any researcher involved in the research activities as well as 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 IREB member to own or have license rights to the technology.

Any IREB member, voting or nonvoting, with a conflict of interest in a study, must abstain from the final discussion and vote on the research activities. An exception is to provide information specifically requested by the committee. 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. Members are expected to advise the director if they are assigned a protocol, continuing review or amendment as a reviewer so that the protocol may be reassigned. members are also expected to notify the chair during a meeting if they have a conflict of interest for an initial review, continuing review, modification, adverse event, unanticipated problem or review of non-compliance. Abstaining from the voting due to conflict (i.e., a listed investigator, financial or other conflicts) must be documented in the minute of the meeting including the reasons for their absence.

2. IREB Roles & Responsibilities

1. The IREB members will evaluate a research proposal based on three basic principles which are "respect for persons", "beneficence" and "justice".
2. A research proposal should be reviewed by the IREB secretariat to ensure the completeness and classification of involved risks in three distinct groups- exempt from review, expedited review, and full review.
3. The IREB shall carry out its study assessment through a systematic review of the proposed research with respect to two levels of risk and benefit, accounting for the population concerned and the knowledge thought to result.
4. During the review of the study plan, the IREB is expected to consider, first, the nature of the study and if the context and the justification given are adequate to justify the conduct of the kind of research.
5. The IREB must determine whether the proposed study is appropriate monitoring of data protection and, if not, if the analysis is carried out necessary requirement to monitor the data collected in order to ensure the protection of the subjects.
6. When the IREB deems the study issue to be justified, considers the statistical merit. IREB would consider whether the technique is capable of generating useful results, procedures that are feasible for logical sequencing, or order of events.
7. Analysis protocols should be structured to avoid unwanted exposure to risk. The IREB will assess the use of questionnaires, written or structured recruiting programs to ensure equal access to information.
8. The IREB needs to verify the informed consent is obtained and recorded from any prospective subject or lawfully approved agent of the subject.

9. The IREB will consider the conditions of the case, whether or not, a prospective participant would be granted ample opportunity to decide whether to engage and whether the risk of pressure or unfair interference is reduced.
10. The IREB must also take note of the clauses in the protocol to protect the identity and personal rights of subjects as well as methods in order to ensure the confidentiality of the data gathered.

3. IREB Review

3.1. Identification of "Human Subject Research"

Not all study includes individual subjects. The first criterion for the review is the identification of human subject research. A human subject may be defined as a living person from whom the researcher (whether a specialist or a student) obtains research data. (1) Details through interference or contact with a person or (2) identified private information. The IREB should review the secondary study of current databases where subjects are personally identified. Defining the human subject focus on what information or content is derived from individuals. Thus, if any of the following is accurate, the study procedure includes human subjects-

- They may be directly engaged in the analysis process, such as listening to a surveyor being questioned or investigated.
- Individually identified data on individual beings can be obtained from a database such as public documents, current repositories, medical reports, or other media.

3.2. Proposals & Applications to be forwarded

The Primary Investigator must complete the Application for Ethical Approval with an Excluded or Full Examination self-assessment and insert the necessary documentation. The requirement requires the applicant to give a thorough overview of their proposed study and to provide appropriate details for the IREB to classify them. All applications must be submitted in the pre-defined application format. The application forms contain the following components:

1. The Investigators' descriptions
2. Plan, Aim, and Analysis Design
3. Criteria on the basis on which the exempt status is granted (for Exempt Examination Research Only)
4. Details on potential conflicts of interest
5. Information of informed consent together with the consent form
6. Privacy and data access system
7. Review of data and findings
8. The application (for an exception or a full review)
9. Documents relevant to the proposal for research

Supporting documents may also be requested based on the nature of the proposition.

3.3. Criteria for IREB Approval of Research

1. It is anticipated that all members of the board will be familiar with the research, and the lead reviewer will usually be responsible for presenting a thorough description of the proposed study, outlining how it meets each requirement for acceptance, and raising any questions or concerns so that the board will engage in an informed discussion.

2. IREB is expected to take additional measures to remove, limit, or resolve disputes before a study can be started. The IREB; (and/or its parent organization) shall determine the threshold above what dispute records must be made.
3. No IREB may have a member participate in the IREB's initial or continuing review of any project in which the member has a conflicting interest, except to provide the information requested by the IREB.
4. The decision of IREB shall be informed to the Principal Investigator in a written format.
5. The IREB is entitled to the continuous analysis of the study and making sure that the project continues to follow the acceptance requirements as it advances.
6. Any improvements to the study must be accepted in advance by the IREB, and the prosecutor, cannot implement any reform without IREB clearance unless the modifications help to remove any obvious imminent dangers to subjects.
7. IREB is going to require an investigator to have a progress report describing any progress analysis, appropriate intermediate outcomes, accounts of the experience of subjects to date, and any improvements to the study that have not been established by the IREB.
8. The IREB must determine the general quality of the study and determine if the justification, processes, is expected risks and rewards remain acceptable and still warrant the inclusion of human subjects.
9. The study represents knowledge of cultural sensitivities and customs.
10. Both participants or their legal guardians receive informed consent.

3.4. Type of Reviews:

A proposal that presents less than minimal risk falls within the category of the exemption from review and the administrative review does not require a review by the board. A proposal with no more than minimal risk to research participants may fall within the category of expedited review and it is usually reviewed by the subcommittee. All research with more than minimal risk or proposals/works which are not entitled to fall into the scope of the exemption from the review, expedited scrutiny, and proposals/works affecting vulnerable communities and particular groups shall be subject to review by all members of the IREB. Research intended for publication is usually subject to approval by the IREB.

3.4.1. Exempt from Review:

Proposals that do not include human subjects or raise less than negligible risk fall under the limits of the 'Exempt Review' group and may be administratively reviewed. Applications must be rendered by the Exempt Review Application Process.

Risk is low where the chance of injury or pain is expected. The suggested study is not greater than what is generally observed in everyday life— including during regular physical, psychiatric including educational assessments, or exams.

Exemption waives only the need for a thorough review of the IREB and does not negate the need for informed consent of participants, where appropriate. The power to assess and validate exempt status lies with the IREB, not with the investigator.

Criteria for exemption from review and provided upon meeting one of the criteria:

1. Research undertaken in existing or generally recognized school environments concerning standard instructional activities, such as (a) study on daily and special education policies, or (b) research on the efficacy or evaluation of teaching approaches, curricula, or classroom management procedures.
2. Analysis requiring the use of educational assessments (cognitive, psychological, aptitude, achievement), assessment methods, questioning or evaluation of public behavior, unless: (a) the information gathered is collected in such a way that individual subjects can be recognized, either explicitly or by means of identifiers linked to subjects, (b) Any publication of human reactions outside the study may fairly position subjects at risk of criminal or civil prosecution or damage the financial status, employability or credibility of the subjects.
3. Analysis including the compilation or compilation of current evidence, documentation, information, etc. pathological specimens, or forensic tests, where these records are freely accessible or where the material is reported by the investigator in such a way that the subjects can not be marked, either explicitly or by means of markers connected to the subjects.
4. The study focuses mainly on quality assurance or process enhancement. These studies are usually researched within the institution, compared reality/practice with existing norms, and are carried out and implemented only within the institution and are not planned for dissemination.
5. A study done as part of an in-class assignment is usually deemed to be excluded from the review of the IREB. The goal of the IREB is to review studies performed using human subjects. Many in-class programs in which human beings are used for the study are not standardized or generalizable.

3.4.2. Full Board Review:

All research involving more than minimal risk or proposals not eligible for exemption from review and/or proposals involving vulnerable populations and specific groups is subject to a 'Full Board review' and is subject to approval by all IREB members. The IREB is responsible for assessing the potential risks and forms it may take, and for weighing the likelihood of the risk occurring and the intensity of the harm that may result. It must then assess whether the expected benefit, either in the creation of additional knowledge or in the context of the research results, is reasonable in relation to the risk taken.

Applications for a full board review must be provided in the form of a full board review application. Researchers with research projects requiring a full board review should permit sufficient time to complete the review process, as this type of review may take more time than other review processes.

Criteria of research studies that require full review by IREB:

1. Projects requiring deliberate manipulation of subjects, such as deceptive or false knowledge, may be given to participants.
2. Initiatives targeting disadvantaged or endangered groups (e.g. infants, prisoners, individuals with developmental disorders, etc.).

3. Initiatives who aim to use techniques that are emotionally disruptive, frustrating, or invasive, potentially stressful (the stress may be physical, psychological, emotional, financial, or legal).

3.4.3 Expedited Review:

The IREB may utilize the expedited evaluation to examine either or both of the following:

1. Some or all of the research identified by the reviewer(s) shall not involve more than a minimal risk.
2. Minor changes to previously approved research during the period (of 1 year or less) to which the approval is authorized.

Within the framework of the expedited review procedure, the review may be carried out by the chairperson of the IREB or by one or more experienced reviewers appointed by the chairperson of the IREB from among members of the IREB.

In reviewing the research according to the expedited review procedure, the reviewers may carry out all of the tasks. The IREB authorities, except that the reviewers may not despise of the research. A research project activity may be disapproved only after evaluation in compliance with the full periodicity of the non-expedited activity that is commonly preceded by the IREB. IREB that uses an expedited evaluation protocol shall follow a system of preservation for all IREB members referred to study projects that are accepted in the context of the expedited approval process.

3.5 Potential benefit/risk analysis:

3.5.1. Review by Institutional Authority

Analysis protected by the above rules, which have been authorized by the UIU IREB/ERC, can be carried out more effective inspection and acceptance or rejection by officials of the institution, includes the Administrative Official and/or the Head of the Research Unit. However, such officials could be exempted and may not authorize the research if it has not been authorized by the IREB. The university-wide IREB/ERC works as an impartial authority to study, authorize and disapprove of the research procedure.

3.5.2. Informed Consent

Ethical research demands that study subjects have the ability to contribute to their involvement in the research to the extent that they are capable of doing so. It's called "Informed Consent." Any informed consent process should contain the following three core components:

Informative: This provides information on the analysis process, its goals, risks, and potential rewards, and a declaration that allows the participant the right to raise questions and to withdraw from the study at any moment. Many informed consent procedures often provide knowledge about the testing agency or entity.

Comprehensible: The manner in which informed consent and knowledge on research are provided as essential as the information itself. Researchers are responsible for ensuring that the information is interpreted by the prospective research participant prior to giving informed consent, the information is provided in a manner that allows time for clarification or interrogation, the information in the preferred format has been presented language, and ensure that it does not require high-level literacy.

Voluntary Consent: Consent to participate in research is only valid if it is voluntary without intimidation, disproportionate influence, or strain.

Consent can be received in the form of a "Consent Form". An effective informed consent form will contain the following:

1. A declaration that the study includes a clarification of the aims of the research and the anticipated length of the involvement of the subjects and a description of the procedures to be followed.
2. A summary of any fairly possible threats or inconveniences to the topic.
3. A summary of any advantages to the subject or others that might possibly be obtained from the study.
4. A declaration specifying the degree to which privacy of information identifying the subject would be preserved if any.
5. A description on whom to ask for answers to specific research questions. and the interests of research subjects (Contact information of both the Principal Investigator and the IREB).
6. A statement that participation is voluntary; that failure to participate does not entail any cost or lack of profit to which the subject is otherwise entitled, and that the subject might be discontinued involvement at any time without charge or lack of profit to the subject is otherwise qualified.
7. The consent form does not contain any wording that releases or appears to free the applicant or his or her institution from obligation or that suspends or appears to waive all of the constitutional rights of the subject.

In other situations, other requirements for securing informed consent might be necessary. This is in the following instances, the element must be included:

- If the applicant is unable to read or understand written or spoken English, the consent document must be converted into an alternative language (e.g., Bangla), followed by a simplified edition of the Informed Consent Form.
- If the participants cannot read or understand written or spoken English and cannot read alternate languages (e.g., Bangla) but understand it orally, the simplified version of the Informed Consent Form should be read for that person and the use of the alternate language should be recorded orally. In this case, the witness may also sign the paper.
- When minors (< 14 years of age) are included in testing, the consent of the child or minor and the approval of the parent(s)/guardian(s) must be sought instead of the consent of the participants.
- Compensation is intended to compensate for the time and difficulty of involvement and to serve as an incentive to participate. In addition to supplying evidence to the IREB, test

participants should be adequately aware of any reimbursement for participating in the consent process.

- The Principal Investigator shall discuss issues related to specific cases (e.g., persons with cognitive or physical disabilities as participants) with the IREB and take the necessary action with respect to informed consent.
- A copy of the consent form must be provided to the person signing the form. For reference, the template of the Consent Form is attached.

3.5.3 Waived from Informed Consent

Renunciation of informed consent completely waives the requirement to obtain informed consent. The IREB may authorize a consent procedure that does not include or modify some or all of the consent requirements, or rescind the prerequisite to obtain informed consent, provided that:

- Research does not involve a risk to subjects
- Relinquishment or alteration shall not adversely affect the rights and welfare of subjects;
- When appropriate, additional relevant details will be available to subjects after they have participated in the study.
- The study could not be carried out without a waiver or modification. Alteration can involve a condensed or deferred consent form.

3.6. Protection of Data:

Researchers are required to have access to a limited volume of personal data for research purposes and to allow the use of personal information only where appropriate. All research needs the security of privacy and confidentiality of the data obtained. Maintaining human data safely with an acceptable degree of secrecy, confidentiality or de-identification is a crucial element in maintaining a minimum risk barrier for subjects, researchers, and the institution. Research initiatives with sensitive data need to provide clear analysis policies regarding privacy and secrecy.

As such, the Principal Investigators (PIs) and their study teams are expected to detail the data management and secrecy protocol for the IREB evaluation submission. The strategy would contain the following:

- Determining who has access to the data
- Specifying who preserves the secrecy of the data
- Explaining steps to protect data protection
- Ensure that all data management and recording systems are secured with a secure password.
- Encrypts all confidential data information on handheld computers.
- Restricting access to recognizable data for members of the study team.
- Ensure that codes, data, and keys are kept in different password-protected/encrypted data and each file is saved in another safe place.
- Ensure that verification and permission are required for those who have access to confidential data by offering firewalls, data encryption, and password protection.

- Create a contingency plan to deal with any infringement of secrecy.

4. Responsibility of Principal Investigator

The Principal Investigator (PI) is solely responsible for ensuring consistency with relevant University IREB policies and practices, academic supervision, and informed consent. The responsibilities of the Principal Investigator include:

- Ensure the participation of appropriately qualified and trained co-investigators, research assistants, and data collectors (if applicable) in the proposal.
- Submit a complete document for review. Provide supplementary documentation as needed by the IREB.
- Ensure appropriate protection of human subjects while conducting research.
- Once the research has been approved by the IREB, the investigator will need to interact with the IREB if there are changes to the study methodology, adverse events (if any) and/or project renewals.

4.1. Project Alternation

If the project changes in such a manner that the themes are handled differently from those specified or defined in the initial plan, the study project amendment form detailing the modifications must be submitted to the IREB for approval. If the adjustment has been accepted, the researcher(s) can continue with the investigation.

A change to a resolution may include a change to the consent form(s). Forms of approval requested for approval with an amendment form, two separate consent forms must be requested:

1. The initial form of consent
2. The proposed updated consent form(s) with all of the improvements listed (boldfaced, shaded, etc.)

4.2. Adversarial Events

Unanticipated complications or severe adverse effects requiring harm to human subjects must be notified promptly to the IREB. Any such incidents must be reported to the IREB using the required Adverse Event Reporting Form.

The IREB will decide if the incident satisfies the requirements. The following incidents match IREB 's concept of "any unexpected issues involving threats to subjects or others" that should be published within a period of 10 days:

- Any incident that occurred unanticipated which posed a new or elevated danger to participants or others and relevant to testing procedures.
- Any unintended or unwanted alteration to an IREB-approved project raises the risk or is likely to recur.

- Any departure from the project taken without proper inspection by the IREB to avoid obvious imminent danger to the study subject.
- Any incident that suggests an unforeseen shift in the risk/benefit ratio of the study.
- Any violation of secrecy that could pose a danger to the subject or others.
- Any issue of a topic that cannot be answered by the researcher.
- Any other occurrence that represents an unanticipated danger.

4.3 Addition or Deletion of Investigator

If investigators are inserted or excluded from the study, the IREB must be told. Submission to a Research Project Alteration type is a prerequisite in such situations. Additional documents can be required from the investigator(s) if considered necessary. The approval of the elimination or attachment of staff or inspectors shall be provided to the principal investigator.

5. IREB Record

The IREB shall establish and maintain sufficient details of the activities of the IREB, including the following:

- Copies of all study proposals/protocols reviewed, scientific findings, if any, underlying proposals, accepted sample consent papers, progress reports from inspectors, and records of accidents (adverse events) to subjects.
- Minutes of meetings of the IREB, which shall be sufficiently informative to signify (a) participation at meetings; (b) the measures are taken by the IREB; (c) the vote on such acts, including the number of representatives voted in favor, opposed and abstaining; (d) the reason for demanding improvements to or disapproving research; and (e) a written description of the conversation
- Records of current evaluation events.
- Copies of communications between the IREB and the investigator.
- A list of IREB members listed by name; received degrees; parliamentary capacity; proof of qualifications such as board certifications, permits, etc, sufficient to explain the intended contributions of each member to the IREB deliberations; and any jobs or other partnership with each member and the institution.
- Statements of important new observations made of subjects by research inspectors.
- The documents provided by this regulation shall be maintained for a duration of at least 3 years after that date. The conclusion of the study and the documents shall be made available for inspection and copying by approved members of the university and/or government regulators.

6. IREB Policy Upgradation

Under the delegated authority of the Vice-Chancellor, the Executive Director, IAR, UIU retains the right to do so. Authority to modify, review and change this policy provision, as necessary, internally and/or external considerations related to the development and application of basic operating procedures for the conscientious conduct of the study in general human subjects. Revised, amended, and/or revised policy statements of the current policy for human subjects research at UIU shall be approved in due process, involving the review of the Academic Council, the Syndicate, and the Board of Trustees. When such approved amendments, revisions and/or updates are made, this policy statement shall reflect the date on which such changes occur. Previous policy announcements are archived for administrative reference but otherwise remain available for research purposes.

Appendix

Appendix-I: "No Review Research" Application Form

SECTION A

Ensure that all IREB guidance is reviewed. The project that is not human subject research should not be submitted for IREB review, with rare exceptions.

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

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

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

2. Possible conflict of interest

Will members of the research team have a 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:

3. Purpose of Research Project

Provide a 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 a 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 a description:

SECTION B

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 □ Revision required	Remarks	
Detail any revisions or additional information required:			
Name of reviewer(s):		Date:	

Appendix II: Exempt Review Application Form

The IREB Reviewer may determine that the proposed activity is human subject research because it meets the human Research definition*, please read the Institutional Research Ethics Board Policy before completing this form to determine whether you should complete this form. An exemption is only awarded where the proposed research meets one or more of the categories mentioned in the Institutional Research Ethics Board Policy.

Completed forms must be submitted to the Institutional Research Ethics Board (IREB) for the final decision regarding exemption**.**

List all Co-Investigators below, including those from other institutions:

Name	Responsibility for Research Project	Designation	University/ School	Email
1.				
2.				
3.				

SECTION A - Project funding, purpose, and research design

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

** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes or generates private identifiable information or identifiable biospecimens.*

2. Possible conflict of interest

Will members of the research team have a 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:

3. Purpose of the Research Project

Provide a 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 a 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 a description:

SECTION B - Exemption Criteria

The proposed research is exempt from the full ethical clearance process based on the following criteria:	
1. The research will be conducted in established or commonly accepted educational settings, involving normal educational 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. The 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. The 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 is 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 is 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 C - 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 a human subject.
Please provide details:

SECTION D

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 Research Ethics Board Policy)	□ TRUE
If there is a 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 IREB It is strongly recommended that teachers do not use their students as subjects in their research, as the 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 IREB 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 agree to a continuing exchange of information with the UIU- Institutional Research Ethics Board (IREB) and to obtain approval before making any changes or additions to the project.	□ TRUE
I agree to report promptly to the IREB all unanticipated problems or serious adverse events involving risk to human subjects.	□ TRUE

SECTION E - 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 UIU, or collaborative institutions.	□ YES □ N/A

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

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

Appendix III: Full Board Ethical Clearance Application Form

The IREB Reviewer may determine that the proposed activity is human subject research because it meets the human Research definition*, please read the Institutional Research Ethics Board Policy before completing this form to determine whether you should complete this form. An exemption is only awarded where the proposed research meets one or more of the categories mentioned in the Institutional Research Ethics Board Policy.

Completed forms must be submitted to the Institutional Research Ethics Board (IREB) for the 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 for Research Project	Designation	University/ School	Email
1.				
2.				
3.				

** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or bio specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio specimens, or (2) obtains, uses, studies, analyzes or generates private identifiable information or identifiable bio specimens.*

SECTION B - Project funding, purpose, and research design

1. Current or planned funding source (internal or external)	
Is project funding applied/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 a 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:

3. Purpose of the 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 a 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 a 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 IREB 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	Illiterate people	□ Yes □ No
Investigators' students	□ Yes □ No	Other UIU member	□ Yes □ No

Please provide details:

2. Risk mitigation

Detail below any possible risk factors for subject involvement, including emotional distress, personal or cultural embarrassment, and 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 the anonymity of the data, especially if audio/video recordings or images will be collected; Specify procedures for data sharing with entities external to UIU; 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 the 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 the 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 the 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 UIU, or collaborative institutions	□ Yes □ N/A
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 UIU IREB and to obtain approval before making any changes or additions to the project.

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

Signature of PI:	Date:

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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
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 IV: Extension Request for Approved Research

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

Research Project #:_____ IREB #_____Date of Approval:_____

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

Date of expiry of IREB approval:

Previously proposed period for the Research Proposal:

Please mention the reason for the 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 V: Research Project Amendment Form

Investigators are required to inform the IREB in writing, of project changes before their initiation**.**

IREB#:_____

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 a copy. Changes must be highlighted.)

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

Additional*

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

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

• Signature:_____

Deletion

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

Deleted individual(s) must sign below

Signature: _____

Signature of Principal Investigator: _____

Date: _____

APPENDIX-VI: Adverse Events Reporting Form

IREB 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 a revised consent form with changes highlighted.

□ No Explain why not:

Explain:

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 VII: Sample Consent Form

Name of the Ethics Committee: IREB-UIU IREB Ref. No.....

Title of the Project Proposal:

Principal Investigator:

Collaborators' Name, Address, Tel. No. & Email:

The proposal was reviewed in a meeting held on (date) at (time). The following members were present.

1. Chairperson

2. Member

3.

4.

5.

6.

7.

8. Member Secretary

The committee resolved to

[ ] Approve - indicating that the proposal is approved as submitted;

[ ] Approve- after clarifications - indicating that the proposal is approved if the clarifications

Requested are provided to the satisfaction of designated committee members;

[ ] Approve after amendment/s - indicating that the proposal is approved subject to the incorporation of the specified amendments verified by designated committee members;

[ ] Defer - indicating that the proposal is not approved as submitted but it can be re-assessed after revision to address the specified reason/s for deferment;

[ ] Disapprove - indicating that the proposal is not approved for the reasons specified*.

Comments:

Date of Approval:

Member Secretary,

IREB, Ethics Committee

Consent Form

Part I- PIS, Part II-ICF

Title of the Project:

Investigators:

Collaborators:

Potential Funding Agency:

PART -I Participant Information Sheet (PIS)

A brief description of the study objectives in simple language.....

.....

Section- A. The following have been explained to me,

1. Purpose of the Study [ ] Explained in Detail

2. Study Procedures [ ]

3. Risk of the Study [ ]

4. Benefits from the Study [ ]

5. Complications [ ]

6. Compensations [ ]

7. Confidentiality [ ]

8. Rights of Participant [ ]

9. Alternatives to Participation in the Study [ ]

10. Any Other [ ]

Name of the Subject/Participant:

Signature of Patient/Guardian of Participant:

Relationship to Participant:

Date:

Investigator's Statement:

I, the undersigned have explained to the parent/guardian in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signature of the Investigator:

Date:

Name of the Investigator:

Signature of the Witness:

Date:

Name of the Witness:

PART-II Informed consent Form (ICF)

The advantages and disadvantages of the research in which I am expected to participate, for which I have to ----------has been explained to me.

I willingly, under no pressure from the researcher agree to take part in this research, and agree to participate in all investigations which will help acquire knowledge for the benefit of mankind, and agree to ----------

My consent is explicitly not for disclosing any personal information. For disclosing any such personal information obtained from the investigations conducted on my samples, further consent should be obtained.

I have been informed that UIU and the researchers (PI ..... and her/his colleagues) will take my prior consent before they draw benefits from research based on my samples.

Signatures

_____	_____	_____
Subject/patient	Witness	Principle Investigator

SAMPLE II

This consent form, a copy of which will be given to you, is only part of the process of informed consent required by the UIU- Institutional Research Ethics Board (IREB) Committee. You are invited to take part in a project called '_____' perspective. The Purpose of this Project is to _____.

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.

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 discussions.

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 '_____' years after publication and then destroyed by shredding and deletion of computer data.

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.

DECLARATION BY THE PARTICIPANT

I have read/ I have been communicated the purpose and other details of the IREB rules and about my voluntary participation in the study. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBED.

Name and Signature of Participant _____

Date _____

DECLARATION BY THE INVESTIGATOR

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consent to participate.

_____ _____

Name and Signature of the Investigator Date of the Interview

Appendix VIII: Types of Risk to Research Subjects

Risk: The probability of harm occurring as a result of participation in 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 an 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 considers private. Another risk associated with the confidentiality of data concerns safeguarding the information that has been given voluntarily by one person to another. The IREB 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 IREB review.

Reference

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9. Accessdata.fda.gov. 2020. *CFR - Code Of Federal Regulations Title 21*. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107