Manual on Institutional Review Boards

BMRC

World Health Organization
Bangladesh

Contents

Background

Bangabandhu Sheikh Mujibur Rahman, the visionary leader and father of the nation, founded the Bangladesh Medical Research Council (BMRC) in 1972 as an independent agency under the Ministry of Health and Family Welfare (MOHFW). The council's goals, norms, and regulations were established by MOHFW resolutions in 1974 and 1976 (1).

The BMRC's mission and vision:

- To identify medical and health-related difficulties and roadblocks, as well as to prioritize research questions based on needs, aims, laws, goals, and policies in the field of health.
- To promote and organize research in a variety of disciplines of health science, as well as training of workforce in health research and the dissemination of research findings for appropriate application.
- To strengthen research facilities for promoting health research throughout the country.

One of the primary roles of the World Health Organization (WHO) is to shape the research agenda by encouraging the development, translation, and dissemination of useful information. New study fields have evolved, which has led to the emergence of new ethical dilemmas. Currently, research ethics is focused on educating researchers about the ethical concepts that underpin legislation, as well as overseeing and reviewing research initiatives.

BMRC is the key organization for all biomedical, behavioral, and social researches in Bangladesh according to a government mandate. It has "National Research Ethics Committee (NREC)" that examines the ethical issues of national research initiatives. This Committee advises the MOHFW on research ethics management in Bangladesh and adjudicates on ethical problems.

In Bangladesh, there are several Institutional Review Boards (IRBs) that review and issue ethical clearance for students/faculties regarding their theses, dissertations, and research projects respectably. However, there are number of issues with the formation/composition and functionality of IRBs. Issues such as insufficient management support, inadequate formal trained staff on research ethics (leading to purely scientific evaluation), lack of proper standard operating procedure (SOP), absence of coordination between IRBs and the BMRC, have been identified as important challenges. As a result, the BMRC has taken initiatives to enhance institutional IRBs with WHO's technical assistance. In light of this, a guidebook for members of the IRBs has been developed in order to ensure a quality and uniform ethical review process.

Chapter 1
Introduction and History of Research Ethics

1.1 Definitions

Moral principles, conventions, and attitudes are all examples of ethics. It is a set of guidelines or regulations that define which behaviors are acceptable and which are not (2).

Bioethics is a branch of philosophy concerned with the social, legal, cultural, epidemiological, and ethical issues that arise in healthcare and life science research (3).

Research ethics establishes guidelines for conducting ethical biomedical research. Furthermore, research ethics educates and supervises researchers to ensure that they maintain a high ethical standard (4).

1.2 Important Research Ethics Milestones

The Nazi physicians carried out the most heinous experiments in the twentieth century. Following World War II, in December 1946, the US military courts have filed criminal proceedings against 23 German doctors and staff for their role in research-related atrocities against humanity. The Nuremberg Code is the result of this tribunal's work.

• The Nuremberg Code defined several regulations for "Permissible Medical Experiments" in 1947 (5).

• In 1948, the United Nations General Assembly adopted the Universal Declaration of Human Rights highlighted concern about the rights of those who have been exposed to involuntary mistreatment (6).

• In 1964, the World Medical Association has developed general principles and specific guidelines for people's use in medical research, known as the Declaration of Helsinki, which has been revised from time to time based on the preliminary efforts of the Council for International Organizations of Medical Sciences (CIOMS) in Helsinki (7).

• The International Covenant on Civil and Political Rights declared in 1966 that "no one should be tortured or subjected to cruel, barbaric, or degrading treatment or punishment" (8).

• The Belmont Report (9) was published in 1979, and it outlines three basic ethical guidelines for engaging human subjects in research:

- Respect for persons
- Beneficence
- Justice

• The "International Ethical Guidelines for Ethical Review in Epidemiological Studies" was published in 1991(10).

• In conjunction with underdeveloped nations, the WHO created the 'CIOMS' in 1993(11).

• In the United States, the Office of Human Research Protections (OHRP) was established in 2000 in response to more widely known ethical violations (12).

• The "Universal Declaration on Bioethics and Human Rights" was adopted in 2005(13).

Chapter 2
Research Involving Human Subjects

2.1 Introduction

Any social science, biological, or epidemiological activity that involves systematic data collection or analysis with the purpose of generating new knowledge involving human participants is considered research with human subjects. People are subjected to investigators' manipulation, intervention, observation, or other forms of engagement, either directly or through changes in their environment. Individuals can be identified through the actions of investigators such as the use of materials, records etc. (14).

Uncertainty emerges with every therapy; this is particularly evident when typical medical regimens depart from a conventional method. However, rather than providing new scientific information, this therapy is intended to benefit the patient. These distinctions are intended to have both practical and moral implications. Even while the individual participant may gain secondarily, most studies focus on the generation of knowledge rather than the advantages to individuals (15).

2.2 Principles of Ethics

The core ethical principles in research aim to maximize potential benefits while minimizing damage to the population.

• It is also critical that all participants in research be valued and treated equally, in accordance with distributive justice principle.

•Furthermore, the individual's well-being must be balanced against the community's and society's overall welfare.

• The CIOMS/WHO Guidelines for Research place a strong priority on the informed consent of people or communities being researched.

• Participants in research studies have the right to be fully informed about the study's goals and outcomes (16).

a. Ethical approach while planning research:

- The goal of the research should be to benefit the community and society as a whole (17).
- The study should have a scientific foundation (18).
- Potential dangers should be considered in a study.

b. Protecting participants' rights:

- Informed Consent
- Maintaining Confidentiality
- Inducement and Compensation
- Ensuring an Equitable Risk and Benefit
- Transparency
- Conflict of Interest
- Responsibility to Community

2.3 Informed consent

The term "informed consent" refers to the process of getting research participants' consent by telling them about the study's precise information. It has three parts: a) information, b) understanding by participants, and c) consent. The investigator must seek informed permission from all potential participants in any study involving humans. The Informed Consent Form (ICF) is the document that is used to get participants' consent. The example of an ICF for an adult person is shown in **Annexure-A**. The information should be presented in a language that the participants can comprehend; for example, for Bangladeshi subjects, the ICF should be written in "Bangla" with an English version. The ICF must be submitted to the IRB together with the research proposal. When assessing the application, the reviewers and committee will pay close attention to the issue of consent (19). In the case of an illiterate person, the investigator must explain the research verbally in the presence of literate and understandable witnesses. In the instance of such verbal permission, a finger stamp is preferred and witness signature is required.

2.3.1 Consent for Incompetent Persons

If a person is unable to offer informed consent, proxy or surrogate permission must be acquired from a legally authorized representative (LAR). The participant/legal guardian must have signed the informed consent form. It is crucial to double-check that all documents are in order. For persons with special needs, such as dyslexia, alternative documentation formats should be made available.

2.3.2 Children

Children aged between 7 years to 17 years require assent along with consent from the parents or legal guardian. **Annexure B** includes an example of an 'Assent' form. Children aged between 0 years to less than 7 years require only parental consent.

2.3.3 Waiver of Informed Consent

Individual agreement is not required in the event of a government-wide poll. For a non-intervention form of research or survey including the whole community, the community's agreement is not required.

2.3.4 Voluntariness

Consent should be freely given. Participants are free to exit the study at any time and without having to justify themselves. No compulsion is allowed. This information must be provided on the consent form. Participants must be given sufficient time to consider whether or not they want to participate, as well as the chance to discuss the study with family and friends.

If participants request that their information be removed, their data will be removed. It will not be able to remove one individual's data from a focus group since what one person says will influence the replies of others. It should be made explicit on the participant information sheet that data cannot be withdrawn in this situation.

2.3.5 Content of an Informed Consent

The following information is required on the Informed Consent Form:

- Introduction of researcher/data collector
- Objective of the research
- Brief methodology
- Why particular subjects are required to take part in this research?
- Duration of participation as well as the date and manner in which samples/records will be destroyed
- Benefits anticipated as a result of the research
- Participation-related risks and discomfort
- Risk-reduction measures need to be specified
- Additional consent is required if personally identifiable information will be utilized for dissemination, such as images, voice, and so on.
- Confidentiality of records
- The investigators will provide medical services if needed
- In the event that a subject is injured, disabled, or dies, there is a provision for compensation.
- Statements stating that the participant has the right to refuse and to withdraw from the research at any moment without any penalty or loss of advantages to which he or she would otherwise be entitled.
- Contact person's name, address, phone and email should be provided.

2.3.6 Privacy/Confidentiality

Confidentiality relates to how information is managed once it has been revealed by a subject (person) with the expectation that it would not be shared. Because disclosing data might cause injury or distress to participants. The investigators must safeguard the confidentiality of study data. The investigator should treat the information in such a manner that no one may be recognized (19).

Extending data-collection technique utilizing internet platform has improved numerous fields of social scientific inquiry during the last decade. Nowadays, web surveys are rather widespread. Web-based research has the potential to be more anonymous than previous data gathering methods. As a result, study participants may have a higher feeling of security and anonymity. The investigator and the subject do not have to contact face to face, worry about being suitably clothed, or even be worried about the investigator's gender, hence numerous key conventional reasons of researcher reactivity are eliminated.

To protect confidentiality, the investigator should take the following steps:

- Code numbers can be used for individual data.
- Remove the core sheets (containing names and addresses of the subject).
- Identifications are not included.
- Prevent unrestricted data access.
- Train associated personnel on the importance of maintaining confidentiality.
- Keeping research documents in secured cabinets.
- Provide digitized records with security codes.
- The investigator must put in place protections to protect the study data's confidentiality.
- If the investigators' ability to safeguard confidentiality is questioned, the subjects should be informed, as well as the potential implications of breaches of confidentiality in the ICF.
- The investigator's duty in a case study is to maintain anonymity by hiding the bulk of the subject's face in a photograph so that the individual cannot be identified.
- During publishing, the results will be kept anonymous. Subjects should be informed that their names will not be published or broadcast in the media.

2.4 Risk-Benefit

- **Risk**

The likelihood of danger or pain as a result of taking part in a research project is referred to as risk. Harm is defined as anything that is detrimental to the participants' well-being. Risk is an unavoidable part of research. Physical, psychological, social, and economic risks all exist. As a result, the IRB will be focused on the participants' safety by maximizing benefits while reducing risks (20).

The likelihood and extent of potential injury might range from minor to serious. A risk is modest, on the other hand, when the likelihood and amount of injury or pain predicted are not more than those faced in everyday life.

- **Benefit**

The term "beneficence" refers to the research's advantages. Once the study is completed, the participants will be eligible for benefits. When developing a hypothesis, beneficence may be difficult to anticipate, particularly in qualitative research (21).

- **Risk/Benefit Assessment**

Judgments, scientific evidence, management, communication, and the monitoring process may all be used to evaluate risk. These elements should be scrutinized by the IRB during the protocol review.

When the consequences of not treating the patient are dire, dangerous therapies with a high risk of injuring the patient are warranted. As a result, the non-maleficence principle is not absolute. It needs to be evaluated against the beneficent concept. Morphine, for example, is a sedative

with a high potential for addiction. Analgesics such as morphine or another type of analgesic is given to dying patients to help them cope with their pain and suffering.

The kind, degree, and quantity of possible dangers, as well as the patient's value system, must all be evaluated. In assessing risk-benefit in research, the IRB should be aware of cultural and religious diversity. The job of risk assessment is significantly more challenging. For example, ethics committees evaluating proportionality of risk and reward in human gene transfer research face severe hurdles since they have no means of known effect in the future. Committees must take decisions, which are often made on a case-by-case basis. The risk-benefit ratio is assessed by the members of the IRB. The procedure should be altered if the hazards exceed the benefits.

2.5 Inducement

The term "inducement" refers to the process of persuading people to take part in a research. The following situations justify providing an incentive to participants (22):

• Inconvenience and time spent by participants may be compensated.

• They should be paid for expenditures spent as a result of their study involvement, and they may also be eligible for free medical treatment. The payments, on the other hand, should not be so big or the medical treatments so comprehensive that potential volunteers are persuaded to participate in studies that oppose their better judgement (undue inducement).

• All payments, refunds, and medical services to study participants must be disclosed in the study application and approved by the IRB.

2.6 Compensation

Participants in research who are physically wounded as a result of their involvement are entitled to financial or other support to sufficiently compensate them for their temporary or permanent impairment or handicap, and surviving dependents are reimbursed in the event of their death.

2.7 Conflict of Interests (COI)

The term "conflict of interest" refers to a situation in which professional judgment or impartiality is influenced for personal gain. The conflict between the rule of requirements and the rule of interest is known as COI. The COI has the potential to taint the research's integrity (23). The COI is unprofessional, unethical, and unlawful. The COI may originate from a variety of sources, including employment, consulting, grants, financial assistance, and conferences.

Advantages of disclosing a conflict of interest:

• Disclosure of COI demonstrates conformity with the protocol and adheres to the ideal of transparency.

• The COI is disclosed to readers so that they can assess the procedure in light of the COI. If the investigators are not forthcoming about their industry affiliations, the presentation/publication must be dishonest as well. Making a COI public enhances transparency and public confidence.

How to handle conflict of interest?

When examining various sorts of submissions or research, many reviewers, researchers, and writers experience these kinds of conflicts.

• If there is a conflict of interest, the authorities should be informed.

• It is ethical to disclose the COI in order to guarantee that the research's quality is not jeopardized.

• Providing training on COI to help employees understand what conflicts of interest are and to remind them of their responsibility to recognize particular situations that could result in a conflict of interest.

• The IRB should have a documented policy on how to handle COI that may be updated if necessary.

• On a case-by-case basis, the term "conflict of interest" should be operated.

2.8 Vulnerable Group

People who are unable to preserve their rights and wellbeing are said to be vulnerable. Research that focuses on a vulnerable group will be scrutinized more closely than non-vulnerable groups. This extra examination ensures that people are not being forced to participate and that the consent should be a culturally accepted technique. It is also important to remember that vulnerability must be assessed in the context of the protocol in question; not all groups are vulnerable in all situations. (24).

- Pregnant women,
- Children,
- The elderly,
- Imprisoned people/refugees
- Mentally sick people
- Critically ill people
- Dying patients
- Learning difficulties
- Sedated patients
- Unconscious persons, etc.
- HIV-positive
- Economically or educationally disadvantaged individuals and groups, etc.

Vulnerable Groups Receive Special Attention

It may be possible to try to guarantee that persons or groups asked to participate in research are chosen in such a manner that the costs and benefits of the study are divided equitably (24).

a) In genetic research, racial equality should be preserved. Economically or socially disadvantaged people should not be employed in study if there are those who are better off.
b) Mentally challenged and mentally differently able people who are unable to provide informed consent or who have behavioral problems must have their rights and welfare

safeguarded. After the subject has been fully told about the research, appropriate proxy permission from the legal guardian should be obtained. The permission procedure as a whole should be meticulously recorded.
c) Particular care should be taken when engaging participants with limited autonomy, such as prisoners, students, subordinates, workers, and service people, since the consent given may be in jeopardy or for other compelling reasons that need acceptable explanation.

2.9 Genetic Research in Human Populations

Human genetics and genomics are fast becoming fascinating scientific fields. Specific genetic abnormalities detected may suggest higher vulnerability to/or forecast the emergence of illnesses such as cancer and metabolic syndrome. It is critical to recognize that the usage of cutting-edge gene-based technologies should be unrestricted to better understand hereditary aspects connected to health that are helpful, but that there should be grave ethical implications for people, their families, and the environment. As a result, IRB members should carefully examine the methodology for human genetics and genomics research (25,26).
Medical science may benefit from research using biological samples from juvenile biobanks. Genetic cohort studies, for example, may give insight on the interplay of genes and environment and aid in the understanding of disorders including asthma, food intolerances, autism, and attention deficit hyperactivity disorder. Additionally, illness-specific collections could help researchers better understand how gene variations affect disease progression. Sample collections and extracted DNA may often be preserved for extended periods of time, and study on them can evolve over time (27).

Normally there is no direct advantage from Biobank. Direct benefit is never the main goal of pediatric biobank research, and the majority of the children who participate in pediatric biobank research may never realize any health advantages as a result of their participation. The dangers of using preserved tissue samples for research are smaller than those of clinical trials.

2.10 Plagiarism

Plagiarism is the act of taking the words, ideas, creative works or research of another person and claiming them as one's own without giving credits. It is an intellectual theft and a clear violation of the code of ethics. Following are some examples of plagiarism:

- Copying part or all of another person's research
- Copying paragraphs or sentences directly from texts or the internet without enclosing them in quotation marks
- Using concepts or developed ideas, even if paraphrased or summarized, from another person, from texts or the internet without acknowledging the source

The IRB members should check plagiarism when review a research project. They should not permit plagiarized research projects. They should encourage researchers to give due credit to another person's work by giving references.

Plagiarism is a significant kind of scientific malpractice. Plagiarism is a crime that is penalized under the law. Apology letters, retraction of the published work, and, in the worst-case situation, criminal proceedings and the confiscation of the writers' degrees are all options. Plagiarism is common among academics since they are unsure of what constitutes plagiarism and how to prevent it (28).

Chapter 3
Intervention Studies

3.1 Introduction

There are two types of intervention studies: therapeutic/clinical and preventative. Patients participate in therapeutic (or secondary preventive) studies. A preventive (or primary prevention) study assesses whether a drug or treatment decreases the chance of acquiring illness in people who are healthy at the time of recruitment. As a result, preventative trials may be undertaken on healthy people who are at a normal risk of getting a disease or on people who have already been diagnosed as having a high risk of developing a disease.

A therapeutic/clinical trial is a controlled investigation of a novel drug(s) or technology in a human subject to establish its safety and/or effectiveness. To assure safety, enough data generated from animal research must be available before undertaking a human trial. Its purpose is to assess the safety and efficacy of novel medications and formulations in a prospective manner.

The trial should be carried out only when the medicine has been approved by the Directorate General of Drug Administration (DGDA). Regardless of whether the medicine was produced in Bangladesh or elsewhere, or if clinical trials were conducted in Bangladesh or not, all of the guiding principles should be followed. On a case-by-case basis, the toxicological and clinical data requirements for expediting pharmaceutical development for life-threatening illnesses or diseases of particular concern in Bangladesh will be defined. In such instances, the Licensing Authority, i.e. the DGDA, rather than the NREC, has the authority to abbreviate, delay, or omit studies. Good Clinical Practices (GCP) principles based on national and international standards give operating ideas for the moral and medical requirements for establishing a protocol, as well as the conduct, recording, and reporting techniques that must be properly followed to conduct a study (29,30).

3.1.1 Phases of Clinical Trial

Clinical studies are divided into five stages (Phase 0, I, II, III & IV).

The five phases are:

- Phase 0: Pharmacodynamics and Pharmacokinetics in humans: Phase 0 trials are optional first-in-human trials. Single sub therapeutic doses of the study drug or treatment are given to a small number of subjects (typically 10 to 15) to gather preliminary data on the agent's pharmacodynamics (what the drug does to the body) and pharmacokinetics (what the body does to the drugs). For a test drug, the absorption, distribution, metabolism, and removal (excretion) of the drug, and the drug's interactions within the body, to confirm that these appear to be as expected.

- Phase I: Human Pharmacology

- Phase II: Therapeutic Exploratory Trials
- Phase III: Therapeutic Confirmatory Trials
- Phase IV: Therapeutic Use Trials

All clinical trials on new drugs or molecules or devices including bio-equivalence and bio-similar studies should be approved by NREC. This, however, can be accomplished by statutory institutes/organizations such as BSMMU, BCPS, and icddr, b. Necessary approval from DGDA should be uniformly applicable for all these items. Simple interventional studies such as health educational interventions, psychological interventions, community interventions, treatment regimens using DGDA approved drugs, and students' theses/dissertations on small scale clinical trials can be approved by the IRBs. The NREC will follow the ethical guideline of BMRC. The NREC will continue oversee reviewing ethical aspects of clinical studies including non-registered medicinal compounds/devices, new indications for already-registered medicinal substances and all foreign funded clinical trials.

3.1.2 Preventive trial

Clinical trials are almost generally done on people, but preventative trials may be undertaken on either individual (as in the Francis field trial of the polio vaccine) or whole populations (as in the Newburgh- Kingston dental carries study).

3.2 Data and Safety Monitoring Board (DSMB)

The DSMB is an independent panel of experts who evaluate trial data at regular intervals to track progress and provide recommendations to the IRB, sponsor/PI, and trial investigators on whether to continue, change, or cancel the study for safety or ethical reasons.

3.2.1 Composition

The kind of trial and the degree of expertise necessary define the size of a DSMB. A DSMB is made up of at least three members (with an odd number allowing for a definitive decision in case a vote is required). Members of DSMBs often have scientific knowledge of the disease/patient population under investigation, as well as practical expertise and skill in current clinical trial conduct and technique, and one or more epidemiologists and statisticians. (31).

3.2.2 Principal Responsibilities

• Conduct frequent reviews and analyses of the obtained research data for participant safety, study conduct and progress, and efficacy, if necessary.

• Make recommendations to the IRB and/or sponsor/PI on whether the trial experiment should be continued, modified, or terminated.

3.2.3 Terms of Reference (ToR)

Before implementing a procedure, the DSMB should assess each procedure for any substantial flaws in the study. Throughout the study, the DSMB should review the trial's safety, conduct,

scientific validity, and integrity by analysing cumulative trial data. Members of the DSMB must be satisfied that the data submitted for review is timely, thorough, and accurate enough to assess the safety and well-being of study participants. The DSMB should assess the overall study operations as well as any other relevant problems as appropriate. The DSMB's recommendations are sent directly to the IRB Chairperson (31).

Items reviewed by the DSMB include:

- Interim/cumulative data to look for evidence of adverse events related to the study;
- If applicable, interim/cumulative data for evidence of efficacy in accordance with pre-established statistical parameters;
- Data completeness, accuracy, and timeliness;
- Each site’s performance;
- Factors that could have an impact on the study's outcome or jeopardize the trial's data confidentiality, such as protocol violations, unmasking, and so on.

Chapter 4

Institutional Review Board

4.1 Research Ethics Committees

Depending on country or institutions, research ethics committees are known as Institutional Review Boards (IRBs), Institutional Ethical Review Boards (IERBs), Institutional Ethics Committees (IECs), Independent Ethics Committees (IECs), Ethics Review Boards (ERBs), or Research Ethics Boards (REBs). Except for the NREC of the BMRC, all institutional ethics committees in Bangladesh shall be referred to as IRBs in this document. The IRB is a committee that approves, monitors, and reviews human biomedical, behavioral and psychosocial researches. An IRB's two defining characteristics are competence and independence (29).

4.2 Importance of IRB

1. The IRB oversees the process in order to safeguard and manage the least risk to human participants in research.
2. It examines procedure in order to ensure the safety and well-being of human subjects.
3. It guarantees that the ethical ideals and concepts that underpin research are followed.
4. It ensures that only ethically and scientifically sound research is carried out.
5. It lessens the public's worries regarding the appropriate carrying out research.
6. It safeguards the participants' privacy.
7. It safeguards the research such that the benefits are maximized while the risks to the participants and society are reduced.
8. It protects children' right to informed consent or assent, as well as incompetents' right to surrogate consent.
9. The IRB provides specific protection to some vulnerable groups, such as prisoners, children, and the elderly.

4.3 Challenges of IRB

1. Reviewing a protocol is itself a lengthy process, and consumes a substantial time of reviewers and the team that manages the approval process.

2. Many IRBs are overburdened, under-skilled, and subjected to a variety of skepticism to provide decision timely.

3. Many IRBs lack the resources and relevant experts to accomplish the task.

4. Issues in establishment, composition, and operating challenges

5. Training for key personnel on protection of human subjects is lacking.

6. Not all IRB members receive the same level of research ethics training and understanding.

7. There are many unanswered concerns about how IRBs understand and react to problems regarding researches supported by the private sector specifically industry.

8. Issues with data integrity, auditing, and quality assurance.

9. Independence of the IRB members are jeopardized occasionally because blinding in strict sense may not be feasible

4.4 Formation of IRB

The committee will have an odd number of members.

1. There must be at least five members on the committee. The committee should not be very big for its operational simplicity.

2. There must be adequate experience, knowledge, and variety among the members to make an educated judgment.

3. A chairman will be appointed to the committee.

4. There must be men and women on the committee.

5. The committee should be interdisciplinary and cross-sectoral.

6. The committee should include both scientific and non-scientific specialists, such as a lawyer, a religious expert, and laypeople.

7. According to international law, a layperson must be present. Quorum is defined as the presence of a majority of members at a meeting.

8. At least one person (if it is a five-member committee) who is not linked with the institution must be a member of the IRB. For bigger committees, at least 40% of the members should be external to the institute/organization.

9. In order to achieve standards for competence or diversity, the IRB may consult with outside experts.

10. The IRB members must not vote on their own projects. All other IRB members are eligible to vote. The presence of more than half of the board members is required to vote on a proposal, and a non-scientist must be present as well.

4.5 Terms of Reference (ToR) of IRB:

The IRB is an impartial body that reviews, evaluates, approves, and monitors the scientific and ethical elements of researches, as well as determining the research participants' risk-benefit ratio. Its scope pertaining to interventional studies have already mentioned under section 3.1.1.

1. Its primary goal is to safeguard the rights, safety, and well-being of the trial participants.
2. The study proposal will be reviewed and classified based on the level of risk involved, with exemption from review, expedited review, and full review being the options.
3. Members are expected to preserve tight secrecy.
4. Minutes of meetings, as well as any supporting paperwork, must be retained.
5. Maintain audit if it is necessary.

6. At least once a year, each continuing protocol should undergo a continual evaluation.
7. If applicable, the IRB must collect the following clinical research documents:

- Trial protocols and revisions, written informed consent forms, and consent forms that the investigator recommends for use
- If the IRB believes that the extra information adds material to the protection of the subjects' rights, safety, and/or welfare, the IRB may seek it. The IRB must evaluate that the proposed method and/or accompanying documentation appropriately address the appropriate ethical objections and meet the applicable regulatory criteria of the trial in the case of a non-medical trial.
- This should involve an evaluation of the remuneration amount and manner to ensure that there are no issues of coercion or negative impacts on the trial volunteers.

IRB Submission Format

For submitting research procedures, the IRB should have its own format which is included in **Annexure C**.

4.6 Review process of a protocol by IRB

- The protocol can be sent to one or two primary reviewers for expert opinion.
- The review summary will be delivered online first, followed by a printed copy to the IRB chairman.
- During the meeting, a member of the IRB will present the protocol.
- The majority of IRB members must be in consensus on a research project proposal before the IRB decide.

4.6.1 Criteria for Review and Approval of Protocol Submitted in IRB

1. The IRB must assess the "respect for persons," "beneficence," and "justice," before reviewing and approving a protocol.
2. The primary principle is to respect others. The IRB will examine whether the participants' permission is voluntary and that they have been fully and completely informed, as well as if their privacy and confidentiality are safeguarded.
3. The principle of beneficence is the second. The potential advantages to the individual or society justify the hazards of study, and if those risks are minimized, the risks are justified.
4. The third principle is justice. The equal allocation of risks and rewards among participants will be judged by the IRB. A segment of the population should not bear all of the risks and earn all of the rewards.
5. Members will assess the ethical implications of a given research project.
6. A planned clinical study (if applicable) and documents must be reviewed by the IRB within a reasonable time frame.

7. According to the International Conference on Harmonization of Good Clinical Practice, an IRB must defend the rights, safety, and well-being of all study participants (ICH- GCP).
8. The investigator's credentials for the proposed study will be evaluated by the IRB, which will include a recent curriculum vitae and any other relevant material required by the IRB.
9. Additional information to the proposed procedure, such as other regulatory needs, will be overseen by the IRB.
10. Both the amount and manner of payment, as well as the payment schedule for studies, will be reviewed by the IRB. Payment to a subject should be prorated and not entirely reliant on the subject's successful completion of the study The IRB should make sure that the written informed consent form and protocol include all of the necessary information.
11. The IRB will examine the budget to see whether it is representative.
12. The IRB will be in charge of the technical aspects of the study, such as methodology, statistics, and so on. If the research approach is ineffective, it is likewise ineffective morally.
13. The IRB will review the research instruments, such as questionnaires, checklists, and guidelines.
14. The IRB will check plagiarism of the research protocol.

4.6.2 When a project proposal is exempted from IRB review

Participants in exempted research are exposed to nearly no risk. Some projects are exempt from IRB review because they represent no or very low risk to human participants. The IRB chairperson and member secretary shall determine suitability of protocols for such exemptions. The following categories will be exempted from review:

1. Instructional techniques for normal and special education (curricula or classroom management methods)
2. A study of the efficacy of various educational strategies
3. Research employing educational exams (cognitive, diagnostic, ability, accomplishment), survey techniques, interview procedures, or public behavior observation, unless the following conditions are met:

3.1 The information obtained is recorded in such a way that human participants can be identified, either directly or through identifiers linked to the participants; and

3.2 Any outside exposure of the human participants' responses could expose them to criminal or legal liability, as well as jeopardize their financial standing, employability, or reputation.

4. If the investigator can access the data, documents, records, pathology specimens, or diagnostic specimens, or if the information is recorded in such a way that participants cannot be identified, either directly or through identifiers linked to participants.

5. Research and demonstration projects that are carried out by or with the permission of department or agency heads and are designed to explore, assess, or investigate:

5.1 public benefit or service programs;

5.2 application procedures for benefits or services under those programs;

5.3 proposed changes or alternatives to those programs or procedures; or

5.4 possible changes in payment methods or amounts for benefits or services delivered under those programs.

6. Consumer acceptability studies, and evaluations of taste and food quality, for example, if wholesale foods without additives are consumed.

4.7 Standard Operating Procedures (SOP)

What is the IRB's Standard Operating Procedure (SOP)?

The purpose of an IRB standard operating procedure (SOP) is to provide the institution's standard approach to the interpretation of the evaluation and approval process of research protocols by the IRB in accordance with best practices, local laws, and international standards. The SOP describes the IRB review and approval process, administration, and function in terms of policies, procedures, regulations, and legislation. The SOP is a reference document for IRB members, IRB Office personnel, research investigators, and prospective study participants.

The SOP's Objectives

The SOP's goals are to improve efficiency, output quality, and performance consistency while eliminating misunderstanding and failure to follow IRB regulations and procedures.

The IRB's mandate

• The Institutional Review Board (IRB) is an independent administrative body established to conduct a critical and rigorous review of research protocols to be conducted under the auspices of that Institution, either by its scientists or by investigators from collaborative institutions from within and outside the country, in order to ensure the technical and scientific soundness of these research protocols.

• To make the best possible use of available funding, personnel resources, and field locations while doing research.

• To supervise and monitor the application of research protocols in order to assure the validity of research protocols performed under the institution's auspices.

Any organization's IRB is only allowed to examine research protocols from its own institutes. But if an institute has no IRB, they can take ethical approval of their protocols from a nearby IRB. Only NREC has the authority to examine any protocol from any institution, whether collaborative or not.

REVIEW CRITERIA FOR UNDERTAKING

Technical and scientific soundness:

• Whether the research protocol's title is appropriate.

• Whether the protocol application format has been filled in correctly.

• The research questions are appropriate in the context of the institution's strategic priority.

• A summary of the project.

• The validity of the hypothesis to be investigated.

• Does the theory that will be examined have a complete explanation?

• The study goals and/or research questions are sound and acceptable for testing the hypothesis.

• The background and introduction, including the rationale for the current research protocol, a critical assessment of existing information, and the knowledge gaps that the research protocol aims to address.

• Dignity, respect, beneficence, justice, rights, and the amount of danger to research participants are among the essential ethical concepts.

• The thoroughness of the literature review.

• Has the study's logic and importance been clearly explained?

• All research procedures must be reviewed by the IRB for scientific and technological soundness, since any unethical study on people is inherently unethical.

• Free from plagiarism.

Design of the Study

• Is the research approach adequately described? Appropriateness of study site(s), suitability of suggested research design and methodologies, and appropriateness of participant kinds and procedures.

• The suitability of the study plan, which outlines the explicit, quantifiable goals and procedures for achieving them.

• Have the methods for participant recruiting, inclusion and exclusion criteria, enrolling, and follow-up been outlined clearly?

• Study design that is inclusive (adequacy of plans to include all genders, and children as appropriate for the scientific goals of the research). If the conditions have not been met, has sufficient reason been provided?

• Is there an operational specification of the procedures to be employed in the study protocol?

• Has an ideal sample size been provided to assure the study's validity, the applicability of the sample size calculation method, and the accuracy of the computation?

• The approach for sampling is sound. Have appropriate arguments been offered for supplying placebo if the study procedure expects to utilize a control arm? Have you explained the laboratory procedure(s) in detail?

• Data collecting methods List that can be changed. Plan for analysis, including statistical procedures that are applicable. When acronyms are used for the first time in protocol language, are they defined?

• Have you included any research instruments (questionnaires, checklists, instructions, etc.) that will be utilized in the study protocol? If so, are they in accordance with the study protocol?

• Adequacy of Data Safety Monitoring Board (in situations of research procedures that fit the criteria of Randomized Clinical Trials) (RCT).

• A list of references.

Activities of IRB Officials

• The primary responsibility of the IRB Officials is to assist the IRBs in the evaluation and approval of research protocols involving human involvement, as well as to arrange for approval letters when all approval procedures have been completed;

• Ensure effective organization of IRB meetings and maintain communication with the institution's chairpersons, members, PIs, and investigators, briefing new scientists, outlining general research methods and approval processes;

• Prepare agenda-specific notices for IRB meetings, Data and Safety Monitoring Boards (DSMBs), and Audit-Monitoring Committee meetings, and distribute them to all committee members on time (in hard copy and online);

• Prepare minutes of all committee meetings; make all office correspondence for PIs containing committee's recommendations based on the minutes of the meetings, selecting appropriate primary reviewers among the members of respective committees for review of the research and assign protocol for review and comments as primary reviewer at least 8-10 days prior to the meeting day.

Approval Process Types

1. Review procedure without approval (exempt); research initiatives pose no or extremely minimal risk to human participants. (Please see section 4.6.2).
2. Review procedure that is expedited: (Outbreak investigation, Pilot Study, Secondary Analysis, Student protocol, Formative research, Observational study, Short Surveys etc.)
3. Full Committee Review Process.

Informed Consent Forms are available in a variety of formats

1. Parental Consent Form (for children aged 0 to 7 years)
2. Children's Assent Form (7–17 years old) and parental consent form
3. Adult Consent Form (18 years and above)

Chapter 5

Registration of IRB

5.1 Registration

All IRBs in Bangladesh must be registered with the BMRC, according to the BMRC's current guidelines (32, 33).

The registration procedure is outlined below:

1. The first step in enrolling for an IRB is to get a submission number.

2. To get a submission number, submit a request to the BMRC using the Electronic Submission System (ESS).

3. A valid official email address and password are required for the submission of the request and must be generated.

3. After the request has been completed, the system will provide an automatic e-mail answer with a unique submission number. It is not recommended to make several requests for the submission number from the same organization.

4. If they do not get the automatically produced e-mail, they should contact BMRC for help at the same postal address or by phone (+8802-222298396, +8802-222299311) during office hours (9 a.m. to 5 p.m.) and explain the situation.

5. Any institution that receives a submission number will have that number valid for 60 days.

6. To continue, the following information must be supplied using the Electronic Submission System (ESS) after obtaining the submission number:

A. Information about Institution:

1) *Institution or Organization's name: _____*
2) *Type of Institution/ Organization:*
   a) *National institution*
   b) *International organization*
   c) *Private organization*
   d) *NGO*
   e) *Educational institution (University, medical college etc.)*
   f) *Research institution*
   g) *Other (please specify…)*
3) *Address:……*
   ……..
   a) *Phone: _____*
   b) *E-mail: _____*
   c) *Fax: _____*

B. Contact person providing this registration information:

1) *Name: _____*
2) *Educational qualification: _____*
3) *Title or position: _____*

4) *Name of institution or organization (if different from the name in section A):* _____

5) *Address: ……..*

……..

a) Phone: _____

b) E-mail: _____

c) Fax: _____

7. Please submit the following documents to the relevant field of the electronic submission system (ESS). Registered facilities may provide color-scanned copies of the following documents

a) All full-time / part-time members who manage the IRB must provide personal information (name, gender, nationality, education level, complete contact information, etc.). The IRB requires at least five members (one lawyer and at least one member, preferably a non-institutional member, and at least one female member). The committee should include members from different disciplines so that they can consider ideas from different disciplines. Changes in committee members should be reflected in the registration process as soon as possible.

The table below may be used (an extra row can be added):

Sl no.	Name of members	Designation	Gender M/F	Educational Qualification	Scientific (S) Or Non-Scientific (N)	Affiliation with Institution Y/N	Duration	Comments
1.								
2.								
3.								
4.								
5.								
6.	Duration of the Committee			……..				

a) The application must include the IRB's Standard Operating Procedures (SOP).

b) The IRBs should report formally to the BMRC annually.

c) The following people will be contacted by email after registering:

i. The Chief Executive/Institutional head of the organization.

ii. The organization's contact person/assigned Officer.

iii. The Chairperson of the IRB.

d) After obtaining registration number, an IRB must be renewed its registration every five years and any updates of IRB must be submitted to the online platform of BMRC on a regular basis.

Here is a summary of the entire registration process:

1. Using a valid official email address and password, submit a request for a number to BMRC through ESS.

2. Each automated e-mail response is granted a unique submission number (valid for 60 days).

3. If the email does not arrive, contact BMRC for assistance during office hours (9 am- 5 pm) at the same postal address or by phone (+8802-222298396, +8802-222299311).

4. To submit required documentation, use electronic submission system (ESS).

5. Registration will be provided within one month after evaluation.

6. An IRB must be renewed its registration every five years and any updates of IRB must be submitted to the online platform of BMRC on a regular basis.

5.2 Reporting

To ensure that the IRBs are executing their tasks appropriately, they must submit their formal report to BMRC annually, and the annual reporting format is provided in **Annexure-D.** However, the approved protocols should be updated in to the online platform of BMRC with fifteen days of the approval. In addition, if any unforeseen problems occur, such as dangers to subjects or others, noncompliance, or the suspension or termination of any of their allowed processes, IRBs should notify BMRC as soon as possible (see **Annexure-E**).

5.3 Training

Members of the IRB should be encouraged to keep up to date on all national and international advances in ethics by attending orientation courses on relevant topics offered by regular training from the BMRC. The goals and contents of the training curriculum are listed in **Annexure-F**. The training modules are the IRB Manual's 5 (five) chapters.

5.4 Coordination Cell

The NREC of the BMRC and IRBs must work together to ensure the rights, benefits, and dignity of human subjects by eliminating and managing duplication of research across the board. In this case, a coordination cell (CC) might be used to supervise the registration status, monitor the functioning of IRBs, and evaluate the IRBs' reporting mechanisms to the BMRC. The Chair, Co-Chair, and one member from each of BMRC and NREC will make up the CC's nine members.

• The NREC's Chairperson will also be the coordination cell's chairperson.

• Director BMRC will serve as co-chair.

• BMRC will appoint an IRB specialist as a member of the CC.

• Three members will be chosen in rotation from three different IRBs: 1. one member will come from a university's IRB. 2. One should come from the IRB of a medical college. 3. a representative of a national or international research group or institution. These three members will be chosen based on seniority, length of experience, knowledge, the appropriate discipline for the CC, and, of course, academic credentials, which will be solicited from all IRBs. These three individuals will serve on the CC on behalf of all IRBs, not as representatives of their own organizations, if the BMRC appoints them to the CC. Once these three IRB members have served the CC for three years, the BMRC will select their successor from the same capacity (universities, medical colleges, and national or international research institutions/organizations). The CVs of potential members will be requested in order to select their replacement, and will be evaluated based on seniority, length of experience, knowledge, required discipline, and, of course, academic credentials.

- The CC may also include WHO research focal point as a member.

The following is the structure of the projected CC:

No	Position	Institution Name
1	Chair	Chair of NREC
2	Co-Chair	Director BMRC
3	Member	NREC
4	Member	BMRC
5	Member	IRB Specialist
6	Member	TBD (from a university IRB)
7	Member	TBD (from a medical college IRB)
8	Member	TBD (from a national or international research institution/organization's IRB)
9	Member	WHO research focal point

5.4.1 Activities of the Cell:

1. The CC usually meets every six months. If necessary, an extraordinary meeting may be called at any moment. The meeting agenda will be examined, and information from the monitoring checklist will be gathered to detect any gaps, deviations, or violations, as well as give advice and recommendations to the respective IRB.

2. To guarantee that IRBs have their own SOPs, to evaluate standard operating procedures of each IRB on a rotating basis and give technical assistance for further refinement, as needed, and to ensure that IRB functions are supported by applicable legislation authorized by the NREC.

3. To offer technical assistance, including the development of adherence monitoring tools for IRBs so that they can follow the SOPs. To provide technical help, such as the creation of adherence monitoring tools for IRBs so that they can comply to the SOPs.

4. To guarantee that every research endeavor has a standard operating procedure for handling biological material.

5. To use the monitoring checklist on a regular basis.

6. To keep a database with information on every submitted study protocol in Bangladesh (both approved and rejected), the completion date of each research, the status of the research, each research collaborative partner institution (both national and international), and funding agencies for submitted proposals (both national and international), each journal publication, technical report, and conference presentation based on an authorized study in Bangladesh should be entered into a database.

7. To examine and exchange information with the respective IRB, to determine whether any study is duplicated, and to give required assistance.

8. The CC shall maintain contact with foreign IRBs to exchange information on new rules, regulations, and laws (both national and international) that will help to standardize research ethical standards, as well as with Bangladesh's NREC/IRBs.

9. To guarantee that the results of any of the permitted research resulted in patent ownership, the CC will give technical help to IRBs in order to keep them up to date with international rules. If that is the case, which institution will own the patent and who has the right to use it?

5.4.2 Checklist for the Coordination Cell:

The CC is encouraged to use the following checklist to follow up with IRBs about registration, monitoring, and reporting:

1. IRB Information		
1.1	Name of Institution	
1.2	Type of Institution	
1.3	The IRB’s responsible person's name, title, and contact information	
1.4	Date	

2. Registration		
2.1	Is there a registration number for the IRB?	☐ Yes ☐No
2.2	Did they submit an online registration application to BMRC?	☐ Yes ☐No
2.3	Did information such as name, postal address, and so on were provided from the desk of the head of the IRB institution?	☐ Yes ☐No
2.4	Did the IRB inform the BMRC the name, postal address, phone number, fax number, and e-mail address of the individual who provided the registration information?	☐ Yes ☐No
2.5	Did the IRB inform the BMRC the name, phone number, and e-mail address of the IRB chairperson?	☐ Yes ☐No
2.6	Is the IRB's web information updated on a regular basis?	☐ Yes ☐No
3. Monitoring		
3.1	Is there a documented informed consent form that the principal investigator submitted to the IRB?	☐ Yes ☐No
3.2	Does the IRB follow the SOP approved by the BMRC?	☐ Yes ☐No
3.3	Does the IRB monitor any unanticipated increase in serious adverse events?	● Yes ☐No
3.4	Does the IRB aware of any subject complaints received at the site and how they handle the situation?	☐ Yes ☐No
3.5	Do they have the ability to keep track of the progress of research at multiple sites?	☐ Yes ☐No
3.6	Do they have a minimum of 5 members on the IRB?	☐ Yes ☐No
3.7	Are there any members of the IRB who have a conflict of interest?	☐ Yes ☐No
3.8	Is the IRB planning a surprise audit of its authorized research procedures to see whether studies are being executed according to the approved protocol?	☐ Yes ☐No
3.9	If a deviation or violation is discovered, has any remedial action been taken to rectify the situation?	☐ Yes ☐No
3.10	Has the IRB any external independent reviewer?	☐ Yes ☐No

3.11	Does the IRB ensure that all investigators have valid ethics certificate from the authorized organization?	☐ Yes ☐No
3.12	Do the researchers/organizations have the capacity to keep site-specific information in a clearly labeled set of IRB documents (e.g., filled-in/collected study tools/questionnaires, and other study-specific materials)?	☐ Yes ☐No
3.13	Is it possible for the researchers and/or their organizations to keep biological specimens for long-term storage and future use?	☐ Yes ☐No
3.14	a) Do the researchers get IRB clearance for storing biological specimens/samples for a long time? c) If so, for how long will it be?	☐ Yes ☐No _____ Years.
3.15	Are all research projects subjected to a critical examination and scientific and technical evaluation?	☐ Yes ☐No
3.16	Does the IRB keep minutes of IRB meetings, including attendance of IRB members?	☐ Yes ☐No
3.17	Are copies of all correspondences between the IRB and the investigators kept on file?	☐ Yes ☐No
3.18	Do they preserve submitted research protocols electronically?	☐ Yes ☐No
3.19	Is the submission of research protocol entirely electronic?	☐ Yes ☐No
3.20	How long do the IRB preserve submitted research protocols from the date of submission?	_____ Years.
3.21	Does the IRB maintain a quorum for approving each protocol?	☐ Yes ☐No
3.22	How often does the IRB meet its routine meetings?	……..
3.23	Does any research protocol use animals as study subjects?	☐ Yes ☐No
4. Reporting		
4.1	Does the IRB report formally about their official activities to BMRC annually?	☐ Yes ☐No
4.2	Does the IRB update information of their approved protocols in to the online platform of BMRC within fifteen days of the approval?	☐ Yes ☐No
4.3	Is the IRB required to disclose each significant unforeseen incident of the human experiment to the BMRC within one week?	☐ Yes ☐No
4.4	Does the IRB notify BMRC of a major unexpected occurrence and arrange an emergency meeting?	☐ Yes ☐No
4.5	Does the IRB report about the sudden changes in its Ethical Committee?	☐ Yes ☐No

4.6	Does the IRB notify BMRC if there is any non-compliance in the study?	☐ Yes ☐No
4.7	Does the IRB notify BMRC within 30 days of any suspension or termination of IRB approval?	☐ Yes ☐No
4.8	Does the IRB report to the BMRC if any member deviates or violates SOP?	☐ Yes ☐No
4.9	Do they ensure that each study team member has received up-to-date 'Human Subjects Research Training'?	☐ Yes ☐No

Review & monitoring of IRB application		
5.1	Name of the IRB	_ _ _ _
5.2	Registration number of the IRB	_ _ _ _
5.3	Formation of the IRB	☐ Adequate ☐Not adequate
5.4	SOP	☐ Yes ☐No
5.5	Reporting mechanism	☐ Yes ☐No
5.6	Does the IRB update its information regularly?	☐ Yes ☐No
5.7	Does the IRB report to BMRC about its decision to disband a registered IRB that has been in operation for more than 30 days?	☐ Yes ☐No

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Annexures

Annexure A: Example of an Informed Consent for Adult

I, Dr..... Principal Investigator and Assistant Professor, ..., Dhaka, respectfully invite you to take part in this research.

The purpose of this research is to explore the relationship between psychological stress and its associated factors with wellbeing of students during COVID-19 at the Dhaka Medical College.

Participants: The study population will consist of undergraduate and postgraduate students from various departments of the Dhaka Medical College. This research will begin on 16 January 2021 and ends on 30 June 2021. The method of data collection will be an online and offline survey by a questionnaire. The period of data collection will be 30 minutes only.

Potential advantages: Although there is no direct reward to the participants, the outcome may be useful to future students. The findings will aid in reducing the problems and anxiety-related disorders that students face as a consequence of the epidemic.

Risks, dangers, and discomforts: The researchers will gather data using the Internet, so there will be no risks, hazards, or discomforts for the participants. Physical distances and health restrictions will be rigorously adhered to during in-person surveys. The participants' permission will be obtained prior to data collection. There will be no monetary reward for participating in this research.

Confidentiality: The information gathered throughout the study will only be used for research purposes. During and after data collection, full confidentiality will be maintained. The data will be saved in a password-protected folder. The participants' identities will not be revealed in the study report.

Right to withdraw from the study: Participants have the right to withdraw from the study at any time if they are uncomfortable, at risk, or in danger.

We need your important cooperation and support in gathering data and information in order to accomplish this research project. We assure you that the information you provide will only be used for this research, that no physical or mental damage will be inflicted during data collection, and that your genuine identities will be kept hidden. Your participation is completely voluntary, and you may withdraw yourself from this research at any moment. We will keep everything discreet, and no one's identify will be revealed in the study report. Now, I am seeking your permission to gather data from you.

In case of contact or complaint: Please contact me if you have any questions or concerns regarding this study now or in the future. Professor.....Head of the Department of..... and..... Medical College Dhaka; phone:....., email

Authorization: If you sign this form, you are giving us permission to use your information in our research. It requires that you fill out an informed consent form (ICF). This form shall be stored in a stored in a secured place at..... Department, Medical College, Dhaka, for a certain period and then will be destroyed. A copy of this form will be given to you for your records. Before signing it, please read it carefully and try to understand fully

Part of Consent: I have been advised that this research will not endanger my health. I am completely aware that the data gathered due to my participation in this research may be utilized in future to benefit patients. I have the freedom to leave the study at any moment for any reason. I will not request any financial support for the research as long as my anonymity is protected. Throughout the duration of the research, I will do my best to follow the investigator's directions.

Name of the participant	Signature	Date
Name of the Witness-1	Signature	Date
Name of the Witness-2	Signature	Date
Name of Interviewer	Signature	Date

Informed consent Bangla

আমি,..... সহকারী অধ্যাপক, ঢাকা মেডিকেল কলেজ, ঢাকা এবং এই গবেষণার প্রিন্সিপাল ইনভেস্টিগেটর। আমি আপনাকে এই গবেষণায় অংশ গ্রহণের জন্য আমন্ত্রণ করছি। এই গবেষণার উদ্দেশ্য হচ্ছে মানসিক চাপ এবং তার সাথে জড়িত বিষয়সমূহ এর সাথে কোভিড-১৯ এর সময় ঢাকা মেডিকেল কলেজের ছাত্রদের সুস্থতার মধ্যে সম্পর্ক খুঁজে বের করা ।

অংশগ্রহণকারীরাঃ
ঢাকা মেডিকেল কলেজের বিভিন্ন বিভাগের স্নাতক এবং স্নাতকোত্তর ছাত্র ছাত্রীরা এই গবেষণায় অংশগ্রহণ করবেন।

গবেষণার সময়কাল, এবং তথ্য সংগ্রহের পদ্ধতি:
এই প্রকল্পটি ১৬ জানুয়ারী, ২০২১- শুরু হবে এবং ৩০ জানুয়ারী, ২০২১-এ শেষ হবে। গবেষণাটি ক্রস-সেকশনাল পদ্ধতিতে পরিচালিত হবে। তথ্য সংগ্রহের জন্য মেডিকেল কলেজের শিক্ষার্থীদের একটি অনলাইন এবং অফলাইন সমীক্ষা ব্যবহার করা হবে।

সম্ভাব্য সুবিধাঃ যদিও অংশগ্রহণকারীদের সরাসরি কোনো পুরস্কার নেই, এই গবেষণার ফলাফল ভবিষ্যতের শিক্ষার্থীদের জন্য উপকারে আসতে পারে। মহামারীকালীন সময়ে শিক্ষার্থীরা যে সমস্যাগুলি এবং উদ্বগের মুখামুখি হয় এই গবেষণা তা হ্রাস করতে সহায়তা করবে।

ঝুঁকি, বিপদ এবং অস্বস্তিঃ গবেষকরা ইন্টারনেটের মাধ্যমে তথ্য সংগ্রহ করবেন, তাই অংশগ্রহণকারীদের জন্য কোন ঝুঁকি, বিপদ বা অস্বস্তি থাকবে না। ব্যক্তিগত সমীক্ষার সময় শারীরিক দূরত্ব এবং স্বাস্থ্য সংক্রান্ত বিধিনিষেধ কঠোরভাবে মেনে চলা হবে। তথ্য সংগ্রহের আগে অংশগ্রহণকারীদের অনুমতি নেওয়া হবে। অংশগ্রহণের জন্য অংশগ্রহণকারীদের কোন ভাতা দেওয়া হবে না।

গোপনীয়তাঃ গবেষণায় সংগৃহীত তথ্য শুধুমাত্র গবেষণার উদ্দেশ্যে ব্যবহার করা হবে। তথ্য সংগ্রহের সময় এবং পরে ব্যক্তিগত গোপনীয়তা সম্পূর্ণভাবে বজায় রাখা হবে। একটি পাসওয়ার্ড সুরক্ষিত ফোল্ডারে সমস্ত তথ্য সংরক্ষণ করা হবে। গবেষণা প্রতিবেদনে অংশগ্রহণকারীদের পরিচয় প্রকাশ করা হবে না।

গবেষণা থেকে প্রত্যাহার করার অধিকারঃ অংশগ্রহণকারীরা অস্বস্তিকর অবস্থা, ঝুঁকি বা বিপদে পড়ার আশঙ্কা করলে যে কোনও সময় গবেষণা থেকে নিজেকে প্রত্যাহার করার অধিকার রয়েছে। এই গবেষণা প্রকল্পটি সম্পন্ন করার জন্য তথ্য সংগ্রহে আপনার গুরুত্বপূর্ণ সহযোগিতা এবং সমর্থন প্রয়োজন।

আমরা আপনাকে আশ্বস্ত করিতেছি যে, তথ্য সংগ্রহের সময় আপনার কোনো শারীরিক বা মানসিক ক্ষতি হবে না এবং আপনার আসল পরিচয় গোপন রাখা হবে। আপনার অংশগ্রহণ সম্পূর্ণ ঐচ্ছিক, এবং আপনি যে কোনো মুহূর্তে এই গবেষণা থেকে নিজেকে প্রত্যাহার করতে পারেন। আমরা সব ধরনের গোপনীয়তা বজায় রাখব, এবং গবেষণা প্রতিবেদনে কারও পরিচয় প্রকাশ করা হবে না। এমতাবস্থায়, আমি আপনার কাছ থেকে তথ্য সংগ্রহ করার অনুমতি চাচ্ছি।

<u>যোগাযোগ বা অভিযোগের ক্ষেত্রেঃ</u> এখন বা ভবিষ্যতে এই গবেষণা সম্পর্কে আপনার কোন প্রশ্ন বা উদ্বেগ থাকলে দয়া করে আমার সাথে যোগাযোগ করুন। অধ্যাপক..... বিভাগীয় প্রধান ..... ঢাকা মেডিকেল কলেজ, ঢাকা; ফোন----------, ইমেইল----------

<u>অনুমোদনঃ</u> এই ফর্মটিতে স্বাক্ষরের মাধ্যমে প্রতিয়মান হয় যে, এই গবেষণায় আপনার অনুমতি আছে। সে অনুযায়ী আপনাকে একটি অবহিত সম্মতি ফর্ম (I C F) পূরণ করতে হবে। ফর্মগুলি ঢাকা মেডিকেল কলেজের একটি সুরক্ষিত স্থানে নির্দিষ্ট মেয়াদের জন্য সংরক্ষণ করা হবে এবং তারপর ধ্বংস করা হবে। এই ফর্মের একটি কপি আপনার রেকর্ডের জন্য আপনাকে দেয়া হবে। স্বাক্ষর করার আগে দয়া করে এটি মনোযোগ সহকারে পড়ে বুঝে নিন।

<u>সম্মতির অংশ:</u> আমাকে জানানো হয়েছে যে এই গবেষণাটি আমার স্বাস্থ্যকে বিপন্ন করবে না। আমি সম্পূর্ণরূপে সচেতন যে এই গবেষণায় আমার অংশগ্রহণ প্রয়োজনীয় অবদান রাখতে পারবে; যা ভবিষ্যতে রোগীদের উপকার করার জন্য ব্যবহার করা যেতে পারে। যেকোনো কারণে যেকোনো মুহূর্তে এই গবেষণা থেকে নিজেকে প্রত্যাহার করার স্বাধীনতা আমার আছে। যতক্ষণ আমার নাম গোপন রাখা হবে, ততক্ষণ আমি গবেষণার জন্য কোনো আর্থিক সহায়তা দাবী করব না। গবেষণার পুরো সময় জুড়ে, আমি গবেষকের উপদেশ অনুযায়ী কাজ করার জন্য যথাসাধ্য চেষ্টা করব।

অংশগ্রহণকারীর নাম	স্বাক্ষর	তারিখ
১ নং সাক্ষীর নাম	স্বাক্ষর	তারিখ
২ নং সাক্ষীর নাম	স্বাক্ষর	তারিখ
সাক্ষাৎকার গ্রহণকারীর নাম	স্বাক্ষর	তারিখ

Annexure B: Example of an Assent form

The permission of children under the age of seven will be granted by their parents or guardians (parental consent form). For minors aged 7 to 17 years, an assent form is required, as well as approval from their parents or guardians. Only a permission document is required for adults. The following is an example of an Assent form, broken into two parts: i. Consent form of Guardian; ii. Assent form of Children.

Asalamualikum. I, Dr....., a research assistant/data collector, am writing to invite your kid to participate in.....research. We have created a 'cloud-based smartphone application' that allows users to do self-assisted visual acuity tests and locate the closest eye specialist. Your youngster will be instructed to cover one eye with his or her hand and begin reading letters from the eye chart on the smartphone screen. In a sitting posture, the smartphone device should be positioned at a distance of 14 inches from the eye. The whole screening process may take up to 15-20 minutes to complete. His / her involvement will help us to conduct the research successfully. As you have come to see an eye specialist for your kid, we are inviting him or her to participate in this study.

Participation risks and benefits: We will not take any fluid or tissue from you, thus there is no serious risk or danger in participating in this research. The participants in this research face no major physical, psychological, social, legal, or other risk or danger. The majority of children's games are played on mobile devices. As a result, the impact on the eye is as little as a daily risk. Furthermore, research participants will profit by promptly realizing their eye sight-related facts, and society will benefit by discovering eye-related health concerns in a large number of individuals with less effort thanks to the app. In this research, no experimental medications, placebos, or medical records (hospital, medical, birth, death, or other) will be utilized.

Confidentiality: Your child's vital information will be very helpful to us, and we will make sure that all of the information is kept secret, which means that this data will only be available to those who are directly involved with this survey. Without your child's name, all of the study's information on him or her will be maintained. The outcome will be kept private. Your personal information will be kept private. The findings may be presented at scientific or professional events, or they could be published in peer-reviewed publications. In our study report, the findings will be utilized anonymously.

Right to withdraw: Please realize that your child (reinvolvement)'s in this study is fully voluntary, and you have the right to withdraw your consent or terminate participation at any time without penalty or loss of benefits.

There will be no possible health risk or danger since no fluid or tissue from the child's body will be obtained for this study, and there will be no remuneration or financial gain for participating in this research. Furthermore, there is no outside funding for this study. However, this study will be very beneficial to the general public. In Case of Contact and Complaint: Please contact me if you have any queries regarding this study now or later...…… Head of the Research Team, ...institute Dhaka; phone: ....., email: ..... Please contact Bangladesh Medical Research Council, Mohakhali Dhaka, if you have any issues. (+8802-222298396, +8802-222299।

Authorization: The law requires that you fill out an informed consent (IC) form. This form will be maintained in a sealed envelope at..... University, Dhaka for three years in a

password-protected folder, after which your child's information will be erased. The informed consent form and the assent form will be kept under lock and key for three years, after which the documents will be burned. You will be given a copy of this form to keep for your records. Before signing it, please read it carefully. Guardians' permission to allow their kid to participate in the study: My child(ren) and I were aware of the research aims, procedures, and dangers, as well as our right to decline to participate in the study "Cloud-Based Smart Application for Eye Care in Bangladesh." I have had enough time and opportunity to read and examine this Informed Consent Form and make a decision about whether or not to participate my kid. I have also been given the option of taking this Informed Consent paper home to review it more thoroughly. I agree to allow my kid (ren) to freely participate in this research.

Name of the Guardian	Signature	Date
Name of the Witness-1	Signature	Date
Name of the Witness-2	Signature	Date
Name of Interviewer	Signature	Date

মা–বাবার অবহিতক্রমে সম্মতিপত্র

সাত বছরের কম বয়সী শিশুদের অনুমতি, তাদের পিতামাতা বা অভিভাবক (অভিভাবকের সম্মতি ফর্ম) দ্বারা মঞ্জুর করা হবে। ৭ থেকে ১৭ বছর বয়সী অপ্রাপ্তবয়স্কদের জন্য, একটি কিশোর অনুমতি ফর্ম প্রয়োজন, সেইসাথে তাদের পিতামাতা বা অভিভাবকদের কাছ থেকে অনুমোদন প্রয়োজন। নিম্নলিখিত দুটি অংশে বিভক্ত একটি সম্মতি ফর্মের উদাহরণ: i. অভিভাবকের সম্মতি ফর্ম; ii. শিশুদের সম্মতি ফর্ম. আসসালামুয়ালাইকুম। আমি "বাংলাদেশে চোখের যত্নের জন্য ক্লাউড-ভিত্তিক স্মার্ট অ্যাপ্লিকেশন" নামিয় গবেষণার, একজন গবেষণা সহকারী/তথ্য সংগ্রাহক, আপনার বাচ্চাকে এই গবেষণায় অংশগ্রহণের জন্য আমন্ত্রণ জানাচ্ছি | আমরা একটি 'ক্লাউড-ভিত্তিক স্মার্টফোন অ্যাপ্লিকেশন' তৈরি করেছি যা ব্যবহারকারীদের স্ব-সহায়তা চাক্ষুষ তীক্ষ্ণতা পরীক্ষা করতে এবং নিকটতম চক্ষু বিশেষজ্ঞকে সনাক্ত করতে দেয়। আপনার বাচ্চা তার হাত দিয়ে একটি চোখ ঢেকে রাখতে এবং স্মার্টফোনের স্ক্রিনে চোখের চার্ট থেকে অক্ষর পড়তে শুরু করার নির্দেশ দেওয়া হবে। বসার ভঙ্গিতে, স্মার্টফোন ডিভাইসটি চোখ থেকে ১৪ ইঞ্চি দূরত্বে স্থাপন করা উচিত। পুরো স্ক্রিনিং প্রক্রিয়াটি সম্পূর্ণ হতে ১৫-২০ মিনিট পর্যন্ত সময় লাগতে পারে। তার সম্পৃক্ততা গবেষণাকে সাফল্যজনকভাবে পরিচালনা করতে সাহায্য করবে |

অংশগ্রহণের ঝুঁকি এবং সুবিধাঃ আমরা আপনার কাছ থেকে কোনো তরল বা টিস্যু নেব না, তাই এই গবেষণায় অংশগ্রহণ করার ক্ষেত্রে কোনো গুরুতর ঝুঁকি বা বিপদ নেই। এই গবেষণায় অংশগ্রহণকারীরা কোন বড় শারীরিক, মানসিক, সামাজিক, আইনি, বা অন্যান্য ঝুঁকি বা বিপদের সম্মুখীন হবে না। বাচ্চাদের বেশিরভাগ গেম মোবাইল ডিভাইসে খেলা হয়। ফলে চোখের ওপর প্রভাব প্রতিদিনের ঝুঁকির মতোই কম। তদুপরি, গবেষণায় অংশগ্রহণকারীরা তাদের চোখের দৃষ্টি-সম্পর্কিত তথ্যগুলি অবিলম্বে উপলব্ধি করার মাধ্যমে লাভবান হবেন এবং অ্যাপটিকে ধন্যবাদ কারণ কম পরিশ্রমে বিপুল সংখ্যক ব্যক্তির চোখের স্বাস্থ্য সংক্রান্ত উদ্বেগগুলি আবিষ্কার করে সমাজ উপকৃত হবে। এই গবেষণায়, কোনো পরীক্ষামূলক ওষুধ, প্লেসিবো, বা মেডিকেল রেকর্ড (হাসপাতাল, চিকিৎসা, জন্ম, মৃত্যু বা অন্যান্য) ব্যবহার করা হবে না।

গোপনীয়তাঃ আপনার সন্তানের অত্যাবশ্যকীয় তথ্য আমাদের জন্য খুবই সহায়ক হবে, এবং আমরা নিশ্চিত করব যে সমস্ত তথ্য গোপন রাখা হয়েছে, যার মানে এই তথ্য শুধুমাত্র যারা সরাসরি এই সমীক্ষার সাথে জড়িত তাদের কাছেই পাওয়া যাবে। আপনার সন্তানের নাম ছাড়া, তার সম্পর্কে গবেষণার সমস্ত তথ্য রক্ষণাবেক্ষণ করা হবে। ফলাফল গোপন রাখা হবে. আপনার ব্যক্তিগত তথ্য গোপন রাখা হবে. ফলাফলগুলি বৈজ্ঞানিক বা পেশাদার ইভেন্টগুলিতে উপস্থাপন করা যেতে পারে, অথবা সেগুলি পিয়ার-পর্যালোচিত প্রকাশনাগুলিতে প্রকাশিত হতে পারে। আমাদের গবেষণা প্রতিবেদনে, ফলাফলগুলি বেনামে ব্যবহার করা হবে।

প্রত্যাহারের অধিকারঃ অনুগ্রহ করে বুঝার চেষ্টা করুন যে এই গবেষণায় আপনার সন্তানের অংশগ্রহণ সম্পূর্ণ স্বেচ্ছাসেবী, এবং আপনার সম্মতি প্রত্যাহার করার বা জরিমানা বা সুবিধার ক্ষতি ছাড়াই যেকোনো সময় অংশগ্রহণ বন্ধ করার অধিকার রয়েছে। কোনও সম্ভাব্য স্বাস্থ্য ঝুঁকি বা বিপদ থাকবে না কারণ এই গবেষণার জন্য শিশুর শরীর থেকে কোনও তরল বা টিস্যু নেওয়া হবে না এবং এই গবেষণায় অংশগ্রহণের জন্য কোনও পারিশ্রমিক বা আর্থিক লাভ হবে না। উপরন্তু, এই গবেষণার জন্য কোন বাইরের আর্থিক সুবিধা নেই। যাইহোক, এই গবেষণা সাধারণ মানুষের জন্য খুব উপকারী হবে।

যোগাযোগ এবং অভিযোগের ক্ষেত্রেঃ এখন বা পরে এই গবেষণা সম্পর্কে আপনার কোন প্রশ্ন থাকলে অনুগ্রহ করে আমার সাথে যোগাযোগ করুন ····· গবেষণা দলের প্রধান, ... ইনস্টিটিউট ঢাকা; ফোন: ....., ইমেল: .....

অনুমোদনঃ আইন মোতাবেক আপনাকে একটি অবহিত সম্মতি (IC) ফর্ম পূরণ করতে হবে। এই ফর্মটি একটি সিল করা খামে রক্ষণাবেক্ষণ করা হবে....., ইউনিভার্সিটি, ঢাকায় তিন বছরের জন্য পাসওয়ার্ড-সুরক্ষিত ফোল্ডারে রাখা হবে, তারপর আপনার সন্তানের তথ্য মুছে যাবে। অবহিত সম্মতি

ফর্ম এবং সম্মতি ফর্মটি তিন বছরের জন্য তালা এবং চাবিতে বন্ধ রাখা হবে, তারপরে নথিগুলি পুড়িয়ে দেওয়া হবে। আপনার রেকর্ড রাখার জন্য আপনাকে এই ফর্মের একটি অনুলিপি দেওয়া হবে। এটি স্বাক্ষর করার আগে, দয়া করে এটি মনোযোগ সহকারে পড়ুন।

বাচ্চাদের গবেষণায় অংশগ্রহণের অনুমতি দেওয়ার জন্য অভিভাবকদের অনুমতিঃ আমার সন্তান (বাচ্চা) এবং আমি গবেষণার লক্ষ্য, পদ্ধতি এবং বিপদ সম্পর্কে সচেতন ছিলাম, সেইসাথে আমাদের "বাংলাদেশে চোখের যত্নের জন্য ক্লাউড-ভিত্তিক স্মার্ট অ্যাপ্লিকেশন" গবেষণায় অংশগ্রহণ করতে অস্বীকার করার অধিকার ছিল "বাংলাদেশে চোখের যত্নের" জন্য এই অবহিত সম্মতি ফর্মটি পড়ার এবং পরীক্ষা করার এবং আমার বাচ্চাকে অংশগ্রহণ করা বা না করার বিষয়ে সিদ্ধান্ত নেওয়ার জন্য আমার যথেষ্ট সময় এবং সুযোগ ছিল। আমাকে আরও পুঙ্খানুপুঙ্খভাবে পর্যালোচনা করার জন্য এই ইনফর্মড কনসেন্ট পেপার বাড়িতে নিয়ে যাওয়ার বিকল্পও দেওয়া হয়েছে। আমি আমার বাচ্চাকে (বাচ্চাদের) এই গবেষণায় অবাধে অংশগ্রহণ করার অনুমতি দিতে সম্মত।

অভিভাবকের নাম	স্বাক্ষর	তারিখ
১ নং সাক্ষীর নাম	স্বাক্ষর	তারিখ
২ নং সাক্ষীর নাম	স্বাক্ষর	তারিখ
সাক্ষাৎকারগ্রহণকারীর নাম	স্বাক্ষর	তারিখ

ii. Assent form of children

I have been told about the research's goals, procedures, and risks, as well as my right to decline to participate in the study "Cloud-Based Smart Application for Eye Care in Bangladesh." I have had enough time and opportunity to read and decide whether or not to involve in the assent from. In addition, I have been given the option of completing this 'Assent form' at home in order to consider it further. I willingly accept to participate in this research.

Name of the participant	Signature	Date
Name of the Witness-1	Signature	Date
Name of the Witness-2	Signature	Date
Name of Interviewer	Signature	Date

অপ্রাপ্ত বয়স্কদের অবহিতক্রমে সম্মতিপত্র

আমাকে "বাংলাদেশে চোখের যত্নের জন্য ক্লাউড-ভিত্তিক স্মার্ট অ্যাপ্লিকেশন"গবেষণার উদ্দেশ্য, পদ্ধতি এবং ঝুঁকির সম্পর্কিত তথ্য দেওয়া হয়েছে। পাশাপাশি গবেষণায় অংশ নিতে অস্বীকার করার অধিকার সম্পর্কে অবহিত করা হয়েছে। আমি এই অবহিত সম্মতি ফর্মটি পড়ার এবং বিবেচনা করার জন্য পর্যাপ্ত সময় এবং সুযোগ পেয়েছি। আমাকে এই অ্যাসেন্ট ফর্মটি বাড়ীতে অধ্যয়ন করার সুযোগ দেওয়া হয়েছে। আমি স্বেচ্ছায় এই গবেষণায় অংশগ্রহণ করতে সম্মত আছি।

অংশগ্রহণকারীর নাম	স্বাক্ষর	তারিখ
১ নং সাক্ষীর নাম	স্বাক্ষর	তারিখ
২ নং সাক্ষীর নাম	স্বাক্ষর	তারিখ
সাক্ষাৎকারগ্রহণকারীর নাম	স্বাক্ষর	তারিখ

Annexure C: IRB Submission Format

Documents should be submitted to the Ethics Committee for review

01. Ethical clearance application.
02. Institutional Review Board Abstract (IRB)
03. IRB format for protocol submission for ethical clearance
04. Participants' or the parent's/legal guardian's informed consent form (in both Bangla and English).
05. Schedule for questionnaires or interviews (Both Bangla and English).
06. Checklist for Submitting a Research Protocol to the Institutional Review Board (IRB).
07. Verify that the protocol's content has not been plagiarized.
08. A copy of a genuine scientific review committee's approval (If any).
09. An overview of the investigators' backgrounds.
10. All documentation must be provided to the IRB in two (2) copies, including a soft copy.

1. Ethical Clearance Application

a.Principal Investigator(s): Name: Qualification: Address: Phone (Off. / Res) e-mail:
b.Co-Investigator(s): Name: Qualifications: Address: Phone (Off. /Res) e-mail:
c. Study/Institution(s) Location:
d. Thesis Title:
e. Research Methodology:
f. Study Timeframe:
g. Total Price:
h. Funding Source:
i. Instruments for data collection: The following information should be provided in the abstract if the final instrument/questionnaire is not completed before review:

• A description of the areas to be addressed in the questionnaire or interview that might be regarded sensitive or invading personal space.
• Examples of the kind of questions that should be asked in sensitive regions.

We undertake to seek IRB ethical clearance for any modifications impacting the rights and welfare of participants, as well as any changes to the Methodology, before proceeding.
Signature
Principal Investigator's Name
Date:
Co-investigator(s)' names: (Include all co-investigators)
……
Signatures
a.
b.

2. Abstract for IRB

Instructions for Writing an Abstract for the IRB

Any application that does not provide a detailed abstract for the committee will be rejected by the IRB. By addressing each of the following topics, the abstract should outline the study's goal, methodology, and processes. Please indicate the following if an item is not applicable:

1. Describe the demographic needs and explain the reason for employing special populations such as minors, incompetent people, or groups whose capacity to provide voluntarily informed permission is in doubt.
2. Identify and analyze any possible dangers, including physical, psychological, social, legal, and other concerns, as well as their probability and severity. Describe any alternative approaches that were examined and why they could not be employed if the research methods generate possible dangers.
3. Describe strategies for avoiding or limiting possible dangers, as well as an evaluation of their probable efficacy.
4. Provide a description of the procedures used to maintain confidentiality or anonymity.
5. The investigator must seek written informed permission from the participant where there are possible hazards to the subject or when the individual's privacy is at stake. Informed permission from the subject's legally acceptable representation (LAR) or parent is required for minors. Describe how and where informed permission will be sought, as well as the consent processes to be followed.

(a) Explain why written consent should be waived and propose an alternate option, such as verbal consent, if signed consent cannot be obtained.
(b) Justify withholding information from a subject if this is the case.
(c) If any procedure involves a possible danger to the subject or the individual's privacy, or a loss of work time, add a statement in the permission form specifying whether any compensation will be offered.

6. Describe where and in what context the interview will take place if the research includes one. Give an estimate of how long the interview will take.
7. Evaluate the possible benefit to the individual subject as well as the prospective advantages to society as a whole as a consequence of the activity. Describe how the advantages could exceed the hazards.
8. Provide information on the status of an experimental drug's registration for open sale in Bangladesh and other developed nations, if applicable.
9. For experimental "new" medications, include detailed information on toxicity tests conducted on animals or human volunteers. The papers that have been published in this area will be annexed.
10. If you're going to use a placebo, explain why you're going to use it and why you can't run the research without it.
11. If an experimental "new" medicine is to be utilized, specify who is sponsoring it and what the terms of that sponsorship are.
12. Specify if the activity necessitates the use of records (hospital, medical, birth, death, or other), organs, tissues, bodily fluids, the fetus, or the aborted fetus.

The facts mentioned in items 2, 3, 4, 5(c), and 7 should be included in the statement to the subject, as well as an estimate of the time necessary for participation in the activity.

3. IRB format for protocol submission for ethical clearance

• Protocol title

• Introductory paragraph: (Introduce the topic.) Please provide any relevant background information. Cite only literature that is relevant to the protocol's subject. Complete the information to demonstrate that the technique is founded on strong scientific principles.)

• Goals and objectives: (List the general and specific objectives of the proposed study and state clearly the question that is being posed or the hypothesis being tested.)

• Rationale: (Explain how the planned research relates to national health goals and how the aims relate to current scientific knowledge on the issue.) Refer to relevant literature and research conducted in our nation or abroad.)

• Methodology: (Explain the study's design and methodology in sufficient depth to evaluate how they will contribute to the attainment of the specified goals and to allow adequate budget analysis.) If relevant and significant, a plan for data analysis should be given. Details on the research techniques should be included in this section. Enough information should be provided to determine if the procedures have been tried and are practicable. The following plan is recommended: Variables in the study, Study design, Study Population, Sampling, Statistical Basis for Sample Size, Procedures, Data Collection Methods, Pretesting, Data Interpretation, Statistical Analysis (Correlation, Significance Test, Coefficient of Variation, Evaluation Methods, wherever applicable).

• Making Sense of the Data: (Describe in brief how you perceive that the results from this study may contribute to the healthy development of the Country.)

• Resources (resources, equipment, chemicals, subjects (human, animal), and other study-related items):

Services Provided:

Additional resources are required:

• Head of Department / Institute approval (Not applicable for an individual researcher) Approval by the Head of Department/Institute (Not applicable for an individual researcher)

• Flow Diagram: Diagram of the Process: (Describe the sequence of tasks within the time frame).

• Ethical Implications: (Think carefully about the ethical implications and express your thoughts.) Consult the BMRC's Guidelines for Ethical Review of Human Subjects Projects).

Implications for Ethics: (Think carefully about the ethical implications and express your thoughts.) Consult the BMRC's Ethical Review of Human Subjects Projects Guidelines).

• References: The Vancouver style should be used. References should be written in the Vancouver style.

Budget

- Total budget
- Budget breakdown:

a. Personnel Costs (Professional Scientific Personnel, Technical Personnel, and Other Personnel.) Please provide the proportion of time each person will dedicate to this project).

b. Field/Laboratory Expenses:

c. Materials and Supplies (Items and quantities should be specified):

d. Cost to the patient (if applicable):

e. Travel Costs (Only for internal travel):

f. Goods Transportation:

g. Office Stationery (should be defined in terms of items and quantity):

h. Computer/Data Processing Fees (If Applicable):

i. Reproduction and printing:

j. Contractual Services (not including manpower):

k. Miscellaneous (maximum of 2.5 percent of overall budget).

4. Written in both Bangla and English, the Informed Consent Form should be completed (Please see Annexure A and B)

5. Schedule of Questionnaires or Interviews (Both Bangla and English)

6. Checklist for submitting a research protocol to the IRB for approval

[Please make sure that all of the required boxes are checked.]

1. Have all of the named investigators studied, discussed, and approved the proposal? ❑ Yes ❑ No If you get a negative answer, please explain why:
2. Has the plan been subjected to external peer review? (optional) ❑ Yes ❑ No ❑ External Review Exempted If you get a response of "No" or "External Review Exempted," please explain why: Whether you answered "Yes," could you kindly tell me if you addressed all of their concerns? ❑ Certainly (please attach) ❑ No (state the reason(s):
3. Is the budget up to date? ❑ Yes ❑ No (reason):__
4. Have all of the mentioned investigators' valid ethics certificates been linked to the Protocol?

- ❑ Yes
- ❑ No

If the answer is no, please include the following justifications:

5. Has the protocol been accompanied by the Bangla and English Information Sheets and Consent Forms?

- ❑ Yes
- ❑ No
- ❑ Not applicable

If the answer is no, please include the following justifications:

6. Has the protocol been accompanied by the Bangla and English Tools/Questionnaire?

- ❑ Yes
- ❑ No
- ❑ Not applicable

7. Has the Protocol's abstract been added?

- ❑ Yes
- ❑ No

If the answer is 'No,' please provide the reasons:

8. Which of the United Nations' Sustainable Development Goals does this Protocol address? (make a list of all that apply)

- ❑ End poverty in all of its manifestations across the world.
- ❑ Ending hunger, achieving food security and improving nutrition, and promoting sustainable agriculture are all goals that must be met.
- ❑ Ensure that all people of all ages have healthy lives and are well-adjusted.
- ❑ Ensure that all students get a high-quality education that is inclusive and fair, and encourage lifelong learning opportunities.
- ❑ Ensure gender equality and the empowerment of all women and girls.
- ❑ Ensure universal access to water and sanitation, as well as long-term management.
- ❑ Ensure that everyone has access to cheap, dependable, sustainable, and contemporary energy.
- ❑ Encourage long-term, inclusive, and sustainable economic development, as well as full and productive employment and decent labor for all people.
- ❑ Invest in robust infrastructure, encourage inclusive and sustainable industrialization, and encourage innovation.
- ❑ Reduce inequity both inside and across nations.
- ❑ Ensure that cities and human settlements be inclusive, safe, resilient, and long-lasting.
- ❑ Ensure that consumption and production trends are long-term.
- ❑ Take immediate action to address climate change and its consequences.
- ❑ For sustainable development, conserve and sustainably utilize the oceans, seas, and marine resources.
- ❑ Protect, restore, and promote the sustainable use of terrestrial ecosystems; manage forests sustainably; battle desertification; and prevent and reverse land degradation and biodiversity loss.
- ❑ For sustainable development, promote peaceful and inclusive communities, ensure universal access to justice, and construct effective, responsible, and inclusive institutions at all levels.
- ❑ Strengthen and revive the global partnership for sustainable development's implementation mechanisms.

9. Will this Research Specifically Benefit the Disadvantaged (in terms of economics, social justice, and/or other factors):

- ❑ Yes
- ❑ No

10. Is Behavior Change Communication used in this protocol?

- ❑ Yes
- ❑ No

11.Project/Study type

- ❑ Case Control Study
- ❑ Clinical Trial (Hospital/Clinic/Field)
- ❑ Community-based Trial/Intervention
- ❑ Cross Sectional Survey
- ❑ Longitudinal Study (cohort or follow-up)
- ❑ Meta-analysis
- ❑ Program Evaluation
- ❑ Program (Umbrella Project)
- ❑ Prophylactic Trial
- ❑ Record Review
- ❑ Secondary Data Analysis
- ❑ Protocol No. of Data Source: _____
- ❑ Surveillance/Monitoring
- ❑ Systematic Review
- ❑ Other (specify): _____

12. Biological Specimen:

a) a) Is the biological specimen going to be stored indefinitely?

- ❑ Yes
- ❑ No

a) How long will the specimens be stored if the response is yes?
Duration……..
b) What kind of tests will the preserved specimens undergo?
Name: ……..
c) Will the agreement of the research participants be sought for the use of the preserved specimen for purposes unrelated to this study, or will they be asked to re-consent?

- ❑ Yes
- ❑ No
- ❑ Not applicable

b) Will the samples be transmitted to another country or countries? If yes, provide the name of the institution(s) as well as the country or countries where they are located.

- ❑ Yes
- ❑ No
- ❑ Not applicable

Name: _____

c) If the surplus/unused specimen is taken to another nation, will it be returned? If the response is no, the useless or extra specimen must be discarded.

- ❑ Yes
- ❑ No
- ❑ Not applicable

d) Who will be in charge of the specimen?
Name: _____
e) When the specimen is delivered outside of Bangladesh, who will be in charge of it?
Name: _____

f. Who will be the specimens' owner(s)?

Name: _____

g) Has a Memorandum of Understanding (MOU) been made regarding specimen collection, storage, usage, and ownership?

- ❑ Yes
- ❑ No
- ❑ Not applicable

Please attach a copy of the MOU if the answer is yes.

If the answer is negative, a proper rationale for not signing an MOU should be stated. …….
13. Proposed Sample Size Sub-group (Name of subgroup, e.g. Men, Women) and Number of Participants
14. Do you think this study is valid: (mark one) ❑ More than minimum risk ❑ Less than minimal risk ❑ Only portion of the diagnostic exam
_____ _____ Signature of the Principal Investigator Date

7. Ensure that the protocol's content is not plagiarized.

8. A copy of a genuine scientific review committee's approval (If any).

9. Investigators' biographies

10. All documentation must be provided to the IRB in two (2) copies, including a soft copy.

Annexure D: Format for IRB Reporting

Date of the report:	
Reporting period:	
Name of the IRB:	
IRB registration number:	
Address of the IRB: Phone and email:	
Name of the Chairperson:	
Designation:	
Chairperson's contact information (including phone and email):	

Number of meetings conducted in total	
The total number of research protocols/proposals received	
The total number of approved research proposals	
The total number of research proposals that have been turned down	
Total number of approved protocol/proposals with significant revisions	

For each of the procedures that have been authorized (add rows if necessary)

Sl no	Title of research	Research Period	Name of the institution conducting research	Collaboration on a global scale? (Y/N)	Name of Principal Investigator	Current Status of research	Name of the funding agency

_____

(**Chairperson of the IRB's signature**)

Annexure E: Unexpected Problems Reporting Format

Date of the report:	IRB registration number:
Name of the IRB:	
Address of the IRB:	
Name of the Chairperson:	Designation:
Contact Information of the Chairperson:	

For each research proposal causes unanticipated problems (Add rows as necessary)

Protocol ID	**Title of the study**	**Name of Institution**	**Name of Principal Investigator**	**Date of problem occurred**	**Detail description of problem/ noncompliance/ Suspension**	**Serious Problem? Yes/No**	**Is any action taken? (Yes/No)**	**A detailed description of the action**

_____

(Chairperson of the IRB's signature)

*Unanticipated problem- sample from dead body

Annexure F: IRB Members' Training Curriculum

Objectives

Participants will be able to explain the creation, composition, purpose, and functions/Terms of Reference (ToR) of IRBs by the conclusion of this course.

Duration

Over the course of two days, a 6-hour hands-on knowledge session will be held on five different subjects. Counter-argument may be promoted in the classroom to examine participants' knowledge in order to achieve the goals. The contents of text modules have been prepared in accordance with research ethical norms. Other assessment techniques may be developed in the future depending on the results of the curriculum evaluation.

IRB members are the target audience.

Methods of instruction: Lectures, PowerPoint presentations, case presentations, and video evaluations are all options. Pre- and post-test questionnaire to analyze the module's strengths and flaws; Participants' knowledge may be assessed by encouraging counter-argument.

Training Schedule

Chapter	Objectives	Contents	Hours
1. Introduction	To learn the History of Research Ethics	● Introduction and history of research ethics	1 hour
2. Research Involving Human Subjects	Understand the basic concepts of research, Risk Benefit, Informed Consent, Vulnerable group, Genetics, Plagiarism	● Principles of Ethics ● Informed consent ● Vulnerable Participants ● Risk-Benefit Assessment ● Conflict of Interests (COI) ● Genetic Research in Human Populations	1 hour
3. Institutional Review Board (IRB)	To understand the formation, composition & Function of IRB	● Formation of IRB ● Standard Operating Procedures (SOP) ● Checklist for IRB submission	2 hours
4. Clinical Trial	To apply Good Clinical Practice in Clinical Trials Involving Drugs and Devices	● DSMB	1 hour
5. Registration of IRB	IRB registration	● Registration ● Reporting ● Coordination cell	1 hour