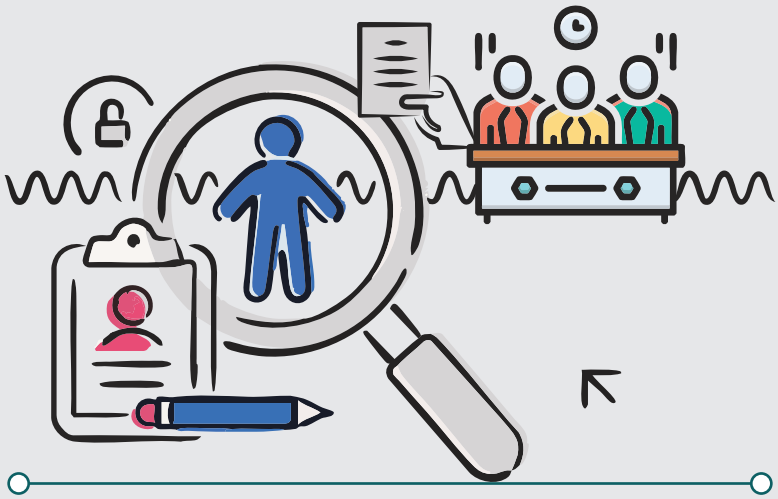
GUIDELINES FOR ETHICS AND RESEARCH REVIEW

INSTITUTIONAL REVIEW BOARD

BRAC James P Grant School of Public Health
BRAC University



[Effective Date: This IRB Guideline is effective as of June 1st, 2025]

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1. Mission

The Institutional Review Board (IRB) of BRAC James P Grant School of Public Health (BRAC JPGPH) was established in 2013 to achieve a quality and consistent ethical review mechanism for research involving human subjects and social research. The IRB is accredited by the U.S. Department of Health and Human Services (HHS) and is entrusted with developing/setting technical and ethical standards and ensuring and overseeing application and adherence by all researchers (IORG#: IORG0009058 Expires: 06/25/2028)
This guideline will dictate the operations of the Institutional Review Board (IRB) at the BRAC JPGSPH, BRAC University. The goal of the IRB is to assess the technical, ethical, and moral standards of research. The IRB ensures that research is carried out respectfully and provides adequate protection against potential harm whenever human subjects are involved. The Board also maintains that special care is held when studies involve vulnerable groups within society, such as children and disabled persons (physically or mentally). These guidelines have been developed based on IRB guidelines of BRAC University, CITI (Collaborative Institutional Training Initiative < https://www.citiprogram.org/>), NIH (National Institute of Health < https://humansubjects.nih.gov/>), BMRC (Bangladesh Medical Research Council < http://www.bmrcbd.org/>), and icddr,b (International Center for Diarrheal Disease Research, Bangladesh www.icddrb.org.

2. Basic Principles

The mandate of the IRB is to provide technical, ethical, and regulatory oversight of research that involves human subjects by ensuring the highest ethical standards by adhering to the ethical principles outlined in the Belmont Report and Helsinki Declaration of the World Medical Association (WMA), in compliance with the policies and regulations of BRAC JPGSPH, BRAC University. The Board is transparent in its functioning, independent of the researchers, the sponsor, and any other undue influence. It will consider the laws and regulations of the country where the research is to be performed.

The IRB doesn't simply review protocols; it maintains continuous oversight of ongoing research. This empowers the IRB to monitor studies and, if necessary, halt them to safeguard participants. The IRB also reviews and approves any proposed amendments to the research protocol to guarantee continued adherence to ethical standards and participant safety. Researchers are required to submit regular monitoring reports, particularly detailing any serious adverse events encountered during the research. Upon study completion, PIs are assigned to submit final reports summarising their findings, conclusions, and insights gained regarding participant well-being.

2.1 Respect for the Human Subjects

Respect for and to human subjects is of utmost importance to the IRB. Research will need to demonstrably respect the autonomy of all participants. This translates into ensuring their right to make informed decisions about participation, providing all necessary information, and obtaining their freely given consent. Participants with diminished autonomy, such as children or individuals with disabilities, require additional safeguards and may need the consent of a legally authorized representative.

2.2 Beneficence

The research team will maximize benefits and minimize harm. Since the participants in a study are unlikely to benefit directly from the research, this requirement dictates that the discomfort or harm should be minimised compared with the expected benefits. Hence, researchers should be competent enough to carry out the study, with a sound study design, and safeguard human subjects' welfare. Therefore, all individuals must be treated not only by respecting their decisions and protecting them from any potential harm but also by making efforts to secure their well-being.

2.3 Justice

The researchers will be expected to treat the human subjects according to what is morally right or give each person what is due to them. This implies avoiding over-researching a particular topic or

sub-population, unfair participation, and fair and non-discriminatory selection of the research subjects.

2.4 Voluntary Participation

The researchers will exhibit due diligence to avoid any appearance and perception of coercion or compulsion on the research subjects to partake in the study. Researchers will obtain informed consent from all participants before their involvement in the study. This consent should be voluntary, freely given, and based on a clear understanding of the research objectives, procedures, potential risks and benefits, and the participant's right to withdraw from the study at any point.

2.5 Privacy and Confidentiality

The researchers should take special care to ensure the privacy and confidentiality of the research subjects. This includes protecting participants' identities and ensuring their data is kept secure and anonymous.

3. Composition of IRB

The Institutional Review Board (IRB) at BRAC JPGSPH, BRAC University, will prioritize both impartiality and expertise in its membership. This fosters a well-functioning board equipped to ethically review research proposals submitted to the BRAC JPGSPH, BRAC University. The IRB is an independent body consisting of 13 board members, known as and referred hereafter as IRB members (ANNEX I). The IRB will be composed of a diverse group of people with a clear policy on qualification, appointment, resignation, and disqualification for its members and guidelines to act upon them as necessary. It should also include policies regarding financial remuneration for the members' services to the IRB, with provisions for resolving possible conflicts of interest.

A clear policy should govern member qualifications, appointment, resignation, and disqualification, outlining procedures for implementation when necessary. Additionally, the IRB will set up an annual meeting with the board members once a year. There, they will review the IRB procedures and provide suggestions for upcoming challenges.

3.1 Diversity

The IRB should be composed of a diverse group of individuals possessing the knowledge and skills necessary to assess the scientific merit and ethical considerations of research conducted at the university. The emphasis lies on this collective capacity to ensure comprehensive review, rather than simply on representativeness, unless such representation calls to uphold the perception of independence of the ethical review.

For studies involving vulnerable populations such as children, pregnant women, or individuals with mental disabilities, the IRB should invite specialists with relevant expertise to contribute to the review process, further enriching the ethical rigour.

3.2 Independence

If there is any scope for the appearance of loss of independence and partiality in reviewing research, the IRB will ensure that the conflict of interest is avoided.

3.3 Quorum

At least five members, including the Chair, should attend each IRB in-person sessions while reviewing proposals for research review and ethical clearance.

3.4 Chairperson

The Chairperson and Co-Chairperson of the IRB will be selected from the research and academic staff of BRAC JPGSPH, BRAC University. They should be minimum at Assistant Professor level or equivalent. The terms of reference/duties and responsibilities are given in Annex II.

3.5 Independent Consultants/ Experts

The IRB, within its capacity and as it deems necessary, can invite independent expert(s) to assist the IRB in reviewing any area of research for which it may lack internal capacity. Such experts may provide their expertise but will not vote in the approval process.

3.6 Indemnity

IRB will provide its members legal protection against "any liabilities that may arise in the course of the conduct of their duties carried out in good faith."

3.7 Conflict of interest

BRAC JPGSPH, IRB members, and researchers should take special care to avoid conflicts of interest, whether actual, potential, or the appearance of conflict. Institutions should develop policies and procedures to identify, eliminate, minimise, or manage conflicts of interest that may affect research.

Should an IRB member have a personal interest in the research under review, that member should disqualify themself from any consideration of the case and refrain from offering their opinion to the IRB on the study under review. The member should disclose an actual, potential, or apparent conflict of interest to the IRB.

Researchers should disclose any actual, potential, or perceived individual conflicts of interest when submitting their research proposals to the IRB and any institutional disputes they know may impact their research. The IRB shall then decide on the appropriate steps to manage the conflict. Threats to research integrity could arise when there is a conflict of interest between those who commission and fund research (including commercial organisations) and those who carry it out (the researchers). Routine checks and balances ensuring the integrity of the research process have developed in universities and other research institutions with a commitment to research.

4. Roles and responsibilities of IRB

The primary role of the IRB is to oversee the technical and ethical standards of all research projects that progress either independently within the School or University or in collaboration with other local or international academic and research institutions.

The IRB members' responsibilities include:

- To review and approve the technical and ethical standards of any independent study by any department/institute of BRAC JPGSPH, BRAC University, or BRAC.
- To evaluate the contents of the study proposal in terms of technical and ethical standards.

Regulations and Procedures:

IRB Review and Appointment of Reviewers: The IRB can appoint two reviewers with relevant scientific expertise to assess a proposal's technical aspects, including:

- Methodology
- Sampling techniques
- Feasibility

*The IRB board continuously updates the reviewer list, enlisting experienced and knowledgeable researchers from every field in the reviewers' database.

IRB Review Process:

- IRB reviewers will evaluate both technical merit and ethical standards for each proposal, providing detailed feedback on both aspects.
- The study's Principal Investigator (or designated representative) will present the proposal to IRB reviewers using a concise presentation (maximum 10 minutes), followed by a question-and-answer session.
- If the volume of proposals is high, the IRB Chair may delegate the initial document review to a single IRB member.

IRB Approval Scope and Duration:

- The IRB will only approve proposals from BRAC JPGSPH, BRAC University, BRAC, or their collaborative work with partner organizations (national/international NGOs, INGOs, and academic/research institutions). The PIs or Co-PIs, Co-Is should be from BRAC JPGSPH, BRAC University, BRAC.
- IRB approval is valid for one year.
- Any changes to study conditions, methodology, or participant rights necessitate re-approval by the IRB for the research to continue.
- Amendment approvals will align with the initial approval period.
- Researchers must submit a time extension form if the study extends beyond one year.

5. Essential Considerations in the Review Process

Human subjects' research aims to understand diseases' causes, development, and effects and improve preventive, diagnostic, and therapeutic interventions (methods, procedures, and treatments). Even the best-proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality. Any research involving humans is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights. While the study's primary purpose is to generate new knowledge, this goal can never precede individual research subjects' rights and interests.

It is the duty of investigators involved in research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for pro-protecting issues must always rest with the investigators or other healthcare professionals and never with the research subjects, even though they have consented. The investigators must consider the ethical, legal, and regulatory norms and standards for research involving human subjects in their countries and applicable international norms and standards. No national or international ethical, legal, or regulatory requirement should reduce or eliminate any protections for research subjects set in the outlined Helsinki Declaration.

Research should be conducted in a manner that minimises possible harm not only to humans but also to the environment.

Only individuals with the appropriate ethics, scientific education, training, and qualifications are allowed to conduct human subjects research. Underrepresented in medical research groups should be provided fair access to participate in the study.

Physicians, who combine medical research with medical care, should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic, or therapeutic value, and only if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects. Appropriate compensation and treatment for any harm due to participating in research must be ensured.

5.1 Scientific Merit

Research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol. The protocol should contain a statement of the ethical considerations involved and indicate how they have been addressed. The protocol should include information on funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects, if any, and provisions for treating and compensating subjects harmed due to participation in the research study. Therefore, all research proposals should have scientific merit. Even if an acceptable organisation elsewhere has already approved the research, it will need technical review by at least two experts engaged by BRAC IRB for conducting the research in Bangladesh.

5.2 Ethics Certificates/ Clinical Practice Certificates

All Principal Investigators and investigators must provide Ethics certificates or Clinical Practice Certificates while submitting the application for ethics approval by BRAC JPGSPH IRB.

5.3 Recruitment and Protection of the Human Subjects

The protocol should have guidelines for compensation and reimbursement to human subjects. It should also include funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for issues, and information regarding provisions for treating and compensating subjects harmed due to participation in the research study.

5.4 Privacy and Confidentiality of the Human Subjects

Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information. Privacy and confidentiality are to be maintained under the following circumstances:

- On handling personal identification information
- Special consideration when collecting information through electronic devices
- On handling administrative or official data where explicit consent is not possible
- Geo-spatial local information, whenever collected

5.5 Vulnerable groups and individuals

Some groups and individuals are particularly vulnerable and are more likely to be exposed to risk of additional. All vulnerable groups and individuals should receive specifically considered protection. Research with a vulnerable group is only justified if the research is responsive to this group's health needs or priorities and the study cannot be carried out in a non-vulnerable group. In addition, this group should stand for the knowledge, practices, or inventions that result from the research.

5.6 Risk, burdens, and benefits

Research involving human subjects may only be conducted if the importance of the objective outweighs the risks and responsibilities to the research subjects.

All research involving human subjects and submitted for IRB approval, must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the study compared with foreseeable benefits to them and other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The researcher must continuously monitor, assess, and document the risks. The investigators may only be involved in a research study involving human subjects if they are confident that the risks have been adequately assessed and can be satisfactorily managed. When the stakes outweigh the potential benefits, or there is conclusive proof of definitive outcomes, investigators must determine whether to continue, modify, or immediately stop the study.

5.7 Informed Consent

Participation by individuals capable of giving informed consent as subjects in research must be voluntary. Although consulting family members or community leaders may be appropriate, only individuals capable of providing informed consent will be enrolled in a research study if they agree.
In research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The possible subject must be informed of the right to refuse to participate in the study or withdraw consent to participate without reprisal. Particular attention should be given to the specific information needs of individual potential subjects and the methods used to deliver the information. After ensuring that the potential subject understands the information, the investigator or another appropriately qualified individual must seek the likely subject's informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All research subjects should be given the option of being informed about the general outcome and results of the study.

When seeking informed consent for participation in a research study, the investigator must be particularly cautious if the potential subject depends on the physician or may consent under duress. In such situations, informed consent must be sought by an appropriately qualified individual completely independent of this relationship.
For a potential research subject incapable of giving informed consent, the investigator must seek informed consent from the legally authorised representative or caregivers. These individuals must only be included in a research study that is likely to benefit them if it is intended to promote the health of the group represented by the potential subject. The research cannot instead be performed with persons capable of providing informed consent.

Research involves minimal risk and minimal burden. When a potential research subject deemed incapable of giving informed consent can give assent to decisions about participation in research, the investigator must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected. However, the JPGSPH IRB considers the consent provided by mature minors to be sufficient and does not require a separate assent form in such cases. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition preventing informed consent is a necessary characteristic of the research group. In such circumstances, the investigator must seek informed consent from the legally authorised representative or caregivers. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent, provided that the specific reasons for involving subjects with the condition that renders them unable to give informed consent have been stated in the research protocol and reviewers have approved the study. Consent to remain in the research must be obtained from the subject or a legally authorised representative as soon as possible.

The investigator must fully inform the subject which aspects of their care relate to the research. The refusal to participate in a study or the patient's decision to withdraw must never adversely affect the patient-physician relationship.

For research using identifiable human material or data, such as research on material or data contained in bio-banks or similar repositories, the investigators must seek informed consent for its collection, storage, and reuse. There may be exceptional situations where consent would be impossible or impracticable for such research. In such cases, the study may be done only after consideration and approval of IRB.

5.8 Statement of Conflict of Interest

The conflict-of-interest statement should be made in case such conflict occurs.

5.9 Plan for research publication and dissemination

Researchers, authors, sponsors, editors, and publishers have ethical obligations concerning the publication and dissemination of the research results from the research protocol submitted for IRB approval. Researchers, while making the research results publicly available, are responsible and accountable for the completeness and accuracy of their reports, protecting the privacy and confidentiality of the research participants. All parties should adhere to accepted guidelines for ethical reporting. Negative, inconclusive, and positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations, and conflicts of interest must be declared in the publication. Research reports not following the the principles of Helsinki Declaration should not be accepted for publication.

6. Responsibilities of researchers

Researchers have a fundamental obligation to conduct research with the utmost integrity, adhering to all relevant laws, regulations, and ethical standards. This includes respecting the terms set by the IRB that approved their project. Any deviations from the approved research plan require prior IRB approval unless such changes are immediately necessary to protect participants or involve purely logistical or administrative aspects of the study. Researchers must notify the IRB upon the completion of their project. They are also responsible for ensuring the IRB approval is renewed before the expiry date if the study continues beyond that point. Any adverse events arising from the research must be reported to the IRB within 15 days. However, serious adverse events (those resulting in death, life-threatening situations, or hospitalization) must be reported immediately. Researchers are expected to conduct themselves professionally, uphold conventions of data management, disclose conflicts of interest, and report their findings responsibly.

In summary, the researchers, therefore, will have the following responsibilities:

- Protect the rights and welfare of human subjects who participate in research.
- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- Personally conduct or supervise the research.
- Ensure that all staff, collaborators, and colleagues assisting in the study are informed about the study, regulations governing research, and organisational policies.
- Ensure that all research activities have IRB approval and other approvals required by the organisation before human subjects are involved.
- Implement the research activity as the IRB approves it.
- Obtain the informed consent of subjects before they are involved in the research and document consent as approved by the IRB.
- Maintain written records of IRB reviews and decisions. Obtain and keep documented evidence of informed consent of the subjects (or their legally authorised representatives [LARs]).
- Obtain IRB approval for any proposed research plan change before its implementation.
- Follow the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others, including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
- Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
- Make provisions for secure retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.
- Verify that IRB approval has been obtained from all participating organisations in collaborative activities with other organisations.
- Notify the IRB regarding the emergency use of an investigational drug or device within five working days (or sooner if required by the IRB's policies) of the test article's administration.

7. Potential consequences when IRB regulations are not followed

If the researchers fail to follow the IRB regulations, they will have the following consequences:

- Suspension of the research project
- Suspension of all of a PI's research projects
- Inability to use data or publish results
- Notification to sponsors, regulatory agencies, and funding agencies of noncompliance
- Department by the Government of Bangladesh from using investigational products
- Inability to receive funding
- Additional monitoring and oversight by the IRB and third-party monitoring of
  — research activities
- Termination of employment
- Loss of licences
- Immediate shut-down of all research at an organisation

8. Types of Review

8.1 Full Review

The IRB will conduct a full review of the proposal and survey documents (including consent forms) if it determines the study poses more than minimal risk to participants. Minimal risk means that any potential harm or discomfort caused by the research activities is no greater than what participants might experience in their ordinary daily lives.

8.2 Expedited Review

Studies with minimal or remote risks may qualify for an expedited review. The IRB will decide whether a formal presentation by the research team is necessary.

8.3 Fast-Track Review

A fast-track review aims to speed up the review process. This process involves a shorter review timeline, usually within one month, compared to the

9. Steps of the IRB Review Process

9.1 Eligibility

The IRB accepts application that meets the following criteria:

a. The applicant is affiliated with BRAC or BRAC University including BRAC James P Grant School of Public Health (BRAC JPGSPH), BRAC Institute of Governance and Development (BIGD), BRAC Institute of Education and Development (BRAC IED), Centre for Peace and Justice (CPJ).
b. In the case of BRAC JPGSPH, the project must be managed technically and financially at BRAC JPGSPH in order to be eligible for approval from the IRB of BRAC JPGSPH.
c. The applicant is a student of BRAC JPGSPH
d. The applicant is a student of another university, but their research is affiliated with BRAC or BRAC University.
e. For applicants who is an employee of BRAC or BRAC University but currently is in study leave with Independent Projects, the research has to be formally affiliated with an institute or organization of BRAC or BRACU (e.g., JPGSPH, BIGD, BIED). At least one co-investigator is a current staff or faculty member of BRAC or BRACU.
f. Adjunct faculty members of BRACU may apply for IRB review, provided their research is institutionally affiliated with BRAC or BRAC University.
g. The IRB approval process is independent of the study's funding status. Once the required fees have been paid and all review criteria have been satisfactorily met, the application will be processed and may be approved accordingly, irrespective of whether the study is self-funded or expected to receive funding at a later stage.
h. Applicants of self-funded studies or studies expected to receive funding at a later stage are eligible for IRB approval. The IRB approval process is independent of the study's funding status. Once the required fees have been paid and all review criteria have been satisfactorily met, the application will be processed.

9.2 Submission of IRB application form by investigator(s)

All research requiring review and approval by the IRB should be submitted in the prescribed Application Form, available on the website (https://bracjpgsph.org/research-irb), or upon contact with an IRB officer.
Applicants are advised to read the guideline carefully before filling in the application form.
For approval, research proposals submitted to the Institutional Review Board of BRAC JPGSPH, BRAC University should be methodologically sound and meet scholarly standards. The Principal Investigator(s) will be informed if and when any comment/query must be addressed.

9.3 Initial Scrutiny of Study Proposal by IRB officers

Upon receiving an IRB application, an IRB officer conducts an initial scrutiny of the application to check that the application meets the criteria of the review process; this includes checking whether all necessary documents have been attached, forms completely filled-in, and attachment of ethics certificates. If deemed necessary, general comments may be provided to the study correspondent at this stage to address initial concerns or clarify aspects of the proposal.

9.4 Suggestion of Relevant Reviewers

The IRB officer facilitates the assignment of reviewers by forwarding suggestions to the Chairperson/Co-chairperson, who make decisions regarding whom to approach for review. During this process, a list of reviewers is made where two of them are approached. In case one is not available, the next person in the list is approached. In this stage, the Chairperson/Co-Chairperson may go through the application, if necessary, to decide which reviewers may be suitable depending on the area of the research topic and methodology. During this process, the Chairperson/Co-Chairperson may also provide comments to IRB applicants for further clarification which will be submitted to the applicant along with the comments from the reviewers. Following this, the IRB officer contacts the potential

reviewers, asking their availability and agreement to review within the requested date, through an email, removing personal details of the PI/Country Lead to prevent conflicts of interest. Confirmation of the reviewers' willingness to undertake the review is sought before proceeding. A reviewer is given 48 hours to decide and respond to the email. If the reviewer does not respond within 48 hours, the IRB officer sends a followup email to notify that another reviewer has been approached and that response is no longer required. The IRB officer then contacts another reviewer.

9.5 Sharing applicant's files with reviewers

Once confirmation is received, the IRB officer emails all relevant study files to the reviewers, typically allowing a 14-day window for feedback submission, in case of fast-track review, a 7-day window is typically allowed. After receiving comments, the IRB shares the feedback with the IRB correspondent of the study keeping the Principal Investigator (PI) and country focal (in the case of an International PI) in the loop, ensuring reviewer anonymity to maintain objectivity in the review process.

9.6 In-person IRB session

Simultaneously while the reviewers review the application, the IRB officer organises an in-person IRB session where relevant experts (other than the reviewers) are invited to provide further technical and ethical feedback to the investigators of the research. The reviewers should represent various community aspects, including journalists, lawyers, social workers, religion specialists, women's activists, etc. The in-person session is chaired by either the Chairperson and/or the Co-Chairperson depending upon availability. One investigator from the team presents the research in front of the reviewers of the in-person session and receives relevant feedback and suggestions. Following the IRB session, the research team is expected to respond within two weeks to the IRB's comments and adhere to any suggestions and feedback provided during the meeting.

All IRB applications should undergo in-person IRB sessions unless there is an unavoidable circumstance!! Any request to postpone or skip the session by the investigators due to unavoidable circumstances must be made in writing to the Chair/Co-Chair (depending on who is overseeing the application) with adequate justification. The Chair/Co-Chair will decide whether the request would be granted or not.

9.7 Reviewer Satisfaction and Final Decision

Once the researchers' responses to the comments are received, the IRB shares the responses with the respective reviewers. The IRB seeks confirmation from the reviewers regarding their satisfaction with the researcher's responses, which plays a crucial role in the final decision-making process regarding the study proposal.

9.8 Issuance of Approval Letter

After reviewers confirm that the responses by the investigators are satisfactory, , the IRB officer sits with the Chairperson/Co-chairperson to review the feedback. If no ethical concerns arise during the review process, the board proceeds to issue an approval letter.

9.9 Fees and Honorarium

- The fees for application is BDT 40,000 . For fast-track review process, the fee increases to BDT 60,000 . However, this fee is waived for students obtaining a master's degree from BRAC University.
- For masters or doctoral students outside BRAC University, where one of the institution of BRAC or BRAC University is affiliated, and the fee will be BDT 20,000.
- If any amendment is made to an existing approved IRB application, the fee is BDT 6500, subject to the nature of the modifications requested.
- The provision for honorarium will be in the following configuration:

  IRB In-Person Session Reviewers will receive an honorarium of BDT 1500 for each proposal reviewed, provided they attend the IRB in-person session. Honorariums are subject to applicable VAT and tax deductions at the payee's end.

Potential Reviewers, who provide detailed technical and ethical reviews without attending meetings, receive an honorarium of BDT 4000 per proposal. In case of a fast-track review process, receive an honorarium of BDT 6000. Honorariums are subject to applicable VAT and tax deductions at the payee's end.

10. AI-driven data policy

AI-driven data analysis is powerful, but ethical concerns must be addressed to ensure fairness, privacy, transparency, and accountability. For this, the Institutional Review Board of BRAC James P Grant School of Public Health, BRAC University, establishes the following AI ethics policies.

10.1 Researchers' responsibility

- Mention the use of AI clearly in the methodology section of the IRB application form.
- Maintain transparency about AI's role in research.
- Mention the use of AI in the information sheet and the consent form if the respondents' data are given to AI for analysis purposes.
- Researchers need to develop ethical guidelines for their team for AI use. Give ethical training to the AI users.

10.2 IRB's responsibility

The institutional review board will oversee the studies and the role of AI.

10.3 Reviewers' Responsibility

Reviewers must ensure that any use of Artificial Intelligence (AI) tools in the submitted research complies with ethical standards and does not compromise the integrity, originality, or confidentiality of the work.

11. Contact Information of IRB Personnel

Email: irb-jpgsph@bracu.ac.bd

Mailing address:
BRAC James P Grant School of Public Health, BRAC University
10-13 Floor, BRAC Tower, 65 Mohakhali,
Bir Uttam A K Khandakar Road, Dhaka-1212, Bangladesh
Facebook | Twitter | LinkedIn | Website
Phone number: 01993379512

12. References

1. Bangladesh Medical Research Council (BMRC).
2. International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B)
3. National Institutes of Health (NIH), US
4. National Health Service, UK (NHS, UK)
5. WHO
6. National University of Singapore
7. Harvard University
8. University of Leeds
9. University of Cambridge, UK
10. BRAC University

ANNEX I

Composition of IRB Members

1. Prof. Zahidul Quayyum, Chairperson, BRAC James P Grant School of Public Health, BRAC University
2. Atiya Rahman, Co-Chairperson, BRAC James P Grant School of Public Health, BRAC University
3. Dr. Laura Reichenbach, Dean, BRAC James P Grant School of Public Health, BRAC University
4. Dr. Kaosar Afsana, Professor, Lead, Humanitarian Hub, BRAC James P Grant School of Public Health, BRAC University
5. Dr. Shams El Arifeen, Senior Director, Maternal and Child Health Division, icddr,b.
6. Dr Fariha Haseen, Associate Professor, Head, Division of RCH, Director, Centre for Gender

and Women's Health Research, Dept. of Public Health and Informatics, Bangladesh Medical University.
7. Nadia Sharmin Rahman, LL.B (Hons) LL.M, Advocate, Supreme Court of Bangladesh, Panel Lawyer of Dhaka Metropolitan Police.
8. Dr Tareq Salahuddin, Journalist, Health Editor of The Daily Star, Member of Public Health Association of Bangladesh..
9. Mohammad Elius, Professor, Department of World Religion and Culture, University of Dhaka.
10. Munshi Sulaiman, Research Director, BIGD, BRAC University
11. Dr. Atonu Rabbani, Professor, Department of Economics, University of Dhaka.
12. Dipak Kumar Mitra, Professor and Chair, Department of Public Health, School of Health and Life Sciences, North South University.
13. Sumana Biswas, Headmistress, Nalonda High School.

ANNEX II

Terms of Reference for the Chairperson of the Institutional Review Board (IRB)

Introduction: The Chairperson of the IRB at BRAC JPGSPH plays a pivotal role in upholding the principles of ethical research, including respect for persons, beneficence, and justice. The Chairperson oversees the functioning of the IRB, promoting the highest standards of research integrity, and ensuring clarity and alignment with institutional goals and ethical standards. The Chairperson plays a crucial role in ensuring the ethical conduct of research involving human subjects.

Responsibilities and Duties

The responsibilities and duties of the Chairperson include:

a) Leadership and Oversight

- Providing leadership to the IRB, promoting a culture of ethical research.
- Ensuring the IRB operates in accordance with the guidelines, institutional policies, and ethical standards.
- Overseeing the review process of research protocols, ensuring thoroughness, consistency, and adherence to ethical principles and quality of the research.

b) Facilitation of Meetings

- Scheduling and chairing IRB meetings, ensuring adequate representation and participation of IRB members and timely review of research protocols.
- Facilitating discussions during meetings to ensure comprehensive evaluation of research proposals and ethical considerations.
- Ensuring the maintenance of accurate records of meeting minutes and decisions taken by the IRB.

c) Collaboration and Communication

- Promoting collaboration and communication among IRB members, technical reviewers, researchers, and institutional stakeholders.
- Serving as a liaison between the IRB and the administration, faculty, students, and external institutions and entities regarding ethical review processes and decisions.
- Providing guidance and support to researchers regarding ethical considerations and compliance requirements.

d) Compliance and Quality Assurance

- Monitoring compliance with IRB policies, procedures, and regulatory requirements.
- Conducting periodic reviews and assessments of IRB activities to identify areas for improvement and ensure the quality and integrity of the review process.
- Addressing any conflicts of interest or ethical concerns raised during the review process promptly and impartially.

e) Representation and Advocacy

- Representing the IRB in institutional committees, professional forums, and external engagements related to research ethics and human subjects protection.
- Advocating for the importance of ethical research practices and the role of the IRB in safeguarding the rights and welfare of research participants.

f) Training and Capacity Building

- Facilitating training sessions for IRB members to enhance their understanding of ethical principles, regulatory requirements, and review processes.
- Promoting continuous learning and capacity building within the IRB to ensure competence and effectiveness in ethical review activities.

g) Reporting

The Chairperson of the IRB shall report to the Dean or Deputy Dean of BRAC JPGSPH or designated institutional authority on matters pertaining to the functioning, performance, and outcomes of the IRB.

h) Confidentiality and Conflict of Interest

The Chairperson of the IRB shall uphold strict confidentiality regarding sensitive information discussed during IRB meetings and declare any conflicts of interest that may arise in the course of their duties.

Period of Appointment

The Chairperson of the IRB shall serve a term of Two Years, renewable subject to satisfactory performance and institutional needs. By fulfilling the responsibilities outlined in these terms of reference, the Chairperson contributes to the advancement of knowledge while upholding the highest standards of ethical integrity and participant protection.

Review and Amendments

The above terms of reference shall be reviewed periodically and may be amended as deemed necessary by the institution to reflect changes in regulatory requirements, institutional policies, or best practices in research ethics.

Terms of Reference for the Co-Chairperson of the Institutional Review Board

Introduction

The Co-Chairperson of the IRB at BRAC JPGSPH plays a role in upholding the principles of ethical research, including respect for persons, beneficence, and justice. The Co-Chairperson will support the IRB Chairperson in overseeing the functioning of the IRB, promoting the highest standards of research integrity, ensuring clarity and alignment with institutional goals and ethical standards, and assisting the Chairperson in playing a crucial role in ensuring the research quality and ethical conduct of research involving human subjects.

Responsibilities and Duties: The responsibilities and duties of the Co-Chairperson are:

A) Leadership and Oversight

- Providing support to the IRB Chairperson in their role of leadership to the IRB, promoting a culture of ethical research.
- Collaborate with the Chairperson to ensure that the IRB operates in accordance with the guidelines, institutional policies, and ethical standards.
- Support the Chairperson in overseeing the review process of research protocols, ensuring thoroughness, consistency, and adherence to ethical principles and quality of the research.

B) Facilitation of Meetings

- Assist in scheduling and chairing IRB meetings, ensuring a quorum of IRB members and and timely review of research protocols submitted for IRB approval.
- Contributing actively to meeting discussions, promoting the comprehensive evaluation of research proposals and ethical considerations
- Supporting the maintenance of accurate records of meeting minutes and decisions taken by the IRB.

C) Collaboration and Communication

- Promoting collaboration and communication among IRB members, technical reviewers, researchers, and institutional stakeholders.
- Serving as a liaison between the IRB and the administration, faculty, students, and external institutions and entities regarding ethical review processes and decisions.
- Providing guidance and support to researchers regarding ethical considerations and compliance requirements.

D) Compliance and Quality Assurance

- Assisting IRB members in monitoring compliance with IRB policies, procedures, and regulatory requirements.
- Participating in periodic reviews and assessments of IRB activities to identify areas

for improvement and ensure the quality and integrity of the review process.
- Assist the Chairperson to address conflicts of interest or ethical concerns raised during the review process promptly and impartially.

E) Representation and Advocacy
- Supporting the Chairperson in representing the IRB in institutional committees, professional forums, and external engagements related to research ethics and human subjects' protection.
- Contributing to advocacy efforts promoting the importance of ethical research practices and the role of the IRB in safeguarding the rights and welfare of research participants.

F) Training and Capacity Building
- Supporting the Chairperson in organizing training sessions for IRB members, enhancing their understanding of ethical principles, regulatory requirements, and review processes.
- Contributing to promoting continuous learning and capacity building within the IRB to ensure competence and effectiveness in ethical review activities.

G) Reporting

The Co-Chairperson of the IRB shall collaborate with the Chairperson in reporting to the Dean or Deputy Dean of BRAC JPGSPH or designated institutional authority on matters pertaining to the functioning, performance, and outcomes of the IRB.

H) Confidentiality and Conflict of Interest

The Co-Chairperson of the IRB shall uphold strict confidentiality regarding sensitive information discussed during IRB meetings and declare any conflicts of interest that may arise in the course of their duties.

Period of Appointment

The Co-Chairperson of the IRB shall serve a term of Two Years, renewable subject to satisfactory performance and institutional needs. By fulfilling the responsibilities outlined in these terms of reference, the Co-Chairperson contributes to the advancement of knowledge while upholding the highest standards of ethical integrity and participant protection.

Review and Amendments

The above terms of reference shall be reviewed periodically and may be amended as deemed necessary by the institution to reflect changes in regulatory requirements, institutional policies, or best practices in research ethics.

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The above terms of reference shall be reviewed periodically and may be amended as deemed necessary by the institution to reflect changes in regulatory requirements, institutional policies, or best practices in research ethics.

Zahidul Quayyum, PhD
Professor
Chairperson, Institutional Review Board
Co-Director, Centre of Excellence for Urban Equity and Health (CUEH)
BRAC James P Grant School of Public Health, BRAC University
Date: 01.06.2025

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