Government of the People's Republic of Bangladesh

Standard Operating Procedures for the Institutional Review Board

Demography and Health Wing
Bangladesh Bureau of Statistics
Parishankhyan Bhaban
E 27/A Agargaon, Dhaka 1207
www.bbs.gov.bd

World Health Organization
Bangladesh

Contents

Acronyms

Acronym	Elaborate Form
AFP	Alternative Focal Point
BBS	Bangladesh Bureau of Statistics
BDT	Bangladesh Taka
DPD	Deputy Project Director
FP	Focal Point
IRB	Institutional Review Board
NSS	National Statistical System
PD	Project Director
SOP	Standard Operating Procedure
USD	United States Dollar
WHO	World Health Organization

Preamble

The Bangladesh Bureau of Statistics (BBS) was formed by merging four statistical offices in 1974 with a vision to become an established National Statistical Organization (NSO) at the local and international level. With the passage of the 'Statistics Act' on 27th February 2013 by the great national parliament, the BBS got a legal basis.

The Demography and Health Wing and other Wings of the BBS undertake many surveys on human subjects, which need the review of an independent research ethics committee as a global requirement from funding partners and peer-reviewed journals. The BBS currently applies to other local research ethics committees of Bangladesh for this kind of ethical review.

The benefits of a research ethics committee under the BBS were discussed. Under the circumstances, it was decided that BBS would form such a committee with guidance from the Bangladesh Medical Research Council – the apex body on health research in Bangladesh (BMRC Resolution, 1976). The World Health Organization (WHO) technically and financially supported the BBS for the formation and activation of the IRB of the BBS.

A 25-member committee consisted with relevant officials from SID, BBS, BMRC, icddr,b and WHO worked on preparing the IRB manual and Standards Operating Procedure (SOP) for outlining the structure and function of the IRB of the BBS led by the Director General of the BBS. After number of meetings and incorporation of suggestions from the committee members, the SOP and the manual have finally got its complete structure.

Background:

Institutional Review Boards (IRBs) are independent committees that ensure the ethical conduct of research and protect human subjects by reviewing, approving, and monitoring studies involving biomedical, behavioral, and psychosocial aspects. (USGAO, 2023; BMRC). Their key features are competence and independence in safeguarding respondents' and participants' rights, privacy, and well-being. In the context of official statistics, an IRB plays a vital role in overseeing large-scale surveys and operations that involve collecting health-related and sensitive data. For the Bangladesh Bureau of Statistics (BBS), establishing an IRB called the IRB of BBS ensures that all activities are conducted with strict ethical and scientific oversight, thereby enhancing the credibility, trustworthiness, and international alignment of national statistical outputs. The Demography and Health wing of BBS serves as the Secretariat for the Institutional Review Board. (IRB)

The Bangladesh Bureau of Statistics (BBS) serves as the National Statistical Office (NSO), responsible for collecting, processing, analyzing, and disseminating official statistics. The Standard Operating Procedure (SOP) established for the Institutional Review Board (IRB) at BBS is intended to ensure consistency, transparency, and accuracy in the planning, implementation, analysis, and publication of studies and surveys that require ethical approval for demographic and health-related data and information. This protocol is designed to maintain the credibility and consistency of surveys related to design, data integrity, and the ethical considerations involving human subjects within the National Statistical System (NSS) of Bangladesh.

The Objectives

The objectives of this Standard Operating Procedure (SOP) for the Institutional Review Board (IRB) of the Bangladesh Bureau of Statistics (BBS) are to:

1. Establish a uniform, transparent, and credible ethical review system for all Demography and Health–related surveys, studies, and research involving human participants conducted or supported by BBS.
2. Ensure the protection of the rights, safety, privacy, and dignity of respondents, with particular attention to vulnerable populations, in accordance with national laws and internationally accepted ethical standards.

3. Define clear procedures and institutional responsibilities for ethical review, approval, monitoring, and documentation to ensure consistency, accountability, and timeliness in IRB operations.
4. Strengthen the credibility, quality, and international acceptability of BBS statistical outputs by ensuring ethical compliance and scientific integrity throughout the research lifecycle.

Mode of Operation

The BBS prioritizes protecting ethical standards and scientific integrity of Demography and Health related research and related survey activities. Surveys/studies for ethical approval should be submitted in the prescribed application pack (**Annexures A, B, and C**), which is also available in the BBS office and on the BBS website www.bbs.gov.bd.

- A survey or study submitted to the IRB for review should meet methodological standards and scholarly quality.
    - The survey or study proposal will either be rejected or carefully reviewed and categorized based on the level of risk involved. Depending on the assessment, the results may include exemption from review, expedited review, or a full review. (Figure 1, Page 8)
        - Rejected for review: How to decide if a project meets IRB review criteria. To determine if a proposal is "rejected" from IRB review, ask the following questions.
        - Does the project or relevant surveys fulfill the criteria of "research"?
        - Does the proposal meet the definition of a "human subject," such as involving the collection of data about living individuals, either through interaction or intervention, or the use of personally identifiable information or biospecimens? If the answer is "yes" to both of these questions, then it is considered human subjects research or relevant surveys that require IRB review.[1]
    - Exempt from review: As it does not fulfill the criteria for review, it is not considered for review.

[1] University of California. What does the term "exempt" actually mean in human subjects research? Available from: https://www.research.ucsb.edu/news/human-subjects-research-integrity/what-does-term-exempt-actually-mean-human-subjects-research [accessed 29 September 2025]

- Specific proposals are exempt from Institutional Review Board (IRB) assessment due to their minimal or negligible, or no risk to human participants. The chairperson of the IRB and the member secretary shall evaluate the appropriateness of protocols for such exemptions and inform the decision of the Committee in writing.

  - Review process that is expedited: Pilot study, secondary analysis, and short surveys.
  - Complete committee review of the study proposal.

- During the Committee meeting, the Project Director (PD) or Focal Point (FP) responsible for the survey or study will deliver a presentation to the committee members. A discussion will ensue involving the entire Committee. The PD/FP may be summoned to meet with the Committee to provide additional information or to clarify the documentation. The Committee's final decision will be based on the consensus of its members. Should the PD/FP also serve as a committee member, they will abstain from voting in that capacity. A designated individual will present the study to the Committee.
- The PD/FP of the survey/study will be informed of comments and queries during the meeting and in writing within two working days. They will then have one week to respond to these queries. However, if more than one week is needed under any circumstances, the PD/FP may notify the Committee Chair to extend the response time, subject to feasibility. Responses to the Committee's comments and queries must be submitted using a pre-set form available in the application pack. (**Annexures A, B, C, D, E, and F**).
- Final approval after considering the justification given/points addressed on the ethical issues of the survey /study proposal.
- Report (technical and/or journal publication) should be submitted periodically and at the end of the study.
- Any protocol deviation, if present, should be duly reported with sufficient detail justifications.
- Any amendments to the protocol must be resubmitted for approval. Changes to the PD/FP and the study location need to be reported to the IRB.
- The Institutional Review Board (IRB) of BBS shall operate in accordance with the provisions outlined in its Manual (**Annexure G**).

- The Committee (**Annexure H**) shall convene as necessary. A quorum (majority of the members) must be present before the transaction of any business by the Committee. All applications for Committee consideration should be submitted in advance, and the meeting must be convened within ten working days following the submission of the application, including complete documentation. If a committee member is unable to attend a meeting, they may suggest the Chair for a suitable replacement possessing comparable technical expertise and familiarity with IRB processes and procedures.

  One complete hard copy of the completed application package, including a forwarding letter addressed to the IRB Chair, along with the fully signed study protocol by the PD/FP and a scanned file of the entire submission, must be submitted to the IRB Secretary for review.

Review and Processing Fee (RPF) for ethical approval

The operating costs of the Institutional Review Board (IRB), including honorarium, hospitality, meeting expenses, and TA/DA for field monitoring of Board members, shall be borne by the respective Project Director (PD) or Focal Point (FP) in accordance with the provisions of the approved Development Project Proforma (DPP). Such costs shall be met from the relevant project budget as per prevailing government financial rules.

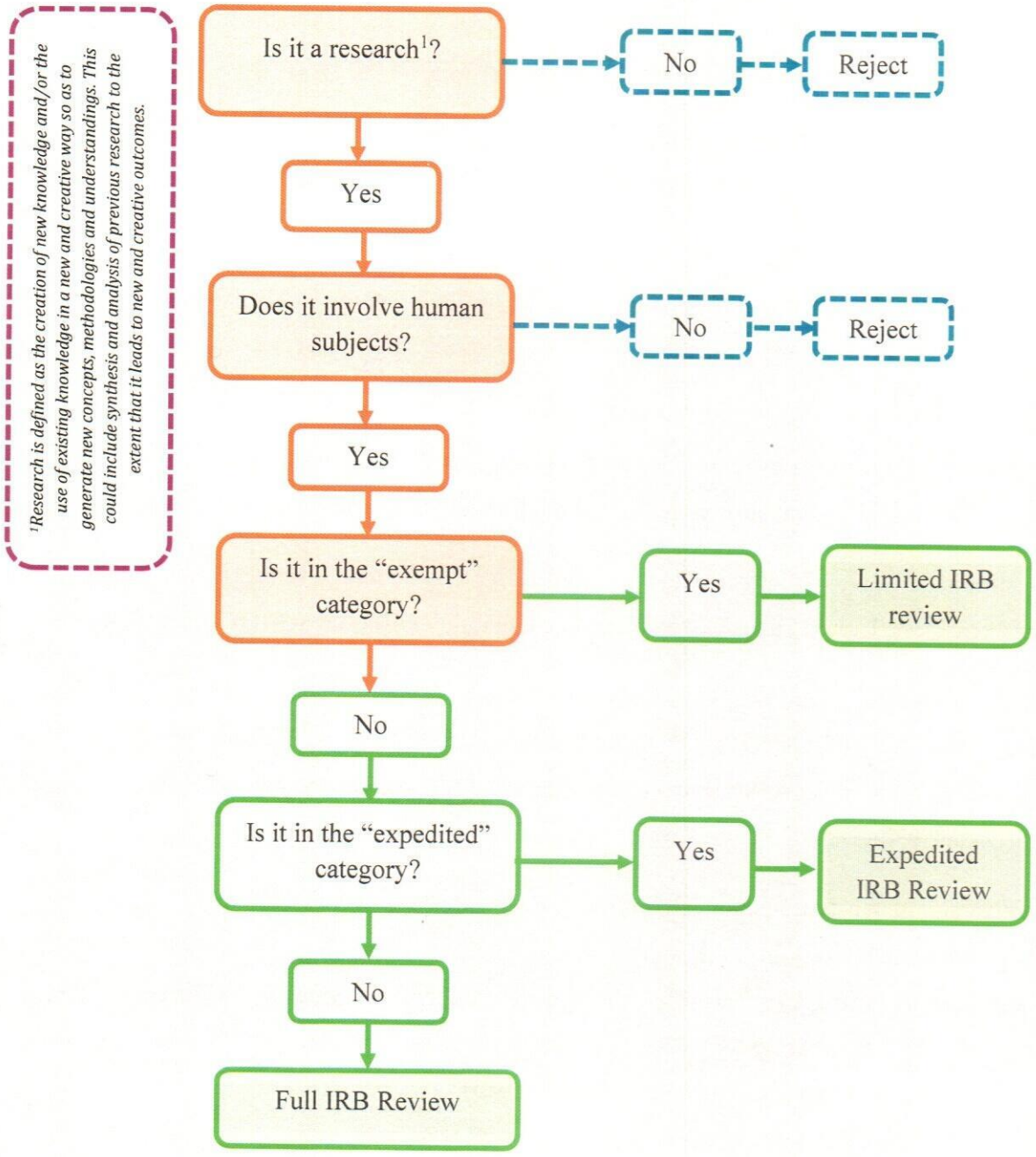

Figure 1: IRB review and approval process.

Bibliography

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Institutional Review Boards, Actions Needed to Improve Federal Oversight and Examine Effectiveness, United States Government Accountability Office (USGAO) [accessed 4 August 2025].

Mayo Foundation for Medical Education and Research. Institutional Review Board. Available from: https://www.mayo.edu/research/institutional-review-board/irb-policy-manual [accessed 4 August 2025]

University of Western Sydney. Definition of Research. Available from: https://www.westernsydney.edu.au/research/researchers/preparing_a_grant_application/dest_definition_of_research#:~:text=The%20Department%20of%20Education%20defines%20research%20as%20follows%3A,as%20to%20generate%20new%20concepts%2C%20methodologies%20and%20understandings. [2 November 2025]

Annexure A: Application for Ethical Clearance

1. PD/ FP's Name:

Designation:

Detail Address:

Mobile: Telephone (Off./Res)

e-mail:

2. DPD/AFP's Name:

Qualification:

Detail Address:

Mobile: Telephone (Off./Res)

e-mail:

3. Place of the Survey/Study/Organization(s):

4. Title of Survey/Study:

5. Type of Survey/Study:

6. Duration of Survey/Study:

7. Total Cost (BDT and USD):

8. Funding Agency:

Circle the appropriate answer to each of the following (If not applicable, write NA)

1. Source of Population:

(a) ILL Participant Yes No

(b) Non-ILL Participant Yes No

(c) Minors or persons under guardianship Yes No

2. Does the survey/study involve?

(a) Physical risks to the subjects Yes No

(b) Social Risks Yes No

(c) Psychological risks to subjects Yes No

(d) Discomfort to Subjects Yes No

(e) Invasion of the body Yes No

(f) Invasion of Privacy Yes No

(g) Disclosure or damaging of information to Subject or others Yes No

3. Does the study involve?

(a) Use of records (Hospital, medical, Death, birth or other) Yes No

(b) Use of organs or Body fluids Yes No

4. Are subjects clearly informed about the-

(a) Nature and purposes of study Yes No

(b) Procedures to be followed including alternatives used Yes No

(c) Physical risks Yes No

(d) Private questions Yes No

(e) Invasion of the Body Yes No

(f) Benefits to be Derived Yes No

(g) Right to refuse to participate or to withdraw from study Yes No

(h) Confidential handling of data Yes No

(i) Compensation where there are risks or loss of working time or privacy is involved in any particular procedure Yes No

5. Will signed consent form/verbal consent be required?

(a) From Subjects Yes No

(b) From parent or guardian (if subjects are minors) Yes No

6. Will precautions be taken to protect anonymity of subjects Yes No

Note: If the final instrument/questionnaire is not completed before review, the following information should be included in the abstract.

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.

2. Examples of the type of specific question to be asked in the sensitive areas.

3. An indication as to whom the questionnaire will be presented to the committee for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects or any changes of the Methodology before making any such changes.

Name of the PD/FP:

Signature

Date:

Sl. No.	Name contributors*	Signature
1.		
2.		
3.		

*Include all the PD/DPD/AFP based on contribution to the study protocol

Annexure B: Preparation of an abstract for institutional review board (IRB)

The Institutional Review Board (IRB) will not review any application that lacks a specific abstract or summary for the committee. The abstract should summarize the purpose of the study or relevant surveys, the methods and procedures to be used, addressing each of the following items. If an item does not apply, please note it accordingly.

1. Describe the requirements regarding the survey/study population and explain the reason for including special groups, such as children, incompetent persons, or groups whose ability to give voluntary informed consent is questionable.

2. Describe and evaluate any potential risks; physical, psychological, social, legal, or other—along with the likelihood and severity of these risks. If certain research or study methods pose potential risks, outline alternative methods considered and explain why they could not be used.

3. Describe procedures for protecting against or minimizing potential risks and evaluate their likely effectiveness.

4. Include a description of the methods used to safeguard confidentiality or protect anonymity.

5. When there are potential risks to the subject or the individual's privacy may be involved, the enumerator or data collector must obtain a signed informed consent from the participant. For minors, informed consent must be obtained from the authorized legal guardian or parent of the subject. Describe the consent procedures to be followed, including how and where informed consent will be obtained.

   a. If signed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure, such as a verbal explanation consent.
   b. If information needs to be withheld from a subject, provide a justification for this decision.
   c. If a procedure poses a potential risk to the subject's or individual's privacy, or could result in a loss of work time, include a statement in the consent form indicating whether any compensation will be provided available.

6. If the study involves an interview, describe where and in what context the interview will take place. State the approximate length of time needed for the interview.

7. Assess the potential benefits to the individual participant as well as the benefits that may benefit society in general as a result of the work. Indicate how the benefits may outweigh the risks.

8. State whether the activity requires the use of records (hospital, medical, birth, death, or other), organs, tissues, body fluids, the fetus, or the abortus.

The statement to the subject should include information specified in items 2, 3, 4, 5(c), and 7, as well as indicate the approximate time needed for participation in the activity.

Annexure C: Format for submission of a research proposal for IRB review

Protocol number: _____

Formatting: Protocol has been prepared with 1.5 line spacing, 2.5 cm margins on all sides, sequential page and line numbering starting on each page, and section numbers beginning with the Introduction (Executive Summary does not have a section) number).

1. Title page: version number with date, title of the study, organizational/unit details including website, partners' logos;
2. Content page;
3. Acknowledgements;
4. Acronym list;
5. PD/DPD/FP/AFP list with contact details;
6. Executive summary including cost of conducting the survey/study (*up to 250 words with 5 key words*): introduction/ background, methods, cost;
7. Introduction/ Background;
8. Rationale;
9. Brief description on implementing organization;
10. Objectives: primary, secondary;
11. Methods: (*a flow diagram summarizing the methods and a Gantt Chart on activity implementation timeline should be included*)
    a. overview,
    b. study population,
    c. study design,
    d. inclusion/ exclusion criteria,
    e. duration of survey,
    f. sample size estimation,
    g. sampling,
    h. questionnaire,
    i. field work (*field staff recruitment, training, data collection procedure*),
    j. data management and analysis linked with the objective/ hypothesis/ research question (*include dummy table/s*),
    k. quality assurance measures, and
    l. responsibilities of different organizations.
12. Ethical issues (*please include ethical approval number*);

13. Risk analysis and mitigation plan
14. Strengths and Limitations (*potential bias, representativeness etc.*)
15. Dissemination of results and publication policy;
16. Budget description with justification and detailed/ summary budget;
17. References: Vancouver style;
18. Annexures:
    a. Composition of technical and steering committees,
    b. Questionnaire (English and *Bangla*),
    c. Assent form/s (English and *Bangla*),
    d. Consent form/s (English and Bangla),
    e. Tables (dummy table/s in data analysis),
    f. Figures (flow diagram summarizing methods).
    g. Terms of reference of the person to be recruited,
    h. Ethical approval obtained,
    i. Ethical approval submitted,
    j. Brief (1 page) CV of investigators (PD/DPD/FP/AFP),
    k. Others: Specify _____

Annexure D: Reply to the RRC comments/observations

Protocol number:

Protocol title:

Reply date:

NOTE: The revised protocol is to be prepared with page numbers and line numbers beginning on each page

Seri	Comment/Observation	Reply by	Changes done on page and
		a. Agreed and texts inserted b. Agreed and text deleted c. Refuted with justification s and	a. Indicate page and line numbers b. Page and line numbers not shown because it disappeared c. Texts remained same because it has been refuted; Texts

Annexure E: Informed consent/assent forms2 written in Bangla and English

Instructions:

- The language used throughout the form should be appropriate for a local student in grades 6–8.
- Please note that these templates, developed by the WHO ERC, are meant to help the PD/FP in designing their informed consent forms (ICF). It is essential that Principal Investigators customize their own ICFs to fit the outline and requirements of their specific study. The institution's logo must be used on the ICF, not the WHO logo. The informed consent form consists of two parts: the information sheet and the consent certificate.
- The consent forms contain guidance and explanations.

These templates include examples of key questions that may be asked at the end of each section, which could help ensure understanding of the information provided, especially if the research study is complex.

Instructions for the following suggested templates (to be used as appropriate):

- *Square brackets indicate where specific information is to be inserted;*
- *Bold lettering indicates sections or wording that should be included.*
- *Standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.*
  - Informed consent for clinical studies: https://cdn.who.int/media/docs/default-source/documents/ethics/ethics-informedconsent-clinicalstudies.doc?sfvrsn=d69ff68a_0
  - Consent for storage and future use of unused samples: https://cdn.who.int/media/docs/default-source/documents/ethics/consent-for-storage-and-future-use-of-unused-samples.doc?sfvrsn=7be576f_0
  - Informed consent for qualitative studies: https://cdn.who.int/media/docs/default-source/documents/ethics/informed-consent-for-qualitative-studies.doc?sfvrsn=c6c75341_0

[2]World Health Organization. Research Ethics Review Committee (ERC) - Templates for informed consent forms. Available from: https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

- Informed assent for children/minors: https://cdn.who.int/media/docs/default-source/documents/ethics/informed-assent-for-children-minors.doc?sfvrsn=cc397f54_0
- Informed parental consent for research involving children (qualitative): https://cdn.who.int/media/docs/default-source/documents/ethics/informed-parental-consent-for-research-involving-children-(qualitative).doc?sfvrsn=e7ba983d_0
- Informed parental consent for research involving children (clinical): https://cdn.who.int/media/docs/default-source/documents/ethics/ethics-informedconsent-clinicalstudies-(1).doc?sfvrsn=69da86b4_2

Annexure F: Template for CV of PD/FP/Team Lead

Name and Contact information:

Name :

Designation :

Institute :

Address :

Email :

Cell phone No. :

Office ID :

Educational Background (Bachelor and above, maximum three):

Name of Degree	Institute, University, City, Country	Year of passing

Training on research methods/ethics (title, organization, duration):

1.
2.
3.

Past three position(s) held (with dates: From – To):

1.
2.
3.

Last five years Survey/Study Conducted by PD/FP or publication in peer reviewed journals (Use Vancouver style; Do not include abstract supplements/proceedings):

1.
2.
3.
4.
5.

Annexure G: Manual of the Institutional Review Board of the Bangladesh Bureau of Statistics

Rationale for Establishing Institutional Review Board (IRB) of BBS

The BBS conducts and supports a wide variety of health and demography-related surveys and studies, often involving sensitive data and vulnerable populations. To maintain the highest ethical standards, the IRB of BBS functions as an independent body to review, approve, and oversee the ethical aspects of all BBS-led, BBS-partnered, and collaborative health research and statistics.

Scope of the IRB of BBS

The Institutional Review Board (IRB) has jurisdiction over Demography and Health related survey/study that involve human health and biospecimen collection. The IRB may decide that the survey or study protocols are exempt from further review or require limited review, in accordance with national guidelines. Based on the level of risk involved, the study proposals will be evaluated and classified as exempt from review, expedited review, or full review review[3].

The review and approval request for the survey/study is voluntary, and there is no administrative enforcement. Each requester and his/her team will determine the necessity for IRB review and/or approval based on established national and international IRB guidelines. The IRB emphasizes and encourages the review and/or approval of Demography and Health related survey/study and collaborative survey/study of BBS with the Government ministries/agencies, universities, non-governmental organizations, and international agencies.

Objectives of the IRB of BBS:

(1) To ensure ethical compliance in BBS's Demography and Health related surveys/studies.;
(2) To safeguard the rights of vulnerable populations in surveys and studies by ensuring compliance with ethical standards.
(3) To ensure the scientific rigor of the research protocol on Demography and Health related surveys/studies

Composition of IRB

To ensure efficiency, transparency, and timely ethical review, a two-tier committee structure shall be established, as follows:

1. **Ethical Review Committee (ERC)**

   A three (3) member Ethical Review Committee (ERC) shall be constituted by the Director General of BBS. The Director, Demography and Health Wing shall serve as the Chairperson. Focal Point Officer, BBS-WHO Biennium Program will be the member secretary and Focal Point Officer, Research and Development Cell, BBS will be the member of the Ethical Review Committee ERC. If any member of this committee is not available then the committee will be reformed by the Director General of Bangladesh Bureau of Statistics. The ERC shall conduct a preliminary screening of submitted survey/ study proposals to determine whether the proposal requires full ethical review or qualifies for exemption, or is eligible for limited or expedited review

   .

2. **Full Institutional Review Board (IRB)**

   If the ERC determines that ethical review is required, the proposal shall be referred to the full Institutional Review Board (IRB), consisting of fifteen (15) members. The full IRB shall conduct a comprehensive ethical and scientific review of the proposal, make the final determination (approval, conditional approval, request for revision, or rejection), and direct all subsequent actions and follow-up measures.

Full Institutional Review Board (IRB)

The committee will have an odd number of members.

1. There should be at least five members on the committee. The committee should not be too large to maintain operational simplicity.
2. To ensure a comprehensive evaluation, it is crucial that the members have adequate experience, knowledge, and diversity.
3. The Chairperson shall head the committee.
4. The committee must be gender diversified.
5. The committee should be diverse in expertise.
6. The committee should include both scientific and non-scientific specialists, such as a lawyer, a religious expert, and civilians or non-experts related to the subject matter.
7. According to international law, a civilian or non-expert person regarding the subject must be present. Quorum is defined as the presence of a majority of members at a meeting.

8. At least one person (if the committee has five members) who is not affiliated with the institution must serve on the IRB. For larger committees, at least 40% of the members should be external to the institution or organization.
9. To meet competence or diversity standards, the IRB may seek advice from external experts.
10. IRB members will not reserve the right to vote on their own research proposals. Such as-if a research proposal or survey or study from Demography and Health Wing is submitted for review then the Director, Demography and Health Wing can not cast vote though he is the member secretary of IRB. All other IRB members are eligible to vote. Besides, majority of the board members must be present to vote on a proposal and at least one non-technical person must be present as well.

The IRB provides approval for:

➢ Survey, Study, and Research Projects (Internal/Intramural)

➢ Projects funded by the GoB and other organizations (both national and international), apart from the GoB (External/Extramural), including multicentric collaborative studies, which are official statistics.

Terms of Reference

1) The main goal of the IRB is to protect the rights, safety, and well-being of respondents and the survey population.
2) Members must uphold strict confidentiality and security.
3) Minutes of meetings, attendee sheets, and any supporting paperwork must be properly documented and preserved.
4) When a research/survey project possesses more than minimal risk, the IRB shall intensify its monitoring/review and adopt any or all of the following mechanisms:
   (i) Annual Review; (ii) Random Audit; (iii) Periodic review of study/survey documents by the Committee; (iv) Review of the adverse event and serious adverse events; and (v) Creation of a Data and Safety Monitoring Board (DSMB).
5) Survey Focal Point Officer or Project Director must submit the study or survey findings to the IRB for archiving, either as a survey report or as an article published in a peer-reviewed journal.
6) If applicable PD or the Focal Point must submit the following clinical research documents to the IRB:

- Study/survey protocols (including a suggested template for study/survey protocol) and revisions (such as the reply template to IRB members' comments), written informed consent forms, and consent forms recommended by the Committee for use.
- Each study/survey protocol for review by the IRB should complete the submission checklist along with the full study/survey protocol, including a complete set of annexures.
- The IRB must evaluate that the proposed method and/or accompanying documentation appropriately addresses the appropriate ethical objections and meets the applicable regulatory criteria of the trial in the case of a non-medical trial.

7) Members need to declare conflicts of interest (COI) and sign the COI document upon joining as an IRB member.
8) Each member should participate in the recommended online training on research ethics once per year and submit the certificate to the Committee. The link to CIOMS International Ethical Guidelines for Health-related Research Involving Humans is provided.
9) The Committee may seek expert opinion from within or outside BBS when necessary or co-opt a person or persons with a special background as member(s) for a single meeting, where appropriate. The Committee may decide on a simple procedure for such co-option.
10) This ToR may be reviewed and revised every three (03) years or earlier, if necessary, by a special meeting of ToR revision. Members shall serve for two (02) years, renewable, and Membership rotation shall ensure continuity and independence.
11) Meetings will be held as required. Demography and Health Wing of BBS will backstop the secretarial support to IRB. The focal point of the WHO-BBS collaboration activities of BBS will support the secretarial activities of the IRB-related activities.
12) The Chairperson will conduct all meetings of the IRB. In the absence of the Chairperson, members of the IRB will elect a chairperson who will conduct the meeting.
13) The IRB will conduct a meeting as required. The agenda should not be so loaded that sufficient time is not available for discussion. The frequency of meetings may increase depending on the number of applications.

14) The Member Secretary is responsible for organizing the meetings, maintaining the records, and communicating with all concerned. The Notice of the meeting should be issued at least 07 (seven) days prior of the meeting.
15) Minutes of the previous meeting should be confirmed. Proceedings of the meetings should be confidential and maintained in a standard format.
16) The proceedings of the meeting should be prepared within three working days after the meeting.
17) All decisions will be communicated in writing to the PD/FP.
18) Research issues having religious or social sensitivity should be approved by IRB.
19) International collaborative research involving the Bangladeshi population will have to get ethical approval from the IRB, while the Government shall give administrative approval.
20) Board members shall conduct field visits/inspections when the survey or study has commenced in the field.
21) Maintain audit, if necessary.

• **IRB should have the following documentation:**

- Copy of all study protocols with enclosed documents, progress reports, and Serious Adverse Effects (SAEs).
- Minutes of all meetings.
- Copy of all existing relevant national and international guidelines on research ethics and laws, along with amendments.
- Copy of all correspondence with members, researchers, and other regulatory bodies. - Final report of the approved projects.
- All documents should be archived.

Updating IRB members:

-All relevant new guidelines should be brought to the attention of the members.
- Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review, and be aware of the latest developments in this area.

Annexure H: Research Ethics Committee of Bangladesh Bureau of Statistics

Sl. No.	Category	Designation in committee	Representation
1.	Chairperson	Chairperson	Director General, Bangladesh Bureau of Statistics (BBS)
2.	Official from the Ministry	Member	Focal point/Nominated official from SID
3.	Senior Statisticians	Member	**Director, relevant wing of BBS
4.	Gender expert	Member	Department of Gender Studies, DU
5.	Sociologist/Economist	Member	Nominated by chair of BBS
6.	Scientist	Member	Scientist from relevant research organization like- IEDCR/ icddr,b
7.	Public Health Researcher	Member	Representative from NIPORT/icddr,b /NIPSOM/BRAC JPGSPH
8.	Physician	Member	Internal Medicine Specialist
9.	External Academic Reviewer	Member	An academician from a public or private university
10.	Legal Expert	Member	Representative from the Law and Justice Division.
11.	Religious Expert	Member	Representative, Department of World Religion and Culture, Dhaka University/Islamic Foundation
12.	A Civilian/Non-Expert member	Member	A civilian/non-expert member, nominated by the chairperson.
13.	World Health Organization (WHO)	Member	WHO Bangladesh Representative or an appropriate nominee with the required research experience;
14.	Bangladesh Medical Research Council (BMRC)	Member	Representative from BMRC
15.	Member-Secretary	Member-Secretary	Director, Demography & Health Wing, BBS

** If any survey or study of the Demography and Health Wing is submitted for review, the Director of the Census Wing shall act as the alternative in place of the Relevant Wing Director mentioned in item 3.