Bangladesh Health Professions Institute (BHPI)

Terms of Reference (ToR) of Institutional Review Board (IRB)

Institutional Review Board (IRB) of BHPI is an administrative body composed of Faculties, professionals, researchers and non- researchers to protect the rights and welfare of human research subjects recruited to participate in research activities.

The IRB of the Bangladesh Health Profession Institute (BHPI) an academic institute of Centre for the Rehabilitation of the Paralysed (CRP) is established under the mandate of Academic Council of BHPI and will work in accordance with guidelines of Nuremberg Code 1947, World Medical Association Declaration of Helsinki, 1964 – 2013 and other applicable regulations.

The Institutional Review Board (IRB) will expedite:

1. **Technical quality of research and**
2. **Adherence to international best practice ethical conduct of research involving human participants.**

Review by the Institutional Review Board (IRB) will include but will not be limited to:

1) Clinical studies of interventions.

2) Administration of new or existing measurements in the practice of treatment and rehabilitation including objective measurements through clinical instruments and equipments and subjective measurements, for instance, questionnaires.

3) Prospective collection of biological specimens for research purposes by noninvasive means.

4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected from a source which is solely for non-research purposes (such as medical treatment or diagnosis).

6) Collection of data from voice, video, digital or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior.

8) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

The committee will fulfill the following terms and conditions:

1. To facilitate research quality by peer reviewing all research projects proposals submitted to IRB.

2. To ensure screening of all research proposals which plan to involve human participants and issue clearances.

3. To verify that all research has been appropriately ethically reviewed which includes BHPI students, CRP staffs and others who would care to request for review their research before IRB.

4. To approve access to researches of students of BHPI and staffs of CRP for the purposes of data generation.

5. To approve access to resources (data, records etc.) of BHPI and clinical departments of CRP for the purposes of data generation.

6. To inform prospective researchers of any changes in the ethical codes of professional and other relevant bodies in order that IRB procedures remain valid.

7. To review procedures for the ethical scrutiny of research in BHPI and CRP on a regular basis and report to the Academic Council of BHPI.

8. The IRB must examine that subject selection is equitable, coercion is minimized, risks and benefits are proportionately reasonable and the participant is informed appropriately.

Members of the IRB of BHPI:

1. The Principal / Vice Principal of BHPI as the Convener of the committee (Total member: 01).
2. Coordinator of BHPI (total member: 01).
3. One senior academic staff or Head of each Department of physiotherapy, Occupational Therapy and Speech & Language Therapy of BHPI (total members: 03).
4. One senior clinical staff or Head of each Department of physiotherapy, Occupational Therapy and Speech & Language Therapy of CRP (total members: 03).
5. Course Coordinators of M.Sc. in Rehabilitation Science and M.Sc. in Physiotherapy (total members: 02).
6. Academic staffs with experience and interest in reviewing research proposals and ethics issues from any department of BHPI or as decided by the Convener of the committee (total members: at least 01 and no more than 04).
7. One representative of Research and Evaluation Department of CRP (Total members: 01).
8. May have a Biostatistician (total member: 01)
9. May Have a representative of the community (a patient from CRP/ Local religious leader / other) (total member: 01).
10. A Member Secretary from the academic staff members of IRB and approved by the IRB committee.

Tenure of the IRB committee and frequency of meeting:

1. Terms of office will be two years and can be renewed / reformed as per requirement.

2. The IRB shall meet once per three months and on ad hoc basis.

5. Requirements of quorum (more than half of the members present) for an IRB are required for a vote on a protocol. If quorum is not met; the meeting will be adjourned and the protocol will be placed on next meeting agenda.

Reporting

Yearly report of IRB will be submitted to the Academic Council of BHPI.

When and how review application to be submitted to IRB?

1. IRB review should ALWAYS be sought before the research has begun.
2. Data collection must start only after review application is approved by IRB.
3. Review applications must be submitted as hard copy. Relevant documentsmentioned in the IRB application sample must be presented at respective IRB meeting for review.
4. The IRB application sample and IRB Approval Letter Sample can be downloaded from BHPI website.
5. Applicants are expected to inform the IRB should there any change in the progress of the study.
6. Review applications can be resubmitted for renewal when there is any change occurring in the course of the study, any revision in the protocol and patient information or informed consent.

How IRB will review the applications?

1. The IRB will review all applications and their protocols within IRB member meetings.
2. A quorum (more than half of the members present) is required for a vote on a protocol. If quorum is not met; the meeting will be adjourned and the protocol will be placed on next month's agenda.
3. All members will accept and sign the decision based on the majority opinion of the members attending the meeting. The convener will take the final decision if there is a tie.
4. Applicants of approved protocols will be rewarded an IRB approval letter in BHPI letter head pad signed by the Member Secretary.
5. Applicants will only be responsible to keep all documents related to IRB approval (hard/soft copies) of his/her thesis/dissertation/research (IRB approval application, IRB approval letter and Documents to be presented at the IRB meeting by the applicant)

Issues to be addressed by IRB includes but not limited to:

1. **Participant Characteristics:**

Separate describe each population is expected. For example, if the research will include parents and their children, the parent population should be described separately from the child population.

2. **Persons / volunteers Assisting with the Research:**

Description of the training that research personnel will undergo to conduct the research is expected.

3. **Access to the Population:**

Description in detail the ability to obtain access to the population included within the research is required. Any potential conflicts of interest or coercive recruiting techniques are prohibited. For example, the IRB generally discourages the direct recruitment of one's own peers or students or staffs.

4. **Inclusion and exclusion criteria:**

Description of any populations that will be included in the research and excluded from the research and scientific justifications to support the inclusion and exclusion are required.

5. Research Methodology or Data Sources:

Audio-recording:

In order to ensure anonymity or confidentiality, description of audio-recording procedures within the informed consent form (ICF) is required. The ICF needs to include provision for the participant to clearly agree or disagree to audio-recording procedures. This can be accomplished by including a check-box system within the ICF.

Web-based research:

Description of the software or survey company that will be used to conduct the research is required. Whether their service will be paid or free and the level of security is required to be mentioned.

Protected Health Information:

Any information that is obtained about a participant through medical or treatment facility or any other organization or institute is required to be along with an authorized information release form

completed by the participant prior to any information being obtained from the participant's file. A wavier of authorization, typically in medical chart review projects, can also be obtained if specific justifications and requirements can be met.

Genetic Data, Sampling and Analysis:

Exact description of the process, purpose and its justification for the inclusion of genetic data and sampling is required.

Photography & Video recording:

Specific details regarding the content of the pictures and videos that are intended to be included within the research process is required includes but not limited to:

Will the participant's face be included?
Will the images include facility content?
When and how will the photos and/or videos be destroyed?
Should the photos or video-recording be used during the data reporting or publicationprocess?

Secondary Data:

The IRB must review research involving the use of secondary data, specifically when the data is not publicly accessible. If the data is NOT publicly accessible a full description is required to include all data fields that will be accessed. In some cases, a data use agreement may be required.

Purpose, Methods & Procedures:

Purpose:

A brief literature review and scientific justification in lay terminology regarding the purpose of the research is required.

Methods and Procedures:

IRB will examine detail description of all research procedures that each population included within the protocol will complete. Such procedures could include assessments, measurements, interviews, surveys, observations, etc.

Participation Time Requirement:

Description of the time required for each method and procedure, including an overall time requirement are required to be mentioned for IRB review.

Reminders:

Reminder follow-up with the participant is required. Specifics should include how many reminders will be sent and if reminders will only be sent to no responders or if they will be sent to the entire sample.

Recruitment, Benefits & Risks:

Names and Contact Information:

Description of how and why the participant population was accessed. Any conflict of interest that may exist with the access or any coercive recruitment techniques are subject to IRB check.

Recruiting Participants:

Review applicants will describe recruitment of the sample and submit all applicable supporting documents.

Research Benefits:

Review applicants will describe the potential research benefits to both the participant and society but do not overstate the benefits as this may cause participant confusion. If there are no direct benefits to the research participant, it is okay to state there are no direct benefits.

Medical Service Availability:

Description of the availability of medical accessibility (if applicable) is required. If there are no known risks, it is okay to state that medical resources are not applicable.

Incentives & Compensation:

Information regarding the incentive and/or compensation that may be offered during the research process is required. Compensation can be considered to offset the cost of a participant's time, effort, transportation, etc. required for the research to be conducted.

Description of Compensation:

The specific amount and type of payment (i.e. cash, gift card, check, extra credit, research credit, etc.) to be made must be included. Generally, incentives or compensation should not affect the participant's ability to reasonably decide to participate.

Student Extra Credit:

The IRB does not encourage any extra credit or marks to be added in the exam results for student volunteers for research activities. However, it does not oppose volunteer certificate or acknowledgement.

Participant Consent:

An informed consent process is one of the most important processes of the research procedures and one of the pillars that an IRB strives to maintain. The consent process should always be thought of as a discussion between an investigator and a research participant.

Conducting the Consent Process:

Obtaining consent from a participant should be thought of as a process and not just a form. An investigator has an obligation to ensure that the participant fully understands all elements of the project before they provide their consent. All applicable supporting consent documents should be uploaded.

Consent Language:

Appropriately translated versions of all documents, for instance, questionnaires, informed consents etc. along with the translation procedure will be required to be submitted, if the original documents are in a language other than the participants' mother language.

Coercion or Undue Influence:

It is required to mention should there any pre-existing relationship(s) between an investigator and the participant, and what processes will be followed to minimize possible participant coercion.

Confidentiality, Anonymity & Data:

Confidentiality: If someone would be able trace the responses back to the participant, then the investigator should maintain the participant's confidentiality.

Anonymity: If people, including the investigators, do not interact with the participant or collect identifying information about them, then the investigator would maintain the participant's anonymity.

Maintenance of Confidentiality:

Description of the maintenance of the data specific to the research protocol is required. For example, for an online survey, the records would typically be maintained in an online secure server that is password protected. Likewise, if paper records are maintained, the files would be kept in a locked office accessible to only the investigators.

Identified During Data Collection:

There are many research projects where the investigator knows the identity of the participant. An investigator should maintain a participant's confidentiality throughout the project. This section should reflect as such.

Reportable Data:

Description of how the data will be reported (e.g. aggregate form or specifically identifying participants) and how the results will be used, is required. For example, the results could be used as a class project, thesis, scientific journal, conference presentation, publication, etc.

Research or data collection site approval:

If approval from research or data collection site is required, documentation from the appropriate signatory official(s) will need to be included with the IRB Review Application form prior to submission.

Approval Documentation:

The approval document should be on company/organization/institutional letterhead. Documentation should include specific statements to illustrate that the organization fully understands what they are being asked to perform or provide.

Review Timelines:

Time required for an IRB approval:

Approval time varies depending on the number of protocols under review, the quality of the protocol submitted and the amount and content of the revisions that were requested.

Terms or glossaries:

Research:

Research is a systematic investigation that involves a prospective plan which incorporates data collection, either quantitative or qualitative. Data analysis is conducted to answer a research question or objective that will either develop a theory or contribute to generalizable knowledge. This knowledge may be applied to populations outside of the specific study population and/or inform policy.

Protocol:

The protocol would include logistical procedures, documents, scripts, and templates that will be reviewed by the IRB and subsequently followed by the investigator to conduct the project.

Project:

The project would be considered to include all steps that the investigator would undertake to go from theory to publication, or the long-term process. This is commonly confused with the term protocol.

Quality Improvement or Evaluation:

Quality Improvement or Evaluation is defined as an activity that is specifically initiated with a goal of improving the performance of a practice in relationship to an established standard.