# The University of Burdwan
# Institutional Clinical Ethics Committee

## Standard Operating Procedure (SOP)
## Study involving participation of human subjects or samples

*[This Standard operating procedure (SOP) has been prepared and accepted in the ICEC meeting held on 24/11/2017 as per ICMR guideline 2017, "National Ethical Guidelines for Biomedical and Health Research involving Human Participants" and based on The university of Burdwan applicability.]*

### Vision

The SOP will ensure the quality and consistency in review of clinical research proposals and to follow the ICMR ethical guidelines for biomedical research on human subjects.

### Activity

As per ICMR, the Ethical Committee should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

It will review and approve all research proposals involving human participants with a view to safeguard the rights, safety and well-being of research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects. It will look into the aspects of informed consent process, risk benefit ratio.

### Application process

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
2. All relevant documents should be enclosed with application.
3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators.
4. The Member Secretary will acknowledge the receipt and indicate any lacunae.
5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
6. The decision of IEC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.
7. PI/Co-PI/PhD student should apply through proper channel with covering letter mentioning the type of review requested for the submitted project.

### Review Procedure

1. Meetings shall be held on scheduled intervals (once in 4 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minute's book and shall be confirmed during the next meeting with signature of Chairperson at each page.

7. All the applicants, whose proposal has been approved, need to submit annual progress report and completion report as per prescribed format.

**A. Exemption from review**

Proposals with less than minimal risk where there are no linked identifiers, for example; research conducted on data available in the public domain for systematic reviews or meta-analysis;
• observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
• quality control and quality assurance audits in the institution;
• comparison of instructional techniques, curricula, or classroom management methods;
• consumer acceptance studies related to taste and food quality; and
• public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

**B. Expedited review**

Proposals that pose no more than minimal risk may undergo expedited review, for example;
research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
research involving clinical documentation materials that are non-identifiable (data, documents, records);
modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
• revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
• minor deviations from originally approved research causing no risk or minimal risk;
• progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

.

## C. Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members. While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

Collection of data through noninvasive procedures routinely employed in clinical practice.

Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

research involving vulnerable populations, even if the risk is minimal;

• research with minor increase over minimal risk;
• studies involving deception of participants
• research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
• amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
• major deviations and violations in the protocol;
• any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
• research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;

**Documentation**

All research proposals should be submitted with the following documents:

| **Checklist for the required documents for EC review of the research project /proposal** |
|---|
| **1.** Cover letter to the member secretary through proper channel mentioning type of review requested |
| **2.** Prescribed application form |
| **3.** Information sheet in English and local languages |
| 4. Consent document in English and local languages |

5. Case record form/ questionnaire
6. Synopsis of the study
7. One merged (point 2 to 6) soft .pdf copy submitted to the e-mail: icec@buruniv.ac.in
8. Permission letter /endorsement letter from the organization involved in the study
9. Declaration of undertaking as per prescribed format.
10. Any other document as per applicable.
11. Two hard copies of the form should be submitted to the Member secretary, Institutional Clinical Ethics Committee (IEC). Dept, of Zoology, BU

**Element of Review**

- ✓ Scientific design and conduct of the study.
- ✓ Assessment of predictable risks/harms and potential benefits.
- ✓ Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
- ✓ Management of research related injuries, adverse events and compensation provisions.
- ✓ Availability of products to the trial subjects after the study, if applicable.
- ✓ Requirements of Patient information sheet
- ✓ informed consent either verbal or written form in English/Bengali /Hindi and local language.
- ✓ Protection of privacy and confidentiality of subjects.
- ✓ Involvement of the community, wherever necessary.
- ✓ Plans for data analysis and reporting.
- ✓ Adherence to all regulatory requirements and applicable guidelines.
- ✓ Competence of investigators, research and supporting staff.
- ✓ Facilities and infrastructure.

**Decision making**

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions.

## Communicating the Decision

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

## Record keeping and archiving

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.

# The University of Burdwan
# Institutional Clinical Ethics Committee

*[In official stationary]*

## DECLARATION OF UNDERTAKING FOR THE APPROVAL OF CLINICAL ETHICAL COMMITTEE

**Title of the study:**

**PhD student**

**PI/Supervisor :**

On behalf of the research team, I /we hereby undertake that in respect to the operation of the above research work, we will follow the approved protocol including amendment if any. I will submit the annual report during the tenure of the research work or PhD study. I/we will conclude the research work within allotted time and shall remain careful regarding the ethical issues during my/our research work. If work can't be concluded within allotted time, prior permission will be requested form the IEC for the extension of the study. I/we also undertake that the patient consent /assent form will be preserved and available to the IEC if required. I /we will submit the study completion report at the end of the project/PhD study. I/we further undertake that I/we shall abide by the approved Ethical Guidelines Involving Human Participants and absolutely liable for any deviations, contraventions or violations at any point of time after or before getting the clearance from the committee.

Signature of the PhD student

Place:

Date:

Signature of PI/PhD Supervisor with seal

# The University of Burdwan
# Institutional Clinical Ethics Committee

## Application form for approval by the IEC of Project/ Ph.D. Study

| |
|---|
| **ICEC ref No:** |

**Proposal Title/ Ph.D. Title:**

| | Name, Designation & Qualifications | Address Tel & Fax Nos. Email ID | Signature |
|---|---|---|---|
| **PI/Candidate** | | | |
| **Co-PI 1.** | | | |
| **2.** | | | |
| **3.** | | | |
| **Collaborators 1.** | | | |
| **2.** | | | |
| **Thesis supervisor (in case of Ph.D. student)** | | | |

# The University of Burdwan
# Institutional Clinical Ethics Committee

- Applications that involve clinical investigations should have clinical collaborators as per ICMR guideline.
- A sample questionnaire should be submitted along with the application if the proposal involves survey. Whenever the study involves persons below 18 years of age, the informed consent should be signed by their parents/guardians.
- A sample form for the "informed consent" should be submitted (in English and its translation in the local language as applicable).

## Cover page

Name of the Source Institute, from where clinical samples will be collected:

Whether permission has been received for sample collection?

Whether any Clinical Person is attached in this study?

If yes, Name, Qualification and Designation:

Specific information about mode of sample collection and clinical involvement

# The University of Burdwan
# Institutional Clinical Ethics Committee

All sections should be "ticked" [√] appropriately. Write "NA" if not applicable

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sponsor Information** : | | | | | | | |
| 1. Indian | a) Government | Centr | ☐ | S | ☐ | Institu al | ☐ |
| | b) Private | | ☐ | | | | |
| 2. International | Government | P te | ☐ | UN agenc | ☐ | | ☐ |
| 3. Industry | National | Mu ational | ☐ | | ☐ | | |
| **Contact Address of Sponsor:** | | | | | | | |
| **Total Budget** : | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **1.Type of Study :** | Epidemiological | Basic ences | ☐ | Animal studi | ☐ | | ☐ |
| | Clinical: Single center | Mult tric | ☐ | Behaviora | ☐ | | ☐ |
| **2. Status of Review:** | New | | ☐ | Revised | | | ☐ |
| **3. Clinical Trials:** | | | | | | | |
| **Drug /Vaccines/Device/Herbal Remedies :** | | | | | | | |
| **i.** | Does the study involve use of : | | | | | | |
| | Drug | Devices | ☐ | Vaccines | ☐ | | ☐ |
| | Indian Systems of Medicine/ Alternate System of Medicine | Any other | ☐ | NA | ☐ | | ☐ |
| **ii.** | Is it approved and marketed | | | | | | |
| | In India | UK urope | ☐ | USA | ☐ | | ☐ |
| | Other countries, specify | | | | ☐ | | |

| | | |
|---|---|---|
| **iii.** Does it involve a change in use, dosage, route of administration? | Yes | No |
| **If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained? | Yes | No |
| **If yes,** Date of permission : | | |

# The University of Burdwan
# Institutional Clinical Ethics Committee

| | | |
|---|---|---|
| **iv.** Is it an Investigational New Drug?<br>**If yes,** IND No: | Yes | No |
| a). Investigator's Brochure submitted | Yes | No |
| b). *In vitro* studies data | Yes | No |
| c). Preclinical Studies done | Yes | No |
| d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ | | |
| e). Are you aware if this study/similar study is being done elswhere ?<br>**If Yes**, attach details | Yes | No |

**4. Brief description of the proposal** – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (attach sheet with maximum 500 words):

**5. Subject selection:**

i. Number of Subjects :

ii. Duration of study:

| | | |
|---|---|---|
| iii. Will subjects from both sexes be recruited | Yes | No |
| iv. Inclusion / exclusion criteria given | Yes | No |

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)
pregnant women ☐ children ☐ elderly ☐
fetus ☐ illiterate ☐ handicapped ☐
terminally ill ☐ seriously ill ☐ mentally challenged ☐
economically & socially backward ☐ any other ☐

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)
institutionalized ☐ employees ☐ students ☐ captives ☐
armed forces ☐ dependent ☐
any other ☐

**6. Privacy and confidentiality**

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ delinked ☐

| | | |
|---|---|---|
| ii. Confidential handling of data by staff | Yes | No |

# The University of Burdwan
# Institutional Clinical Ethics Committee

| | | |
|---|---|---|
| **7. Use of biological/ hazardous materials**<br>i. Use of fetal tissue or abortus | Yes | No |
| ii. Use of organs or body fluids | Yes | No |
| iii. Use of recombinant/gene therapy<br><br>**If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained? | Yes<br><br>Yes | No<br><br>No |
| iv. Use of pre-existing/stored/left over samples | Yes | No |
| v. Collection for banking/future research | Yes | No |
| vi. Use of ionising radiation/radioisotopes<br><br>**If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? | Yes<br><br>Yes | No<br><br>No |
| vii. Use of Infectious/biohazardous specimens | Yes | No |
| viii. Proper disposal of material | Yes | No |
| ix. Will any sample collected from the patients be sent abroad ?<br>**If Yes, justify with details of collaborators** | Yes | No |
| a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? | Yes | No |

# The University of Burdwan
# Institutional Clinical Ethics Committee

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐

**8. Consent :** *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

| | | |
|---|---|---|
| Understandable language | Alternatives to participation | ☐ |
| Statement that study involves research | Confidentiality of records | ☐ |
| Sponsor of study | Contact information | ☐ |
| Purpose and procedures | Statement that consent is voluntary | ☐ |
| Risks & Discomforts | Right to withdraw | ☐ |
| Benefits | Consent for future use of biological material | ☐ |
| Compensation for participation | Benefit if any on future commercialization | ☐ |
| Compensation for study related injury | eg genetic basis for drug development | ☐ |

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse ☐ Counsellor ☐
Research staff ☐ Any other ☐

| | | |
|---|---|---|
| **9. Will any advertising be done for recruitment of Subjects ?** (posters, flyers, brochure, websites – if so kindly attach a copy) | Yes | No |
| **10. Risks & Benefits:** i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? | Yes | No |
| ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐ | Yes | No |
| Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐ | | |
| **11. Data Monitoring** i. Is there a data & safety monitoring committee/ Board (DSMB)? | Yes | No |

# The University of Burdwan
# Institutional Clinical Ethics Committee

| | | |
|---|---|---|
| ii. Is there a plan for reporting of adverse events ?<br>**If Yes,** reporting is done to :<br>Sponsor ☐ Ethics Committee ☐ DSMB ☐ | Yes | No |
| iii. Is there a plan for interim analysis of data? | Yes | No |
| vi. Are there plans for storage and maintenance of all trial database?<br>**If Yes,** for how long ? | Yes | No |
| **12. Is there compensation for participation?**<br>**If Yes,** Monetary ☐ Kind ☐<br>Specify amount and type: | Yes | No |
| **13. Is there compensation for injury?**<br>**If Yes,** by Sponsor ☐ by Investigator ☐<br>by insurance company ☐ by another ☐ | Yes | No |
| **14. Do you have conflict of interest? (financial/nonfinancial)**<br>**If Yes, specify :** | Yes | No |
| **Checklist for attached documents**:<br>Brief description of proposal ☐<br>Patient information sheet ☐<br>Informed Consent form ☐ | | |

Place:
Date:

Signature & Designation of the applicant

# The University of Burdwan
# Institutional Clinical Ethics Committee

**BRIEF DESCRIPTION OF THE PROPOSAL**

4. **General Information:**

   Principal Investigator:
   Title:
   Date of Submission:
   Duration:

5. **Abstract:**

6. **Purpose, Methods and Procedures:**
7. **Details of Drug and/or Therapy:**
8. Subject Selection:

9. **Obtaining Informed Consent:**
10. **Research Personnel:**
11. **Statistical Analysis**:

12. **Storage and Maintainance of Data**:

13. **Maintenance of Confidentiality**:
14. **Sources of Funding**:

15. **Other Ethical Issues**:

**List of enclosures:**

| | | Write "Yes" if submitted and "NA" if not applicable |
|---|---|---|
| 1 | Sample questionnaire (in English and its translation in local language as applicable) | |
| 2 | Template of the informed consent form (in English and its translation in local language as applicable) | |