
# Standard Operating Procedures

for

Institutional Ethics Committee (IEC)

**Standard Operating Procedures (SOP)**
for
**Institutional Ethics Committee (IEC)**
Brainware University, 398, Ramkrishnapur Road, Barasat, Near Jagadighata Market, Kolkata, West Bengal 700125

**Title:** Standard Operating Procedures (SOP) for Institutional Ethics Committee (IEC)

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Through the 19th Academic Council Meeting held on 29th February, 2024

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## NAME OF THE ETHICS COMMITTEE

The committee will be known as **'Brainware Institutional Ethics Committee'**.

## ADDRESS OF THE OFFICE OF THE ETHICS COMMITTEE

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## OBJECTIVE OF THE SOP

The goal of this SOP is to keep the Ethics Committee (EC) functioning effectively and to ensure quality, technical excellence, and consistent ethical review of all concerned research proposals involving human participants in order to protect the rights, safety, and well-being of research participants.

## DECLARATION

The Institutional Ethics Committee for Research in the subjects of School of Medical & Allied Health Science and School of Biotechnology & Bioscience of Brainware University (BWU) would be known as *'Brainware Institutional Ethics Committee'* in this document.

This Standard Operating Procedures (SOPs) are laid down in consensus following the Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017) and (2019).

## NEED FOR NEW OR AMENDING SOP

When the need for revision of existing SOP due to inconsistency/ discrepancy or for a new SOP has been identified and agreed on in the duly entitled EC meeting, a panel for the same will be made and to be approved for implementation in EC meeting.

## AUTHORITY UNDER WHICH BRAINWARE INSTITUTIONAL ETHICS COMMITTEE IS CONSTITUTED

The *'Brainware Institutional Ethics Committee'* is a formal institutional ethics committee that will be formed by The Registrar in consultation with the Vice Chancellor, Brainware University. The Registrar in consultation with the Vice Chancellor will appoint the Chairperson and other members of the committee based on their credentials, competence, and experience in assessing and evaluating the scientific and ethical elements of study projects.

## PURPOSE AND SCOPE OF IEC

**The Purpose of IEC-BWU**

The purpose of IEC-BWU is to review proposed studies with human participants and biomedical research to ensure that they conform to internationally and nationally accepted ethical guidelines, monitor concerned studies and, where relevant, take part in follow-up action and surveillance in this context.

**Scope of the Ethics Committee**

- To advise and recommend on ethical matters arising in relation to research involving human participants and other biomedical research aspects.
- To ensure research is designed and conducted in accordance with the ICMR rules and regulations for the responsible conduct of biomedical research.
- To consider the ethical implications of all research proposals received by the Committee, followed by approval or revision or rejection of research proposal on ethical grounds.
- To monitor in order to verify that the conduct of research conforms to the proposal that is approved by the Committee.
- To adopt measures to identify and manage any real, potential and/or perceived conflicts of interest of IEC members and or researchers.
- To handle any complaints about research or the conduct of research on living beings.

## ROLES AND RESPONSIBILITIES OF IEC

The 'Brainware Institutional Ethics Committee' is a multidisciplinary, competent and independent body in its functioning with the chairperson and 50% members as non-affiliates. The 'Brainware Institutional Ethics Committee' will be responsible for reviewing the research proposal in light of the four fundamental principles and 12 general principles provided by ICMR while planning, conducting, and reporting on the planned study.

- Before approving the research proposals, the "Brainware Institutional Ethics Committee" will review all forms of research involving human participants to protect the dignity, rights, safety, and well-being of all current and prospective research participants. Research objectives, no matter how significant it might be, will never take precedence over the safety and well-being of human subjects.
- The "Brainware Institutional Ethics Committee" will determine whether the planning, carrying out, and reporting of the research adheres to all of the fundamental ethical principles of research, including autonomy, beneficence, non-maleficence, respect for free and informed consent, respect for human dignity, respect for vulnerable individuals, respect for privacy and confidentiality, and justice.
- The "Brainware Institutional Ethics Committee" will investigate protocol review, participant selection, potential participants' voluntary participation, informed consent procedure, risk-benefit ratio, burden-benefit distribution, confidentiality and privacy preservation, and provisions for suitable compensation. It will use suitable, well-documented procedures to review the proposals both prior to the start of the study and throughout the duration of the investigation. The periodic study progress reports provided by the investigators, as well as any monitoring and internal audit reports from the sponsor and/or site visits, will serve as the basis for the review.
- Through appropriate, meticulously documented procedures, it will review the proposals prior to the start of the study and then on a regular basis until it is finished. Such an evaluation could be predicated on the sponsor's monitoring and internal audit reports, the investigators' periodic study progress reports, or on-site visits to the study locations.
- The mandate of the IEC shall be to review all research projects to be conducted at the institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency.

- The 'Brainware Institutional Ethics Committee' will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.
- In case, the 'Brainware Institutional Ethics Committee' revokes its approval according to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the investigator / investigators as well as to the licensing authority
- 'In case of a serious adverse event or death occurring to the clinical trial participant, the 'Brainware Institutional Ethics Committee' shall forward it's reporting on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the licensing authority for conducting the clinical trial, to the chairman of the expert committee constituted by the licensing authority with a copy of the report to the licensing authority within twenty-one calendar days of the occurrence of the serious adverse event of death.
- Slaughter of living beings is strictly prohibited in the Brainware University Campus.

## COMPOSITION, AFFILIATIONS AND QUALIFICATIONS OF THE INSTITUTIONAL ETHICS COMMITTEE MEMBERS

The composition of the members of *'Brainware Institutional Ethics Committee'* will be multidisciplinary and independent. The composition, affiliations and qualifications of the Institutional Ethics Committee will be as per ICMR National Ethical Guidelines 2017 & 2019 as given below –

**Table 1: Composition, affiliations and qualifications of EC members**

| Members of EC | Affiliation Status | Qualifications |
|---|---|---|
| Chairperson | Non-affiliated | A well-respected person from any background with prior experience of having served/serving in an EC. |
| Vice Chairperson (optional) | Non-affiliated | A well-respected person from any background with prior experience of having served/serving in an EC. |

| | | |
|---|---|---|
| Member Secretary/ Alternate Member Secretary (optional) | Affiliated | Should be a staff member of the institution.<br>Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills.<br>Should be able to devote adequate time to this activity which should be protected by the institution. |
| Basic Medical Scientist(s) | Affiliated/ non-affiliated | Non-medical or medical person with qualifications in basic medical sciences.<br>In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist. |
| Clinician(s) | Affiliated/ non-affiliated | Should be individual/s with recognized medical qualification, expertise and training. |
| Legal expert/s | Affiliated/ non-affiliated | Should have a basic degree in Law from a recognized university, with experience.<br>Desirable: Training in medical law. |
| Social scientist/ philosopher/ ethicist/theologian | Affiliated/ non-affiliated | Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities. |
| Lay person(s) | Non-affiliated | Literate person who has not pursued a medical science/ health related career in the last 5 years.<br>May be a representative of the community and aware of the local language, cultural and moral values of the community.<br>Desirable: involved in social and community welfare activities. |

## OFFICE BEARERS AND MEMBER SPECIFIC ROLES AND RESPONSIBILITIES

The IEC will have the following office bearers who have the expertise and professional qualifications to review the proposals submitted.

**Duties of the Chairperson**

- Managing the IEC and the matters brought before it, with fairness and impartiality.
- The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of this individual. It is imperative that the IEC be viewed as unbiased and equitable, free from any influence from the RIMS administration, the investigators whose protocols are presented to it, or any other professional or non-professional entity.
- The IEC Chairperson will respect the diverse backgrounds, perspectives, and sources of expertise of all IEC members, especially the contributions of the non-scientists, and must have the ability to foster such respect among the IEC members.
- The chairperson will ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations and ratify minutes of the previous meetings.
- In the absence of the chairperson of IEC for scheduled IEC meeting, he / she should nominate a committee member to serve as the acting chairperson, or the members in attendance may choose the acting chairperson on the day of the meeting.
- The Acting Chairperson would be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- The chairperson will seek COI declaration from members and ensure quorum and fair decision making.
- He will also handle complaints against researchers, EC members, conflict of interest issues and requests for use of IEC data, etc.

**Duties of the Member Secretary**

- He/she will schedule meetings, prepare the agenda and minutes, and organize a productive process for receiving, preparing, circulating, and reviewing each proposal.
- The member secretary will be in charge of EC documentation, communication, and archiving.
- He/she will also ensurwe that the EC members receive the necessary training.
- The member secretary will ensure that SOPs are updated on a regular basis and that EC functioning adheres to those.

- The member secretary will be in charge of organizing the procedures for audits and inspections.
- Additionally, he or she will make sure that the paperwork is complete when it is received and that it is added to the agenda for the EC review on time and determine whether a full review, an exemption from review, or an accelerated review is required.

**Duties of the Secretariat**

The Secretariat will be composed of the Member Secretary - IEC, and the administrative supporting staffs. The supporting staff consists of staff members. The secretariat shall have the following functions:

- Setting up a productive and successful tracking system for every proposal that is received.
- Distribution, upkeep, and preparation of study files.
- Arranging for frequent IEC meetings.
- Putting together the meeting agenda and minutes,
- Upkeep of the IEC archives and records.
- Interaction between PIs and IEC members.
- Organization of staff and IEC members' training.
- giving the Member Secretary of the IEC the required administrative support for IEC-related activities.
- Acceptance of IEC processing fees and issuance of official receipts for projects funded by pharmaceutical companies.

**Administrative Staffs**

There will be administrative attendant/s /helper/s who will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staffs may be appointed and duties assigned as and when deemed necessary by the IEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications may be recommended by IEC members during regular IEC meeting and will be recorded in minutes. These will be forwarded to the Registrar, Brainware University, Kolkata. The administrative staff will be appointed by conducting formal interviews as per Brainware University policy.

**Duties of the Administrative staffs:**

- Providing necessary administrative support for IEC related activities to the Member Secretary, IEC.
- Corresponding with the IEC members, external experts and investigators.
- Filing study related documents, Maintaining IEC records and archives of records and study files.
- Receiving IEC processing fees and issuing official receipts for the same, maintaining records.
- Preparation for accreditation, audits
- Making the pre and post-arrangements of IEC meetings.

**Duties of the Attendant/s /Helper/s:**

- Assisting the secretariat in arranging the IEC meetings.
- Dispatching sets of study documents to IEC members and external experts.
- Receiving the study related documents from and dispatching the IEC letters to the investigators.
- Filing study related documents. Archiving and maintaining the study files
- Corresponding with the IEC members and external experts.

**Duties of the IEC Members**

Determine the scientific and ethical validity of the research as well as the protection of the safety, rights and confidentiality of the research participants.

- Review progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest, if any - IEC members shall disclose to the IEC all conflicts of the IEC member, their spouse/domestic partner, and their dependent children. Such disclosures shall be sufficiently detailed to allow the IEC Administration to transfer the project to another IEC member or allow time for an alternate member to attend the IEC meeting to meet quorum.
- Carry out work delegated by the Chairperson, Vice-Chairperson and/or Member Secretary.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat and others.
- In the absence of the Chairperson, Vice Chairperson will chair the meeting. In the absence of both, a member who is independent of the institution will chair the meeting as the Acting Chairperson.

**Basic scientist**

- Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmacodynamics in case of clinical trials.

**Clinician**

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure and all other protocol details

**Legal expert**

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions (NAC-SCRT, HMSC etc) compliance with guidelines etc. Interpretation and information to EC members about new regulations if any.

**Social scientist/ philosopher/ ethicist/theologian**

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

**Lay person**

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

## MEMBERSHIP REQUIREMENTS

1. They must be independent of political, Institutional, professional and market influences.

2. Members are drawn from different institutes and specialties to give a multisectorial multidimensional structure.

3. Members should have qualities which include interest and motivation, commitment and availability, experience and education ,respect for divergent opinion ,interest in divergent work, integrity, diplomacy, trained in bioethics or conversant with ethical guidelines and laws of country.

4. In the interest of the Institute's research program, the IEC members including the Chairperson, Member Secretary will be selected by the Vice Chancellor / Registrar taking into consideration their expertise, research interests and experience in ethics.

5. Committee members will be selected based on the basis that they are willing to publicise full name, profession and affiliation. Their Curriculum Vitae should be submitted to the EC office for records.

6. Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.

7. The duration of the appointment will be initially for 3 years

8. At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced by a defined procedure.

9. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

10. A member can tender a resignation from the committee with proper reasons to do so.

11. All members should maintain absolute confidentiality of all discussions during the meeting.

12. A member can be replaced in the event of long-term non-availability (three consecutive meetings). The authority to replace the member shall be with the Head of the institution.

13. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term.

14. Conflict of interest needs to be avoided.

15. Conflict of interest if any shall be declared by members of the IEC at the beginning of every meeting.

16. Members will be required to sign a confidentiality agreement at the start of their term

18. The committee should inform in writing to the licensing authority in case of any changes in the ethics committee.

19. Licensing authority has the right to issue show cause notice in the event of any complaints and wrong doing.

20. The authority has the right to cancel the registration of the committee.

## PROCEDURE FOR SELECTION, RESIGNATION, REPLACEMENT OR REMOVAL OF MEMBER

Anyone who qualifies for *'Brainware Institutional Ethics Committee'* membership may apply for it immediately. The request letter may also be sent to the specified member by the Chairman, Vice Chairman, or member secretary. However, the selection of the *'Brainware Institutional Ethics Committee'* member(s) is entirely dependent on the committee's requirements and the member's qualifications. The requirement can be decided by the member secretary and Chairman jointly, or by the Chairman with the assent of at least three members. There will be no restriction on members serving more than one term, however it is preferable to have around one-third new members. In the case of long-term absence [three consecutive meetings], a member can be replaced. The member should be asked for explanation, and if deemed unconvincing, he or she should be dismissed with one week's notice. Members must quit freely and notify the *'Brainware Institutional Ethics Committee'* one month in advance. If a member is discovered to be in violation of the SOPs, he or she should be asked for clarification, which may be addressed in the meeting, and if found to be unconvincing, the member should be removed with one week's notice.

It is desirable that a backup of such member should be first prepared and included in the Institutional Ethics Committee so that the membership requirement of the committee should be maintained.

Authority to replace/Remove the member shall be with the Chairman.

Any member shall stand disqualified and his/her membership revoked with immediate effect if He / She

- Is held to be / declares himself / herself insolvent.

- Is convicted for moral turpitude or imprisoned.
- Is guilty of any professional malpractice.
- Does not act in good faith and in bonafide discharge of their function as a member of the Institutional Ethics Committee

If any member participating in clinical trial which will have been submitted for review, in such case, ethically, respective member will be devoid of voting rights and will not participate in decision making. If required, he/she will be replaced with the member having same profile to fulfill the quorum.

## TENURE

The tenure of the Institutional Ethics Committee members will be for 3 years from the date of implementation and will be revised with necessary changes filed from time to time.

## RENEWAL OF MEMBERSHIP

The membership will be renewed after the stated term of three years. Selection of members shall be done at least one month in advance.

## RESIGNATION FROM MEMBERSHIP

If any member wishes to discontinue from the EC, he/she would be required to inform the Chairperson, in writing. Members may voluntarily resign from the committee at a month's notice citing appropriate reasons and in case of internal members their membership would be considered withdrawn, if they resign from the Institute.

## THE PROCEDURE OF TERMINATION OR DISQUALIFICATION FROM MEMBERSHIP

During the tenure, the Chairperson shall have the power to terminate or disqualify any member if the member has not adhered to the terms of their appointment or has missed three meetings in a row without informing to the chairperson, or if there is some seriously calls into question the member's ethics or integrity. The chairperson must inform the Registrar and the Vice Chancellor of the University of any such situation before the

termination takes place. All the members will be notified the same after termination and the termination will be documented in the minutes of the ensuing duly constituted EC meeting.

## REQUIREMENTS FOR MEMBERSHIP OF 'BRAINWARE INSTITUTIONAL ETHICS COMMITTEE'

The following are the requirement to be an EC member -

1. Updated CV of the EC member
2. Consent letter to be EC member and NOC to place her / his full name, profession and affiliation to the EC in the public domain
3. Undergo training or update their skills / knowledge during their tenure

## TERMS OF REFERENCE (TOR) FOR IEC

Terms of reference will be maintained in the office of IEC-BWU. This includes

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bi or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

## TENURE OF THE IEC

The tenure of the Internal Ethical Committee is of three years.

## CONVENTION AND CONDUCT OF IEC MEETING

The Chairperson will conduct all meetings of the *'Brainware Institutional Ethics Committee'*. In the absence of the Chairperson an alternate Chairperson will be elected from the other members on the day of meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting. The alternate or acting chairperson should be non-affiliated person.

The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. In the absence of Member Secretary, alternate Member Secretary among the members, will organize the EC meeting.

The recommendations by the Institutional Ethics Committee will be communicated to all the PIs and guides/HODs and / or other competent authority. If required additional review meetings can also be conducted with a short notice period.
The meetings can be held on virtual platform also.

## TYPES OF PROJECTS REVIEWED

The IEC will review scientific and ethical aspects of all types of research studies on leftover biological fluids or tissue of human participants and the analysis including epidemiological, biochemical, genetic, molecular biology, biotechnical and microbiological. Pharmaceutical analysis of herbal drugs, nanoparticles, probiotics studies, etc on cell lines or culture. All dissertation projects of undergraduate, postgraduate & PhD students, research projects carried out under the guidance of teachers and internal or external investigator-initiated research studies which are self-funded / funded by institutional funding bodies / NGOs/ Govt. funding agencies.

## APPLICATION PROCEDURES

- All proposals should be submitted to IEC on any working day 3 weeks in advance of scheduled meeting in the prescribed application form along with relevant documents.

- Eight (8) hard Copies and soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / should be submitted to IEC
- Principle Investigators shall be forwarded their application to the Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office.
- An IEC registration number will be assigned to each application, which should be used for any further correspondence and references. The PI will be notified of the IEC meeting date in order for them to attend, provide a brief presentation of the proposal, and address any questions asked by the members. In certain circumstances, IEC may recommend virtual investigator presentations and online meetings.
- If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
- The processing / administrative fee will be applicable as per norms Witten in this SOP.

## REVIEW PROCEDURES

The meetings of the IEC, Brainware University, Kolkata will be held on periodic intervals of 6 months unless otherwise specified by the member secretary. Additional review meetings can also be planned as per the requirement for the expedited IEC approval with short notice as and when required.

- The proposals should be sent to the IEC at least 1 month in advance of scheduled meeting.
- Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson, Brainware Institutional Ethics Committee, through member secretary. Receipt of the application will be acknowledged by the IEC office.
- The notice of each IEC meeting along with the agenda shall be sent to all the members at least one week before the meeting.
- The IEC'S member-secretary shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review.
- Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.

- Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to be available and to clarify the points raised by the members if any.
- The decision of the committee on the proposal 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 or before the next meeting.
- Researchers will be invited to offer clarifications if need be. The PI / research scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the co-PI will present the proposal.
- Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
- Minutes of the meeting will be written down and chairperson's approval will be taken in writing. The IECs Member Secretary or the Secretariat shall screen all the proposals for their completeness and depending on the risk involved, categorize them into three types: Exemption from Review, Expedited Review and Full Review.

## RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATIONS

Brainware Institutional Ethics Committee is committed to ensuring the protection of vulnerable subjects in research, such as children, prisoners, fetuses/neonates, pregnant women, and individuals with consent capacity impairment. They seem to consider various group characteristics like economic, social, physical, and environmental conditions to implement suitable precautions.

Brainware Institutional Ethics Committee aims to follow ethical guidelines, particularly those laid down in the ICMR-Ethical Guidelines for Biomedical Research. These guidelines aim to provide a robust framework for safeguarding that research is conducted ethically and with respect for the rights and welfare of all vulnerable participants such as Children, Elderly, People with Disabilities, Pregnant Women, Prisoners, Ethnic etc.

- Efforts will be made to ensure that individuals or communities invited for research are selected in such a way that the burdens and benefits of the research are equally distributed.
- Rights and welfare of mentally challenged and mentally differently abled persons who are incapable of giving informed consent or those with behavioural disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, the need for participation, the risks and benefits involved and the

privacy and confidentiality procedures. The entire consent process should be properly documented.

- Adequate justification will be checked for the involvement of participants such as prisoners, students, subordinates, and employees, service personnel etc. since the consent provided may be under duress or various other compelling reasons.
- Persons, who are terminally ill, have incurable disease and mental illness will be under vulnerable group consideration.
- The committee will give special consideration to the proposals involving vulnerable population for protecting the right and welfare of vulnerable subjects.
- The Committee will include representation in selected vulnerable population if additional expertise is needed in reviewing and approving the proposed research that involves vulnerable subjects. The committee may work with these participants, as a part of the review process. The documentation for the same will be maintained.
- The Committee will follow the applicable regulation and guidelines in reviewing the research that involves vulnerable population as research subjects.
- The Committee will ensure that adequate justification for the involvement of vulnerable subject is provided in the protocol and other pertaining document wherever applicable.
- The new study submission including vulnerable groups as potential research participants will be reviewed by the full board meeting.
- Subsequent review of amendment and continuing review applications involving vulnerable group as potential research participants can be reviewed by expedited review procedures.

## OBLIGATIONS/DUTIES OF STAKEHOLDERS FOR THE VULNERABLE GROUPS

It is the responsibility of the Committee members to identify study proposals including vulnerable population and ensure that measures for safeguarding rights and interests of vulnerable participants are mentioned in the face sheet, study proposal, Participant /Assent Information Sheet/ and informed consent/assent form.

They will have the responsibility to ensure that the vulnerable populations are not exploited and they will guide the Investigators to design protocols and describe the process of informed consent for smooth completion.

| Stakeholders | Obligations/duties |
|---|---|
| **Researchers** | ➢ Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.<br>➢ Justify the inclusion/exclusion of vulnerable populations in the study.<br>➢ Must ensure a balanced benefit-risk ratio.<br>➢ Conflict of Interest (COI) issues must be addressed.<br>➢ Ensure that prospective participants are competent to give informed consent.<br>➢ Seek permission from the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.<br>➢ Research should be conducted within the purview of existing relevant guidelines/regulations. |
| **Ethics Committees** | ➢ During review, determine whether the prospective participants for particular research are vulnerable or not.<br>➢ Examine whether inclusion/exclusion of the vulnerable population is justified.<br>➢ Ensure that Conflict of Interest (COI) does not increase harm or lessen benefits to the participants.<br>➢ Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.<br>➢ Suggest additional safeguards, such as more frequent review and monitoring, including site visits.<br>➢ ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research.<br>➢ ECs should have SOPs for handling proposals involving vulnerable populations. |
| **Sponsors** . | ➢ The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety.<br>➢ The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). |

| | |
|---|---|
| | ➢ The sponsor should ensure protection of the participants and research team if the research is on sensitive topics |
| **Reviewers** | ➢ Committee Members will review the protocol and the informed consent document or assent form.<br>➢ Committee members will discuss in the committee meeting and letter regarding approval/modification/ disapproval will be sent to the principal investigator.<br>➢ The discussion will be documented in the minutes.<br>➢ Member Secretary will ensure that the recommendations of the Committee have been incorporated in the revised protocol and protocol related documents |

## REVIEWING PROTOCOLS WITH VULNERABLE PARTICIPANTS

In addition to systematic review process, the research protocol will be reviewed to evaluate if the following points are addressed:

- Can the research be performed involving any other non-vulnerable participants?
- Is there justification to use vulnerable population?
- Do the benefits justify the risks?
- Are the participants selected equitably?
- Have the measures to protect autonomy of the vulnerable population been described?
- Committee members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.
- The review must address all concerned points as given in ICMR guidelines for different vulnerable populations

## GENERAL ETHICAL ISSUES

- Researchers must protect the dignity, rights, safety and well-being of research participants.
- They should have appropriate qualifications, competence in research methodology and be compliant towards the scientific, medical, ethical, legal and social requirements of research.
- The researcher and Institutional Ethics Committee must conduct a benefit–risk assessment and actively attempt to maximize benefits and minimize risks to participants.

- Benefits to the individual, community or society refer to any sort of favourable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.
- The Institutional Ethics Committee can decide about the type of review required (exempted, expedited, full committee) based on the type of research involved.
- The researcher must obtain informed consent from the participant/legally acceptable/ authorized representative in writing.
- Informed consent documents (participant information sheet and informed consent form) should carry the specified elements in simple, layman's language. These documents should be approved by the *'Brainware Institutional Ethics Committee'*.
- Oral consent/waiver of consent/re-consent may be obtained under certain conditions, after due approval by the Institutional Ethics Committee.
- Researcher(s) should safeguard the privacy and confidentiality of participants and research-related data from unauthorized access.
- Benefits and burdens of research should be equitably distributed among the participating individuals or communities.
- Participants should not be made to pay for research-related expenses incurred.
- Research participants who suffer direct physical, psychological, social, legal or economic harm are entitled to financial compensation or other forms of assistance.
- Policies for declaration and management of financial or non-financial (personal, academic or political) conflict of interest for researchers must be disclosed by the researchers.

## RESPONSIBLE CONDUCT OF RESEARCH (RCR)

- Major components of RCR are values and policies; planning and conducting research; reviewing and reporting research; responsible authorship and publication aspects.
- Institutions must have policies for the protection of participants and should assign responsibilities to stakeholders.
- Researchers must follow professional codes of conduct and have personal conviction about ethical requirements.
- Completed research, irrespective of results, must be published in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE).
- Issues related to ownership, sharing of materials/data, joint publications, research findings,

conflict of interest, commercialization should be addressed in collaborative research.

- The Institutional Ethics Committee must safeguard the dignity, rights, safety and well-being of research participants and review research before initiation.
- The Institutional Ethics Committee is responsible for scientific and ethical review of research proposals and should have well defined standard operating procedures (SOPs) for all functions.

## QUORUM REQUIREMENTS

A minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. The quorum will have 5 members with following representations:

(a) Basic medical scientists (preferably one molecular biologist).

(b) Clinicians

(c) Legal expert

(d) Social scientist/representative of non-governmental voluntary agency/philosopher / ethicist/theologian or a similar person

(e) Layperson from the community.

**Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.*

## RECORD KEEPING AND ARCHIVING OF DOCUMENTS

All Research proposals (8 hard copies along with soft copy) along with the information and documents submitted will be dated and filed The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study. Institutional Ethics Committee members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived

1. Constitution of Institutional Ethics Committee
2. SOP
3. CV & consent of Institutional Ethics Committee members
4. Registration under Institutional Ethics Committee
5. Honorarium details, Income and expenses
6. Agenda & minutes of the meetings
7. One copy of proposal
8. Copy of recommendations/decision communicated to applicant
9. Review reports, documents received during the follow up period and final reports of the study

## TRAINING OF THE INSTITUTIONAL ETHICS COMMITTEE MEMBERS IN RESEARCH ETHICS

- An individual selected as a new member of the *'Brainware Institutional Ethics Committee'* will be required to attend one meeting asan 'Observer' before being inducted as a member of the committee.
- Member Secretary or an *'Brainware Institutional Ethics Committee'* member will provide introductory training in research Ethics and SOPs to the new member.
- A newly inducted member should submit certificate of training in 12 months.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- Institutional Ethics Committee will conduct workshops on ethics in clinical research and SOPs from time to time to impart training and update the Institutional Ethics Committee Members and Institutional faculty members.

## FEES

An application fee will be assessed by the Ethics Committee (EC) for projects involving sponsored research. An administrative/processing fee will be applied to all research proposals and clinical trials. For studies that are not funded studies affiliated to Brainware University, may apply for the concession / waived off of these fees to the Member Secretary - Brainware Institutional Ethics Committee.

Before an application can be processed, a mandatory application fee must be submitted with it. The

cost must be deposited into the corresponding accounts via demand draft or electronic transfer. The EC shall charge a non-refundable, initial one-time review fee as administrative charges given below:

| Fees | Amount |
|---|---|
| **INITIAL REVIEW FEE** | |
| • Pharmaceutical Industry and Contract Research Organisation (CRO) Funded Clinical Trials | Rs. 50,000/- or 10% of the budget whichever is more |
| • Investigator Initiated Projects (Funded by Non-Govt. Funding Agency) | Rs. 20,000/- |
| • Investigator Initiated Projects (From outside Brainware University) | Rs. 25,000/- |
| • Investigator Initiated Projects (Funded by Govt. Funding Agency) | Rs. 5,000/- |
| • Student research (thesis) | Rs. 500/- |
| **STUDY RENEWAL FEE*** | Rs. 5000/- |
| **AMENDMENT FEE**** | Rs. 2000/- |
| **ARCHIVAL FEE***** | Rs 75000/- |

Note:

** Study Renewal Fee for the study's second-year review that is still ongoing. The costs of the Committee renewal review of the ongoing review of adverse events, protocol deviations, and site visits are covered by the study renewal review fee. The committee looks over the previous year's activities and progress reports for each Investigator.*

*** The EC will charge an amendment fee of for any amendment(s) in the ongoing study.*

**** The EC will charge archival fee for a tenure of 5 years.*

All applications need to be mandatorily accompanied by the application fee before it can be processed. The fees shall be deposited by Demand Draft in favour of "*Brainware Institutional Ethics Committee"*, payable at Barasat.

## OFFICE EXPENSES

For the maintenance of the office, a sum of Rs 2000/- per month will be given to the secretariat.

## COMPENSATION AND REIMBURSEMENTS TO EXTERNAL MEMBERS

For attending the IEC meetings and examining the proposals, the members of the IEC will receive an honorarium of Rs 1000/-.

For each meeting attended, all external members and invited experts (if any) will receive an honorarium of Rs. 1000. The institution will also either provide transportation facilities or reimburse travel expenses incurred in order to support the IEC's operations in accordance with its policies. Bills that are appropriate must be submitted to the Member Secretary of the IEC for reimbursement of fees.

## CONFLICT OF INTEREST

The protocol should not be accepted for consideration by the Committee Member who has a conflict of interest. If a member has a conflict of interest with regard to any protocol submitted for review, the member must notify the Member Secretary / Chairperson / Committee well in advance of the scheduled meeting and resign from the discussion or debate of that specific protocol.

If Committee members require information on the research from a member who has a conflict of interest, the member may stay in the meeting room throughout the presentation of the study. The member must then exit the meeting room throughout the procedural deliberation and vote. The same will be recorded in the Declaration of Conflict-of-Interest Form and Minutes of Meeting.

## WEB PAGE FOR THE ETHICS COMMITTEE

A dedicated webpage will be created and maintained for the ethics committee. Details of composition, SOP, registration details, circulars / notifications related to IEC meetings and status of submitted proposal, details of ongoing projects, submission forms, guidelines and contact details will be displayed on this page.

## CONTACT DETAILS

Member Secretary
Brainware Institutional Ethics Committee
Brainware University, 398, Ramkrishnapur Road, Barasat, Near Jagadighata Market, Kolkata, West Bengal 700125

Contact number: 9775174928
Email ID: biec@brainwareuniversity.ac.in

## ANNEXURE NO 1: PROPOSAL SUBMISSION FORMAT

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC), Brainware University

(For attachment to each copy of the proposal)

**Proposal Title:**

| **For office use only** | |
|---|---|
| Serial number of IEC, Brainware University, Barasat | |

| **To be filled by Pl** | | | | |
|---|---|---|---|---|
| **Title of Project** : | | | | |
| **Name, Designation, Department,Qualification** | | **Address, TelephoneNo., Mobile No., Email id** | **Number of projects already with investigator** | **Signature** |
| **Principal Investigator** | | | | |
| | | | | |
| **Co- Investigators** | | | | |
| 1. | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| Please attach detailed Curriculum vitae of all Investigators (with subject specific publicationslimited to previous 5 years). | | | | |
| **Sponsor information** (Tick appropriate box) | | | | |
| 1. Indian | a. Government | | | |
| | Central | | State | | Institutional | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | b. Private | | | | | |
| 2. international | Government | | Private | | UN agencies | |

| | | | | | |
|---|---|---|---|---|---|
| 3. Industry | National | | Multinational | | |
| **Contact Address of Sponsor:** | | | | | |
| **Total Budget:** | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Who will bear the costof investigation / implants drugs / contrasts? | 1. | Patient | | 2. | Project | | 3. | Exempted | |
| | 4. | Other Agencies (Name) _____ | | | | | | | |
| 1.Type of Study: | Cross sectional | | Case control | | Cohort | | Clinical Trial | | Review |
| Participating Centre: | Single centre | | Multi centre | | Other (Specify) | | | | |
| 2.Status 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 / AlternateSystemof Medicine | | Any other | | NA | |
| II.Is it app roved and marketed | | | | | |
| In India | | UK & Europe | | USA | |
| Other countries | | Specify: _____ | | | |

| | | |
|---|---|---|
| III. Does it involve a change in use, dosage, route of administration? | Yes | No |
| **If** Yes, whether DCG I ' s /Any other Regulatory authority's Permission is obtained?If yes, Date of Permission: | Yes | No |
| IV. Is it an Investigational New Drug (IND)? | Yes | No |
| **If** yes, IND 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 /simi lar study being done elsewhere?<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<br>whether it is of national significance with rationale (Attach sheet with maximum 500 word s): | | |
| **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 subject | | Volunteers | | Patients | |
| VI. | Vulnerable subjects<br>(Tick the appropriate boxes) | | Yes | | No | |
| Pregnant women | | | Children | | Elderly | |
| Foetus | | | Illiterate | | Handicapped | |
| Terminally ill | | | Seriously ill | | Mentally/ Challenged | |
| Economically & socially backward | | | Any other | | | |
| VII. | Special group subjects<br>(Tick the appropriate boxes) | | Yes | | No | |
| | Captives | | Nurse/dependent | | | |
| | Students | | Institutionalized | | Armed forces | |
| | Any other | | Staff | | | |
| **6. Privacy and confidentially** | | | | | | |
| I. | Study involves - Direct Identifiers | | | | | |
| | Indirect Identifiers/coded | | | | | |
| | Completely anonymized / delinked | | | | | |
| 11. | Confidential handling of data by staff | | | | Yes | No |
| **7. Use of biological/ hazardous materials** | | | | | | |
| I. | Use of fetal tissue or abortus | | | | Yes | No |
| II. | Use of organs or body therapy | | | | Yes | No |
| 111. | Use of recombinant/gene therapy | | | | Yes | No |
| | **If yes,** has Department of Biotechnology (DBT) approval forDNA products been obtained? | | | | Yes | No |

| | |
|---|---|
| Facility available but not being accessed | |

| | | | | | |
|---|---|---|---|---|---|
| | | | | If so, reasons..... | |
| **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 | |
| Bene fits | | Consent for future use of biological material | |
| Compensation for participation | | Bene fits if any on future commercialization eg. Genetic basis drug development | |
| Compensation for study related injury | | | |
| *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 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/ discomfort? | Yes | No |
| If Yes, Minimal or no risk | | |
| More than minimum risk | | |
| High risk | | |
| III. Is there a benefit a) to the subjects? | | |
| Direct | Indirect | |
| b) Benefits to society | | |
| **11. Data Monitoring** | | |
| I. Is there a Data & Safety Monitoring Committee /Board (DSMB)? | Yes | No |
| II. Is there a plan for reporting of adverse events? If Yes, reporting is done to: | Yes | No |

| | | | | | |
|---|---|---|---|---|---|
| **Sponsor** | | **Ethics committee** | | DSMB | |

| | | |
|---|---|---|
| III. Is there a plan for interim analysis of data? | Yes | No |
| IV. Are there plans for storage and maintenance of all trialdatabase?<br>**If Yes,** for how lo ng ? | Yes | No |
| **12. Is there compensation for participation?** | Yes | No |

| | | | |
|---|---|---|---|
| If **Yes,** Monetary | | In kind | |
| Specify amount and type: | | | |
| **13. Is there compensation for injury?** | | Yes | No |
| **If Yes,** By sponsor | | By Investigator | |
| By Insurance Company | | By any other | |
| **14. Do you have conflict of interest?(financial / nonfinancial)**<br>If **Yes, specify** : | | Yes | No |

| | |
|---|---|
| Conflict of interest for anyother investigator(s) (if yes, please explain inbrief) | 1 _____ Yes<br>2 _____ Yes<br>3 _____ Yes<br>4 _____ Yes |

| | | |
|---|---|---|
| **15.** Participant Information **Sheet** (mark √ if yes) | | Attached English version |
| | | Attached Hindi version |
| | | Certified that Hindi version is a truetranslation of English version |
| 16.Participant Informed Consent form (mark √ if yes) | | Attached English version |
| | | Attached Hindi version |
| | | Certified that Hindi version is a true translation of, English version |
| **17.Whet her any work on this project has started or not?** | | (mark √ if yes, X if no) (Please enclose a separate certificate tothis effect). |
| l8. In case of clinical trials CTRI status | | |

## ANNEXURE NO 2: INFORMED CONSENT DOCUMENT (ICD)

**Patient / Participant information sheet**

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Bengali which can be understood by the participant.

1) Title of the project
2) Name of the investigator/guide
3) Purpose of this project/study
4) Procedure/methods of the study
5) Expected duration of the subject participation
6) The benefits to be expected from the research to the participant or to others and the post-trial responsibilitiesof the investigator
7) Any risks expected from the study to the participant
8) Maintenance of confidentiality of records
9) Provision of free treatment for research related injury
10) Reimbursement for participating in the study
11) Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leadingto disability or death.
12) Freedom to withdraw from the study at any time during the study period without the loss of benefits that theparticipant would otherwise be entitled
13) Possible current and future uses of the biological material to be generated from the research and if the material islikely to be used for secondary purposes or would be shared with others, this should be mentioned
14) Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, this should be mentioned
15) Address and mobile number of the Principal investigator (PI) and Co- PI, if any :
16) Address and mobile number of the Member Secretary of the Brainware Institutional Ethics

Committee:

Signature of the participant:

Signature of the investigator:

Place:

Date:

## ANNEXURE NO 3: CONSENT FORM

**Title of the Research work**:

Participant's name:

Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent to participate in the above study. (I also consent / do not consent to use my stored biological samples for future scientific purposes: Yes/ No – if applicable)

Signature of the participant/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

## Annexure No 4: PROCESS FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF IEC-BWU

Submit eight (8) copies of the Research Project along with Covering letter and 'soft copy' on email **biec@brainwareuniversity.ac.in** along with a blank CD with the following information to the Member Secretary, Institution Ethics Committee at Room No. 207, University Building 4, Brainware University. The principal investigator must submit a protocol forwarded through the Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the Institution Ethics Committee with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Bengali/Concerned local Language, in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website, before it can be considered for placing before the Institution EthicsCommittee.

**Project Submission Time**: Submissions will be received on all working days. Proposals received till 15$^{th}$ of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15$^{th}$ will be processed in the next Institution Ethics Committee meeting.

While submitting replies raised by the Institution Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethic Committee. Moreover if the approval is required in a particular format, the same may be submitted in a CD.

**Amendment Submission:** While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

## Annexure No 5: ONGOING APPROVED RESEARCH REVIEW SUBMISSION FORM

1. Reference number
2. Month / Year of approval
3. Number of ongoing reviews
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begun, give reasons and proceed to No:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

## Annexure No 6: SIX MONTHLY PROGRESS OF PROJECT

**Institute Ethics Committee Reference No.**
**Study title:**
**Name of the Principal Investigator**
**Designation / Department**
**Duration of Study**
**Date of Starting of the Study**

Period of Six-monthly progress report: from_____to

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Signature of Principal Investigator

Date:_____

## Annexure No 7: COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

IEC No.

| | | |
|---|---|---|
| Protocol title: | | |
| Principal Investigator: | | |
| Name & Address of Institution: | | |
| New review | Revised review | Expedited review |
| Date of review (D/M/Y):<br>Date of previous review, if revised application: | | |
| Decision of the IEC/ IRB:<br>Recommended ☐ Recommended with suggestions ☐<br>Revision ☐ Rejected ☐ | | |
| Suggestions/ Reasons/ Remarks: | | |
| Recommended for a period of: | | |

Please note *
Inform IEC immediately in case of any adverse events and serious adverseevents.
Inform IEC in case of any change of study procedure, site and investigator
This permission is only for period mentioned above. Annual report to besubmitted to IEC
Members of IEC have right to monitor the trial with prior intimation.

**Signature of Member Secretary**

**IEC-BWU**

## Annexure No 8: IEC APPROVAL NOTICE

No. IEC. ----------  Date:

To: [Name], Principal Investigator

Date:

Re: IEC Proposal No.__: [Title]

I am pleased to inform you that at the convened meeting of____the IEC voted to approve/ approve an amendment, and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, youare responsible for fulfilling the following requirements of approval:

**All co-investigators must be kept informed of the status of the project.**

Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval **prior** to the activation of the changes.The IEC number assigned to the project should be cited in any correspondence.

Adverse events should be reported to the IEC. New information that becomes availablewhich could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.

Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IEC-BWU may conduct audits of all study records, and consent documentation may be part of suchaudits.

IEC-BWU Office require review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the IEC inorder to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in the termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.

**Sincerely**

**Member Secretory**
**Institutional Ethical Committee, Brainware University**

## Annexure No 9: Conflict of Interest Agreement Form for Ethics Committee Members

It is recognized that the potential for conflict of interest will always exist but has faith in the Institutional Ethics Committee, Brainware University (IEC-BWU) and its chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is the policy of the IEC-BWU that no member may participate in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC-BWU for Clinical Studies/research. The Undersigned will immediately disclose to the Chairperson of the IEC-BWU any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals. While signing the attendance register, the member documents the proposal for which he/she has Conflict-of-Interest (COI).

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC-BWU review or approval except to provide information requested by the Committee.

Examples of conflict-of-interest cases may be any of the following:

A member is involved in a potentially competing research program.

Access to funding or intellectual information may provide an unfair competitive advantage.

A member's personal biases may interfere with his or her impartial judgment

## Annexure No 10: AGREEMENT ON CONFLICT OF INTEREST

Please sign and date this Agreement, if the undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC-BWU. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals. I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

Undersigned Signature Date:

Name

Chairpersons Signature Date:

Name: Dr. Debidas Ghosh

## Annexure No 11: DECLARATION OF CONFLICT OF INTEREST

I, ……., have following proposal(s) with the undersigned as Principal Investigator/Co-investigator or real/potential/perceived competing research program under review by the IEC-BWU. I shall abstain from any participation in discussions or recommendations in respect of the proposal.

I shall maintain all the project related documents and information confidential and shall not share or reveal the same to anyone other than the project related personnel.

Agenda No.

Research Proposal No.

Research Proposal Title.

Signature Of PI / Co-PI Date: