STANDARD OPERATING PROCEDURE (SOP)

For

Institutional Ethics Committee (IEC)

BLDE (Deemed to be University)
VIJAYAPURA–586103 (KARNATAKA)

Registration No. ECR/383/Inst/KA/2013/RR-20

SOP revised Version 3.0
Effective date: 1st March, 2025
Valid till: 28th February, 2030

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REGISTRAR
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1. DCGI version Registration History

Sl. NO.	Status of the IEC	Description	Validity upto	Approved by
1	Registration of IEC under CDSCO as Institutional Ethics Committee	ECR/383/Inst/KA/2013 issued under Rule 122 DD of the Drugs & Cosmetics Rules 1945.	2013-16	**IEC BLDE(DU), VIJAYAPUR**
2	Renewal of IEC Registration under CDSCO as Institutional Ethics Committee	ECR/383/Inst/KA/2013/RR-16 issued under Rule 122 DD of the Drugs & Cosmetics Rules 1945.	2017-2019	
3	Renewal of IEC Registration under CDSCO as Institutional Ethics Committee	ECR/383/Inst/KA/2013/RR-20 Issued under Rule 122 DD of the Drugs & Cosmetics Rules 1945.	2020-2025	
4	Renewal of IEC Registration under CDSCO as Institutional Ethics Committee	ECR/383/Inst/KA/2013/RR-20 Issued under Rule 122 DD of the Drugs & Cosmetics Rules 1945.	2025-2030	

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2. Introduction:

Name of Institutional Ethics Committee (IEC): This committee will be known as BLDE (Deemed to be University) the Institutional Ethics Committee (IEC).

BLDE (DU), Vijayapura is under-graduate and Post-graduate Medical Institute with ultra-modern health care facilities. It also has 1350 bedded Hospital. In addition it also runs Ph.D programs in Medical Allied Health Sciences. The Institution provides support to care Biomedical Research utilizing hospital resources or funded by BLDE (Deemed to be University) or by external agencies. In order to protect rights and well-being of human participants it is necessary to constitute Institutional Ethics Committee to review scientific and ethical aspects of Biomedical research to be carried at BLDE (DU)'s Shri B.M.Patil Medical College Hospital and Research Centre & College of Allied Health Sciences, Vijayapura.

The Institutional Ethics Committee (IEC) is hereby constituted in compliance with the requirements laid down in the "New Drugs and Clinical Trials Rules 2019" (GSR 227 €), Ministry of Health and Family Welfare, Notification dated 10th March, 2019). The functioning of the IEC is guided by the guidelines of Good Clinical Practice (GCP), Ethical principles set forth in the declaration of HELSINKI and National Ethical Guidelines for Biomedical and Health Research involving Human participants, 2017" by the Indian Council of Medical Research (ICMR).

3. Purpose of IEC

The purpose of this Standard Operative Procedure (SOP) is to describe a working procedure for Institutional Ethical Committee (IEC) of BLDE (DU), Shri B.M.Patil Medical College Hospital & Research Centre and College of Allied Health Sciences, and to describe the procedures for effective functioning of the Ethics Committee of BLDE (DU) Medical College & Hospital so that a consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Institutional Ethics Committee and to follow the ICMR guidelines,, DCGI Regulations, Indian GCP , ICH-GCP and New drugs & clinical Trials rules (2019) guidelines in order to:

- Protect the dignity, rights and well-being of the potential research participants.
- Ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- Assist in the development and the education of a research community responsive to local health care requirements.
- The objective of this Standard Operative Procedure is to contribute to the effective functioning of the IEC so that a quality and consistent ethical review mechanism for health and biomedical research with highly scientific and ethical standards in patient care, professional education and clinical research and community interest is put in place for all proposals dealt with by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects of Indian Council of Medical Research (ICMR), and New drugs & clinical Trials rules (2019).

The IEC is established under the authority of the BLDE (Deemed to be University) Vijayapura, Karnataka. It is administratively governed under same authority.

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4. Scope:

Applicable to :

(i) All members of the Ethical Committee

(ii) All personnel of the Ethical Committee Office and

(iii) All investigators / Sponsored / Companies submitting an application & Research staff.

(iv) IEC will review the research proposals involving human participants to be conducted at the various Health and Allied Institutes of BLDE (DU), Vijayapura and their collaborators, to evaluate the possible risks to the subjects and expected benefits.

5. Role of IEC:

Institutional Ethical Committee of BLDE(DU) constituted to review and monitor the research proposals involving human subjects that are conducted within the institution or Institutions / center's which have MOU with BLDE DU)/SBMPMC/School of Allied Health Sciences, under the condition that PI/ one of the Co PI must be from BLDE(DU)'s SBMPMC.

The primary objective of the Institutional Ethical Committee is to ensure the safety, rights, dignity, and well-being of the actual and potential subjects of the proposed study and to ensure that the proposed study is credible, carried out according to requirements of ICH-GCP, Indian GCP, Principles, ICMR guidelines, and New drugs & clinical Trials rules (2019) guidelines as appropriate, and remains confidential.

The Institutional Ethical Committee is intended to ensure a competent review of scientific and ethical aspects of the project proposals received. The IEC is entrusted not only with the initial view of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the Ethics of the approved programmes till the same are completed With respect to Autonomy, Beneficence, Non - maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research, it will also look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. The committee also examine compliance with all regulatory requirements, applicable guidelines and laws. It will review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency

IEC has the authority to take final decision on approval and may approve or suggest the require modifications for approval or disapprove the submitted research proposal.

6. Composition of IEC:

The IEC constitutes the members based on their competencies, integrity and could be drawn from many public or private institute anywhere in the country.

i. The IEC is multidisciplinary and multi sectorial in composition. Independence and competent.
ii. The IEC is compliant to ICMR Guidelines, ICH-GCP Guidelines, and New drugs & clinical Trials rules (2019) with the applicable laws and regulations.

The composition of IEC is as follows:

1. Chairperson
2. Clinicians
3. Basic Medical Scientist preferably a Medical Pharmacologist
4. Legal Expert
5. Social Scientist/ Representative of Non-Governmental Voluntary Agency / Philosopher, Ethicist or Theologian.
6. Lay Person from the community
7. Member Secretary

The number of persons in the ethics committee is kept fairly small (8-15 members). The Institutional official should appoint a chairperson The Member secretary will be appointed by the Institutional official who should be from the same institution. Other members should be a mix of medical/nonmedical, basic science, scientific and non-scientific persons including lay person/s to represent the differed points of view. The ethics committee (EC) can have as its members, individual from other institutions or communities with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community / society. If required, subject experts will be invited to offer their views, for instance, a pediatrician for pediatric conditions, cardiologists for cardiac disorders etc. Similarly, based on the requirement of research area, such as HIV, genetic disorders etc, it is desirable to include a member from specific patient groups in the committee.

- Each Ethics Committee has at least eight members with varying backgrounds to promote complete and adequate review of research commonly conducted by organization.
- Basic medical scientists (preferably one pharmacologist). Should have post graduate qualification and adequate experience in their respective fields.
- Clinicians from various institutes. Should have post graduate qualification and adequate experience in their respective fields.

  - Legal expert (Advocate)
  - Social scientist or representative of non-governmental voluntary agency.
  - Philosopher or ethicist or theologian. Lay person from the community.
  - The chairperson must be from outside the institute to maintain the independence of the Committee.
  - The Member Secretary of IEC belongs to the same institute, and conducts the proceedings of the Institutional Ethical Committee.

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- There should be adequate representation of age, gender, and community on the ethics Committee to safeguard the interests and welfare of all sections of the community.
- At least one member who represents the perspective of research subjects, such as a former or current research subjects or a research subject advocate.
- At least one member whose primary area of interest or specialization is nonscientific
- At least one member who is independent of the Institution. IEC can review all the phases of clinical trials.
- IEC works with independence in functioning and decision making.
- At least 50% of members from outside the institute
- At least one woman member representative is mandatory

I. **Quorum for approval:**

The Quorum is met when majority of its members not less than 50% & the specific mandatory Category are present for meeting for approval of any document. The specific category of members must be present are

a) One basic medical scientist (preferably one pharmacologist),
b) Clinician,
c) One legal expert,
d) One social scientist/ representative of non-governmental organization /philosopher / ethicist / Theologian or a similar person &
e) One lay person from the community.

Quorum must be present throughout the meeting for the discussion & approval of any documents. A single member may represent more than one category. For research to be approved it has to receive the approval of a majority of members present at the meeting

7. Terms of reference :

- A Conflict of interest will be declared by members of the IEC
- The non-member Subject experts are invited to obtain their suggestions on specific indications with clinical trial projects of Paediatric / HIV related/ Cancer/ Cardiology/ Psychiatry Etc., by sending a written invitation 15 days prior to the IEC Meeting. However, Non-member subject experts will not be allowed to vote in the decision making Procedure.
- The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be selected from those members who are external members of the IEC, who is going to be intimated in writing in advance and taken his permission and conduct the meeting in presence of alternate Chairman. OR an alternative chairman is elected from the External members by the members present in the meeting and continue to conduct the meeting.
- The Member Secretary is responsible for organizing the meetings, maintaining the records And communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman.

- A list of members, their qualifications, and affiliation and contact details will be maintained by the Institutional Ethical Committee. A copy of the Institutional Ethical Committee Composition and operating procedures are to be made available to any member of the Hospital/Institute for filing of research projects, upon written request for the same to the EC.

8. Responsibilities:

All the members of IEC are responsible for review and according approval to safeguard the Rights, safety and well-being of human subjects. Ethics committee shall decide on the Form/type of consent to be taken or its waiver based on the degree of risk that may be involved. All non- exempt human subjects research conducted must be reviewed and Approved by the IEC prior to the initiation of the research.

8.1 Roles and Responsibilities of IEC :

IEC will review and approve different types of study protocols and relevant documents **involving** human participants in order to safeguard the dignity, rights, safety and well- being of all actual and potential research participants. The goals of research are never permitted to override the health, Safety and well-being of the research subjects. The IEC members are required to follow their SOP, regulations and guidelines.

The basic responsibility of the Institutional Ethical Committee is to ensure a competent review of all scientific and Ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity.

If the EC members wants any change in the SOP it will be documented and changes will be made once in three years OR addendum is permitted as and when required to update the SOP and this will be communicated to all the PI in writing and the same SOP addendum is trained to all IEC members.

The EC will take ensure that all the cardinal principles of research ethics viz. **Autonomy, Beneficence, Non- maleficence** and **Justice** are taken care of while execution of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden, benefit and provisions for appropriate compensations wherever required.

It will review the proposals before start of the study as well as monitor the research throughout and after completion of the study through appropriate documented procedures. For example continue annual reviews, site visits, final reports, Audit report of IEC members & study close out reports etc.

It will also examine compliance with regulatory requirements, applicable guidelines and laws. The mandate of the EC will be to review all study protocols involving human subjects to be conducted at the hospital, irrespective of the funding agency.

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EC takes responsibility to protect the privacy and confidentiality of all the research participant especially when it's related to studies involving disease areas like HIV.

EC will not review or approve studies in which the sponsor / CRO is affiliated with the institution.

The responsibilities of the Institutional Ethical Committee are defined as follows:

a) To safeguard the dignity, rights, safety and well-being of all trial subjects.

b) To ensure that universal Ethical values and international scientific standards are expressed in terms of local community values and customs.

c) To assist in the development and the education of a research community responsive to local health care requirements

d) The committee will review the projects which are associated with pharmaceuticals, biomedical devices, epidemiological studies, retrospective studies, neutraceuticals, and isolated components of herbal products.

e) IEC ensure that Clinical trial projects carried out:

i. Are sound in design and are conducted in accordance with ICH-GCP/ Indian GCP and other regulatory requirements as appropriate.
ii. Do not compromise safety of study patients.
iii. Are conducted under the responsible investigator qualified by education, training and experience in the respective research field.
iv. Patients enrolled in the study must have given voluntary informed consent. IEC insist on re consenting of ICF as per SOP of IEC, JSMC &ICMR guidelines. To assist in the development and the education of a research community responsive to local health care requirements.
v. Revision of SOP will be done once in 5 years / earlier if required, prepared by Member Secretary and approved by Chairman and reviewed by the external member or internal members and all other members with effective date and termination date and the same will be trained to all the IEC members.
vi. IEC will review the proposals before start of the study and monitor till the completion of the study once in 3 months.
vii. The IEC will monitor the projects every year / end of the project whichever occurs earlier.
viii. IEC will review any non-compliance or protocol violation submitted by the PI in the Concomitant meeting.

ix. The stake holders are communicated through the PI as and when the situation arises (viz., SAE review, & submission of SAE report to DCGI)

x. IEC will inform the Authorities of BLDE(DU), in case of PI violating the guidelines of SOP inspite of repeated reminders.

8.2 Roles & responsibilities of individual IEC members:-

Chairperson

The chairperson of the committee should not be a current or retired employee of the institute, he or she should be from outside of the institute to maintain the independence of the committee. Chair the meetings Facilitate and participate in IEC educational activities Keep abreast of regulations and policies governing IEC review of research and the conduct of human subjects' research.

Secretary

- The secretary shall be from the institute and will be in charge of the secretariat of the IEC and responsible for reporting to the chairperson on all matters related to the IEC Organization of an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organization of regular IEC meetings. Preparation of the agenda and the minutes of the meetings.
- Maintenance of the IEC records.
- Communication with IEC members and Investigators.
- Arrangement of trainings/workshops for personnel and IEC members. Receipt of IEC processing fees.
- Maintain financial records which includes details of IEC fee for their services, honorarium payment to members and other expenses incurred.
- Prepare for financial audits and maintain the financial audit reports. Organizing the preparation, review, revision and distribution of SOPs providing the necessary administrative support for IEC related activities to the Chairperson of the Committee.
- Correspondence with Chairperson and IEC members, with Investigator and with Regulatory Authority.

Clinicians:

- A Clinician should have post-graduate qualifications and adequate experience in his/her respective field. A clinician should be an MD/ MS in Medical / Surgery or allied subjects. Review the protocol in total with more emphasis on scientific validation of the project.

Basic Medical Scientist

- A basic medical scientist should have post-graduate qualifications and adequate experience in his/her respective field. A basic medical scientist should be an MD/ MS/ M Pharm/ M Sc , P hD in one of the basic sciences. Basic sciences include anatomy, physiology, biochemistry, pharmacology, microbiology, and pathology. Review the investigator brochure and also the clinical trial protocol details.

Lay Person

- Cover people with a diversity of backgrounds outside of the specific science being reviewed or conducted. This could include individuals with expertise in ethics, animal welfare, and social sciences as well as members of the local community. Ideally, individuals should have no vested interest in the research and be independent of the particular science faculty or establishment.
- Represent the interests of the community/participant at large. Be able to take a balanced view of the likely harms and benefits of a research project bringing a lay perspective to bear.
- Review the Informed Consent form. Lay person's primary role is to share their insights about the communities from which participants are likely to be drawn. The role of lay person is to emphasize on aspects like the comprehensibility of the informed consent and other study documents to be used for participants, the study schedule and related activities and caregiver involvement.
- The lay person will visit the site along with other members and witness the informed consent process and interview the subjects enrolled in the study. This procedure is followed and the same will be documented in the concurrent IEC meeting.

Legal Person

- Is a qualified advocate with Bachelor or Master Degree in La? A legal person can be an Advocate. The clear articulation of law by legal person improves the ethical analysis of study. Should review agreements and insurance in clinical trials.
- Role of Legal expert is as primary reviewer of the contract to review the insurance, Compensation and Clinical trial agreements.
- Review agreements and insurance in Clinical trials.

Social Scientist/ Representative of Non-Governmental Voluntary Agency/ Philosopher/ Ethicist / Theologian

- A graduate with specialization in social ethics, intercultural ethics, and the ethics of gender and vulnerable population.
- Serve as resource persons to religious beliefs and faith concerning the spiritual and value dimensions and values of illness and health even if patients or their families have no apparent religious affiliation.
- Bring expertise in spiritual, theological, ethical, and moral values to the multidisciplinary team in the clinical setting.
- Review the Informed Consent form.
- Role of theologian is to understand if there are any religious implications to any of the trial activities.
- The Social Scientist will visit the site along with other members and witness the informed consent process and interview the subjects enrolled in the study. This procedure is followed and the same will be documented in the concurrent IEC meeting.

Expert member/ independent consultants/ subject expert:

- Subject matter experts may be invited to offer their views on review of research protocols, the rapeutic area and causality assessment for SAE, however the expert members or independent consultants will not be voting members.
- Their inputs shall be maintained on record and considered when reaching a decision. This is to ensure that scientific review is appropriate, approval of the trial meets regulatory requirements and vulnerable participants are protected from undue risk. i.e. a cardiologist for cardiac disorders and a pediatrician for review of pediatric studies, Psychiatrists for Psychiatry Studies . Similarly based on requirements of research areas like HIV, genetic disorders, etc., it is desirable to invite an expert from specific patient groups to the committee meeting, like a social worker who has experience in working with HIV patients can be invited.
- They will give their opinion through written document after a detailed assessment of the clinical trial document and its scientific validation (through checklist) and give their opinion accordingly. This will be recorded in the minutes of the meeting. They will declare the Conflict of Interest. The CV of the subject experts will be collected and made available in the IEC office.

8.3 A separate Informed Consent Form for the pharmacogenomics study:

- A clause can be included in the contract that the pharmacogenomics results will not be used for commercial purposes (cloning or generating immortalized cell lines) & the same to be reflected in the Informed Consent Form.
- The pharmacogenomics as an end point will be accepted with clarity to the above point and it needs to reflect in the Informed Consent Form.
- The subject has right to know the areas of usage of the sample and the results

To approve the Pharmacogenomics of the study

- It is the responsibility of the EC to see that the quorum is met and the timelines are followed for giving the communication letters to the PI is within 10 days of the EC meeting in case of clarifications or approval.
- In case of Serious Adverse Event of death/ Injury occurring to the research subject, the Ethics Committee shall analyse and in case of clinical trial shall forward its report on the Serious Adverse Event of death, after due analysis, along with its opinion on the financial compensation, if any to be paid by the sponsor to DCGI within 30 days of receiving the report of SAE. For academic studies and PI initiated studies the ethics committee will take a call of continuing the proposal or terminating after due diligence.
- IEC can send an initial SAE within 30 days and a follow up report later than 30 days of reporting of SAE to IEC. to DCGI
- In case of the Serious Adverse Event, other than death occurring to the clinical trial or research subject, the Ethics Committee shall forward its report on the Serious Adverse Event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, who had obtained permission from the Licensing Authority for conducting the clinical trial /or research.

8.4 . SOPs of Institutional Ethics Committee:

- Member Secretary shall be responsible for drafting and editing the Institutional Ethics Committee SOPs. It will be reviewed by all members and approved by chairperson, IEC.
  - The IEC SOPs shall be valid for a period of 5 years from effective date. Member secretary will review SOPs at least once in 5 year. SOPs can be amended in between 5 years if required.
  - Amendments to the SOP shall be proposed in writing or can be proposed in the IEC meeting by regular members.
  - The proposal for amendment shall be presented to the regular members at a scheduled committee meeting. Only regular members shall vote to accept or reject the proposed amendment. A proposed amendment shall be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.
  - If the changes on a final version are minor the version will be indicated as Version 1.1, version 1.2 etc. If there are major amendments, the version will be indicated as Version 2.0.
  - Storage and Distribution of SOPs. Paper copies of current and superseded SOPs are maintained in SOPs master file. Soft copy (PDF format) shall be available for distribution among members and Investigators of projects. Administrative staff of IEC shall be responsible for distribution of SOPs to members, and or concerned Investigators of Projects.
  - The electronic copy of the SOPs (PDF format) can be downloaded from website after completion of online SOP download form www.dypatil.edu or can be obtained by request by mail on Website :www.bldedu.ac.in OR E-mail: iec@bldedu.ac.in.

9. Procedure:

9.1 Membership of IEC

The committee will consist of members who collectively have the experience and expertise to review and evaluate the ethical, scientific, medical, and regulatory aspects of a proposed research project. A list of committee members, their qualifications and their affiliations (hospitals, colleges, etc.) described in this document will be maintained in the committee's records.

9.2 Composition of the IEC for clinical trial, BA and BE study

The Institutional Ethics Committee shall have at least 7 and a maximum of 15 members from medical, non-medical, scientific with at least:

i. One lay person.
ii. One female member.
iii. One legal expert.
iv. One independent member from any other related field such as scientist or representative of non-government voluntary agency or philosopher or ethicist or theologian.
2. The IEC shall have representation from both male and female.
3. The IEC shall have at least 50% of its members who are not affiliated with the institute or organization.

9.3 Chairperson:

1. The Chairperson will be selected and appointed by Registrar. BLDE (Deemed to be University), Vijayapura (Karnataka).
2. The chairperson shall not be affiliated to BLDE (Deemed to be University), Vijayapura (Karnataka).
3. The chairperson will be responsible for conducting all committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals
4. The chairperson will preside over the administrative matters regards to the committee's functions.
5. In the event of the Chairperson's anticipated absence, they will nominate an external individual as Acting Chairperson, who is not affiliated with the University. The Acting Chairperson will have the full authority of the Chairperson for the duration of that meeting

9.4 Members:

1. The members will be selected and appointed by the Registrar, BLDE (Deemed to be University), Vijayapura (Karnataka) provided they are willing to participate as an Ethics Committee Member.
2. A member shall be willing to publicize his/her full name, profession, affiliation and contact details.
3. A member will sign a confidentiality agreement (Annexure- I) and conflict of interest (Annexure-II).
4. A member will be trained in ethics and regulatory aspects for clinical trials and shall be willing to undergo such training.

9.5 Member Secretary:

1. The Registrar will appoint a Member Secretary from among the IEC members of University.
2. In consultation with the Chairperson, the Member Secretary will be responsible for the following.
   - i. Receiving all research proposals.
   - ii. Numbering the proposals.
   - iii. Forwarding proposals to committee members for review.
   - iv. Establishing time limits for receipt of reviewers' comments.
   - v. Preparation of agenda for all committee meetings.
   - vi. Inviting experts from relevant therapeutic areas to the scheduled meetings.
   - vii. Notification of review outcome to investigators of research proposals.
   - viii. Preparation and circulation of minutes
   - ix. Retention and safekeeping of all records and documentation.
   - x. performance of other duties assigned by the Chairperson.
   - xi. Preparation and amendments of SOPs
   - xii. Communication to Investigators regulatory bodies or any other concern authority on behalf of the IEC.

9.6 Tenure of Membership:

- A member will be a regular member a period of 5 years.
- Extension of membership will be determined willingness of member to continue and appointment by Registrar, BLDE (Deemed to be University), Vijayapura (Karnataka)
- There is no limit to the number of times that the membership can be extended.
- New members will be appointed to replace members according to the process described in the relevant sections of this document.

9.7 Resignation of Members

Members may resign before completing their terms by writing their intention to the chairperson of the IEC.

9.8 *Termination of Membership*

The membership will stand to be terminated under the following circumstances:

- If a member resigns from the committee.
- If a member remains absent for 3 consecutive meetings without informing either telephonically/email or giving a valid reason.
- If a member is incapable of performing his/her duty as an ethics committee member.
- In case of conflicts of interested identified to limit independent functioning of ethics committee.
- In case of demise of a member.

9.9 Appointment of New Members

New members will be selected and appointed under the following circumstances:

- When a regular member completes his tenure and does not wish to continue his/her membership.
- If a regular member resigns.
- In case of the termination of membership of a regular member.
- A new member will be preferably but not necessarily appointed by the Dean from the same category as that of the member being replaced.

9.10 Administrative Staff

- Administrative staff for the IEC will be appointed by Registrar.
- Administrative staff may be present during course of meeting however they will not participate in voting or in decision making process.
- Role of administrative Staff

i. Collect documents received for IEC submission or notification and submit to member secretary for acknowledgement
ii. Review documents received for each proposal for completion as per checklist
iii. Preparation, maintenance and distribution of study files
iv. Organizing Ethics committee meeting regularly
v. Communicating Ethics committee meeting agenda to applicants and members
vi. Maintaining Ethics committee documentations and to archive the documents
vii. Communicating with Ethics committee members and applicants
viii. Communicate decision of IEC to Principal Investigator of research proposal
ix. Organizing the distribution of SOPs and guidelines
x. Maintaining record for inward outward commutations of Ethics committee
xi. Providing the necessary administrative support for Ethics committee related activities to the Member Secretary (e.g. communicating a decision to the applicant)
xii. To receive fees and maintain record of Ethics committee fees and all financial transactions.
xiii. Any other work as told by Member Secretary

9.11 Office Attendant

Office attendant will be appointed by Registrar.

9.12 Role of Office Attendant

1. Arrangements for all ethics committee meetings and activities including maintenance of meeting room, circulating documents during meeting, water etc.
2. Technical assistance for meetings including computer, projector, telecom etc.
3. Maintenance of documents, filing of documents, storage cupboard etc.

9.13 Declaration of conflict of Interest and Confidentiality Agreement

- Every member at beginning of the tenure must declare conflict of interest and sign conflict of interest (Annexure - 11) and confidentiality agreement form (Annexure - 10) and submit it to chairperson for acknowledgement.
- Every observer attendee attending the IEC meeting must sign confidentiality agreement form (Annexure - 10) before initiation of meeting and submit it to chairperson for acknowledgement.
- At start of every meeting, Chairperson will ask every member attending the Ethics Committee meeting to declare conflicts of interest for study projects to be discussed in respective meeting. Every member must read and sign conflict of interest form (Annexure - 11) and submit it to chairperson before initiation of meeting. After acknowledging, Chairperson will ask concerned member to leave meeting venue and he/she will not participate in voting or decision making process. The same will be recorded in minutes of meeting.
- Every member of the IEC should declare any new conflict of Interest raised during his/her tenure to the chairperson.
- Every Independent Consultant/Independent Monitor/ Auditors should signs confidentiality agreement (Annexure - 10) and submit it to chairperson for acknowledgement.

9.14 Responsibilities of the Committee

- The members of the Ethics Committee shall follow the provisions of all the rules, Good Clinical Practices Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of study/research subject.
- The committee's responsibility will be the protection of confidentiality of the research subject.
- The committee will review all documents related to the research proposals in scientific, ethical and regulatory perspectives.
- The committee will review all research proposals submitted to it within specified time limits.
- The committee will keep information submitted to them confidential especially the proprietary information.
- The committee will maintain concise but clear documentation of its view on the research proposals.
- The committee will review the progress of each research project at appropriate and specified intervals.
- 8. The committee will review the qualifications of all investigators participating in the proposed research study.

10 Functions and Operations IEC

10.1 Functions of IEC

This IEC for clinical trials and BA/BE studies shall perform the following functions for *a* person, institute or organization; namely -

i. Review and accord to a clinical trial, bioavailability or bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with Good Clinical Practices Guidelines and other applicable regulations.

ii. Make at appropriate intervals, an ongoing review of the clinical trials for "which it has accorded approval and such review may be based on periodic" study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

iii. Indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licensing Authority.

iv. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial 0r bioavailability or bioequivalence study, the Ethics Committee shall analyze the relevant documents pertaining to such event and forward its report to the Central Licensing Authority and comply with the provisions accordingly.

v. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the Institution conducting clinical trial and the Central Licensing Authority.

vi. Allow any officer authorized by the Central Licensing Authority to enter with or without prior notice, to inspect the premises, any record, or any, documents related to clinical trial furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial. and to verify compliance with the requirement of these, rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects;

vii. Comply with the requirements or conditions in addition to the requirements specified under the Act and these rules as may be specified by the Central Licensing Authority with the approval of the Central Government to safeguard the rights of clinical trial subject.

10.2 Submission of the Research Proposals

1. All research projects involving human participation must be approved by the IEC.
2. All prospective and retrospective studies (on drugs, investigational techniques, as well as devices or any other procedure), involving humane volunteers or patients to be conducted by Shri B.M. Patil Medical College & Research Center, and shall have EC permission before commencing such a study.
3. Each project along with a duly completed application/ submission form shall be submitted through electronic copy (PDF format) and at least 2 paper sets of the same. The application form will be available at the office of the IEC. The information to be given on the application form shall be filled in legible handwriting. It shall have the designation and signatures of Principal investigator. All details in the form such as type of patients. phase of drug, trial, duration of study, sponsoring agency, budget of the trial, availability, of Drugs Controller General of India [DCGI] permission and other relevant approvals etc. shall be completed while submitting the proposal.
4. Any person or institution or organization which intends to conduct clinical trial of a new drug or an investigational new drug shall make an application to the Central Licensing Authority duly filled in Form CT-04 (Rule 21 of the New Drugs and Clinical Trial Rules, 2019) and shall submit the permission to conduct clinical trial from the office of the DCGI before recruitment of any participants. If the DCGI permission is awaited, a letter; of approval from IEC will be issued and final IEC approval will be given after a copy of DCGI permission is submitted to the IEC. A study cannot begin until the final letter of permission is issued by the IEC.
5. In case a clinical study is planned on an "alternative system of medicine" a co-investigator from that "system will be required on that study. For Ayurveda or herbal drugs, which are not marketed, a copy of the marketing/manufacturing license issued by FDA to the company shall be submitted.
6. All required fees shall be collected at the time of submission of the project. The amount to be collected as processing fee will be reviewed at the end of 1 year.
7. The project proposal shall be submitted in soft copy (PDF format) via email and three hard copies. Documents should be submitted to at least 15 days prior to scheduled ethics committee meeting for initial review and amended documents. Each set shall contain the documents on A4 size paper in, arranged in a file in the order mentioned below.

    i. EC application form duly filled

ii. Summary of protocol or Protocol Synopsis

iii. Protocol and any amendments to it with version and date.

iv. The informed consent document (ICD), including any amendments/addendum and its translation(s) into regional language(s)

v. A copy of Informed Consent Document for Audio visual Consent if applicable

vi. Case Record Form (CRF) / Questionnaire.

vii. Principal investigator's current Curriculum vitiate.

viii. Subject recruitment procedures (e.g. advertisements / letters to doctors/posters)

ix. Investigator Brochure (This should give details of the study drug, toxicology studies phase I, II, ill data wherever available, safety information etc.)

x. DGG(l) clearance [for Phase I, II, III studies on new drugs and other studies as applicable as per Schedule Y of the Dugs and Cosmetics Act]

xi. Investigator's agreement with sponsor

xii. Investigator's undertaking to DCGI [for Phase I, II, III studies]

xiii. Health Ministry Screening Committee (HMSC) clearance wherever applicable.

xiv. Food & Drugs Administration (FDA) marketing/ manufacturing license for herbal drugs

The guidelines for submission of a research proposal are described in Annexure 04 and the checklist for documents to be submitted is as described in Annexure 02.

10.3 IEC Procedures

- All communications with the committee shall be in writing or electronic form (e-mail).
- The project proposals in the format mentioned in 9.2 above will be accepted in office of the IEC as a soft copy (PDF format) and at least 3 set of paper copies.
- The submitted project/s will be circulated 10 days prior to the IEC meeting for initial review to all committee members via email or paper copy and the proposal shall be reviewed for elements described below.
- A meeting (as described in 9.7) of all members will be held every quarter of the year (March, June, September and October) based on availability and convenience of the IEC members. However, meetings can be arranged more frequently as per requirement.
- Each proposal shall be discussed in detail in the IEC meeting and decisions arrived at based on votes of the members/written approval.

10.4 Elements of Review-

The submitted proposal with all necessary documents as needed reviewed ethical aspects and to safeguard the interests of the study participants/patients/subjects in accordance with the principles of Good Clinical Practices (GCP).

i. Justification/Rationale for human participants in the study
ii. Selection criteria for subjects
iii. Subject recruitment procedures and methods
iv. Patient retention activities
v. Potential benefits to the study subjects/participants
vi. Predictable risks to the study subjects/participants
vii. Criteria for discontinuation/withdrawal of subjects/ participants
viii. Justification for use of placebo, if any
ix. Monitoring of serious adverse events
x. Compensation to subjects for participating in the study
xi. Compensation for study related inquiry
xii. Post-study benefits
xiii. Protection of privacy and confidentiality
xiv. Informed consent documentation and procedure
xv. Competence and necessary qualification of investigators, supporting staff and infrastructure facility
xvi. Study agreements including financial agreements (for funded studies/projects).
xvii. Approval of regulatory authorities

Members shall refer Annexure 2 Risk Benefit assessment tool to categorized Research study project into any one of following category

- Class A: High Risk Low Benefit,
- Class B: High Risk High Benefit,
- Class C: Low Risk High Benefit
- Class D: Low Risk Low Benefit

10.5 Review of Informed Consent Documents (ICD)

The IEC will examine the ICD for the presence of the following points (if applicable) while reviewing the patient information sheet/information Consent Form. Sample format of ICD, Annexure - 5)

- Voluntary, non-coercive recruitment, participation/ withdrawal
- Procedures for obtaining informed consent for Audio-Video Recording
- Contents of the patient information sheet - title, objective, study design and procedures

- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages
- Language used - plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about search participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts physical / mental / social
- Alternative treatments
- Benefits - to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment for study related injuries
- Compensation for study-related injuries: Reasonable
- Travel Reimbursement biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness

All members of the IEC present during meeting will be responsible for review of projects. However, members are expected review specific documents in detail which are in their own expertise (e.g. legal expert are expected to review Clinical trial agreement and insurance policy).

Every reviewing need to fill study assessment form (Annexure - 9) present during meeting.

Study assessment form can be share either as Signed Hard copy or filled soft copy through email Admin officer will keep all filled. Study assessment form-in respective study project file.

10.6 IEC Meetings:

- The IEC will hold regular meetings once every three months.
- If there are no research proposals to review, meetings may be held less frequently but not less than once every 12 weeks.
- All committee members will receive meeting schedules at least 1 week in advance.
- All research proposals will be reviewed by committee members before the meeting.
- Proposals may be sent to a subject expert for additional assessment and opinion. The subject expert may be invited to attend the meeting.
- The investigator and/or co-investigator may be invited to attend the meeting to provide clarifications on the study protocol, if necessary.
- The Member Secretary will invite the concerned investigator and/or co-investigator to the meeting when required.

10.6.1 Quorum for the meeting

Meetings will be held as scheduled provided there is a quorum. In accordance with Schedule Y (20th January 2005), the quorum of the IEC will be at least five members with the following representations:

- Basic Medical Scientist/Pharmacologist.
- Clinician.
- Legal expert.
- Social scientist/worker/representative of NGO.
- Lay person.

10.6.2 Hierarchy

- There will be one Chairperson and one Member Secretary
- The Chairperson will be the head of the committee.
- The Member Secretary will be the guardian of all documents and funds in the committee's possession.
- All other members will be regular committee members with equal ranking.
- Members will elect 'Acting Chairperson' among available external members in case of chairperson absence or his/her conflict of interest. Elected acting chairperson will chair respective ethics committee meeting, including all discussion as mentioned in agenda In case chairperson has declared conflict of interest for particular project, the acting chairperson will convene the meeting for that particular project

10.6.3 Minutes of meeting

- The Member Secretary will be responsible for coordination and recording of the proceedings of the meeting.
- The proceedings of the meetings shall be recorded in English and in the form of minutes.
- The minutes shall be approved by the chairperson and circulated within 10 days of the EC meeting.

10.6.4 Decision making

- Decision for each proposal shall be voting by simple majority/written approval.
- A majority vote for approval, disapproval and request for modifications, suspension or termination of a research proposal or an ongoing study is defined as one of the members who have reviewed the project.
- All members present at the IEC will vote on the research proposal/ written approval.
- Absent members shall not vote / provide written approval.
- Member(s) of the committee who is/are listed as investigator(s) on a research proposal or having conflict of interest will opt out from all deliberations on the proposal and will not vote on the proposal/ provide written approval.
- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedure of the committee.
- Specific patient groups or Subject experts shall be invited for the_ meeting will not vote or participate in the decision making procedures.

10.6.5 Review Outcome

The Committee will document its view on the following:

- Final Approval
- Provisional approval subject to regulatory approval Request for modification giving reasons, Request for additional information Clear disapproval giving
- Termination/suspension of an ongoing study giving reasons

10.6.6 Notification of Review Outcome

The outcome of committee's review shall be communicated to the investigator within U working days of the meeting and the reply for Submitted by the-principal investigator within 90 days of receipt of the letter. If there is no reply or any other communication within 90 days, the project will be considered closed and shall be archived.

10.6.7 Conflict of interest

- No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the research or bioequivalence study protocol being reviewed by it and all members, shall sign a declaration to the effect that there is no conflict of interest.
- While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson.
- The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

10.6.8 Approval

All projects will be given approval for the entire duration of the study.

10.6.9 Review of the Modified Proposal

1. When modifications to the proposal, as recommended by the committee, are minor, the revised documents may not be re-circulated. The revised proposal shall be reviewed by either the Chairperson of the committee, the Member Secretary of the committee, or by one or more experienced reviewers designated by the chairperson from among the members of the committee. An approval may then be issued if the revised documents are satisfactory. The committee will keep all members of the committee informed of these approvals.
2. When modifications to the proposal, as recommended by the committee, are major, the revised proposal will be re-circulated and discussed again at next meeting.

10.7 Procedures for Appeal

For research proposals rejected/disapproved by the committee the applicant may appeal for a repeat review in within 90 days of the receipt of the committee's decision. While doing so, the applicant shall give justification relevant to the issues/objections raised by the committee.

10.8 Expedited Review Procedures

1. The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.
2. Under an expedited review procedure, the review may be carried out by the Member Secretary of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the, committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.
3. An on-going research activity may be disapproved only after review in accordance with non-expedited review.
4. The committee will keep all members of the approvals under the expedited review procedure.
5. Only the Member Secretary shall make the decision to allow an expedited review

10.9 Review of Subject Recruitment Procedures

All advertisements, letters to doctors, posters, notices to be used for recruitment subjects shall be reviewed and approved by the committee in full Board meeting prior to their implementation in the study.

10.10 Review of On-going Studies

1. The committee will conduct a continuing review of each on-going study every 6 months.
2. The committee can monitor study as is felt appropriate to the degree or risk (o the human subjects
3. The-committee may also ask for a status report from the investigator at earlier intervals as is felt appropriate to the degree or risk to the human subjects.
4. On the basis of the review, the committee shall recommend continuation with/without modifications, temporary suspension or termination of ongoing clinical trials for reasons such as patient safely.

10.11 Review of Amended protocol/ Protocol related documents for Approved Projects

1. No changes in the protocol, case record form, ICD or any other protocol related documents shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject.
2. The amendment package (hard & soft copy) forwarded by the principal Investigator will be received by the Admin staff of the IEC.

3. The documents should highlight changes from previous version and should submit Annexure 06 which mentions;
   - Mention the amendment/List of Amendments.
   - Provide the reason for the amendment
   - State any untoward effects with original protocol
   - State expected untoward effects, if any because of the amendment
4. Member Secretary will acknowledge amended documents along with all requirements after confirmation from Admin staff. The Member Secretary Chairperson decides whether the proposed protocol amendment(s) need to undergo *a* full board review, review by designated IEC members or a review, by the Member Secretary/Chairperson. The Member Secretary / Chairperson can take the decision if the amendment(s) is / are of administrative nature.
5. The Protocol or other study related documents amendment which increases risk to study participants, as judged by the Chairperson and/ or the Member, .=- Secretary, such as a change in study design, which may include but is not limited to:
   - Additional treatments or the deletion of treatments
   - Changes in inclusion/exclusion criteria.
   - Change in method of dosage formulation, such as oral changed to intravenous
   - A significant change in the number of research participants (if the. decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)
   - Change in study schedule or any study procedures
   - Significant Changes in informed consent documents which may affect subject decision to participate
   - Significant change in case record form/ Additional data recording
6. The Member Secretary will indicate decision on the Protocol/Protocol related Documents Amendment. Documents will consider for next full board review after Secretary/Chairperson.
7. If the IEC approves, the protocol/ protocol related documents amendment, the member Secretary will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 14 days of the meeting. The decision regarding disapproval (stating- reasons) or request for modifications (stating specific changes needed! shall be communicated 14 writing to the investigator within U days of the meeting.
8. In a case of minor/administrative changes in protocol/ protocol related documents amendment approved by Member Secretary/Chairperson, Member Secretary will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 7 days of submission of documents. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 7 days of submission of documents if applicable. Member secretary will inform this decision to all members in next full Board meeting.

10.12 Notification received from Principal Investigator regarding on-going approved project:

1. Notification along with supporting documents if any (hard and soft): copy forwarded by the Principal Investigator will be received by the IEC.
2. Notification received from Principal Investigator regarding ongoing approved projects may include but not limited to
   - Change in study team delegation
   - Administrative Change in Clinical Trial Agreement (CTA) / Memorandum of Understanding
   - Updated Insurance
   - CTRI registration number
   - Administrative changes related to Principal Investigator Institute or Sponsor
3. Member Secretary will acknowledge and review notification received from PI along with any supporting documents. Member Secretary may send a letter to PI requesting more clarification or any documents if required within 7 working days of notification.
4. Any other internal 1EC member preferably clinician may acknowledge notification in case of non-availability of Member Secretary or conflicts of member secretary in any study projects.
5. The IEC will send acknowledgement letter within 7 working days of receipt of notification
6. Member Secretary will inform all notification received .from PI members in next full Board meeting

10.13 Protocol Deviation/Non-Compliance/Violation

1. Protocol deviation/ non-compliance/ violation may be reported by Investigator/study site staff to the Chairman/Secretary of the IEC. Members may detect protocol deviation/non-compliance/ violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator or site.
2. Member secretary will acknowledge reported Protocol deviation/ non-compliance/violation and present it in next full Board meeting. Member, secretary shall inform Protocol deviation/ non-compliance/ violation to all members considering seriousness and may schedule urgent full board, meeting within 7 working days.

3. IEC members will review the .information available and take a decision depending on the seriousness of the violation in full board meeting; decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus In case, the decision is not reached by consensus, voting will be taken. The actions taken by the IEC could include one or more of the following:

- Inform the Principal Investigator (PI) that the IEC has noted the vjplation/ non- compliance/ deviation and direct the PI to ensure that deviations/non-compliances/violations do not occur in future and .follow IEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations/non-compliances/violations do not occur in future Reprimand the PL.
- Call for additional information
- Suspend the study till information is made available and is scrutinized.
- Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
- Inform the Head of the Institute.
- Revoke approval of the current study and Inform DCGI/ Other relevant regulatory authorities (if applicable).
- Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
- Any other action considered appropriate by the 1EC for safeguarding the interests of the research participants participating in the current trial and in future trials.

4. The IEC will send communication with action to the concerned Ft/Institute director (If applicable) /Regulatory body (If applicable) signed by the Member Secretary within 10 days of the meeting.

10.14 Reports required from investigators

The research investigator shall submit the following reports to committee:

1. Continuing Review Application form should be submitted 6 months-following of the final IEC.
2. Subsequent reports shall be submitted | at every |i monthly following the first report.
3. The investigator should ask written permission to recruit more patients than no of patients approved by the IEC along with the Continuing Review Application Form.

4. Study completion report; A brief report of the study shall be submitted to the committee at the end of the study.
5. Member Secretary shall present all Continue Study reports/ Study, completion reports to all members in next full board meeting.
6. Member Secretary shall communicate in written to principal Investigator alter reviewing continues review reports regarding ongoing review within 14 days from meeting.
7. Member Secretary shall send confirmation letter to Principal Investigator for closing study after submission of final study completion reports with 14 days from meeting.
8. If the Principal Investigator fails to submit the continuing review report within one month of the due date (i.e. 6 months from the date of approval or last review report, unless specified otherwise), Member Secretary will send a reminder as per the format mentioned within 14 working days of this due .date. If there is no response within 15 days after the date of reminder, Member Secretary will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to,
   - A letter of reprimanding the investigator.
   - Not reviewing future projects from the PI for a specified period of time.
   - A letter asking the investigator to put recruitment of new participants on hold.

   In addition, the investigator shall also promptly report the following to the committee
   - Deviations from/changes to the protocol to eliminate immediate hazards to trial subjects.
   - Changes that may increase the risk to subjects and /or affect the conduct of the trial.
   - New-information that may affect adversely the safety of the subjects or the conduct of the trial.

10.15 Study Monitoring

1. Selection of study: The IEC will identify the study projects for routine monitoring at the time of approval of the project depending on risk profile.
2. The IEC may initiate 'for cause' monitoring due to following reason but not limited to:
   - High number of protocol violations or non-compliance
   - Large number of, studies carried out at the study site or by the investigator
   - Remarkable number of SAE reports
   - High recruitment rate

- Non-compliance
- Suspicious conduct
- Complaints received from participants

3. The Chairperson will identify and select one or more members or independent monitor to conduct monitoring of a site.

4. The Member Secretary will-inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator, study team members and, study participants (if necessary), to-be available for the monitoring visit.

5. Designated Monitors will conduct monitoring of all study documents including but not limited to ICD, AV Consent recording, Source documents, Case record forms, Subject files, study Master file IP, storage facility, Clinical Examination, lab reports etc.

6. Monitors shall conduct interview of PI, other study team members and few study participants during monitoring visit. Monitors will complete monitoring report as per Annexure –

7. The member secretary will present the monitoring report at the next full board meeting and the concerned member will provide additional details/clarifications to members, as required.

8. The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
   - Continuation-of the project with or without changes,
   - Restrictions on enrolment,
   - Recommendations for additional training
   - Recruiting additional members in the study team,
   - Revising qualifications/experience criteria for members of the study
   - termination of the study,
   - Suspension of the study

9. The Secretariat will convey the decision to the principal investigator in writing within 14 days of the meeting including any recommendation and will ask PI to submit action item report including Corrective a preventive Action (CAPA), if applicable for the IEC review

11. Training of Members - New Members:

1. All new members will be trained on Good Clinical Practices (GCP) guidelines, Current ethical and regulatory guidelines and the SOP of IEC.
2. The Chairperson will identify the training requirements of the committee members.
3. The Chairperson and the Member Secretary will organize workshops are training programs for the committee members. It is recommended to conduct GCP refresher training and training on current regulatory guidelines once in once in 2 years.
4. The type of programs, areas for training and mentors (Internal/External) for these workshop or training programs will be decided by Member secretary.
5. The Chairperson and the Member Secretary will inform all members about any updates on ethical and regulatory guidelines regularly during meetings

12. Records Retention

1. All records including study documents shall be kept at the office of the IEC located in BLDE (Deemed to be University) Vijayapura (Karnataka).
2. All documents will be accessed only by the IEC members and IEC staff.
3. IEC will maintain 1 copy of paper copy and electronic copy of all documents received by IEC and all communications for every study. Member secretary will maintain individual study project file for each projects received by/the IEC for review.
4. The committee will archive the following records for a period of at least five (5) years.
   - Standard operating procedures (SOPs) of the committee.
   - Guidelines for submission established by the committee.
   - Membership list
   - Curriculum Vitae of the members
   - Agenda of meetings
   - Minutes of meetings

   The committee will also archive the following records for a period of at least 5 years following the completion of a study
   - All correspondence by the committee with the research investigator regarding application, decision and follow-up.
   - One copy of all materials submitted by a research investigator
   - A copy of the decision and any advice or requirements sent to an applicant
   - All written documentation received during the study.
   - The notification of the completion, premature suspension or premature termination of a study
   - A summary of the final report of the study.

   The records shall be made available to relevant statutory authorities upon request.

12.1. Reports to the Vice Chancellor/Registrar/ Dean Faculty of Medicine

The committee will make a yearly activity report for submission to the Vice-Chancellor Registrar, BLDE (Deemed to be University), Vijayapura, Karnataka Institutional Ethics committee, which will include the following elements.

1. A quantitative evaluation of the activities of the committee in a year
2. The list of the proposals received in a year
3. Status of each study proposal.

12.2 List of committee members with their affiliations and qualifications

The present composition of the Institutional Ethics Committee (2025):

Sl No	Name	Qualification	Designation	Position	Member Internal/ External
01	Dr. Santoshkumar Jeevanagi	MBBS (MD - Pharmacology)	Professor & HOD Dept. of Pharmacology, MRMC	Chair Person	External
02	Dr.Santosh Ramdurg	MBBS,MD-Psychiatry	Professor & HOD Dept. of Psychiatry BLDE (DU) SBMPMC H & RC	Clinician	Internal
03	Dr. Deepa Sajjanar	MBBS (MD-Biochemistry)	Additional Professor Dept. of Biochemistry BLDE (DU) SBMPMC H & RC	Basic Medical Scientist	Internal
04	Dr. Vijaya Sorangvi	BSc (MSc.,Ph.D-Statistics)	Assoc. Professor/Statistician Dept. of Community Medicine BLDE (DU) SBMPMC H & RC	Scientific Member	Internal
05	Mr. Suresh K Hakki	B.A (LLB)	Advocate	Legal Expert	External
06	Dr. Vijaya Patil	MBBS (MS-General Surgery)	Professor Dept. of Surgery BLDE (DU) SBMPMC H & RC	Clinician	Internal
07	Dr. Ramesh Rathod	M.V.Sc.,PhD,PGDCR,PGDMLS	Veterinary Surgeon	Scientific Member	External
08	Dr. Chandrasekar C. Patil	B.Pharm, M.Pharm, Ph.D	Professor Dept. of Pharmaceutics BLDEA'S Pharmacy College	Scientific Member	External
09	Dr.Jyoti S.Patil	MBBS (MD - Pharmacology)	Assistant Professor, Dept. of Pharmacology BLDE (DU) SBMPMC H & RC	Scientific Member	Internal
10	Dr. Satish Nadagaddi	Ph.D (Nursing)	Assoc. Prof Dept. of Medical & Surgical Nursing BLDEA'S Shri B M Patil Institute of Nursing Sciences	Scientific Member	External
11	Dr. Prasadshakti G. Gannur	BAMS,MS (Ph.D)	Professor & HOD Dept. of Shalyatantra BLDEA'S AVS Ayurveda Mahavidhyalaya	Scientific Member	External
12	Mr.Maliksab Jamadar	B.Ed, MA	HoD Journalism and Mass Communication	Lay Person	External
13	Mr Sidramappagoud S. Patil	MSW, B.Ed	Faculty of Sociology	Social Scientist	External
14	Dr. Smitha Bagali	MBBS (MD-Microbiology)	Additional Professor Dept. of Microbiology BLDE (DU) SBMPMC H & RC	Scientific Member	Internal
15	Dr. Shailaja Patil	MBBS (MD – Community Medicine)	Professor Dept. of Community Medicine BLDE (DU) SBMPMC H & RC	Member Secretary	Internal

12.3 SOP for Review of Serious Adverse Events (SAE) Reports

12.3.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) and unexpected adverse events (SAE) reported to BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee occurred at BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee

12.3.2 Scope

This SOP applies to the review of SAE reports submitted to the IEC.

12.3.3 Responsibility

It is the responsibility of the IEC affiliated to BLDE (Deemed to be University) Vijayapura, Karnataka to review SAEs reported to the BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee. These could be SAEs occurring at BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee or other sites for the given project/related project.

12.3.4 Serious Adverse Event (SAE) Subcommittee

12.3.5 Purpose of SAE subcommittee

1. The SAE Subcommittee will review serious adverse events (SAE) and unexpected adverse events (SAE) at BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee and allies (Sister Concerns) in all types of research studies involving human participants approved by BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee. The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants. SAE can be discussed directly in full board BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee meeting if meeting is already planned with review timeframe as per regulatory requirements

2. The SAE Subcommittee will work according to its established Standard Operating Procedures based on the Operational Guidelines for Ethics Committees that review Biomedical Research (WHO, 2000), International Conference on Harmonization- Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013 and 8th February 2013) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006). The mandate will be
   - To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.
   - Provide public assurance of that protection
   - To ensure appropriate compensation as per Schedule Y, 30th January 2013 amendment is provided to the research participants.

   The SAE Subcommittee is established and functions in accordance with the relevant national law and regulations in force from time to time

12.3.6 Composition of the SAE Subcommittee:

- The SAE Subcommittee will be appointed by the Chairperson of the BLDE (Deemed to be University), Vijayapura, Karnataka, Institutional Ethics Committee for a tenure of 5 years.
- The SAE Subcommittee will have a multidisciplinary and multi-sectorial composition.
- The Subcommittee will consist of at least 4 members, including a legal expert.
- The members of the SAE Subcommittee should preferably come from medical and scientific backgrounds.
- All members will be part of the BLDE (Deemed to be University), Vijayapura, Karnataka, Institutional Ethics Committee.
- The SAE Subcommittee will include one Subcommittee Head and one Executive Secretary.
- The Head of the SAE Subcommittee and the Executive Secretary will be appointed by the Chairperson of the BLDE (Deemed to be University), Vijayapura, Karnataka, Institutional Ethics Committee.

12.3.7 Roles and Responsibilities of the SAE Subcommittee members

1. To attend the SAE Subcommittee Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider adverse event reports submitted for evaluation.
3. To review Serious Adverse Event and unexpected adverse reports and recommend appropriate action(s) as follows:

- SAE reports will be reviewed completely in the SAE subcommittee meeting with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participant as per Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013)
- The SAE subcommittee while reviewing may solicit opinion of one or more independent consultant (s) in writing, if the Sub-committee decides to consult experts. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality cause and abide by the rules and regulations of IEC or the necessary confidentiality documents are signed. The independent consultant would be requested to provide an opinion in writing within 3-5 working days, depending upon the gravity and seriousness.

4. The following decisions/actions including the following but not limited to, are listed below:

- Note the information about the SAE in records for future reference
- To opine on compensation entitled to research participants (as per Drugs and Cosmetic Act 1940, Schedule Y - amendment 20th January 2005, 30th January 2013) experiencing Serious Adverse Event and unexpected adverse events and adverse events and recommend appropriate action(s)
- Request further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation
- Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier).In case of pregnancy as SAE to send follow up reports of the child in utero and post-delivery of the baby till 1 year.
- If appropriate to the discussions, the recommendation regarding a specific action or combination of actions to be taken is arrived at by the SAE subcommittee meeting. The recommendations will be communicated to all members within 5 working days.

5. To maintain confidentiality of the documents and deliberations of the SAE Subcommittee meetings and to declare any conflict of interest.

12.3.8 List of Members of SAE sub-committee

Sr.	Name of the Member	Designation	Gender
01	Dr. Santoshkumar Jeevanagi	Chairman & Pharmacologist	Male
02	Dr. Santosh Ramdurg	Clinician	Male
03	Dr. Vijaya Patil	Clinician	Female
04	Dr. Shailaja Patil	Member Secretary (Community Medicine)	Female
05	Dr.Sidramappa Biradar	Social Scientist	Male
06	Mr. Suresh Hakki	Lawyer	Male
07	Dr.Chandrashekhar Patil	Scientific Member	Male
08	Dr.Jyoti S.Patil	Scientific Member	Female

12.3.9 Process flow in case of an SAE

No.	Activity	Responsibility
1	Receipt of SAE report	Administrative staff, IEC
2	Circulation of SAE report to the all members within 2 days of receipt of Initial SAE reports	Member Secretary, IEC Administrative staff
3	Decide to call SAE subcommittee meeting or discuss in coming full Board meeting	Member Secretary, IEC
4	Scheduled SAE subcommittee meeting within 7 days of receipt of SAE analysis reports	Executive Secretary, SAE Sub-committee
5	Agenda and Minutes of the Subcommittee	Executive Secretary, SAE Sub-committee
6	Review and discussion of SAE report at the Subcommittee meeting	Members, SAE Subcommittee
7	Communication of the SAE Subcommittee decision about SAE review to Chairperson and other BLDE (Deemed to be University), Vijayapura, Karnataka Institutional Ethics Committee members within 5 days of meeting	Executive Secretary, SAE Sub-committee
8	Schedule IEC full board emergency meeting if required within 5 days	Member Secretary, IEC Chairperson, IEC
9	Communication of the decision about SAE review to the principal investigator	Member Secretary, IEC
10	Communication of the IEC decision about SAE review to the Licensing authority /DCGI if applicable within 30 days	Member secretary, IEC
11	Discussion/ Information at the full board IEC meeting	Member secretary, IEC

12.3.10 Receipt of SAE on site: Detailed instructions

The IEC administrative staff will receive the following documents within the specified time frame pertaining to SAE experienced by the research participants ON SITE for research proposals approved by the BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee.

1. On site SAE Assessment Report to be submitted by the Principal Investigator within 24 hours of their occurrence (as per Appendix XI of Schedule Y) along with the SAE Assessment Report (Annexure - 12).
2. SAE Analysis Report with due analysis will be submitted by the Principal investigator and Sponsor within 14 calendar days along with the format specified in Annexure - 13.
3. The follow up reports of all on site SAE / unexpected AE reports till the event is resolved.
   - The IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) or Sponsor as the case may be and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as a violation.
   - The IEC Member Secretary will sign and write the date on which the report is received.

12.3.11 Communication to the IEC Members

1. Member secretary will communicate minutes of SAE subcommittee meeting within 5 working days of meeting
2. After confirmation of comments from the IEC members, the decision will be communicated to the Licensing authority (DCGI) and PI within 30 calendar days of the occurrence of the SAE.
3. If objection is received from more than 2 members of IEC, an emergency meeting will be scheduled within 7 days for the same.
4. The decision taken at the emergency meeting regarding the onsite SAE report will be communicated to the Licensing authority (DCGI) and PI within 30 calendar days of the occurrence of the SAE.

12.3. 12 Communication to Principal Investigator (PI)

1. The Member Secretary will draft a formal letter to the concerned Principal Investigator and inform him/ her about the IEC decision. This letter will be signed and dated by the Member-Secretary and will be sent to the Principal Investigator within a period of 7 days from the date of the SAE subcommittee meeting or full board meeting after submission of SAE analysis report
2. The Principal Investigator will be requested to reply to the query letter on the SAE report within 7 working days. If no response is received (within 7 days of dispatch of EC query letter) from the investigator regarding the query raised on the given SAE, a reminder letter will be sent to the investigator stating that the response to the query letter must be sent within 5 working days of the dispatch of reminder letter. If no response is received to the reminder letter, this should be informed by the member secretary of the IEC in the full board meeting and decision will be taken on case to case basis.
3. The principal investigator will be requested to forward follow-up reports after due analysis of the SAE report to the IEC till SAE resolves
4. The Administrative officer will file a copy of all SAE related communication in the study file.

12.3. 13 Communication to Drug Licensing authority (DCGI)

1. The Member Secretary will forward the letter describing the opinion on the SAE report death or other SAE, along with the opinion on financial compensation as per applicable rule as and when, to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE-death.
2. PI/Sponsor is also obliged to pay the expenses of the patients' treatment till the time that it is proved that the SAE is not related.
3. The Administrative officer will file a copy of these letters in the study file.

12.3. 14 SAEs occurring at other sites:

Sr	Country	MFR Control No. (If applicable)	Type of Report	SAE event	Date of Onset of ADR	Date of ADR report	Outcome	Causality	
									Sponsor

The investigator will need to submit the SAEs occurring at other sites (CIOMS, SUSARS and Annexures 12 and 13 as applicable) in the form of soft copies (in CD/DVD/PD) / hard copies along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details preferably in the following format:

1. The SAEs occurring at other sites will be acknowledged by member secretary and discussed in the forthcoming scheduled SAE Subcommittee or Full Board meeting whichever is earliest. The agenda and minutes of the SAE Subcommittee/Full Board meeting will include the information on SAEs at other sites.
2. The discussion will be communicated by the SAE Subcommittee Executive Secretary (if discussed in SAE subcommittee meeting) to all IEC members.

12.3.15 Review of SAE in IEC meeting

1. In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.
2. If appropriate to the discussions and any issues regarding to SAE decision can be arrived at by voting (a majority vote for a decision is $2/3^{rd}$ majority of the members present and voting) or by consensus.

12.3.16 Possible actions to be taken in case of an SAE

- Terminate the study
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued)
- Suspend the study till additional information is available
- Suspend the study for a specified duration of time
- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents
- Suspend the study till amendments requested for by the IEC are carried out;
- Suspend enrolment of new participants;

- Suspend certain activities under the protocol
- Direct the Investigator to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial
- Direct the Investigator to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment
- Note the information about the SAE in records for future reference
- Request further follow up information and/ or additional details
- Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier)
- Any other appropriate action;

The decision shall be recorded in the minutes of the full board IEC meeting;

- If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the Principal Investigator through telephone, fax or email within 24 hours. Such a communication will be documented by the Member-Secretary in the study file. A formal letter to the Principal Investigator informing about the IEC recommendations in such situations will be sent within 5 working days of the meeting of IEC having taken place.
- IEC will ensure that appropriate compensation is paid to the research participant as per applicable regulatory requirements.
- Investigator should ensure safety monitoring of recruited patients to be continued till SAE resolved.

12.3.17 Compensation for SAE

Any compensation for occurrence of an SAE shall be estimated/calculated as per the "FORMULAE TO DETERMINE THE QUANTUM OF COMPENSATION IN THE CASES OF CLINICAL TRIAL RELATED INJURY OR DEATH" (7th Schedule of the New Drugs and Clinical Trial Rules, 2019).

12.3.18 Functions of the IEC Administrative staff

1. To prepare the agenda of the SAE discussion with help of Member Secretary of the SAE Subcommittee. The agenda for the SAE discussion will include the information on SAE at the site in the following format

Participant ID	Letter no./ and date of reporting	Type of report	Type of SAE/ UAE	Date of onset	whether study drug withheld	Outco	Causality in the opinion of PI

The agenda will also include information about onsite SAE reports for the SAE occurring at other trial sites.

2. To prepare the minutes (to be prepared within 5 working days of the meeting) with the help of the Member Secretary. The minutes of the SAE Subcommittee will include the information on SAE at the site in the following format:

Participant ID	Letter no./ and date of reporting	Type of report	Type of AE/SAE/ UAE	Date of onset	whether study drug withheld	SAE Outcome	Causality in the opinion of PI	Recommend actions by the SAE Sub Committee

13 SOP for reviewing proposals involving vulnerable Populations

13.1 Purpose

The purpose of this Standard

Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOPs provide clear, unambiguous instructions so that the related activities of the Board are conducted in accordance with Indian laws and relevant, National and International Guidelines. It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

13.2 Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable population submitted to the BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee.

13.3 Responsibility

1. It is the responsibility of the IEC secretariat to maintain up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.
2. IEC Chairperson/ Member Secretary is responsible for ensuring that the IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise or representative from the vulnerable population as needed for selected reviews.
3. All members is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

13.4 Role of administrative staff

1. Administrator will maintain on file the update checklist (A-F) which conforms to applicable regulations and guidelines.
2. Document review of risk assessment in the IEC minutes for the protocols involving vulnerable population.
3. Confirm that the complete informed consent and assent documents as relevant.
4. Chairperson/Member Secretary will select appropriate primary reviewer(s) as applicable for the vulnerable population.
5. IEC members will complete checklist during review of research with vulnerable populations and present recommendations at the convened meeting.

13.5 Detailed instructions: Review of protocol with vulnerable population

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, and patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox society.

The protocol should be reviewed keeping in mind the following points when . it concerns research that involves groups that could be potentially vulnerable to coercion:

- Measures to protect autonomy
- Risk/benefit determinations with respect to the vulnerability
- Bearing unequal burden in research

Any member of the IEC who would be dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study. The checklist for different vulnerable population is being provided in Annexure - 14 to Annexure - 17.

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

13.6 Administrative officer Responsibilities

1. Provide a suitable checklist according to the subjects to be recruited in study to the investigator. Inform the investigator to download the appropriate application form and informed consent document/ assent form from the internet/intranet site.
2. Provide appropriate reference material or help reviewer locate such material related to vulnerable populations when specifically requested for, by a reviewing member.

13.7 Appointment of Reviewers

The Chairperson will appoint two or more members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar and trained in the concept of vulnerability and protections for participants with diminished autonomy.

Subject experts or representative of vulnerable subjects shall be invited as required with prior intimation. Subject experts or representative of vulnerable subjects will be asked for their inputs or opinion on respective research projects. Subject experts or representative of vulnerable subjects will not participate in voting or decision making process.

13.8 Reviewers responsibility

1. IEC Members will review the protocol and the informed consent document or assent form.
2. The reviewers comments will be discussed in the IEC meeting and the final comments will be sent to the PI.
3. The discussion will be documented in the minutes.
4. The member secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.

13.9 Approval of the protocol

1. The final version of the protocol will be approved by the board with the appropriate checklist as given in annexure (1-5).
2. Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes for e.g. unconscious patient gaining consciousness, then the protocol and ICD should be amended and resubmitted to the IEC for reconsideration and approval Following which the participant should be re-consented and reconsidered for the same.

13.10 Policy of communication with different stake holders

IEC communicates with different stakeholder involved in research process including Principal Investigator or any other study team designee, Regulator (DCGI), Head of Institute, and Sponsor (If required).

IEC may communicate following to respective stakeholder but not limited to:

13.11 Principal Investigator

- Study Project Approval/Rejection letter/ Query Letter
- Study documents Amendments Approval/Rejection letter/ Query Letter
- Response to Serious Adverse event notification
- Opinion on compensation of Study injury/death
- Response to Protocol deviation/Violation/Waiver
- Response to Continue review/study completion report
- Study termination letter

13.12 DCGI

- SAE reports
- Opinion on compensation of Study injury/death
- Study Termination letter
- Ethics Committee registration Communications
- Submission of protocol and protocol related documents in case of academic study with change of dose/ administration route/indication etc.

13.13 Vice Chancellor /Registrar

- Annual reports of IEC including status of all studies

13.14 Study Participants:

- Response to complaints (if any) filed by study participants

13.15 IEC members:

- Study documents for review
- Agenda and Minutes of meeting
- Agenda and Minutes of SAE subcommittee

14 Policy Financial declaration of payments received and disbursed

1. All payment received as submission fee are separately maintained under 'Institutional Ethics Committee'
2. Account officer will receive all payment cheque/DD and will submit to account department of institute.
3. All expenditure of Admin are managed through payment received as fee including Admin Manager/EC supporting staff Salary, meeting arrangement cost, Travel reimbursement to chairperson and external members, Stationary charges, Cupboard, Electricity and telephone bills infrastructure requirement including Computer, Xerox, Scanner, Ethics Committee Member Training arrangement.
4. Chairperson shall be paid a remuneration of INR 5000.00 sitting fees along with TA +DA (as actuals) and per meeting and all other members shall be paid a remuneration of INR 1000.oo (sitting fees + TA+DA) per meeting.
5. All financial payments received and disbursed shall be reviewed at end of every financial year and presented to all Admin members.
6. All financial communication is liable under Institute's internal routine financial Audit.

15 SOP for complaints by the research participants

1. The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with requests by research participants/ patients regarding their rights as a participant or to resolve their complaint(s) that is/ are related to their participation in research/ trial approved by IEC.
2. Subject Participants can contact Secretariat of IEC for any request complaints or query as contact details are mentioned on IEC approved Informed Consent Documents.
3. Member Secretary will ascertain if the concerned individual has been approached to participate in the study or is already participating in the study based on documents available with. If required, Member Secretary will call for relevant information and documents from the Investigator, as required.
4. Member Secretary will inform to all members within 7 days of receipt of complaint
5. Member Secretary may consider matter for next full board meeting with confirmation from chairperson. All available information along with required documents will be discussed in meeting
6. Chairperson may appoint 1 or 2 members from IEC for enquiry in order to resolve the matter.
7. The Chairperson/ Member Secretary will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.
8. The final decision will be informed to the research participant, concerned investigator, Head of Institute by the Member Secretary within *4* week from filing of complaint.
9. The IEC members are informed about the action taken and the outcomes in the forthcoming meeting.
10. All relevant records and communication regarding complaints are maintained.

16 Procedures to safeguard and monitor Research Participant's rights, safety and well-being

1. The IEC ensures that Rights and responsibilities of Research participants (Annexure - 22) are displayed at research site including OPD room, and office in English and Hindi languages.
2. Rights and responsibilities of Research participants are also displayed at electronic display of hospital and on Hospital website in English and Hindi languages.

3. IEC will instruct Principal Investigator in the approval letter to ensure that all rights and responsibilities of research participants as mentioned in Annexure 25 are informed to all research participants to be enrolled in study.
4. IEC ensures contact details of IEC contact person (secretary) are included in the informed consent document to contact research participants in case of any issue related to rights and integrity.
5. Research participant can raise any complaint to IEC at any point as mentioned in section 22 (SOP for complaints by the research participants)
6. IEC shall monitor violation of any rights of research participants by interviewing research participants during onsite BLDE (Deemed to be University), Vijayapura, Karnataka Institutional Ethics Committee monitoring.
7. IEC will monitor safety and well-being of research participants of ongoing study by reviewing
   - Continue review report and study completion reports
   - Review of Serious Adverse Events at site and other sites
   - Review of period safety updates report and Investigational brochure or any other new information available which may affect participants' safety
   - Periodic on-site Monitoring of flagged High risk studies
8. IEC shall arrange periodic training of Admin staff, Investigators and other study staff on procedures to safeguard and monitor Research Participant's rights, safety and well being

17 Self-Assessment of IEC

1. Self-Assessment of IEC shall be done on the basis of self-assessment checklist mentioned in Annexure - 21.
2. Self-Assessment shall be conducted 6 monthly. Member Secretary and Admin officer will together conduct self-assessment and review performance of ethics committee.
3. Chairperson may appoint other ethics committee internal/external member to conduct self-assessment if required.
4. The member Secretary will present Quality Assurance self-assessment reports to all members in subsequent full Board meeting.
5. After reviewing Quality Assurance self-assessment, recommendation including corrective and preventive action will be finalized in full board meeting for its future implementation.

18. Annexures:

Annexure – 18.1: Cover letter for submission of research proposal to IEC

Date : xx-xxx-xxxx

To,

BLDE (Deemed to be University)

1st Floor, Research & Development Section,

BLDE (Deemed to be University),

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103

BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 ,

Website: www.bldedu.ac.in

E-mail:iec@bldedu.ac.in & deanrd@bldedu.ac.in

Subject: Research Proposal and documents for review and approval by the IEC Study title: .....

Dear Sir/Madam,

With reference to the above subject and reference, please find attached the following study related documents for review and approval by Institutional Ethics Committee (IEC):

1. Project Submission Application Form to IEC
2. Research Protocol/Synopsis
3. Checklist along with all necessary documents

I hereby state that I would conduct my research as per the applicable rules and regulations, and principles of Good Clinical Practice guidelines issued by the ICMR and comply with all required regulations.

I request you to kindly review and approve the same. Thanking you

Dr. XXXXX XXXXXX

Principal Investigator (PI) Designation

Contact: XXXXXXXXXXX ; Mail: XXXXXXXXXXX

REGISTRAR
BLDE(Deemed to be University)
Vijayapura-586103, Karnataka

Annexure -18.2 : Proposal Submission Application Form to IEC (template)

A. Please fill in the details in legible hand-writing OR typed

B. Tick √ in the box for the appropriate answer

C. Tick/ Write NA if question is not applicable

Title of the study/protocol

_____

_____

_____

	Name	**Designation &Qualifications**	**Department& Institution**	**Signature**
Principal Investigator				
Co- Investigator				
Co- Investigator				

If additional collaborators attach details and letter of Consent by the collaborator (s) on a separate page. Please attach brief curriculum vitae of the study team members. (Principal investigator, co- investigator, study coordinator)	Yes	No
Non-sponsored		
Investigator Initiated		
Sponsored study		

1. Sponsor Information:

1. Indian □ a)Government Central / State □ b)Private □

2. International Government □ Private □ Other agencies □

3. Industry □ National □ Multinational □

Contact Address of Sponsor:

If sponsor is from out of India, contact address in India:

2. Total Budget: Rs.
Research Fund will be deposited in (Account details):

3. Type of Study: (Tick the appropriate boxes)
Observational ☐ Interventional ☐
Prospective ☐ Retrospective ☐ Cross-sectional ☐ Human participant ☐ No human participation ☐ In-vitro ☐
Drug ☐ Devices ☐ Surgical procedure ☐ Life-style modification ☐ Single center ☐ Multi-centric ☐
Any other .....
If multi-centric, how many centers: India....Globally.... (attach list of countries)

Clinical Trials: (Tick the appropriate boxes)
Drug ☐ Vaccines ☐ Device ☐ Alternative systems therapy(AYUSH) ☐
Any other, specify :.....

Is it approved and marketed?
India ☐ UK & Europe ☐ USA ☐ NA ☐
Approved indications :.....
Other countries, specify.....

Does it involve change in use, dosage, route of Administration?	Yes	No	NA
If yes, whether DCGI's /any other Regulatory authority's Permission is obtained?	☐	☐	☐
If yes, Date of permission			
If No, whether DCGI's / any other Regulatory Authority's Permission applied for?	☐	☐	☐
Is it an Investigational New Drug (IND)? If yes, IND No:	Yes	No	NA
Investigator's Brochure (IB) submitted	Yes	No	NA
In-vitro studies data	Yes	No	NA
Preclinical Studies done	Yes	No	NA
Phase of Clinical Study in India	1	2	3 | 4
To submit package insert in case test drug is already marketed in India, attached?	Yes	No	NA
Are you aware if this study is being done elsewhere? **If Yes**, Specify details	Yes	No	NA
Whether DCGI's permission for testing IND Obtained? If yes, Date of permission	Yes	No	NA
For any other formulations involving alternative systems of medicine (AYUSH), a copy of the marketing/ manufacturing license issued by the FDA to the company to be submitted	Yes	No	NA

4. Protocol of the research proposal – (Submit as attachment) Introduction & background Aim(s) & objectives Justification for study Study methodology describing the potential risks & benefits Outcome measures Statistical analysis methods including sample size justification				
5. Research participants selection: Number of research participants at this centre : Number of research participants at other sites in India: Total number of research participants at all sites (in the world):				
Duration of study:				
Will research participants from both sexes be Recruited?		Yes	No	NA
Inclusion / Exclusion criteria given		Yes	No	NA
Type of research participants: Healthy Volunteers ☐ Patients ☐ NA ☐				
6. Vulnerable research participant		Yes	No	NA
Pregnant women ☐	Elderly/Geriatric ☐	Mentally challenged ☐		
Infants ☐	Illiterate ☐	Handicapped ☐		
Children ☐	Captives ☐	Terminally/Seriously ill ☐		
Students ☐	Dependent staff ☐	Institutionalized ☐		
Economically/Socially Backward ☐	Employees ☐	Any Other ☐		
7. Privacy and confidentiality: Patient identity details (including face photograph) captured in study Yes No ☐				
8. Biological material handling			No	NA
Use of biological/ hazardous materials Use of fetal tissue or abort us tissue			☐	☐
Use of organs or body fluids			☐	☐
Use of pre-existing/stored/left over samples			☐	☐
Use of Infectious/bio hazardous specimens			☐	☐
Proper disposal of material			☐	☐
9. Will any sample collected from the patients be sent abroad?			No	NA
If no, test on samples be carried out:	Hospital		☐	☐
	Outside hospital	☐	☐	☐
If Yes, Sample will be sent abroad because (Tick appropriate box): Facility not available in India Facility ☐ Central laboratory for multi-centric studies ☐				

10. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)

Yes ☐ No ☐ NA ☐

11. In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction obtained from appropriate authority?

Yes ☐ No ☐ NA ☐

12. Informed Consent:

Written* Verbal ☐ Audio-visual NA Waiver requested ☐

	Yes	No		Yes	No
Understandable language	☐	☐	Statement that study involves research	☐	☐
Alternatives to participation	☐	☐	Confidentiality of records of Sponsor of study	☐	☐
Purpose and procedures	☐	☐	Statement that consent is voluntary	☐	☐
Benefits	☐	☐	Right to withdraw	☐	☐
Compensation for study related injury	☐	☐	Compensation for participation	☐	☐
Benefits if any on future commercialization	☐	☐	Consent for future use of biological material	☐	☐
Risks & Discomforts	☐	☐			

		Yes	No	NA
13. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – if so kindly attach a copy)		☐	☐	☐
14. Risks & Benefits: Is the risk reasonable compared to the anticipated benefits to research participants / community / country?		☐	☐	☐
Is there a benefit	To the research participants?	☐	☐	☐
	Benefit to society	☐	☐	☐
Is there any anticipated risk or discomfort?	If Yes, minimal or no risk	☐	☐	☐
	More than minimum risk	☐	☐	☐
	High risk	☐	☐	☐
15. Data Monitoring Is there a data & safety monitoring committee/ Board (DSMB)?		Yes	No	NA
Is there a plan for reporting of adverse events?		☐	☐	☐
If Yes, reporting is done to :	Sponsor	☐	☐	☐
	Ethics Committee	☐	☐	☐
	DSMB	☐	☐	☐
Is there a plan for interim analysis of data?		☐	☐	☐

REGISTRAR
BLDE(Deemed to be University)
Vijayapura-586103. Karnataka

Are there plans for storage and maintenance of all trial databases? **If Yes,** for how long? years	☐	☐	☐
16. Is there compensation for participation If Yes, Monetary In kind Specify amount and type: ----------	☐	☐	☐
17. Is there compensation for injury? If Yes by	☐	☐	☐
Sponsor ☐			
Investigator ☐			
Insurance ☐			
Any other party..... ☐			
18. Do you have any conflict of interest in the present study? (financial / non-financial) If Yes, specify	Yes	No	
19. Current Brief Curriculum Vitae (signed and dated copy) of the study team members- principal investigator, co-investigator and study coordinator (Information required -age, designation and department, educational qualification, previous research experience in last five years) (To be enclosed along with the form)	Yes	No	
Information about GCP training of PI and co-investigator	Yes	No	
20. GCP training certificates Certificates of principal investigator and coordinator/s (mandatory only for drug and device trials not for observational studies). Certificate to be enclosed along with the form.	Yes	No	
21. Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India (CTRI)/ any other WHO platform registry **Registration number:** If not registered, state the reason	Yes	No	NA
22. Whether study is approved by IRB? Date of Approval:	Yes	No	NA

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the Schedule Y (Drugs and Cosmetic Act 1940), Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research(2017).

We also ensure that Principal Investigator / Institution will pay for treatment and / or compensation if study related injury occurred due to protocol violation by PI / study team.

Signature of Principal Investigator (PI) with date: .....

Signature/s with date of Co-investigators:

Name	Signature
1.	.....
2.	.....
3.	.....

Annexure – 18.3: Check-list of documents for research protocol submission

(Tick accordingly; compulsory documents have to be submitted)

Sr	Document	No. of copies	No	Date by which it will be submitted if pending	NA
1.	Project submission application form duly filled				
2.	Letter to Member Secretary/ Chairperson				
3.	Summary of protocol (not more than 500 words)				
4.	Research Protocol / Synopsis (dissertation/thesis)				
5.	Informed Consent Document (ICD) in English				
6.	Informed consent documents in Regional languages (Total languages .....)				
7.	Translation/back translation certificates				
8.	Case Record Form (CRF)				
9.	Research participants recruitment procedures: advertisement, notices (If applicable)				
10.	Patient instruction card, identity card, patient diary etc. (If applicable)				
11.	Research participants Questionnaire/s (If applicable)				
12.	Investigator Brochure (If applicable)				
13.	Insurance certificate and policy (If applicable)				
14.	Investigator's undertaking to DCGI (If applicable)				
15.	DCG(I) approval / Acknowledgement of application to DCG(I)				
16.	Clinical Trial Agreement (CTA) for drug trial / Memorandum Of Understanding (MOU) (as applicable)				
17.	FDA marketing/manufacturing license for alternative system of medicines (AYUSH)				
18.	Signed and dated brief current curriculum vitae (CV) of the study team members (principal investigator, co-investigator, study co-coordinator)				
19.	Documentation of CTRI registration/ any other clinical trial registry (WHO platform)				
20.	GCP training certificates of Principal Investigator				
21.	Any other Documents submitted (specify				

Annexure – 18.4: Guidelines for Investigators

1. All the studies qualifying as 'clinical research' or involving human participation in any form need to be submitted to the Institutional Ethics Committee (IEC), BLDE (Deemed to be University) Vijayapura, Karnataka.
2. Approval of the Institutional Ethics Committee (IEC) is mandatory for all research involving human participation in any form before commencing any study related procedure.
3. Location and Office Address of the Institutional Ethics Committee (IEC): Institutional Ethics Committee(IEC)

   BLDE (Deemed to be University)
   1st Floor, Research & Development Section,
   BLDE (Deemed to be University),
   Smt. Bangaramma Sajjan Campus,
   B. M. Patil Road (Sholapur Road), Vijayapura - 586103
   BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 ,
   Website: www.bldedu.ac.in, | E-mail:iec@bldedu.ac.in & deanrd@bldedu.ac.in

4. Office hours of IEC:
   Monday to Saturday: 10.00 am to 05.45 pm
   The office will remain closed on Sundays and all public holidays.
5. There will be no meetings held in the month of May and November. In case a meeting is to be held during this period due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.
6. The principal investigator (PI) should be GCP trained before initiating the study and copy of the GCP training certificate within the preceding five years should be provided to the IEC at the time of submission of a new study proposal.
7. The SOPs are available with the IEC office and can be shared on request (electronic copy) or can be downloaded from Website: www.bldedu.ac.in, or mail to iec@bldedu.ac.in
8. The following steps need to be followed by investigators while communicating with the Institutional Ethics Committee:

A. Prior to approval of a research study

I. Submission of a New Study Proposal

i. Investigator(s) should submit study proposal only after approval of the study documents by the Institutional Review Board (IRB) of BLDE (Deemed to be University), Vijayapura, Karnataka.

ii. The submission should include the following:

a. Cover letter of application (Annexure –1)

b. Project Submission Application Form (Annexure–2)

c. Check-list of documents for research protocol submission (Annexure – 3)

d. Protocol/synopsis and all necessary documents as per the above check-list.

iii. Three sets of documents should be submitted along with a soft copy (pdf-format) of all the documents.

iv. Each set shall contain the documents mentioned in Annexures1,2 and 3 on A4 size paper arranged in a plastic file/binder in the same order.

v. The investigator should ensure that there is an 'Ethics Section' in the protocol is in compliance with the ICMR-GCP Guidelines.

vi. An investigator is required to fill in all the details in the form **Annexure 01** very clearly in legible handwriting along with the photo copies of the same. **Incompletely filled forms/forms without signatures and seal will not be accepted.**

vii. All submissions should be made through heads of the respective departments.

viii. Documents should be submitted at least **21 days** prior to IEC meeting.

ix. The study proposals will be circulated to all the IEC members **10 days** prior to the IEC meeting for review.

x. All required fees shall be collected at the time of submission of the project as below:

Projects	Type of submission	IEC Fees
Investigator initiated/ Academic Projects	Initial submission (External Grant/External Faculty – other than BLDE(DU) who pursuing academic research projects)	
Industries sponsored projects	Regular submission	
	Expedited submission	
	Amendment(s) to Protocol or study documents	
Archival services (SMO)	Archiving of trial documents up to 5 years from the date of trial completion.	

Mode of payment : Cheque/DD/NEFT
In favor of : BLDE (Deemed to be University)
Vijayapura, Karnataka,

PAN No.
TAN No.
Bank details :
RTGS/ NEFT IFCS code -

xi. Submissions for funded / sponsored studies/ projects would not be processed by the IEC until receipt of the prescribed fees.

xii. The principal investigator (PI) / Co-investigator is required to be present during the IEC meeting to discuss issues related to the study proposal. The schedule of the IEC meeting at least 3 days before the IEC meeting.

xiii. The PI may call up the IEC office to know the date of next scheduled IEC meeting.

xiv. For clinical studies on "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator or sponsor.

xv. An investigator is expected to submit reply to any recommendations/ queries sent by the IEC within 90 days of date of receipt of the letter. In the absence of any response, the project will be declared closed for the IEC office records.

xvi. The PI should register all clinical studies at the clinical trials registry of India on www.ctri.nic.in OR any other WHO clinical trials platform.

B. Once approval for a study is granted

I. An approval will be granted for the entire duration of the study

II. Submission of study related documents for IEC Review

i. Any study related documents (updates to any study documents, IB updates, SAE reports, status reports, study completion reports, protocol deviations/ violations) to be submitted to IEC for review and approval as appropriate.

ii. Two sets of the above stated study related documents need to be submitted to the IEC.

iii. Agenda of the IEC meeting to discuss such matter will be prepared 2 days prior to the date of meeting and is sent to the members at least 1 day in advance. Hence, the responses to the IEC queries and other documents received within seven days and other types of documents within 2 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next IEC meeting for discussion (Exception: any matter which in the opinion of the IEC secretary/chairman such as SAE report, major protocol violation).

III. Submission of Amended Protocol and Protocol Related Documents

i. All amendments to the approved research proposal should be submitted to the IEC as soft copy (PDF format) and only 2 set of hard copies for its review no later than 7 seven days prior to the date of forthcoming meeting.

ii. No changes in the protocol, case record form and/or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).

iii. A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.

IV. Submission of report of protocol deviations/ violations

i. Please provide any deviation / non-compliance / violation report in writing to the IEC Office.

ii. Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC immediately.

iii. If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC secretary and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issues/objections raised by the committee **within 90 days** of the receipt of the committee's decision. In absence of appeal, the project will be declared closed for the IEC office records.

V. Submission of study completion report/status review report

i. For studies which are completed within the IEC approval period, a study completion report as per the format given in Annexure 8 should be submitted to the IEC by the principal investigator.

ii. The study completion report is expected for review within 1 month of completion of the study at the site.

iii. A brief study report containing data analysis from all centers should be submitted once available from the sponsor.

iv. Investigator need to submit continue review report every 6 monthly from date of approval or last reports submitted to IEC.

VI. In case a study is not initiated or terminated

i. The same should be communicated to the IEC stating reasons for the same.

ii. The IEC archives all the study related documents for a period of 5 years after the study is completed / terminated/ reported as not initiated at our site.

iii. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same.

C. Regulatory permissions

I. DCGI approval:

i. Studies which plan to use a new drug require DCGI permission. For such studies, a copy of the permission letter issued by the DCGI to the pharmaceutical company/ investigator also needs to be submitted to the IEC along with application submission.

ii. If the DCGI permission is awaited, a letter of conditional approval will be issued by the IEC. However, the copy DCGI permission is to be submitted to the IEC before commencement of the study related procedures.

iii. For regulatory studies, no study should be initiated until the DCG(I) approval is received by IEC.

II. FDA marketing/manufacturing license for Ayurveda/ herbal formulations/Nutraceuticals

III. Health Ministry Screening Committee (HMSC) approval in case a study involves collaboration with any foreign laboratory/clinic/institution

IV. Clinical Trials Registry Registration

It is mandatory as per the directive by the DCG(I) to register clinical trial at clinical trial registry of India at www.ctri.nic.in before enrolling first patient in the study.**(Registration is mandatory for interventional clinical trials)** Process flow of Submission of Projects to IEC.

Annexure -18. 5: Sample format for Informed Consent Document (ICD)

Informed Consent Document (ICD)

[Participant Information Sheet (PIS) & Informed Consent Form (ICF)]

Protocol No.: .....

Study title: .....

.....

.....

Principal Investigator Name: .....

Designation:.....

Address:.....

Phone (24 hours):.....

Mail: .....

Participant's Name: .....

Participant Information Sheet (PIS)

1. **Invitation paragraph**

   You are invited to participate in the study titled The purpose of this document is to provide you with information about this study. Please read this document carefully and ask your doctor questions or seek clarification if anything is not clear to you.When all your questions have been answered to your satisfaction and if you are willing to participate in the study, you will be required to sign the consent form.You will be provided with a copy of this information sheet for your reference.

2. **Information about the study(introduction)**

   (Briefly explain in lay terms the background of the problem, the need & purpose of the study, Use simple explanatory language / words that can be understood by an averagely literate individual such as non- matriculate)

3. **Why am I being requested to participate in this study?**

   You are requested to participate in this study as you are suffering from.....

4. **What are the benefits of my participation?**

   State possible benefits of the study if any or print your participation may or may not benefit you directly, however the information obtained from the study will be of benefit in the treatment of future patients

5. **What will the study involve?**

(Explain how long the patient will be required to be in the research. How often will he / she will require visiting a clinic if applicable).

Provide details of the study procedure e.g. examination, intervention (drugs, surgery) tests, radiology etc. Explain (allotment to a study group) if it is a blinded study.

6. **What are the risks involved?**

* For non-intervention studies state none as No extra investigations or new therapy is involved.
* For intervention studies or where extra investigations are involved- list possible side effects (common & uncommon)

7. **What will be the cost of participation?**

All costs of the treatment or diagnostics, over & above those involved in standard diagnosis & treatment will be borne by the hospital. Costs as involved in routine care will be borne by the patient

8. **Will my results be informed tome?**

Print as applicable)

9. **What are my responsibilities?**

Explain are there any lifestyle restrictions, dietary restrictions, advise to follow all study related instructions, keep follow up dates, report any adverse reactions etc.

10. **Is my participation compulsory?**

No, your participation is voluntary and non-participation will not in any way affect your treatment at the hospital.

11. **Can I withdraw from the study?**

You are free to withdraw from the study at any time without giving any explanation. This will not affect your care at the hospital. No further test(s) etc. will be done. However, data already collected may be used for analysis of results.

12. **If something goes wrong what happens? Who treats & bears the cost?**

Any study related complication (diagnostic procedures & therapy) will be treated by the hospital. The hospital will bear the costs of any conditions arising out of study participation.

Mention availability of insurance, if any.

(State if no additional or new intervention is done the patient will bear the cost for such events.)

13. **Do I get any compensation in case of research related injury?**

Research related injury is an injury that occurs to the subject as a result of research participation. Injuries may range from relatively minor harms (such as bruises or infected wounds) to major injuries (such as organ damage or temporary disability) to catastrophic injuries (such as permanent disability or death).

An injury may require only acute or emergency care, or it may require continuing care. Injuries can be physical or psychological /emotional.

In case of research related injury, the study subject shall be entitled for financial compensation as per the recommendation of the IEC and the expert committee as per prevailing regulatory guidelines.

In case of death of the subject, his /her nominees are entitled for financial compensation as per the recommendation of the IEC and the expert committee as per prevailing regulatory guidelines. The financial compensation shall be over and above any expense incurred on the treatment of the subject.

The decision for compensation shall be taken during the IEC meeting and adequately decided as per the provisions of rule 122DAB of The Drugs and Cosmetics Rules, 1945, and other guidelines provided by CDSCO.

14. **What about the confidentiality of my data?**

All the information obtained in this study will be kept strictly confidential and used for scientific purposes only.

Data taken from this study may be published or presented in scientific meetings. However, your name and other identifying information will be kept confidential and will not be made publicly available.

Investigators, study team members, ethics committee members & regulatory authorities (if required by law) may review your personal and medical records.

15. **Is the study approved by ethics committee or review board?**

Yes.

The study has been reviewed & approved by the Institutional Ethics Committee of BLDE (Deemed to be University), Vijayapura, and Karnataka.

16. **Whom can I contact for more information?**

For any study related information:

PI / Research fellow and 24 hours contact details (refer first page) For your rights contact the following:

Member Secretary/Chairman Institutional Ethics Committee

1st Floor, Research & Development Section, BLDE (Deemed to be University),

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103

BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in,

E-mail:iec@bldedu.ac.in

Informed Consent Form (ICF)

Protocol No.: .....

Study title: .....

.....

Principal Investigator Name: .....

Subject's Initials: .....

Subject's Name: .....

Date of Birth/Age: .....

Address of the subject: .....

Qualification: .....

Student / self- employed / service / Housewife / Other (Please tick as appropriate)

Annual Income of Subject: .....

Name of nominee: .....

Relation to the subject: .....

REGISTRAR
BLDE(Deemed to be University)
Vijayapura-586103. Karnataka

Sr		Please initial inbox (Subject)
1	I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions.	[ ]
2	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 my medical care or legal rights being affected.	[ ]
3	I understand that the study team member, Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However,I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
4	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)	[ ]
5	I agree to take part in the above study.	[ ]

Signature (or Thumb impression) of Subject OR Legally Acceptable Representative (LAR)		Date:__/__/_____
Signatory's Name		
Signature of the Impartial Witness		Date:__/__/_____
Name of the Impartial Witness		
Signature of the Investigator		Date:__/__/_____
Study Investigator's Name		

Annexure – 18.6: Amendment Request and Assessment Form

IEC Protocol Number: IEC Approval reference No.	
Protocol Title:	
Principal Investigator :_____ Department:_____	
Approved date:	No. of amendment: (Attach List of Amendment)
State/describe the amendment: type of document/ part of document amended **Reasons for the amendment** **Impact of your amendment on your present study at this site**: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other	
Have the changes modifications in the amended versions been highlighted/ underlined? Yes ☐ No ☐ **Copy of List of Changes attached -** Yes ☐ No ☐	
Name of Principal Investigator: _____ **Signature with Date:_____**	
Type of review :- (Decision by the Chairperson/ Member Secretary) Review by Member ☐ Disapproved ☐ Next full board discussion Full Board discussion and review ☐ **Sign and Date of Member Secretary _____**	
FullBoard Decision: Approved ☐ No ☐ If disapproved, reasons for disapproval/Further revision or modification required **Sign and Date of Member Secretary _____**	

Annexure – 18.7: Continuing Review Application Form
Date:

Protocol No.: IEC Approval reference No.	
Protocol Title:	
Principal Investigator:_____	
Summary of protocol participants number of participants approved by BLDE (Deemed to be University), Vijayapura, Karnataka Institutional Ethics Committee New participants recruited so far_ Number of on going patients_____ Number of patients who have already Completed the study_____	Has any information appeared in the literature, or evolved from this or similar research that might affect the BLDE (Deemed to be University), Vijayapura, Karnataka Institutional Ethics Committee evaluation of the risk/benefit analysis of participants involved in this protocol? No Yes (attach separate sheet if needed)
Have any participants been withdrawn from this study? No Yes (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)	Have any unexpected complications or SAEs been noted since last review at our site? No Yes (attach separate sheet if needed) No. of patients who had SAEs- Whether reports of SAEs at have been submitted to the Bhakti Vedanta HEC- -
Impaired participants Physically Cognitively Both Have there been any amendments in protocol/ Informed Consent Document since the last review? NO YES	Have any unexpected complications or SAEs been noted since last review at our site? No Yes (attach separate sheet if needed) No. of patients who had SAEs- Whether reports of SAEs at have been submitted to the Bhakti Vedanta HEC- -

Were these protocol/ Informed Consent Document (ICD) amendments approved by BLDE (Deemed to be University), Vijayapura, Karnataka Institutional Ethics Committee? No Yes If no, mention the amendments not approved	Which protocol amendment is the site following at this date
	Which ICD amendment is the site following at this date
Number of Protocol Deviations _____ (Attach list of Protocol Deviations separately) No of Adverse Event_____ Types of adverse events with nos. of participants- (Attach list of adverse event with causality assessment separately)	Have any participating investigators been added or withdrawn since last review? No Yes (Identify all changes in the attached narrative)
Is report of interim data analysis available? No Yes (submit as an attachment) Is report of the data safety and monitoring board available? No Yes (submit as an attachment)	Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest? No Yes (Append a statement of disclosure)

Signature of the Principal Investigator with Date:

Annexure -18.8: Study Completion Report Form

(To be filled by Principal Investigator)

Protocol No: IEC Reference No.	
Protocol Title:	
Principal Investigator:	
Department:	
Total no. of study participants recruited	
Total no. of study participants approved by the BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee for Recruitment	
Duration of the study	
*Results (Summary) with Conclusion: (use extra blank paper, if more space is required). **Note: If the final report is not available from sponsor, it may be submitted later to the BLDE (Deemed to be University), Vijayapur, Karnataka Institutional Ethics Committee once it is ready.*	
Number of SAEs at our center:	

Reasons for withdrawal:	
Number of Adverse Events (Attach list of adverse Events with causality assessment separately)	
Number of Protocol Deviations/ Violations (Attach list of Protocol Deviations/ Violations separately)	
No. of patients withdrawn	
Signature of Principal Investigator	Date :-
Committee	

Annexure – 18.9: Study Assessment Form to be used by the Reviewer

(Print copy or by Email)

IEC Protocol Number :		Date :	
Protocol Title			
Principal Investigator:			
Department			
No. of Participants at the site:		No. of Study site(s):	

Mark and comment on whatever items applicable to the study.

1	Objectives of the Study clear unclear	What should be improved?
2	Need for Human Participants Yes □ No □	Comment:
3	Methodology: clear □ unclear □	
4a	What should be improved? Background Information and Data sufficient □ insufficient □	Comment:
4b	Risks and Benefits Assessment Acceptable □ unacceptable □	
4c	Inclusion Criteria appropriate □ inappropriate □	Comment:
4d	Exclusion Criteria appropriate □ inappropriate □	Comment:
4e	Discontinuation and Withdrawal Criteria Appropriate □ inappropriate □	Comment:
5	Involvement of Vulnerable Participants: Yes □ No □	Comment:
6	Voluntary, Non-Coercive Recruitment of Participants Yes □ No □	Comment:
7	Sufficient number of participants? Yes □ No □	Comment:
8	Control Arms (placebo, if any) Yes □ No □	Comment:
9	Are Qualification and experience of the Participating Investigators appropriate? Yes □ No □	Comment:
10	Disclosure or Declaration of Potential Conflicts of Interest Yes □ No □	Comment:
11	Facilities and infrastructure of Participating Sites Appropriate □ Inappropriate □	Comment:
12	Community Consultation: Yes □ No □ NA □	Comment:
13	Benefit to Local Communities Yes □ No □	Comment:

14	Contribution to development of local capacity for research and treatment Yes □No □	Comment:
15	Availability of similar Study/Results: Yes □ No □	Comment:
16	Are blood/tissue samples sent abroad? Yes □ No □	Comment:
17	Are procedures for obtaining Informed Consent appropriate? Yes □ No □	Comment:
17 a.	Audio Visual Recording of Informed Consent (If Applicable) Yes □ No □	Comment:
18	Contents of the Informed Consent Document: Clear □ unclear □	Comment:
19	Language of the Informed Consent Document: Clear □ unclear □	Comment:
20	Contact Persons for Participants Yes □ No □	Comment:
21	Privacy &Confidentiality Yes □ No □	Comment:
22	Inducement for Participation Unlikely □ Likely □	Comment:
23	Provision for Compensation for Participation appropriate □ inappropriate □	Comment:
24	Provision for Treatment for Study-Related Injuries Appropriate □ inappropriate □	Comment:
25	Provision for Compensation for Study Related Injuries Appropriate □ inappropriate □	Comment:

Any other additional comments

1.

2.

3.

4.

Reviewer's Name: Signature with date

Annexure – 18. 10: Confidentiality Agreement
Confidentiality Agreement Form for those attending the IEC meeting

In recognition of the fact, that I, ...

(Member's name and his /her affiliation) herein referred to as the "undersigned", have been appointed as a member/invitee of the Institutional Ethics Committee (IEC), BLDE (Deemed to be University) Vijayapura, Karnataka and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest and standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines.

Whereas, the appointment of the undersigned as a member/invitee of the IEC, is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member/invitee is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member/invite of the IEC is expected to meet the same highest and standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the Institutional Ethics Committee, BLDE (Deemed to be University) Vijayapura, Karnataka The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

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 office. A copy will be given to you for your records.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information").

I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I,_____

(Name of the member/invitee) have read and accept the aforementioned terms and conditions as explained in this Agreement and I acknowledge that I have received a copy of this.

Signature Date

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature Date

Annexure – 18. 11: Conflict of Interest (COI) Form

It is recognized that the potential for conflict of interest will always exist but the Institutional Ethics Committee (IEC), BLDE (Deemed to be University) Vijayapura, Karnataka and its Chairperson need to manage the conflict issues so that the ultimate outcome is the protection of research participants.

It is the policy of the IEC 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.

The Undersigned will immediately disclose to the Chairperson/ Secretary of the IEC 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 or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.
When a member has a conflict of interest, the member should notify the Chairperson/Secretary and may not participate in the IEC review or approval except to provide information requested by the Committee.
Some 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.

Agreement on Conflict of Interest
(To be signed by all members of IEC)

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 office of the Institutional Ethics Committee (IEC),BLDE (Deemed to be University), Vijayapura, Karnataka..
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 for discussion or decision making in respect of such proposal.
I,_____ (Name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement and I acknowledge that I have received a copy of this.

Signature Date

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature Date

Conflict of Interest (COI) Declaration

(To be submitted by the members in case of any COI before meeting)

I.....hereby declare that I have a conflict of interest for the study titled .....

.....

.....

.....

.....

.....

Study identifier .....

Nature of conflict.....

I state that I would not participate in the decision-making process for the above study.

Thank You

(.....) Date: .....

Time: .....

Annexure -18. 12: Serious Adverse Event (SAE) Assessment Report

Serious Adverse Event Assessment Report (For SAE at the site)

Name of the Principal Investigator:_____ Department:_____
BLDE (Deemed to be University), Vijayapura, Karnataka. Institutional Ethics Committee Protocol No:_____ Protocol Title:
Patient ID:_____Event / SAE term:_____ Report Date: _____ Date of Onset of SAE:_____ Initial Follow-up No. of Follow-up
Attach a narrative for details of SAE, history of the case and relevant laboratory findings and treatment given:
Outcome of SAE: resolved on-going

Seriousness: Death Life threatening Hospitalization – initial prolonged /Incapacity Disability Congenital Anomaly Any Other…	Relation to Drug Device study procedure Not related Possibly Probably Definitely related Unknown Whether study drug withheld: Yes ☐ No If yes, since when:

Details of compensation: Who has paid for medical treatment?_____ Whether compensation given to participant in case of study related injury?
Signature of the Principal Investigator: Date:_____

Acknowledged/ Reviewed by

Name of Member Secretary Sign and Date_____

REGISTRAR
BLDE(Deemed to be University
Vijayapura-586103. Karnataka

Annexure – 18.13: Serious Adverse Event (SAE) Analysis Report
(For SAE at the site)

Sr.	Details		
1	Country (Name of the country should be specified)		
2	SAE report of death or other than death, Please tick (✓)	Death	Other than Death
		Yes /No	Page No.
3	In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box		
4	Protocol Title		
5	Protocol Study No./ ID /Code		
6	Copy of Clinical Trial permission obtained from CDSCO		
7	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8	Sponsor (Address with contact no and Email)		
9	CRO (Address with contact no and Email)		
10	Initial / Follow-up (FU)		
11	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12	Patient Details		
a	Initials & other relevant identifier (Hospital /OPD record number etc.)		
b	Gender		
c	Age and/or date of birth		
d	Weight		
e	Height		
13	Suspected Drug(s)		
a	Generic name of the drug.		
b	Indication(s) for which suspect drug was prescribed or tested.		
c	Dosage form and strength.		
d	Daily dose and regimen (specify units -e.g., mg, ml, mg/kg).		
e	Route of administration.		
f	Starting date and time of day.		
g	Stopping date and time, or duration of treatment		
14.	Other Treatment(s)		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).		
15.	Details of the events		
a	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b	Start date (and time) of onset of reaction.		

c	Stop date (and time) or duration of reaction.		
d	Dechallenge and rechallenge information.		
e	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	Outcome		
a	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol		

Sr.	Details		
	abuse; family history; findings from special investigations etc.		
17.	Details about the Investigator		
a	CT Site Number, if any		
b	Name		
c	Address		
d	Telephone/Mobile Number & Email		
e	Profession (specialty)		
f	Date of reporting the event to Licensing Authority:		
g	Date of reporting the event to Ethics Committee overseeing the site:		
h	Signature of the Investigator		
18.	Details about the Ethics Committee		
a	Name & Address		
b	Name of Chairman & Address		
c	Telephone/Mobile Number		
d	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a	Duly filled SAE Form as per Appendix XI of Schedule Y		
b	Laboratory investigations report /Discharge summary (if available and applicable)		
c	Post-mortem report (if applicable)/ Any additional documents)		

Annexure – 18.14: Checklist for Research Involving Children

IEC protocol no._____Name of Principal Investigator_____

Risk Determination	Benefit Assessment	IEC Action
Minimal	With or without direct benefit	**Approvable**
Greater than minimal risk	Potential to child	**Approvable**
Greater than minimal risk	**No direct benefit to individual offer general knowledge about the child's condition or disorder.**	**Approvable** on **case** to case basis

i. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

ii. Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

iii. Approval to proceed with this category of research must be made by the Administrator of the IEC, with input from selected experts.

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Are the studies conducted on animals and adults, appropriate and justified?			
If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a BLDE (Deemed to be University), Vijayapura, Karnataka IEC.			

Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a. which has implications for other family member ? (for example, genetic risk , HIV infection , Hepatitis C)			
If Yes:			

	Yes	No	NA
Are there adequate mechanisms in place to deal with other members of the family?			
Are parents being required to be present during the conduct of the research? Are proposed subjects to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?			

Comments:

Name & Signature

Primary Reviewer Sign and Date

Annexure -18. 15: Checklist for Research Involving Pregnant Women & Fetus

IEC protocol no. ____ Name of Principal Investigator_____

Section 1: This Research Involves Pregnant Women or Fetuses Prior to Delivery	**Yes**	**No**	**NA**
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non- pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetus;			
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;			
Any risk is the least possible for achieving the objectives of the research;			
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions , unless altered or waived in accord with 45 CFR			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;			
If the research involves children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission will be obtained in accord with the provisions of subpart D of that part;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and			
Individuals engaged in the research will have no part in determining the viability of a fetus.			

If the response to any of the above is No, the research is not approvable by the IEC, BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee.

Section 2: This research involves fetuses after delivery	Yes	No	NA
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses;			
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate pregnancy;			
Individuals engaged in the research will have no part in determining the viability of a fetus.			

AND

This research involves Fetuses of uncertain viability	Yes	No	NA
Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research; OR			
The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research.			
The legally effective informed consent of either parent of the fetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary Incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

AND/OR

This research involves Non-viable fetuses	Yes	No	NA
Vital functions of the fetus will not be artificially maintained.			
There will be no risk to the fetus resulting from the research.			
The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; AND			
The legally effective informed consent of both parents of the fetus will be obtained in accord with the subpart A of 45 CFR 46, except that the waiver and alteration provisions of and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a non-viable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.			

If the response to any of above is No, the research is not approvable by the BLDE (Deemed to be University) Vijayapura, Karnataka Institutional Ethics Committee.

Section 3: This research can be conducted only after:

a) The Institutional Ethics Committee BLDE (Deemed to be University) Vijayapura, Karnataka finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or fetus .

b) The secretary, after consultation with a panel of experts in pertinent disciplines (for examples: science, medicine, ethics, law) is satisfied that:
   a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetus.
   b. The research will be conducted in accord in sound ethical principles; and
   c. Informed consent will be obtained in accord with prevailing regulations.

Comments:

Primary Reviewer Name _____ signature Date _____

Annexure – 18.16: Checklist for Research Involving Cognitively Impaired Adults

IEC protocol no. _____

Name of Principal Investigator_____

The purpose of this checklist is to provide support for the Institutional Ethics Committee members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.

1. For review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
2. For review during the convened IEC meting to document determinations required by the regulations and protocol specific findings justifying these determinations.

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject (All items must be "Yes")		
One of the following is true (Check the box that is true) • The risk to the subjects is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. • More than minimal risk to subjects is presented by monitoring procedure that is likely to contribute to the subjects well –being.	Yes	No
The risk is justified by the anticipated benefit to the subjects.	Yes	No
The relation of anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.	Yes	No
The proposed plan for the assessment of the capacity to consent is adequate.	Yes	No
Assent is required of: (*One of the following must be* **"Yes"**) One of the following is true **(please tick)** • All Subjects • All Subjects capable of being consulted. • None of the subjects	Yes	No
The consent document includes a signature line for a legally authorized representative.	Yes	No
2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")		
The proposed plan for the assessment of the capacity to consent is adequate.	Yes	No
The objectives of the trial cannot be met by means of study of subjects who can give consent personally.	Yes	No
The foreseeable risks to the subjects are low.	Yes	No
The negative impact on the subject's well-being is minimized and low.	Yes	No
The trial is not prohibited by law.	Yes	No
Subjects have a disease or condition for which the procedures in the research are intended.	Yes	No

Primary Reviewer Name _____ signature Date _____

Annexure – 18.17: Checklist for Research Involving Students, Employees or Residents

IEC protocol no._____

Name of Principal Investigator_____

Subjects who are students, employees or residents require special considerations.

Does the employer or supervisor of the research subject need to be aware of the research project?	No	Yes
Is there a letter of support and/ or internal services checklist?	No	Yes
Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to subjects been minimized?	No	Yes
Have subjects been assured that participation is voluntary (no signs of coercion)?	No	Yes
Have subjects been assured that confidentiality will be protected or maintained?	No	Yes

Comments:

Primary Reviewer Name _____ Signature Date _____

Annexure – 18.18: Checklist for Genetic Research

IEC protocol no._____

Name of Principal Investigator_____

	Yes	No
Will the samples be made anonymous to maintain confidentiality? If yes, stop here		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Has the appropriateness of the various strategies for recruiting subjects and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the studies without consent?		
Will the samples be destroyed in the future?		
Is genetic counseling being offered?		

Comments:

Primary Reviewer Name _____ signature Date _____

Annexure – 18.19: Site Monitoring Visit (SMV) Report
(To be completed by IEC monitor)

IEC Protocol No.			Date of the Visit:	
Study Title:				
Principal Investigators:				
Department:				
Total number of participants enrolled:		Total participants ongoing:		
No. of participants completed:		No. of drop outs including reasons:		
Sr		**Yes**	**No**	**Comment**
1	Are the present study team members as per the list approved by the IEC			
2	Are site facilities appropriate?			
3	Is recent version of Informed Consent Document (ICD) used?			
4	Is it approved by the IEC?			
5	Whether consent has been taken from all patients?			
6	Whether appropriate vernacular consent has been used?			
7	Any other findings noted about the ICDs			
8	Is recent version of protocol used?			
9	Is it approved by the IEC?			
	Any adverse events found?			
11	Any SAEs found?			
12	Were the SAEs informed to IEC within 24 hours?			
13	Any there any protocol non-compliance deviations/violations?			
14	Have the protocol non- compliance deviations/violations been informed to IEC			

15	Are all Case Record Forms up to date?			
16	Are storage of data and investigating products locked?			
17	Any safety concern for study participants?			
18	Audio Video Recording of Informed Consent review (If Applicable)			
19	Interview of PI, Study Team member, study Participants (If Applicable)			
20	Any outstanding tasks or results of visit?			
21	Duration of visit:_____hours	Started From		Finished To
22	Name and signs of IEC members and representatives who attended the monitoring visit:	1		
		2		
		3		

Final Decision at the IEC meeting held on:

Chairperson, IEC Signature with date

Annexure – 18.20: Application Form for Requesting Waiver of Consent

1) Principal Investigator's name:_____
2) Department:
3) Title of project:
4) Names of other participating staff and students:
5) Request for waiver of informed consent:

Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

Research involves 'not more than minimal risk'

There is no dir18. ect contact between the researcher and participant in emergency situations as described in ICMR Guidelines (ICMR 2006 Guidelines-
http://www.icmr.nic.in/ethical_guidelines.pdf)

Any other (please specify) .....

6) Statements assuring that the rights of the participants are not violated
7) State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

Principal Investigator's signature with date:

Final decision at full board meeting held on: ...../...../.....

Waiver granted: Yes / No.

If not granted, reasons: .....

.....

Signature of the Chairperson with Date:

Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation.

The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants.

The following criteria (ICMR GCP guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. (ICMR GCP guidelines) e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the perform once of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].
2. When it is impractical to conduct research since confidentiality of personally identifiable information must be maintained throughout research as maybe required by the sensitivity of the research objective. (ICMR GCP guidelines) E.g. conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.

The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IRB.

[In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized].

The following points need to be considered.

3. The following documents need to be submitted for the IRB review. A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
4. The interview schedule (questions to be asked) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.
5. Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart can indicate the participants as participant 1, participant 2, and participant 3. A column can indicate that verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.
6. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies. (ICMR 2017)guidelines
7. Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. (ICMR GCP guidelines)

8. In emergency situations when no surrogate consents can be taken. (ICMR GCP guidelines) when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IRB can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.

References:

1. Ethical Guidelines for Biomedical research on Human Participants, ICMR 2006 http://www.icmr.nic.in/ethical_guidelines.pdf.
2. 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005. Website http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm, paragraph 46.116- 'General Requirements for Informed Consent.

Annexure – 18.21: IEC Self-Assessment Tool

Institutional Ethics Committee (IEC), BLDE (Deemed to be University) Vijayapura, Karnataka.

Total Maximum Score – 50

(Please give Score 1 for Response 'Yes' and 0 for Response 'No')

Sr.	Sections	Response			
		Yes	No	Score	Comments (If any)
Section I: Organizational Aspects					
1	Whether IEC is established under the highest authority of the Institute i.e. Head of Institute and availability of documented Evidence to support it?				
2	Whether IEC have documented policy to ensure its independency in functioning and decision making?				
3	Does the IEC have documented evidence to confirm appointment of Chairperson and all IEC members by Head of Institute?				
4	Does the IEC have a policy for signing Confidentiality Agreement for all members at time of appointment and Documented evidence to support it?				
5	Does the institution/organization regularly evaluate the operations of the IEC (e.g., budgetary needs, adequacy of material resources, adequacy of policies and procedures and practices, the training requirements of the IEC members				
Section II: Membership, Qualification And Training					
6	Does the current membership of IEC comply with quorum requirements as per applicable rules and regulations?				
7	Does IEC maintain updated educational records (i.e Curriculum Vitae, Medical registration certificate or any other Supporting documents etc.) of all members?				
8	Do all the members of IEC attend ICH-GCP training or ICH- GCP refresher training at least once in every 2 years?				
9	Do all members of IEC attend updated SOPs training and can provide SOP training records?				
Section III: Managing Conflict Of Interest					
10	Does the IEC have a policy for disclosure and management of potential conflicts of interest for members of the research team?				

11	Does IEC ask all members to declare written conflict of interest at time of appointment?				
12	Does IEC chairperson ask all members to declare written conflict of interest for study projects to be discussed at start of every meeting?				
13	Do the minutes reflect that members were asked whether they had a conflict of interest regarding any of the protocols to be Discussed and indicate that such members did not participate in the decision making process of the relevant protocols?				
Section IV: Initial Review of Projects					
14	Are the New study projects submitted to IEC as per the checklist provided in IEC SOPs				
15	Do the IEC members receive protocol and other study related documents (initial dossier) either as soft copy or hard copy at a specified time prior to IEC meeting?				
16	Does the IEC review the investigator's qualification and experience in clinical trials to conduct the study and check his/her ICH-GCP training records?				
17	Does the IEC review adequacy of study team including the supporting staff and facilities available to conduct the study at the site?				
18	Does the IEC perform the risk benefits assessment; evaluate the benefit against risks involved to the human subjects while participating in the research project?				
19	Does IEC review Clinical Trial Agreement including study budget for every clinical trial?				
20	Does the IEC consider whether the study sponsor/PI has adequate insurance to cover treatment of injury related to the study?				
21	Does IEC review English and other vernacular informed consent documents for adequate information provided to study participants?				
22	Does IEC confirm the presence of 24 hr contact details of Investigator in case of emergency and contact details of IEC in the Informed Consent Documents for research participants to raise any issue related to their rights, safety and integrity?				
23	Compensation of study related injury or death occurred during study periods in Informed Consent Documents?				

24	Does the IEC follow IEC SOP regarding the decisions for approval or disapproval for the study is made?				
25	Does the IEC follow IEC SOP for communicating the study decision to the investigator?				
26	Does the IEC ensure approval from regulatory body before issuing final IEC approval letter to Principal Investigator?				
27	Does the IEC mention approval duration and timeline for submission of periodic study reports in IEC approval letter?				
28	Does the IEC ensure final CTRI registration of Clinical trial which includes the name of PI, Site and IEC before enrollment of first subject at site?				
29	Does the IEC follow SOPs for reviewing research projects involving vulnerable participants and				
30	Does the IEC follow IEC SOP that lists conditions requiring wavier of ICF?				
Section V: Agenda and Minutes of Meetings					
31	Does the member secretary of IEC circulate agenda prior to Full board meeting as per timeline mentioned in SOPs to all members?				
32	Is the Required Quorum as per regulations met for all full Board meeting conducted by IEC?				
33	Does the member secretary of IEC circulate agenda prior to Full board meeting as per timeline mentioned in SOPs to all members?				
34	Is the Required Quorum as per regulations met for all full Board meeting conducted by IEC?				
Section VI: Ongoing Review of Projects					
35	Does the IEC review continuing review reports and study completion report submitted by Principal Investigator in Full Board meeting?				
36	Does the IEC ensure submission of safety updates i.e list of adverse event occurred at site along with continuing review report?				
37	Does the IEC review Protocol deviation/Violation or non compliance submitted by PI?				
38	Does the IEC take required action against the investigator in case of violation, deviation, non compliance or in condition where patient safety has been compromised which has been identified during continuing review process?				
Section VII: Review of Serious Adverse Events					

39	Does the IEC follow strict timelines with regard to SAE Analysis (Initial and FU Review), Compensation Calculation and reporting to the licensing authority within the stipulated time?				
40	Does the IEC check whether compensation is paid to patient and whether amount is verified by IEC?				
41	Does the IEC verify whether adequate medical care is provided for serious adverse events as per applicable rules and regulations?				
Section VIII: Periodic Monitoring					
42	Does the IEC periodically monitor ongoing research project as per procedures defined in IEC SOPs?				
43	Are the Monitoring reports discussed in Full Board meeting and does the IEC communicate the follow up with the PI for closure of action items including preventive and corrective actions?				
Section IX: Research Participant's Rights					
44	Does the IEC ensure display of research participant's rights and responsibilities at research sites and IEC office?				
45	Does the IEC have a mechanism whereby enrolled research participants can file complaints or direct concerns regarding research participant's rights, safety and wellbeing?				
Section X: Resources					
46	Does the IEC have its own yearly budget including budget for training of administrative staff and IEC members?				
47	Does the IEC have Full time administrative staff to mange administrative function on day to day basis?				
48	Does the IEC have resources/infrastructure i.e. Separate Office room, access to a meeting room, computer and printer, documents storage areas etc.?				
Section XI: Storage And Archival					
49	Does the IEC store one hard copy and one soft copy of all documents and communications submitted to IEC of ongoing research projects under secure and protected place?				
50	Does the IEC archive documents (1 soft copy and 1 Hard copy) for at least 5 years from date of study closeout/ termination?				

SCORING

Section	Title	Maximum Score	Obtained Score
I	Organizational Aspects	5	
II	Membership, Qualification And Training	4	
III	Managing Conflict Of Interest	4	
IV	Initial Review Of Projects	17	
V	Agenda And Minutes Of Meetings	4	
VI	Ongoing Review Of Projects	4	
VII	Review Of Serious Adverse Events	3	
VIII	Periodic Monitoring	2	
IX	Research Participants Rights	2	
X	Resources	3	
XI	Storage And Archival	2	
Total Score		**50**	

Six Monthly Performance of (IEC), BLDE (Deemed to be University), Vijayapura, Karnataka.

Items	Period: From-to
Number of Full Board meetings	
Number of new protocols reviewed in full board meetings	
Number of protocols disapproved in full board meetings	
Number of Amended study protocols reviewed in Full Board	
Number of continuing review report/ study completion reports reviewed in Full Board	
Number of serious adverse Events (at site) reviewed	
Number of protocol deviation/Violation reviewed	
Number of Monitoring visits of ongoing studies	

Period of Self-Assessment	From_____to_____	
Date of Self -Assessment:		
Duration		
Name of reviewer	Sign	Date
1.		
2.		
3.		
4.		
Presented in Full Board Meeting dated		
Sign and Date of Chairperson		

Annexure – 18.22: Rights and Responsibilities of Research Participants

A. Rights of Research Participants

1. Right to information about Research study in an understandable language.
2. Right to informed consent before participation in any research study
3. Right to information on the expected cost of treatment, duration, alternative treatment available traveling or any other compensation provided for participation
4. Right to personal dignity, privacy and confidentiality
5. Right to get the information on plan of care
6. Right to uniform care for all classes of patients.
7. Right to information on how to voice a complaint against any violation in rights and integrity (e.g. Ethics committee contact details)
8. Right to get 24 hours emergency contact details of Research doctor
9. Right to refusal of participation or withdrawal of participation any point of study without disclosing any reason.
10. Rights to get information on medical management of any injury and compensation in case of any study related injury or death
11. Right to confidentiality of patient information/details recorded in the hospital.
12. Right to access clinical records.

B. Responsibilities of Research Participants

1. Provide complete and accurate information about:
   - Your health including present and past illness, hospitalization, medication and allergies and surgeries.
   - Full name, address and other information.
   - Medical Insurance.
2. To follow the prescribed treatment plan, schedule and instructions given by doctors carefully.
3. To ask question when he/she does not understand what the Doctors or other healthcare team members tells about diagnosis or treatment.
4. Not to take any medications without the knowledge of Doctor and health care professional.
5. To accept the measures taken by the Hospital to ensure personal privacy and confidentiality of medical records.
6. To inform your study doctor immediately in case of any injury or development of any new medical conditions.
7. Treat hospital staff, other patients and other visitors with courtesy.

Annexure -18. 23: Risk-Benefit Assessment Tool

HIGH RISK /LOW BENEFIT (CLASS – A)	HIGH RISK / HIGH BENEFIT (CLASS – B)
BENEFITS	**RISKS**
• Completely new drug/formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. Of participants • Violation legal/statutory regulations • Inadequate project documentation • Inadequate PI/Staff expertise • New/untried procedures	• Completely new drug/formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. of participants • Violation legal/statutory regulations • Inadequate project documentation • Inadequate PI/Staff expertise • New/untried procedures
BENEFITS	**RISKS**
• Cost of treatment/drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post trial alternatives	• Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over existing cures/treatments • Minimal side effects visa vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/mode (ex. Pelvis surgery) • Extension of benefits /availability of Treatment post trial • Benefits large no. of participants

HIGH RISK /LOW BENEFIT (CLASS – C)	HIGH RISK / HIGH BENEFIT (CLASS – D)
BENEFITS	**RISKS**
• Proven/Acceptable toxicity • Proven safety and efficacy • Drug/formulation variation of approved drug/class of drugs • SAEs indicate minor/acceptable reactions ,side effects • No drug but only data analysis • Minimal data disclosure/leakage possibilities • Minimal risk to legal/statutory regulations • Standard operating/surgical procedures	• Proven/Acceptable toxicity • Proven safety and efficacy • Drug/formulation a variation of approved drug/class of drugs • SAEs indicate minor/acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/leakage possibilities • Minimal risk to legal/statutory regulations • Standard operating/ surgical procedures
BENEFITS	**RISKS**
• Cost of treatment/drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post trial alternatives	• Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over existing cures/treatments • Minimal side effects visa vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/mode (ex. Pill vs surgery) • Extension of benefits / availability of treatment post trial • Benefits large no. of patients

Annexure – 18.24: Undertaking to be submitted by Principal Investigator

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s))

   Medical Council Registration Number:..... CV Attached:.....
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Review board that is responsible for approval and continuing review of the study.

Institutional Ethics Committee (IEC) First Floor,

Research & Development Section, BLDE (Deemed to be University),

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103

BLDE (DU): Phone: +918352-262770, Fax: +918352-263303 , Website: www.bldedu.ac.in,

E-mail:iec@bldedu.ac.in

5. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. "..... ....."
8. Commitments:

a. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Review board and regulatory approvals have been obtained.

b. I agree to conduct the study in accordance with the current protocol. I will not\ implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favorable opinion from the Review board of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

c. I agree to personally conduct and/or supervise the clinical trial at my site.

d. I agree to inform all subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and review board review and approval specified in the GCP guidelines are met.

e. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.

f. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

g. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

h. I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Review board, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

i. I agree to promptly report to the Review board all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

j. I agree to inform all unexpected serious adverse events to the Sponsor as well as the Review board within seven days of their occurrence.

k. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

l. I will not enroll any subject prior to registration of this study at the clinical trial registry of India (www.ctri.nic.in).

m. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

n.

Signature of Investigator with Date

Annexure – 18.25: Format for Communication of IEC decision to the Investigator

Date

To,
Investigator Name
Designation, Address
Contact Details
Reference: Protocol title with version & date---

Dear Dr._____

The Institutional Ethics Committee (IEC) of BLDE (Deemed to be University) Vijayapura, Karnataka has reviewed and discussed your application to conduct the clinical study entitled Protocol title with version & date on date. The following documents were reviewed:

a) Study-protocol synopsis
b) Study Protocol (including protocol amendments), dated____Version No(s)_Participant Information Sheet (PIS) and Informed Consent Form (ICF) including updates if any in English and/ or vernacular language.
c) Investigator's Brochure (IB), dated_____Version No. _____
d) Official prescribing information for products which are marketed in India/other countries / scientific literature of the drug substance or product supporting the use of the drug in the said indication.
e) Regulatory status of the new drug in India and developed countries.
f) Approval of the DCGI no._____dt._____(if applicable).
g) Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
h) Principal Investigator's current CV.
i) Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
j) Investigator's Agreement with the Sponsor/CRO.
k) Details of research grant (if any)
l) Investigator's Undertaking (Annexure –24).

The following members of the IEC were present at the meeting held on (date, time, and place) and approved:

1. _____Chairman of the IEC
2. _____Member secretary of the IEC
3. _____Name of each member with designation.

None of the study team members including principal investigator were a part of the voting procedure.

DECISION

- The IEC hereby approves the study to be conducted in its presented form.
- The validity of this approval is for the duration of the study period.
- Applicable mandatory regulatory and other permissions to be obtained prior to commencement of the study.
- The investigator team members should be trained on the protocol & protocol related procedures and the Good Clinical Practices (GCP) Guidelines prior to commencing the study.
- The study to be registered at the "Clinical Trials Registry – India (CTRI)" at "http://ctri.nic.in" before commencement of study subjects (first patient in(FPI)).
- Participating subjects should not be put to additional financial burden due to participation in the study.
- The IEC is required to be informed about the following:

4. Periodic safety update reports (PSUR).
5. Any other safety related information received by the PI from sponsor/CRO/any other source to be communicated to the IEC immediately.
6. Any SAE occurring during the study to be communicated within 24 hours of information to the IEC and the sponsor/CRO.
7. Progress of the study to be reported annually to the IEC.
8. Any amendments/changes in the protocol and/or patient information / informed consent document.
9. To provide an abridged copy of the final report after completion of the study.

Yours sincerely,

Chairperson / Member Secretary IEC

Seal of IEC