Standard Operating Procedures
For
Institutional Ethics Committee

SRI BALAJI MEDICAL COLLEGE, HOSPITAL & RESEARCH INSTITUTE
AIRPORT ROAD RENIGUNTA, TIRUPATI – 517520

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Prepared By	Designation: Member Secretary, IEC Name: Dr C. Vishnu Priya Signature 
Reviewed and Approved BY:	Designation: Dean Name: Dr N Prema Nadam Signature 
Responsibility of Updating	Designation: Member Secretary, IEC Name: Dr C. Vishnu Priya Signature 

Sri BALAJI MEDICAL COLLEGE, HOSPITAL
& RESEARCH INSTITUTE
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TO WHOM IT MAY CONCERN

This is to declare that I Dr. Prema Nadam (Dean, Sri Balaji Medical College, Hospital & Research Institute, Tirupati.) hereby authorize the formation of Institutional Ethics Committee, Sri Balaji Medical College, Hospital & Research Institute (Name of Ethics Committee) under Sri Balaji Medical College, Hospital & Research Institute, Airport Road, Renigunta, Tirupati, A. P., (Name & address of the organization under which the Ethics Committee has been constituted). The Ethics Committee will function under our authority as per Rules & Regulations notified by MoH&FW

DEAN

DEAN
Sri Balaji Medical College, Hospital
& Research Institute
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PREAMBLE

My dear colleague,

You are aware that the goals of SBMC is to be a Globally Acclaimed Institution Recognized for Excellence in Medical Education, Scientific Research and Patient Care. In line with this, the organization encourages research by the faculty. However, even a quality research work done will see light only when one religiously adheres to best practice and research guidelines to protect oneself, the subject, a patient, organisation and society at large. To achieve this, an Institutional Ethics Committee (IEC) is formed to review the research proposals of the faculty and provide guidance as well as approval.

Our "Institutional Ethical Committee Guidelines" is largely based on "***National Ethical Guidelines For Biomedical And Health Research Involving Human Participants"*** released by Indian Council of Medical Research (ICMR). It is expected that all the faculty will step up their research to the highest level in order to achieve the goals of the college and bring laurels to the organization.

We sincerely place on record our acknowledgements to all the organizations cited as references in our book, for their valuable guidance.

Dean

SOP : SOP-1

NAME: Constitution of Ethics committee

version number	1			
prepared by	Dr C. Vishnu Priya	Member Secretary		
reviewed by	Dr Prema Nadam	Dean		17-10-2024
approved by	Dr Prema Nadam	Dean		17-10-2024
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Subheadings

I Short Title and Scope:

The following may be called as "Standard Operating Procedures for the Institutional ethics committee (IEC) of Sri Balaji Medical College, Hospital & Research Institute, Tirupati (SBMCH&RI)". The present SOP covers functioning of Ethics Committee reviewing all research on Human subjects done at SBMCH&RI as well as those done at other locations under the aegis of a principle investigator / co-investigator employed at SBMCH&RI.

II Name of the Ethics Committee :

Institutional Ethics Committee (IEC), Sri Balaji Medical College, Hospital & Research Institute, Tirupati

Address of the Office of the Ethics Committee

The Secretary
Institutional Ethics Committee
Sri Balaji Medical College, Hospital & Research Institute,
Airport Road Renigunta, Tirupati – 517520
Phone No: Fax
No: Email ID:

III Objective:

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC), is to ensure quality and technical excellence and consistent ethical review of all the submitted research proposals involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

IV Terms of reference:

The Ethics committee is mandated to examine research proposals to ensure that research is carried out in accordance with ethical principles and conducted according to the ICMR and ICH / GCP guidelines.

The research proposals maybe

- where research is to be wholly or partially carried out at SBMCH&RI
- Where the research proposal is a sponsored proposal
- Where the research proposal is from an outside the institution which requests examination of ethical aspects of the proposal

In case of outside proposals requesting to be examined, a processing fess of Rs 5000/- will be levied to the organization requesting the examination of ethical aspects of their research proposals

The head of the institution shall appoint all EC members, including the Chairperson. The appointment letter issued to all members shall specify the Role and responsibility of the member in the committee, Duration of appointment, and Conditions of appointment that the member shall abide by all the guidelines laid down by Institutional ethics committee (IEC) of Sri Balaji Medical College, Hospital & Research Institute, Tirupati (SBMCH&RI)"

The term of EC membership is 3 years.

The Dean , at his/her discretion, can extend the term for two more terms of 3 years each

The Dean shall ensure that all EC members

- Povide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, wherever applicable;
- Either be trained or undergo training in human research protection and/or GCP

- Be willing to undergo training or update their skills/knowledge during the tenure as an EC member;
- Be aware of relevant guidelines and regulations;
- Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
- Sign a confidentiality and conflict of interest agreement
- Be willing to place her/his full name, profession and affiliation to the EC in the public domain
- Be committed and understanding to the need for research and for imparting protection to research participants in research

A minimum of 10 % of EC members shall be changed every three years

EC members shall be given a honorarium of Rs. 2000/- for attendance at the meeting.

V Authority under which the Ethics Committee has been constituted, Membership Requirements, conditions of appointment and the quorum required.

1. **Authority under which the Ethics Committee has been constituted**: The Dean, SBMCH&RI, is authorized to nominate the Chairperson of IEC and members in consultation with the Chairperson of the IEC among those who possess the qualifications and experience.
2. **Membership Requirements:**
   Ethics committee shall be multi-disciplinary and multi-sectorial with adequate representation of age and gender.The percentage of non-affiliated members shall be not less than 50%. The ethics committee shall have a balance between medical and non-medical members

Institutional Ethics committee will be constituted with the following:

1. Clinician - Affiliated.
2. Clinician –Affiliated.
3. Clinician – non- affiliated
4. Clinician – non- affiliated
5. Basic Medical scientist –affiliated
6. Basic Medical scientist –affiliated
7. Basic Medical scientist –affiliated
8. Scientific Member – affiliated
9. Scientific Member -non-affiliated
10. Scientific Member Clinician Veterinary -non-affiliated
11. Social Scientist–non-affiliated
12. Legal expert- non-affiliated
13. Layperson- non-affiliated
14. Additional member(s) in any of the above categories as required

Adequate representation of age and gender will be ensured. Medical Scientists shall hold a Post Graduate Degree in Medicine of MD/ MS. The Non-Medical Scientific members are required to have a Ph.D in Life Sciences / Veterinary Sciences. Legal Expert is required to be an Advocate

with basic qualification of B.L. All members are required to have good moral character and should not have been convicted for any offence.

Roles of the members of Ethics committee

Chairperson: Shall be non-Affiliated; Qualifications A well-respected person from any background with prior experience of having served/serving in an Ethics committee will be identified.	Chairperson shall be responsible for Conduct of Ethics committee meetings and be accountable for independent and efficient functioning of the committee Ensure active participation of all members in all discussions and deliberations; Ratify minutes of the previous meetings; Nominate a non-affiliated committee member as Acting Chairperson in case of anticipated absence at a planned meeting; Seek COI declaration from members and ensure quorum and fair decision making; Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data
Member Secretary – Affiliated One of the affiliated members of Ethics committee will act as member secretary	Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review Organize EC documentation, communication and archiving Ensure training of EC secretariat and EC members Ensure SOPs are updated as and when required Ensure adherence of EC functioning to the SOPs Prepare for and respond to audits and inspections Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC .review Assess the need for expedited review/exemption .from review or full review
Clinician - Affiliated/ non-affiliated Qualifications – Shall be individual/s with recognized medical qualification, expertise and training	Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics

	Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
Basic Medical scientist / Scientific Member/ Clinician Veterinary Affiliated/ non-affiliated Person with qualifications in basic medical sciences	In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
Social Scientist - Affiliated/ non-affiliated Social scientist/ philosopher/ ethicist/theologian	Ethical review of the proposal, ICD along with the translations. Assess impact of community involvement, socio–cultural context, religious or philosophical context, if any Qualifications Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities Serve as a patient/participant/societal community representative and bring in ethical and societal concerns.
Legal expert- non-affiliated Qualifications Should have a basic degree in Law from a recognized university, with experience Desirable: Training in medical law.	Interpret and inform EC members aboutnew regulations if any Ethical review of the proposal, ICD along with Affiliated/ non-affiliated translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
Layperson- non-affiliated Qualifications Literate person from the public or community Has not pursued a medical science/health related career in the last 5 years May be a representative of the community from which the participants are to be drawn	Ethical review of the proposal, ICD along with translation(s). Non-affiliated Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. Is aware of the local language, cultural and moral values of the community Desirable: involved in social and community welfare activitie Serve as a patient/participant/community representative and bring in ethical and societal concerns. Assess on societal aspects if any.

3. Procedure for appointment of Members:

A. The Dean, SBMCH&RI, after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC.

- Members shall be selected in their personal capacities based on their qualifications,experience, interest, commitment and willingness to volunteer the required time and effort for the EC.
- Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting.
- The role of Chairperson/Member Secretary is an additional activity to their primary responsibility based on their qualifications.

B. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

C. Non institutional committee members are paid an honorarium for each meeting.

D. The normal term for IEC member will be for 36 months.

VI Procedure for resignation, replacement or removal of members

E. During the term, Dean can disqualify any member if the contribution is not adequate and, or there is long period of (member) non availability.

F. Member can discontinue from membership of IEC after giving at least 3 months advance notice.

G. Dean can renew the appointment of the member for a maximum of two more terms on the basis of Contribution.

H. Dean can replace the member of IEC as and when required.

VII Quorum requirements for EC meetings

a. The quorum required shall be a minimum of 7 members with at least one non-affiliated member and shall include both medical, non medical or technical or/and non-technical members.

b. Preferably the lay person should be part of the quorum.

c. The quorum for reviewing regulatory clinical trials shall be in accordance with current CDSCO requirements.

d. No decision is valid without fulfilment of the quorum.

SOP : SOP-2

NAME: Review of Proposals

version number	1			
prepared by	Dr C. Vishnu Priya	Member Secretary		
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Subheadings

VIII Type of clinical research reviewed by the committee

Prospective clinical studies involving healthy subjects, medical and surgical patients and the specimens obtained from participants of the research work, epidemiological studies, retrospective studies and drug trials.

IX Review of the proposal

Every proposal received is reviewed by IEC for

1. The appropriateness of the study design, the statistical methodology, and the potential for reaching relevant conclusions with adequate sample size.
2. Source of funding
3. The adequacy of infrastructure, manpower, and relevant emergency procedures for satisfactory conduct of the study.
4. Requirement of research participants:
    a. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).
    b. The means by which initial contact and recruitment is to be conducted.
    c. The means by which full information is to be conveyed to potential research participants or their representatives.
    d. Inclusion criteria for research participants.
    e. Exclusion criteria for research participants
5. Ethical considerations involved in the research
6. Consent form in English and local language (Telugu) in case of studies on human subjects.
7. Case report forms and other questionnaires/ documents intended for research participants.
8. Details of compensation to be given to research participants and arrangements for indemnity, if applicable, along with insurance coverage for research participants if applicable.
9. Appropriateness of investigator: The ethics committee shall review the CV of the investigator, including qualifications, current designation and experience to determine whether he / she has appropriate capability to undertake the research in question (including clinical trials).
10. All previous IEC's decisions and other relevant regulatory authorities for the study under review.
11. The justification for use of control arms
12. Criteria for prematurely withdrawing the research participants
13. The adequacy of provisions made for monitoring and auditing the conduct of the research.

X Procedure for submission of application for ethics review:

a. The Principal Investigator can submit an application in a prescribed format along with study protocol to the office of the Chairman, IEC, SBMCH&RI on any working day.

b. The proposals and documents must be submitted in English language, at least 4 weeks in advance from the schedule date of IEC meeting.

c. Eleven copies of study proposal (with all documents) must be submitted along with application form duly signed and dated by the investigator(s)

d. The applications received will be given a IEC registration number that will be used for all future correspondence.

SOP : SOP-3

NAME: Conduct of IEC- policies

version number	1			
prepared by	Dr C. Vishnu Priya	Member Secretary		
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Subheadings

XI Conduct of IEC meetings:

A. Meeting of the Ethics committee will be held once in three months. Applicant, sponsor or investigator will be invited to make a slide presentation on the proposal.
B. The IEC will evaluate the possible risks to the subject, the expected benefit and adequacy of documentation for ensuring privacy and confidentiality.
C. Meetings will be conducted only where the quorum is complete.
D. Independent expert/s may be invited by the chairperson, if required, to the meeting to provide written comment, subject to applicable confidentiality agreement.
E. Copies of proposals will be given to members 7 days in advance to review study proposals and the relevant documents.
F. All Deliberations that take place during IEC meetings will be documented.
G. Only members who participated in review and discussion will participate in decision making.
H. In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and Re-review procedure.
I. Negative decision will be supported clearly by stated reasons.
J. **Protection of research participant confidentiality:**
    a. A description of the persons who will have access to personal data of the of the research participants, including medical records and biological samples;
    b. The measures taken to ensure the confidentiality and security of personal information concerning research participants.
    c. **Informed consent process:** A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent. Consent form in English and local language in case of studies on human subjects will be reviewed.
    d. **Community considerations:** The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn and the steps taken to consult with the concerned communities during the course of designing the research.
K. **Selection of special groups as Research Subjects**
    a. **Pregnant or nursing women and Children:** Pregnant or nursing women and Children should not be the subject of any research unless the research carries no more than minimal risk to the these vulnerable groups and the object of the research is to obtain new knowledge about these groups. There should be enough justification and details of protection clearly mentioned and the committee will approve only after getting satisfied that the vulnerable grou requirements re adequately taken care of.
    b. Before undertaking trial in children the investigator must ensure that a parent or legal guardian of each child has given proxy consent and the child as well as parent can obtain adequate medical and psychological support. The child's refusal to participate in research must always be respected

XII Policy on protection of vulnerable population:

- Adequate justification is required for the involvement of vulnerable groups in research who have reduced autonomy as research subjects.
- Research on genetics should not lead to promotion of racial inequalities.
- Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.
- The key principle to be followed when research is planned on vulnerable persons is that the ethics committee should keep in mind that

- Vulnerable populations have an equal right to be included in research but others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own unless when the research is addressing the health needs of the vulnerable group participating in research.
- In vulnerable populations, when potential participants in research lack the ability to consent, a legally authorized/acceptable representative (LAR) should be involved in decision making.
- Special care must be taken to ensure participant's privacy and confidentiality. Also, precaution should be taken to avoid exploitation/retaliation/reward/credits, etc.,

- Following are considered as vulnerable populations or groups:
  - economically and socially disadvantaged (unemployed individuals, orphans, abandoned
  - individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.);
  - unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;
  - children (up to 18 years);
  - women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
  - tribals and marginalized communities.
  - refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations
  - afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
  - terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or
  - have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).
  - Other vulnerable groups include the economically and socially disadvantaged, homeless, refugees, migrants, persons or populations in conflict zones, riot areas or disaster situations.
- Obligations / duties of Ethics committee while assessing proposals involving vulnerable people
  - During review, determine whether the prospective participants for a particular research are vulnerable.
  - Examine whether inclusion/exclusion of the vulnerable population is justified.
  - Ensure that COI do not increase harm or lessen benefits to the participants.
  - Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.
  - Suggest additional safeguards, such as more frequent review and monitoring, including site visits.
  - ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation from the guidelines governing research.
  - The informed consent process should be well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalization.

- Additional precautions should be taken to avoid exploitation/retaliation/
- reward/credits and other inducements when individuals belonging to vulnerabnle group are to be recruited as research participants.
- Benefit-risk assessment should be performed considering perception of benefits and risks by the potential participant.
- Participants who are terminally ill who are in search of new interventions having exhausted all available therapies are vulnerable as they are ready to give consent for any intervention that can give them a ray of hope. These studies are approved ensuring that the scientific community or professional groups do not deny such patients the possible benefit of any new intervention that is not yet validated.

- ECs have to satisfy themselves with the justification provided to include participants belonging to vulnerable group and record the same in the proceedings of the EC meeting.
- The EC should carefully review post-trial access to the medication, especially if it is beneficial to the participant.
- Ensure that all stakeholders implement additional procedures as per the ICMR National Ethical Guidelines 2017

XIII Conflict of interest – IEC members

Member having the conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes. Where there is conflict of interest, member will withdraw from the decision making procedure.

XIV Policy regarding training for new and existing committee members along with SOPs

The Secretary of the Ethics committee collects the information on Drugs and Cosmetics rules, notifications and supplementary amendments from time to time and informs the committee members. Formal training in Good Clinical Practice along with certification will be organized by SBMCH&RI, Tirupati at regular intervals.

XV Procedure for communicating the decision of IEC to the applicant

The committee will give its opinion on the project in writing in one of the following ways; Approval / Disapproval/ Modification before approval/ Discontinuation of previously approved project

XVI Follow up procedure before completion of the study:

All the requirements and procedures for follow up review will be similar to that of initial and main review. Following instances and events will require the request of follow-up review by the investigator:

Protocol amendment, when rights, safety or well being of research subject in conduct of study are likely to be affected, serious or unexpected adverse reaction related to study or product, action taken by investigator, sponsor and regulatory authority, any event or information that may affect the benefit/risk ratio of the study and premature suspension/termination of the study.

A decision of a follow-up review will be issued and communicated to applicant indicating modification / suspension / termination / continuation of the project.

In case of premature suspension/termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.

During follow up review, the committee shall seek the following from the investigators:

- A progress report on six monthly basis or more frequently as the committee feels it.
- A report of each serious event observed during the conduct of the study.
- Any amendments made to any study-related document.

- Information on study discontinuation with reasons, if the study was discontinued since last review.

Applicant must inform at the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant. IEC can review anytime the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.

With regard to Clinical trials, Data Safety Monitoring Board (DSMB) will be constituted by the Dean, SBMCH&RI or by the trial investigators to review the clinical trial notifications and to report the adverse events if any to the Institutional Ethics Committee. The board will review the clinical trial records for serious adverse events and report periodically to the IEC. Also the investigators have to communicate the observations of DSMB to IEC periodically.

SOP : SOP-4

NAME: Performance of IEC

SOP-1				
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prepared by	Dr C. Vishnu Priya	Member Secretary		
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Subheadings

XVII Procedure for documentation and archiving:

1. All the documents and communications of IEC will be dated, filed and archived in a secured place.
2. Only the person, who is authorized by the chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 5 years in the Institute, following the completion of the study.
4. No documents (except agenda) will be retained by any IEC member.
5. At the end of each meeting every member will return all the research proposal documents to IEC office staff.

XVIII Review of Performance of Ethics Committee:

The Dean, SBMCH&RI who is the constituting authority of the IEC shall periodically assess the performance of IEC members in consultation with the Chairperson and Member secretary of the IEC, in terms of attendance, punctuality, participation in discussion and willingness to learn. The member secretary shall evaluate performance of the IEC itself in terms of time interval between submission of proposal and approval/rejection, maintenance of records, arrangements for meetings etc and shall carry out corrective action. Records shall be maintained of the review and any corrective and preventive action.

XIX Amendment of SOP:

Guidelines in this document may be subjected to amendments as and when the need arises. The faculty/investigators from SBMCH&RI, or any other concerned citizen from public can suggest the need to add/delete, alter/amend certain clauses in this document. The Institutional Ethics Committee of SBMCH&RI or a special committee constituted for that purpose shall discuss the suggestions made before recommending for the same or otherwise. Amended version of the document will be put before the Dean, SBMCH&RI for its consideration and approval.

REFERENCES

1. National Ethical Guidelines For Biomedical And Health Research Involving Human Participants Indian Council Of Medical Research 2017
2. Ethics Committee guidelines of AIIMS, New Delhi.
3. Ethics Committee guidelines of SGPGIMS, Lucknow.
4. Ethics Committee guidelines of NIMHANS, Bangalore.
5. Ethics Committee guidelines of NIMS, Hyderabad.
6. Ethics Committee guidelines of CMC & Hospital, Vellore.
7. Standard Operating Procedures For Institutional Ethics Committee, SVIMS, Tirupati