SHRIDEVI INSTITUE OF MEDICAL SCIENCES AND RESEARCH HOSPITAL TUMKUR-572106

SHRIDEVI MEDICAL COLLEGE ETHICS COMMITTEE (SMCEC)

STANDARD OPERATING PROCEDURES

Version Number: 2

Prepared by: SOP teams of SMCEC

Reviewed by: Dr. Kusuma, Member Secretary, SMCEC

Approved by: Dr. Sreenivasa S, Chairperson, SMCEC

Effective date: 22-08-2022

***The validity has been extended from 22.08.2023 till further orders by the SMCEC based on the updated guidelines from ICMR for further revision.**

Contact details: Shridevi Medical College Ethics Committee; 3rd floor; Shridevi Institute of Medical Sciences and Research Hospital; Tumkur- 572106

Email: ethics@shridevimedical.org

Ph no: 0816-2212192

S. Sreenivasa

Kusuma.

(Member Secretary)

Distribution List

Following are the authorized holders of soft copy of Version No. 2 of SMCEC SOP. Member Secretary of SMCEC is the custodian of the soft copy (MS word) and office copy of the SMCEC SOP.

SL. NO.	Name	Designation
1	Dr. Sreenivasa S	Chairperson, SMCEC
2	Dr. Kusuma	Member Secretary, SMCEC
3	Dr. Rekha Gurumurthy	Member-clinician
4	Dr. Narendra Kumar L	Member-clinician
5	Dr. Sowmya K	Member-Basic medical scientist & Alternate member secretary
6	Dr. Rajesh B	Member-Basic medical scientist
7	Mr. Manjuprakash K P	Member- Legal expert & Vice chairperson
8	Dr. Parshurama K G	Member- Social scientist
9	Dr. Arunkumar N	Member- Scientific member
10	Mr. Brahmadevaiah T V	Member- Layperson

SHRI DEVARAJ URS INSTITUTE OF MEDICAL SCIENCES & RESEARCH HOSPITAL
TUMKUR
572106

Abbreviations

AE :	Adverse Event
CDSCO :	Central Drugs Standard Control Organization
COI :	Conflict Of Interest
EC :	Ethics Committee
GCP:	Good Clinical Practice
ICD:	Informed Consent Documents
ICMR:	Indian Council of Medical Research
IEC :	Institutional Ethics Committee
LAR :	Legally Acceptable/Authorized Representative
PI:	Principal Investigator
SAE :	Severe Adverse Event
SIMS &RH :	Shridevi Institute of Medical Sciences and Research Hospital
SMCEC:	Shridevi Medical College Ethics Committee
SOP:	Standard Operating Procedures
TOR:	Terms of Reference

Table of contents

Standard Operating Procedures (SOP)

SOP 1: INTRODUCTION TO PREPARATION OF STANDARD OPERATING PROCEDURES OF SMCEC

1.1:**Purpose:** To define the process for writing, reviewing, distributing and amending SOP of SMCEC. These SOP ensures that the activities of SMCEC are conducted in accordance with ICMR- "National ethical guidelines for biomedical and health research involving human participants-2017" regulations. Uniformity of the processes of SMCEC is ensured by SOP.

1.2: Scope: Writing, verifying, reviewing, revising/amending and issuing the SOP of SMCEC.

1.3: Responsibilities: The Chairperson of SMCEC appoints the teams for preparation/ revision of SOP. The prepared SOP are reviewed by all members of SMCEC in a meeting. The member secretary verifies and chairperson approves the SOP. The Chairperson authorizes the Member Secretary to issue the SOP as per the distribution list. The secretariat staff of SMCEC assists in clerical work and distribution.

1.4: Procedure:

1.4.1: The Chairperson of SMCEC appoints teams for preparation/revision of SOP. Number of teams will depend on the amount of work involved.

1.4.2: Each team will have a leader and two or three members. The team leader should be the one who has thorough understanding of the ethical review process, evident by his/her experience and the training he/she has undergone.

1.4.3: Each SOP will have following headings: 1) Purpose 2) Scope 3) Responsibilities 4) Procedure in detail and Flow Chart (as applicable). All standard formats of SMCEC have been added at the annexure.

1.4.4: The draft of the SOP will be presented in the meeting of full committee. Suggestions or corrections from the members will be incorporated.

1.4.5: The member secretary verifies all the SOP prepared by different teams and the chairperson of the SMCEC gives approval for final SOP. It will come into effect from that date.

1.4.6: The SOP of SMCEC will be valid for a period of one year from the date of effect.

1.4.7: Amendments/revisions will be made as per the changes done in ICMR regulations.

SOP-2 : Constitution of IEC : Selection, Roles and Responsibilities of Members of SMCEC

2.1. Purpose: The purpose of this SOP is to define and describe the framework for constitution, selection, roles and responsibilities of members of SMCEC.

2.2. Scope: This SOP is applicable to appointment of members of SMCEC; defining their roles and responsibilities

2.3. Responsibility: Every member is expected to follow this SOP.

2.4. Procedure:

2.4.1: **Composition of SMCEC:**

2.4.1.1: SMCEC is a multi-disciplinary and multi-sectorial in composition.

2.4.1.2: It is independent and shall have 7 to 15 members.

2.4.1.3: The Chairperson shall be from outside the institution.

2.4.1.4: The member Secretary will belong to the institution.

2.4.1.5: There will be adequate representation of age and gender, and mix of scientific and non-scientific members.

2.4.1.6: The basic composition of SMCEC is as per CDSCO and ICMR-2017 guidelines.

2.4.2: The SMCEC recommends the following composition, affiliation and qualifications to its members.

1. Chairman -non-Affiliated
2. Member secretary- Affiliated
3. Basic medical scientist - Non affiliated
4. Clinician(s)- Affiliated/non affiliated
5. Legal expert - Non affiliated
6. Social scientist - Non-affiliated
7. Lay person - Non-affiliated

Members of Ethics Committee(EC)	Qualifications
Chairperson	• A well-respected person from any background with prior experience of having served/serving in an EC.
Member Secretary	• Should be a staff member of the institution. • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. • Should be able to devote adequate time to this activity.
Basic Medical Scientist	• A medical 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.
Clinician(s)	• Should be individual/s with recognized medical qualification, expertise and training.
Legal expert	• Should have a basic degree in Law from a recognized university, with experience.
Social scientist	• Should be an individual with social/behavioral science qualification and be sensitive to local cultural and moral values. • Can be from an NGO involved in health-related activities.
Lay person	• Literate person who has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community and aware of the local language, cultural and moral values of the community. • Desirable to be involved in social and community welfare activities.

2.4.2.1: The Chairperson and Member Secretary will not have the dual roles in the ethics committee. They can't fulfil the role of a member (clinician/basic medical scientist/social scientist/legal expert, etc..) as it interferes with their own responsibilities.

2.4.2.2: All members including Chairperson, Member Secretary will review the research proposals.

2.4.2.3: The Member Secretary does not have voting rights.

2.4.2.4: Chairperson will exercise voting if it is required to make a decision on ethical approval to a research proposal.

SOP 3: Terms of reference

Purpose: The purpose of this SOP is to define and describe the terms of reference, which provide the framework for constitution, selection, roles and responsibilities of SMCEC members.

Scope: The roles and responsibilities of SMCEC, it's members, tenure of membership and method of reconstitution of members is explained in the SOP.

Responsibility: The Director of SIMS &RH makes the decision of continuation of existing members and appointment of new members to SMCEC.

Procedure:

3.1: Purpose of SMCEC:- The institutional ethics committee has been formed to ensure that the research is conducted in accordance with four basic principles- respect for persons (autonomy), beneficence, non-maleficence and justice to safeguard the dignity, rights, safety and well-being of the human participants involved in biomedical and health research.

3.1.1: The research should be **DIRECTED** towards enhancing knowledge about the human condition while maintaining sensitivity to the local cultural, social and natural environments.

3.1.2: It should be **CONDUCTED** under conditions such that persons participated in research activities are dealt with in a manner conducive to and consistent with their dignity, well-being, professional fair treatment and transparency.

3.1.3: The investigators are **SUBJECTED** to a regime of **EVALUATION** at all stages, i.e., design, conduct and reporting of the results thereof.

3.2:Scope of SMCEC:-The guidelines are applicable to all biomedical and research for health involving human participants.

3.2.1: A written SOPs will be prepared according to ICMR guidelines for all biomedical and health research to function.

3.2.2: The SOPs will be updated once in a year to reflect the changing requirements.

3.2.3: A copy of the latest version of SOPs will be made available to each member and they will be trained on the SOPs.

3.2.4: The SOPs will be available in the secretariat of the SMCEC as both hard and soft copies.

3.2.5: No Members of the SMCEC should have any known record of misconduct.

3.2.6: The roles and responsibility, tenure and renewal policy of the SMCEC members has been explained in this SOP.

3.3A: Roles and responsibilities of the SMCEC:-

3.3.1: The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

3.3.2: The EC ensures ethical conduct of research by the investigators team.

3.3.3: The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

3.3.4: The EC performs its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

3.3.5: The EC ensures that universal ethical values and international scientific standards are followed in terms of local community values and customs.

3.3.6: The EC assist in the development and education of the research community in SIMS&RH (including researchers, clinicians, students and others), responsive to local healthcare requirements.

3.3.7: The EC ensures that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

3.3.8: The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

3.3.9: The EC recommends appropriate compensation for research related injury, wherever required.

3.3.10: The EC do monitoring visits at study sites as and when needed.

3.3.11: The EC participates in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

3.3.12: The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) will not to be encouraged and submission of same research to different funding agencies will not be accepted.

3.3B: Terms of reference(TOR) for SMCEC members:

3.3.1: The director of SMCEC appoint all EC members, including the Chairperson.

3.3.2: The appointment letter will be issued to all members after obtaining the consent letter, specifying the TORs.

3.3.3: The appointment letter issued includes-duration of appointment; role and responsibilities of the member in the committee and conditions of appointment.

3.3.4:The tenure of each member and any extension is specified in the SOP.

3.3.5: One third of EC members will be changed on a regular basis.

3.3.5: Non affiliated EC members will be given a reasonable honorarium for attending the meetings.

3.3.6: The following are the requirements of each SMCEC member.

Every EC member must:

1. provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;

2. either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment;

3. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;

4. be aware of relevant guidelines and regulations;

5. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;

6. sign a confidentiality and conflict of interest agreement/s;

7. be willing to place her/his full name, profession and affiliation to the EC in the public domain; and

8. be committed and understanding to the need for research and for imparting protection to research participants in research.

3.4: Roles and Responsibilities of SMCEC members:-

3.4.1:Chairperson:-

1. To conduct meetings and to be accountable for efficient functioning of the committee
2. To ensure active participation of all members in all discussions and deliberations
3. Seek conflict of interest from members and ensure quorum and fair decision making

4. Handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data

5. To ratify the minutes of previous meetings

6. To review serious adverse events with causality assessment

7. Is the final authority of SMCEC to take any decision on disqualification of members and recommend to the head of the institution for termination of the member.

8. Responsible for making any communications on behalf of the SMCEC to CDSCO/DCGI and any other regulatory bodies

3.4.3:Member Secretary:-

1. To organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review

2. To schedule IEC meetings, prepare the agenda and minutes

3. To organize IEC documentation, communication and archival

4. To arrange for training of IEC secretariat and members

5. To ensure that SOPs are updated as and when required

6. To ensure adherence of IEC functioning as per SOPs

7. To prepare for and respond to audits and inspections

8. To Ensure completeness of documentation at the time of receipt of protocols, and timely inclusion in the agenda for IEC review

9. To assess the need for exemption from review, expedited review or full review Joint Secretary: Will function as Secretary in his/her absence; helps the Secretary in recording minutes of meetings, sorting out the research proposals for review, documentation, and in preparation for audits and inspections.

3.4.3:Members (In general for all members):-

1) All members are expected to review the research proposals and attend the ethics committee meetings, and participate in the discussions and deliberations

2) To review the revised submissions, additional submissions, progress reports and final reports

3) To review the reports of serious adverse events, and recommend appropriate actions

4) To carry out monitoring visits at study sites as and when needed

5) To maintain confidentiality of the documents and deliberations of ethics committee meetings

6) To declare conflict of interest if any, to the Chairperson

7) To participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

3.4.4: Basic Medical Scientist:-

Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology, statistics, continuing review process, review on serious adverse events, progress report and final report.

3.4.5: Clinician(s):-

1) Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics

2) Ongoing review of the protocol, review of serious adverse events, progress report and final report.

3) Review of medical care, appropriateness of the facility and principal investigator, provision for medical care, management and compensation.

4) Thorough review of protocol, investigator's brochure and other protocol related documents

3.4.6: Lay Person:-

1) Ethical review of the proposal, informed consent documents along with translations

2) Evaluate benefits and risks from the participant's perspective, and opine whether benefits justify the risks

3) Serve as a patient /participant/community representative and bring in ethical and societal concerns

3.4.7: Legal Expert:-

1) Ethical review of the proposals, informed consent documents along with translations, MOU, clinical trial agreement, regulatory approval, insurance document, compensation proposals, other site approvals, investigator's undertaking, and protocol-specific other permissions.

2) Interpret and inform members about new regulations if any

3.4.8: Social Scientist:-

1) Ethical review of the proposals, informed consent documents along with translations

2) Assess impact on community involvement, socio-cultural context

3) Serve as representative of community/society and bring in ethical and societal concerns

3.4.9: Secretariat :-

1) Secretariat is composed of the clerical staff and attender.

2) Secretariat will assist the Member Secretary in all their functions.

3) The clerical staff are involved in receiving the proposals, preparing the communication letters, approval letters, and any other typing work assigned by Member Secretary and Chairperson .

4) They are also involved in typing agenda for the meeting, typing the proceedings of meetings , and preparation for the meetings.

5) The secretariat staff needs to sign a confidentiality agreement.

6) Attenders are involved in distribution of research proposals to members for review and physical arrangements for the meetings.

3.5: Tenure of SMCEC members:

3.5.1: **Tenure of chairman and member secretary:**

1) For the Chairperson and the Member Secretary replacements, the tenure of membership will be for a period of five years.

2) The Chairperson and Member secretary could get a second term after completion of the tenure.

3.5.3: **The tenure of the members:**

1) The tenure of the members in the SMCEC is three years.
2) After the completion of three years, at least 1/3rd of the members will be replaced by new members.
3) The replacement of a member will be done with new member of the same category (clinician/lay person/social scientist/philosopher, etc…).
4) The decision on continuation of a member will be taken by the Director of the Institute.
5) Opinion of Chairperson and Member Secretary may be taken into consideration in this process.
6) A member can have maximum two continuous terms in SMCEC.

3.5.3: **Continuation of membership after the tenure:-**

1) The Chairperson and Member Secretary can have maximum two consecutive terms.

2) The Director will send an appointment proposal letter to the members who will replace existing members, and also to the existing members who are going to continue.

3) After obtaining consent, final appointment letter will be issued.

4) The Director will communicate to those who are replaced, acknowledging their service and contribution to the ethics committee.

3.6: Appointment of New Members:-

3.6.1: New members will be appointed under following circumstances:

1) When a regular member completes his/her tenure.
2) If a regular member resigns before the completion of the term
3) If a regular member ceases to be a member due to any reason such as death or disqualification

3.6.2: The new member will be identified by the Chairperson based on the membership requirements after discussion by the IEC.

3.6.3: The name of new member to be appointed may be suggested by members of IEC.

3.6.4: The Chairperson sends the proposal to head of the institution. The final decision on appointment is taken by head of the institution.

3.7: He/she may become a member again in SMCEC after a gap of at least two years.

3.8: Types of renewal:

3.8.1: The type of EC review will be based on risk involved in the research.

3.8.2: All research proposals will be classified into 4 categories based on the risk involved.

A. **Less than minimal risk:**Probability of harm or discomfort anticipated in the research is nil or not expected.

B. **Minimal risk:**Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely.

C. **Minor increase over minimal risk or Low risk:** Increment in probability of harm or discomfort is only a little more than the minimal risk threshold.

D. More than minimal risk or High risk: Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk.

3.8.3:The Member Secretary shall screen the proposals for their completeness and depending on the risk involved categorize and decide them into three types. All the review procedures has been explained in detail in SOP on review procedures.

A. Expedited review

B. Full committee review

C. Exemption from review

3.8.4: **Expedited review:-**Anexpedited review will be conducted in the presence of chairperson, member secretary, one clinician, one basic medical scientist and a scientific member.Proposals that pose no more than minimal risk will be considered for expedited review. It includes-

1. Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples.
2. Research involving clinical documentation materials that are non-identifiable (data, documents, records).
3. Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).
4. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
5. Minor deviations from originally approved research causing no risk or minimal risk.
6. Progress/annual reports where there is no additional risk, for example activity limited to data analysis.
7. Review of SAEs/unexpected AEs
8. Research during emergencies and disasters

3.8.5: **Full committee review:-**

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review.

1. Research involving vulnerable populations, even if the risk is minimal;
2. Studies involving deception of participants,where a true informed consent may lead to modification and may defeat the purpose of research.A two-step procedure will be followed by

the researchers-an initial consent followed by debriefing to participants after completion of the research project.

3. Research proposals that have received exemption from review, or have undergone expedited review will be ratified by the full committee, which has the right to reverse/or modify any decision taken by the expedited committee.

4. Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk.

5. Major deviations and violations in the protocol

6. Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment.

3.8.6: **Exemption from review:**-Proposals with less than minimal risk where there are no linked identifiers will be considered for exemption from review.

1. Research conducted on data available in the public domain for systematic reviews or meta-analysis.

2. Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person.

3. Quality control and quality assurance audits in the institution.

4. Comparison ofinstructional techniques, curricula, or classroom management methods

5. Consumer acceptance studies related to taste and food quality.

6. Public health programs by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

7. Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

8. **Case reports:** SMCEC issues ethical clearance to case reports for presentation /publication on receiving and verifying informed consent from the patient, abstract of the case report and findings. Wherever possible patient identity must be masked in the photographs used in case reports.The Member Secretary may ask for a copy of the informed consent form signed by the patient whenever the identity of the patient (face) is not masked. Member secretary will go

through (screening for documents to be submitted to IEC) the proposals which are exempted from review, and get the decision ratified in the full committee meeting

3.9: Types of decisions by SMCEC:

1. Approved – with or without suggestions or comments
2. Revision with minor modifications – Approval be given after examination by the member secretary.
3. Revision with major modifications for re-submission – Approval will be given after the full committee meeting permits for reconsideration.
4. Not approved – clearly defining the reasons for not approval.

3.10: Continuing review of protocols:-

3.10.1: All the projects approved by the IEC will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

3.10.2: It is the responsibility of the Member Secretary to ensure a decision regarding whether the project needs to be reviewed more frequently.

3.10.3: The continuing review of protocols is done by SMCEC once in six months for the clinical trials, and once in a year for the academic studies.

3.10.4: For Academic Studies: An annual report is sought from heads of departments that the studies done in the Department are conducted as per IEC guidelines. The heads need to submit the report in the designated format.

3.10.5: Action to be Taken for Failure of Submission for Continuing Review : If the PI fails to submit documents for continuing review within the stipulated date, the Member Secretary sends a reminder notice asking the PI to submit the documents within 7 days. Further, non-response or failure to submit documents will be discussed in the full board meeting of the IEC. Action could be one of the following : one more reminder and asking the PI to give an explanation for the failure to submit documents / withdrawing the ethical approval granted and asking the PI not to

continue the study/ any other action which is deemed appropriate. The head of the institution will be informed of the decision of the IEC.

3.11:Review of Resubmitted and Amended Protocols and Protocol-Related Documents:-

3.11.1:The research proposals which are resubmitted based on the suggestions to the investigator to do so will be verified by member secretary and will categorize the resubmission for exempted from review, expedited review or full review.

3.11.2: : The decision of SMCEC will be communicated by the same procedure which is followed for "new submission".

3.12: Review of Protocol Amendments:-

3.12.1:The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.

3.12.2:The Member Secretary will decide on the type of review required for the protocol amendments submitted by the investigator.

3.12.3:The decision of SMCEC will be communicated by the same procedure which is followed for "new submission".

3.13: On site monitoring of protocols:-

3.13.1:The Chairperson and the Member Secretary of SMCEC are responsible for conducting the onsite monitoring. The members of SMCEC are responsible to participate in the monitoring process as and when they are assigned.

3.13.2: The decision letter issued to the PI during approval of the protocol will have the statement on on-site monitoring of the study.

3.12.3:The routine monitoring of the protocols will be done at least once in a year.

3.12.4:Three minimum visits are done for a study from initiation till completion.

Visit -1 : During recruitment of the first subject (The team of members from FMIEC to visit the site and witness the process of informed consent and recruitment of the subject); Verification of the written record.

Visit-2 : During the progress of the study. After the PI submits the first progress report (six months after initiation of the study) ; Verification of written records.

Visit-3 : At the completion. Once the final report is submitted by the PI.

3.12.5: During the visit the monitoring team will follow the checklist.

3.12.6: After the visit, the Member-Secretary will present the monitoring report at the next full board IEC meeting. The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions.

3.12.7: The decision will be conveyed to the Principal Investigator in writing within 7 working days of the meeting. Opportunities for improvement in any area will be emphasized in the report.

3.13:Review of Protocol Deviations and Violations:-

3.13.1:Protocol Deviation- A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IEC. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IEC using the standard reporting form.

3.13.2: Protocol Violation- A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data.

3.13.3: Minor Protocol Deviation- A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IEC and which does not have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

3.13.4:Actions taken:

3.13.4.1: The action of the IEC will be based on:

A. The nature and seriousness of the deviation / violation.

B. Frequency of deviation/ violation in the study in the past.

C. Frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PI or in the same department.

3.13.4.2:Member Secretary will decide on the impact of the protocol deviation / violation and act accordingly.

3.13.4.3:The Chairperson will take a final decision depending on the seriousness of the violation. The decision will be taken to ensure that the safety and rights of the research participants are

safeguarded. Thedecision will be taken by consensus, and the quorum required for the meeting is same as that required for the initial approval of the protocol.

3.13.4.4:The final decision will be recorded and conveyed to the PI.

3.14:Review of Final Reports and Study Completion Reports:-

3.14.1:Receipt of Study Completion Report : The Secretariat will receive 1 copy each (soft and hard) of Study Completion Report for the academic trials and academic studies .Copy of the publications will be received for academic studies.

3.14.2:The study completion report is expected from the investigator within 1 month of completion of the study at the site.

3.14.3:During the Board meeting The Member Secretary will present the report and members can discuss as needed.

3.14.4:. For Academic Studies, decision on the study completion report review will be intimated to the Head of the Institution. In addition to the PI and the HOD of the Department.

SOP-4: Condition of appointment& quorum requirement

Purpose: The appointment of SMCEC members and quorum requirement for conducting ethical meeting will be done as per the CDSCO and ICMR – 2017 guidelines.

Scope: The SOP defines and describes the conditions of appointment; criteria of selection of it's members and roles and responsibilities of appointed members.The quorum requirement for conducting ethical meeting has been specified.

Responsibility: The Director of SIMS & RH appoints the members of SMCEC. The member secretary ensures that the quorum is met before conducting any ethical meetings.

Procedure:

4.1: Appointment of SMCEC members:-

4.1.1: The appointing authority for the SMCEC is the Director of Shridevi Institute of Medical Sciences and Research Hospital.

4.1.2: The Director appoints the Chairperson, the Member Secretary and other members of the committee.

4.1.3: The Director sends an official request letter to the members who will confirm their acceptance to the Director by providing all required information such as curriculum vitae, and certificates of training on research ethics and good clinical practice.

4.1.4: The consent letter includes consent from the member, declaration of maintaining confidentiality of research project- related data/documents/discussions, and willingness to get updated on research ethics, good clinical practice and regulations on human research.

4.1.5: On receiving this consent, the Director will issue the final appointment order.

4.2: Criteria for Selection of SMCEC members:

4.2.1: Chairperson:-

1) Should be from outside the institution

2) Should have a minimum of three years experience as a member of an IEC

3) Should have undergone training in guidelines for conducting biomedical research on human beings.

4) Should not have any known record of professional misconduct.

4.2.2: Member Secretary:-

1) A faculty from the institution with a postgraduate degree, and with a minimum experience of four years in the institution.

2) Should have undergone training in guidelines for conducting biomedical research on human beings.

3) Should have a minimum of two years experience as a member of an institutional ethics Committee

4) Should have worked as a convener/member of any committees/core teams of the Institution.

5) Should have good communication skills.

6) Should not have any known record of professional misconduct.

4.2.3 Members:-

1) Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC.

2) They should not have any known record of professional misconduct.

3) The basic medical scientists and clinicians should have post graduate qualifications.

4) The Lay Person should not have any graduate or post graduate qualification in any science discipline. He/she is a literate person from the public or community. He/she is aware of the local language, cultural and moral values of the community

5) The legal expert should have a basic degree in law from a recognized university with a minimum experience of three years in the legal field .

6) The social scientist is someone expert in the study of human society and its personal relationship like anthropologist, scientist and penologist. He/She also may be a representative of a non-governmental organization. Theologian is a person involved in preaching of various religious activities while an ethicist has a background in law or philosophy. One of them is included as a member in IEC.

7) A newly appointed member who has not undergone any training in ethics/good clinical practice /ethical guidelines of biomedical research on human beings does not have the voting rights. He/she has to undergo training within six months of the appointment. The member gets the voting rights once he/she undergoes training.

4.3: IEC members should be trained in protection of human research participants, SOP and Good Clinical Practice (GCP) guidelines, and be conversant with relevant ethical guidelines and regulations. A training session will be arranged to all members on recent updates as and when required by the institute.

4.4: Consent to be the members of SMCEC:

1)The secretariat should collect a copy of recent curriculum vitae from all the members.

2) The copies of degree certificates and medical council registration certificates should be collected from medical members of committee. In addition, certificates of training if any, in research methodology/ethics in clinical research/good clinical practice/Guidelines for biomedical research on human beings should be collected and filed in the IEC office.

4.5: Consent letter and confidentiality agreement from members:

1) When the members agree to be part of SMCEC, they need to sign a consent letter in which they declare their commitment for all activities of the committee, and maintaining confidentiality of activities and documents of SMCEC.

2) The staff of secretariat has to sign an agreement of maintaining confidentiality

3) Chairperson of SMCEC will sign on all the confidentiality forms of members and secretariat staff.

4.6: Payment of Remuneration to SMCEC Members:-

The non-affiliated SMCEC members are paid honorarium for attending meeting of IEC and onsite monitoring visit. The remuneration will be decided by the head of the institution. In addition, the institution may sponsor the members to attend training on ethical guidelines and GCP.

4.7: Quorum requirements for conducting ethical committee meeting:-

1. A minimum of five members should be present in the meeting room.

2. The quorum should include both medical, non medical or technical or/and non-technical members*.

3. Minimum one non-affiliated member should be part of the quorum.

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

5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

6. No decision is valid without fulfillment of the quorum.

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

Flow Chart

Constitution of SMCEC

↓

Sending Appointment Proposal Letters : By Director, FMCI

↓

Receiving Acceptance from Members

↓

Sending Final Appointment Letters: By Director, FMCI

↓

Consent Letter signed by the Members

↓

Confidentiality Agreement Signed by the Members

↓

Members Trained on SOP

↓

On completion of tenure; SMCEC Reconstitution Done

SOP 5: Procedure for registration, replacement or removal of members

Purpose: Procedure for registration, replacement or removal of members is described.

Scope: The SOP describes the process of registration of SMCEC members; reasons for replacement and disqualification of members.

Responsibility: The Director will take the decision on the recommendation of chairperson and member secretary IEC.

Process:

5.1: Conditions to be fulfilled by a member for registration: -

1) Members must submit a recent, signed CV.

2) Members must submit training certificates in ethics and GCP (if available during induction).

3) Members should be ready to undergo training in ethical guidelines and GCP and submit the training certificates to the Member Secretary.

4) Members must be willing to publicize his/her full name and affiliation.

5) Should sign the confidentiality agreement, and maintain confidentiality regarding documents, discussions, and related matters of SMCEC.

5.2: Termination of Membership:-

5.2a: This refers to termination from membership even before the member completes his/her tenure. Reasons for termination may be

A. Resignation of the member from the SMCEC
B. Resignation of the member from the institution
C. Death of the member or disqualification of the member.

5.3: Voluntary termination:-

5.3a: It is due to resignation of the member.

5.3b: The resignation has to be submitted in writing to Chairperson, SMCEC.

5.3c: One month prior notice is necessary for the resignation.

5.3d: It will be effective from the date of acceptance by the Chairperson.

5.4: For affiliated members:-

If a member resigns from the institution (SIMS &RH), even if he/she does not submit resignation to SMCEC, the membership to IEC stands automatically cancelled. This termination is effective once the member is relieved from the institution.

5.5:Disqualification:-

A member is disqualified from the membership under following circumstances:

5.5a: **Misconduct-**

a) If the Chairperson or the Member Secretary receives a communication in writing from public / investigators/ another member of SMCEC regarding misconduct of the member.

b) If the Chairperson observes/gets information on any type of professional /ethical misconduct (not maintaining confidentiality /not declaring of conflict of interest/any type of bias towards research studies/investigators reviewed by SMCEC).

5.5a.1: Action to be taken-

a) The Chairperson satisfies himself/herself that prima facie a case exists before initiating any action.

b) If in the opinion of the Chairperson, the matter of significance and integrity of the IEC could be questioned, he/she will first keep the member under suspension till the final decision is taken.

c) During the period of suspension, the member will not have any voting rights, privileges and will not perform any duties of a member of SMCEC.

d) The Chairperson will call for a meeting of SMCEC, following the usual rules of quorum. The suspended member will be given sufficient opportunity to defend himself/herself in the meeting. The decision will be taken by consensus.

5.5b: Disqualification due to continuous absence: -

a) A member will be disqualified if he/she does not attend more than three consecutive meetings of IEC.

b) If the member has given a prior intimation to Chairperson/member Secretary about the absence, the member will be given an opportunity to continue with the membership. This member will be issued a warning from Chairperson. However, the membership will cease if this habit repeats once again.

c) In case of absence without intimation for more than three consecutive meetings of SMCEC, the member is liable for disqualification.

d) The member will be issued a one month notice by the Chairperson seeking explanation for the absence.

e) If the member gives satisfactory explanation for the continued absence and assures attendance for future meetings, the Chairperson may decide on continuation of the membership.

f) In the absence of any reply from the member, the Chairperson will discuss the matter of disqualification of membership in the meeting of SMCEC.

g) Final decision on disqualification is taken by the Chairperson.

h) In all the above cases of disqualification, the Chairperson communicates to the Director, SIMS & RH in writing.

i) The decision of disqualification is communicated to the member by the Director.

SOP 6 - General review of research proposal

Purpose: The purpose of this SOP is to describe the preparation of agenda, preparation for meeting, conducting the meeting and preparing minutes of meetings of SMCEC.

Scope: This SOP applies to administrative processes concerning the preparation of the agenda, conducting meeting and recording minutes of all IEC meetings.

Responsibility: The Member secretary is responsible for preparation of the agenda, recording the minutes of meeting and circulation of the minutes to all members of SMCEC. The Chairman conducts the meetings of SMCEC, and approves the minutes of meeting.

Procedure:

6.1: The meeting schedule:-

6.1.1: The SMCEC meeting is held once a month on the second Saturday. Frequency of the meeting is increased depending on the number of research proposals for full review. The meeting day may be changed (other than second Saturday) if there is a holiday for the institution or due to any other reasons because of which the meeting is not possible on second Saturday.

6.1.2: Preparation of Agenda:-

a. The research proposals received by the SMCEC are categorized for review as- exempted from review, expedited review and full review. This is done by the Member secretary who will do the initial scrutiny of the research proposals. The review is done only for the proposals categorized for expedited and full review. The expedited review will be done by the Chairperson, the Member secretary and one member of SMCEC. The full review will be done by all members of SMCEC.

b. The research proposals categorized for full review will be included in the agenda for presentation during the meeting of SMCEC. The expedited reviews and exempted from review are included for ratification by all members in the meeting.

6.1.3: The format of the agenda is enclosed in the annexure of this SOP. The agenda includes: quorum of previous meeting (list of members present and absent), ratification of the minutes of previous meeting, presentation of the research proposals (full review) by the principal investigators, ratification of the expedited reviews. Presentation of the proposals categorized under "exempted from review" by the member secretary, and any other issues as recommended by the members and approved by the Chairperson. Other issues could be report of onsite monitoring, training needs, accreditation of ethics committee, serious adverse events, review of protocol deviations/amendments, continuing review of research studies, completion reports of research studies, revision of SOPs, changes in the committee composition, report of subcommittees appointed by the Chairperson (if any)and emergency concerns.

6.1.4: Only those research proposals and documents (informed consent documents, protocol deviation/amendment notifications, revised submissions, progress reports, study completion reports) received ten days before the scheduled meeting will be included in the agenda.

6.1.5: The venue of meeting is ensured before sending the agenda to all members. The agenda will mention the date, time and venue of the meeting.

6.1.6: A hard copy of the agenda, copies for research proposals for review and review forms are sent to the members at least one week before the meeting. The secretariat is responsible for sending these documents to all members without fail.

6.1.7: Even if there are no research proposals for review, the committee shall hold meeting at least once a month and discuss issues other than review of proposals.

6.1.8: If any member is unable to attend the meeting, he/she should inform the Chairperson (through the Member secretary) well in advance. (Preferably one week before the scheduled date of meeting). The leave should be requested in a written leave letter. In emergency situations if the member is not able to inform in advance, e mail communication could be done. If the chairperson is unable to attend the meeting, he/she will inform the member secretary, and ask him to conduct the meeting in the presence of acting chairperson.

6.1.9: All regular members of SMCEC, independent consultants and principal investigators of research proposals categorized for full review are required to attend the meeting. Independent consultants chosen for full review are intimated to attend the meeting during the presentation of those research proposals which they have reviewed.

6.1.10: The principal investigator should attend the meeting and present the proposal. Co investigators are allowed to attend the meeting.

6.2: Conduct of Meeting:

6.2.1: The secretariat will help the member secretary in arrangements for the meeting

6.2.2: The SMCEC full board meeting will be held as per the schedule provided.

6.2.3: There should be the presence of at least 6 members out of the total 10 members of the committee to constitute quorum.

6.2.4: Besides the Chairperson and the Member secretary the quorum will consist of One basic medical scientist, One social worker (or a social scientist, theologian, ethicist, philosopher, member or representative of a non-governmental voluntary agency or a similar person), a clinician, a lay person and a legal expert.

6.2.5: The signature of all members who attended the meeting will be taken on the attendance sheet.

6.2.6: The Chairperson initiates the meeting after ensuring quorum. The Chairperson ensures the quorum for every clinical trial presentation in the meeting.

6.2.7: The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict. The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict prior to the start of the meeting.

6.2.7: If a conflict of interest has been declared by a member, the Chairperson will ask the member concerned to leave the meeting room when the concerned issue is being discussed.

6.2.8: The Member secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.

6.2.9: The Member secretary will present the agenda of the day's meeting for discussion.

6.2.10: The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.

6.2.11: The Principal Investigators are asked to present the research proposals as per the order of proposals mentioned in the agenda. When one investigator is presenting the proposal, investigators of other research proposals should not be present in the meeting room. However, co investigators of the same research proposal (or guides in case of postgraduate dissertations) are allowed to be in the meeting room. In case of informed absence of principal investigator, co investigator may be allowed to make the presentation. However, if the members feel that co investigator is not familiar with the protocol details, the principal investigator may be asked to attend the next meeting of IEC for the presentation.

6.2.12: The members of SMCEC should not discuss on the decisions about the research proposals when the investigators are inside the meeting room. The members should discuss only after the investigator leaves the meeting room.

6.2.13: For other matters in the agenda (other than full review), the member secretary will present the review findings (expedited review), list of proposals under exempted from review, protocol deviations/amendments, etc.

6.2.14: Reports of any subcommittees will be presented in the meeting by the heads of respective committees, as per the agenda.

6.2.15: The proceedings of the meeting will be recorded by the Member secretary. If the Member secretary has conflict of interest in any research proposal, the other member, given in charge by chairperson will do this job.

6.3: Decision Making:-

6.3.1: The final decision on approval of a research proposal is by consensus. The Chairperson ensures participation of all members in the deliberations. The decisions are based on risk assessment, scientific validity, and adherence to ethical principles for the initial and periodic approvals. In the review forms, the members need to tick one of the following:

1) Approved

2) Approved with suggestions

3) Resubmit with revisions

4) Rejected

6.3.2: In the "Suggestions" of section of the form, member can write down his/her suggestions of any and points to be considered for revision of the research proposal. Reasons for rejecting the proposal also should be mentioned in the review form.

6.3.3: The independent consultants called to the meeting will be present only for the presentation of the concerned research proposal. He/she will give the opinion during the meeting and will leave the meeting room. They don't have any voting rights.

6.4: Minutes of the Meeting:-

6.4.1: The minutes of the meeting are prepared by the member secretary on summarizing the discussions held in the meeting and decision taken by consensus. The minutes are sent to all members of the committee and their inputs are taken. The Chairperson gives the final approval for the minutes.

6.4.2: The minutes are to be prepared within 3 working days of the meeting day.

6.4.3: The minutes of meeting should include the following contents- 1) Date, time and venue of the meeting 2) List of members who attended and who were absent for the meeting 3) List of guests /observers who attended the meeting. 4) Name of the individual who served as chairman for the meeting 5) Ensuring of quorum by the chairman 6) Ratification of minutes of the previous meeting: to be mentioned 7) Summary of discussions and approval status for full review and

expedited review 8) Research proposals exempted from review 9) Discussion of protocol deviations/amendments; if any onsite monitoring visits, progress reports and final reports with actions taken.

6.4.4: The minutes are presented in the next meeting for ratification.

6.5: Communication of the decision to Principal investigator (PI): -

6.5.1: All communications are done by the member secretary.

6.5.2: In clinical trials, the investigator is asked to register the study in Clinical Trial Registry of India (CTRI). Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies are expected to register the trial in the CTRI before enrollment of the first participant.

6.6: Validity of Approval:-

6.6.1:Though the approval is granted for the entire duration of the study, the validity of the approval letter is only up to one year. The approval will be continued if progress is satisfactory. For renewal of approval, the PI has to submit a request letter to Member secretary.

6.6.2: The decision of IEC may be reversed if IEC receives information that may adversely affect the benefit/risk assessment.

6.7: Calling an Emergency Meeting of SMCEC:-

6.7.1: The Member secretary in consultation with the Chairperson may call for an emergency meeting on following occasions:

1) Urgent issues which if not discussed and decided may have adverse impact on patient safety.
2) Serious adverse events

3) Other issues deemed appropriate by the Chairperson or the Member secretary.

6.7.2: The notice of this meeting may be sent at least one day in advance. The documents for discussion in emergency will be sent by e mail.

6.7.3: The rules of quorum will be applicable. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (at least one scientific and one non-scientific member) are present, given the urgency of the matter under consideration.

6.7.4: The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

SOP 7 – Conflict of Interest (COI)

Purpose: To describe the process to identify and manage conflict of interest among SMCEC members.

Scope: This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all SMCEC members.

Responsibility: All SMCEC members are responsible for self-identifying and disclosing the conflict of interest. The Chairperson is finally responsible for ensuring it during review of research proposals.

Procedure:

7.1:Information to members on COI:-

1) During the appointment of members, the appointment letter makes it clear to declare COI, if any at appropriate time and consent on the same will be taken.

2) The conflict of interest policy of the SMCEC will be explained to the members on induction as a part of the training.

7.2: Types of Conflict of Interest (COI):

7.2.1: Personal COI: -

1) If the member is a collaborator, Principal investigator, co- investigator, financer, research staff, consultant for a research proposal which has come for review in SMCEC;

2) If a research proposal is submitted by a departmental colleague with whom the member has conflict of interest (dispute, bias, any benefits, etc.) –if applicable and if the member feels there is a conflict of interest.

3) If the investigator of a research proposal has close and immediate family relationship with the member of SMCEC (spouse, son/daughter, parents, sibling, dependent) .

7.2.2: Professional COI:-

If , the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

7.2.3: Financial COI:-

If the IEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

7.3: Procedure for Declaring COI:-

7.3.1: The IEC member should identify the COI whenever a research proposal is assigned to him/her for the review. The COI should be declared and submitted to the member secretary. The review is reassigned to other members.

7.3.2: The IEC members should not participate in discussing, or decision making on research proposals' applications reviewed at any level (exempt, expedited, or full-board) except to provide information requested by the IEC.

SOP-8 Review procedures

Purpose: To describe the procedure to categorize new research study protocols submitted by investigators for initial review into full board / expedited review or exemption from review process.

Scope: SOP covers the process of categorization of new research study protocols submitted to IEC for initial review.

Responsibility: The Member Secretary is responsible for categorizing the protocols for review as full review, expedited review and exempted from review. The suggestions/guidance of the Chairperson is taken whenever necessary. It is the responsibility of the members of SMCEC to do the review as per the guidelines.

Procedure:

8.1: Exemption from Review:-

8.1.1: Proposals that are exempted from review include those with less than minimal risk where there are no linked identifiers. This could be seen in following situations –

i) Research conducted on data that is in the public domain for systematic reviews or meta analysis.

ii) Observation of public behavior when information is recorded without linked identifiers and disclosure would not cause harm the interests of the observed person.

iii) Quality control and quality assurance audits in the institution.

iv) Comparison among institutional techniques, curricula, classroom management methods.

v) Consumer acceptance studies related to taste and food quality.

vi) Case reports: SMCEC issues ethical clearance to case reports for presentation /publication on receiving and verifying informed consent from the patient, abstract of the case report and findings. Wherever possible patient identity must be masked in the photographs used in case

reports. The Member Secretary may ask for a copy of the informed consent form signed by the patient whenever the identity of the patient (face) is not masked.

8.1.2: Member secretary will go through (screening for documents to be submitted to IEC) the proposals which are exempted from review, AND get the decision ratified in the full committee meeting.

8.2: Expedited Review:-

8.2.1: The proposals that pose "no more than minimal risk" are considered for expedited review.
8.2.2: Expedited review will be conducted by Chairperson, member secretary and 1-2 designated members. The approval granted through expedited review will be ratified at the next full committee meeting.

8.2.3: Expedited review will be done in the following situations:

i) Minor deviations from originally approved protocols (originally approved through full review by the IEC).

ii) Revised proposal previously approved through full review or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis

iii) Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, left over clinical samples.

iv) Research involving clinical documentation materials which are non-identifiable (data, documents, records).

v) Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigator(s).

vi)Revised proposal previously approved through expedited review, full review or continuing review of approved proposals.

vii) Minor deviations from originally approved research causing no risk or minimal risk.

viii) Progress/annual reports where there is no additional risk e.g. activity limited to data analysis.

ix) When in emergency situations like serious outbreaks or disasters a full review is not possible, prior written permission may be taken before use of test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention. Same participants should not be included in the clinical trial that may be initiated based on the findings of the pilot study.

8.3: Full Review:-

8.3.1: All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review. It includes-

i) All studies involving interventions (clinical trials) involving trials on new drugs or combinations of drugs.

ii) Studies involving vulnerable population even if the risk is minimal.

iii) Collection of blood samples by finger prick, heel prick, ear prick or venipuncture.

iv) Collection of peritoneal fluid, pleural fluid, ascitic fluid and cerebrospinal fluid.

v) Collection of biological specimen by research purposes by non invasive means – skin appendages, dental procedures ,excreta and external secretions, stimulated or unstimulated saliva collection, placenta removed at delivery ,amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, buccal scrapings, skin swab or mouth washings, sputum.

vi)Use of medical devices for study population such as implants and physical sensors.

vii) Use of electrocardiography, electroencephalography, echocardiography, thermography, ultrasound and other imaging techniques, Doppler blood flow.

viii) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, body weight, and health of the individual.

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

IX) Collection of data from voice, video, digital or image recordings made for research purposes.
X) Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8.4: Aspects Considered During Review of Research Proposal:-

1) Scientific design and conduct of the study: Use of valid scientific methods

2) Social Values: The research must have anticipated social value, and outcome should be relevant to the health problems of the society.

3) Benefit-Risk Assessment: The benefits must justify the risk inherent in the research. Risks may be physical, psychological, economic, or social; Withdrawal criteria, and rescue medication or procedures.

4) Selection of the Study Population and Recruitment of Research Participants : To ensure voluntary recruitment, and fair selection of participants as per inclusion and exclusion criteria; participant is given option to opt out without the routine care being affected; No individuals or group of persons must bear the burdens of participation in research without any benefits except in studies where healthy volunteers are involved; Vulnerable group is not recruited unless proper justification is provided.

5) Payment of participation and Compensation Procedures, without inducement but, reimbursing for incurred cost and convenience.

6) Protection of research participant's privacy and confidentiality.

7) Community considerations : Due respect given to community and interests are protected ; no stigma or discrimination ensues from the proposed research ; plans for communication of results

back to the community at the end of study; plan for dissemination of benefits of research to the community.

8) Qualifications of investigators and assess adequacy of study sites.

9) Disclosure of potential conflicts of interest.

10) Review of informed consent process.

11) The review of proposals by members is documented in review forms, and in the minutes of meetings of the SMCEC.

SOP 9- Review of Research Proposals Involving Vulnerable Population

Purpose: To describes the requirements and process of review of research that involves vulnerable participants.

Scope: SOP covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the IEC.

Responsibility: It is the responsibility of the Member Secretary with Secretariat to maintain up to date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines. IEC Chairperson / Member Secretary are responsible for ensuring that IEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programs. The Member Secretary/ Chairperson is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research and for securing consulting expertise as and when required for selected reviews. IECis responsible for conducting review of research planned for vulnerable populations, including an assessment of potential for coercion. **Procedures:**

9.1: Definition of Vulnerable Population:-

9.1.1: Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent.

9.1.2: They are the individuals whose willingness to volunteer in research 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.

9.1.3: **Characteristics of vulnerable population:-**

a) Economically and socially disadvantaged and susceptible to being exploited-unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT) etc.

b) 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-tribal and marginalized communities, refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations.

c) Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions-Women in special situations (pregnant or lactating women, or those who have poor decision making powers/poor access to healthcare).

d) Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently– Children (upto18 years); unconscious, afflicted with mental illness, cognitively impaired individuals, mentally and physically disabled, terminally ill or are in search of new interventions having exhausted all therapies.

e) Suffering from stigmatizing or rare diseases or have diminished autonomy due to dependency or being under a hierarchical system-students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners.

9.2: Principles of reviewing protocols with vulnerable participants: -

9.2.1: Researchers must justify the inclusion of a vulnerable population in the research.

9.2.2: SMCEC must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.

9.2.3: SMCEC carefully determine the benefits and risks of the study and examine the risk minimization strategies.

9.2.4: Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.

9.2.5: Participants must be empowered to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

9.2.6: When potential participants lack the ability to consent, a LAR should be involved in decision making.

9.2.7: Researchers should be cognizant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.

9.2.8: Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.

9.2.9: The informed consent process should be well documented. Additional measures such as recording of assent and re-consent, when applicable, should be ensured.

9.2.10: As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.

9.2.11: Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants. Additional safety measures should be strictly reviewed and approved.

9.2.12: All stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

9.3: Duties/Obligations of stakeholders:-

Stakeholders	Duties/obligations
Researchers	1. Research should be conducted within the purview of existing relevant guidelines/regulations. 2. Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. 3. Justify inclusion/exclusion of vulnerable populations in the study. 4. Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. 5. Ensure that prospective participants are competent to give informed consent. 6. Take consent of the Legal Authority Representative(LAR) when a prospective participant lacks the capacity to consent. 7. Respect dissent from the participant. 8. COI issues must be addressed.
Ethical Committee	1. **Only the full committee do initial and continuing review of proposals on vulnerable population.** It is desirable to have empowered representatives from the specific populations during deliberations. 2. During review, determine whether the prospective participants for a particular research are vulnerable. 3. Examine whether inclusion/exclusion of the vulnerable population is justified. 4. Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible 5. More frequent reviews, monitoring including site visits should be done.

	6. Ensure that COI do not increase harm or lessen benefits to the participants. 7. Caution should be taken, when research is conducted on participants who are suffering from mental illness and/or cognitive impairment and require researchers to justify the study.
Sponsors	1. The sponsor- a government, an institution or a pharmaceutical company should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. 2. They must ensure protection of the participants and research team if the research is on sensitive topics. 3. They must enable monitoring and procedures are in place for quality assurance (QA) and quality control (QC).

9.4: Research among children:-

9.4.1: Children are individuals who have not attained the legal age of consent (up to 18 years).Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other means.

9.4.2: The EC should do the benefit–risk assessment. Research should be conducted in child-friendly settings, in the presence of parent(s) and where child participants can obtain adequate medical and psychological support.

9.4.3: Consent of the parent/LAR is required when research involves children.

9.4.4:Assent:A child's agreement to participate in research is called assent. The researcher explains the proposed research in a very simple manner, in a language that ensures, that the child understands the request to participate in the research.

9.4.5: Condition for assent:

1. No need to document assent for children below 7 years of age.

2. For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.

3. For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.

4. Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the EC.Ex: In behavioral studies in IV drug users, neglect or abuse of child, parental consent may not be possible.

9.4.6:If the child objects, this wish has to be respected. However, if the test intervention is likely to be lifesaving and is available only if the child participates in the study, the dissent by the child may be disregarded provided parental consent and prior approval from the EC is obtained.

9.4.7: Waiver of assent;

A. All the conditions that are applicable to waiver of informed consent in adults also apply for waiver of assent in children.

B. If the available intervention is anticipated to definitely benefit the child but would be available only if the child participates in the study, but all forms of assent/consent have failed. In such cases, approval of the EC should be obtained and prescribe an appropriate mechanism to safeguard the interests of the child.

9.5: **Consent of adults/LAR:**

9.5.1: Generally, consent from **one** parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child.

9.5.2: Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.

9.5.3: Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.

9.5.4: Whenever relevant, the protocol should include a parent/LAR information sheet along with participant information sheet, specifying relevant information about growth and development, psychological well-being and school attendance. The potential benefits and risks must be carefully explained to parents when Cognitively impaired children or children with developmental disorders are studied.

9.5.6: Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

9.6: Research involving women in special situations:-

9.6.1:Informed consent process for some women can be challenging because of cultural reasons. Although autonomy of the woman is important, the researcher must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community.

9.6.2: Researchers must provide the EC with proper justification for inclusion of pregnant and nursing women in clinical trials.

9.6.3: If women in the reproductive age are to be recruited, they should be informed of the potential risk to the foetus if they become pregnant.

9.6.4: A woman who becomes pregnant must not automatically be removed from the study when there is no evidence showing potential harm to the foetus. In case the woman opts for continued participation, researchers and sponsors must adequately monitor and offer support to the woman for as long as necessary.

9.6.5: research related to prenatal diagnostic techniques in pregnant women should be limited to detecting foetal abnormalities or genetic disorders as per the Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, amended in 2003 and not for sex determination of the foetus.

9.6.6: when research is planned on sensitive topics, ex: domestic violence, genetic disorders, rape, etc., confidentiality should be strictly maintained and privacy protected. The EC strictly vigilant regarding on issues whether information acquired from a woman participant be unnecessary, hurtful or appear voyeuristic.In risk mitigation strategies, appropriate support systems such as counselling centers, police protection, etc. should be established.

9.7: Research involving sexual minorities and sex workers:-

9.7.1: There are unique challenges associated with research on sexual minorities and sex workers such as privacy, confidentiality, possibility of stigma, discrimination and exploitation resulting in increased vulnerability.

9.7.2: A representative of specific community under research should be there as a special invitee during the process of review on the proposals by the SMCEC.

9.7.3: SMCEC suggests the researchers to educate and sensitizepeer educators and to set up community advisory board first.They would in turn explain the details to the potential participants from the community who would then understand them better.

9.8: Research among tribal population:-

9.8.1:Research on tribal populations should be conducted only if it is of a specific therapeutic, diagnostic and preventive nature with appropriate benefits to the tribal population.

9.8.2: Due approval from competent administrative authorities, like the tribal welfare commissioner or district collector,the tribal leader, other culturally appropriate authority or the person socially acceptable to the community may serve as the gatekeeper should be taken.

9.8.3: Informed consent should be taken from individual participant,in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses.

9.8.4:Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialization.

SOP 10: Training for new and existing committee members

Purpose: The purpose of this SOP is to describe requirements and methodology for training new and existing committee members.

Scope: This SOP applies to all the SMCEC members and the SMCEC secretariat.

Responsibilities: It is the responsibility of the SMCEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the SMCEC members and the secretariat.

Procedure:

10.1: Topics for training

10.1.1: Relevant research ethics and regulatory guidelines

10.1.2: Roles and Responsibilities of SMCEC members

10.3.3: Review of protocol and related documents, including concepts of risk benefit assessment, autonomy, confidentiality, beneficence, non-maleficence and justice to safeguard the dignity, rights, safety and well-being of the human participants involved in biomedical and health research.

10.3.4: Recent developments in relevant health science specialties.

10.3.5: SOPs of the SMCEC.

10.2: Secretariat should have knowledge and relevant skills for conducting the following activities:

10.2.1: Guidelines for submission of research proposals.

10.2.2: Good communication skills – oral and written.

10.2.3: Maintenance of SMCEC records – both soft and hard copy.

10.3: Induction Training of new SMCEC Members

10.3.1: Every time a new committee is constituted, the members must undergo initial training within three months on ethics in clinical research and good clinical research and SOPs.

10.3.2 : An individual selected as a new member of the SMCEC will be required to attend one meeting as an 'Observer' before being inducted as a member of the SMCEC.

10.3.3: The Member Secretary will provide an introductory training to the new member. The member during the observer period will not have voting rights, but will have to sign letter of confidentiality.

10.3.4: Appointment of observer as member would be on discretion of Chairperson in consultation with members, following which the appointment letter would be issued to the member.

10.3.5: The newly inducted member will be encouraged to undergo training on good clinical practice, bioethics and guidelines on clinical research.

10.3.6: The authorities of FMMC may sponsor the member for such trainings.

10.4:Training for new members:-

10.4.1: The new member will receive trainings from Chairperson or Member Secretary on the above topics.

10.4.2: An expert from clinical research, bioethics or GCP will be invited to SMCEC to give training

10.4.3: The in- house training sessions of SMCEC will have pre test and post test to assess the effectiveness of trainings.

10.4.4: The Member Secretary and the Chairperson will orient all the members on the SOP of the SMCEC.

10.5: Training to existing committee members: -

10.5.1: Chairperson ,member Secretary and members will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year. The authorities of SIMS &RH may sponsor the members for such trainings.

10.5.2: The Member Secretary of SMCEC in consultation with the Chairperson prepares an annual training schedule, and will conduct trainings or workshops on good clinical practice, bioethics, relevant guidelines on clinical research and other relevant topics.

10.5.3: The resource persons for such trainings could be a member of SMCEC, or an external GCP trained personnel or a bioethics expert. The trainings is imparted not only to the SMCEC members but, also to the institutional faculty who are investigators of ongoing research studies or potential investigators.

10.6: Training of the Secretariat: -

10.6.1: The SMCEC Member Secretary along with other members will train the Secretariat.
10.6.2: There will be initial training and at least one training session per year on.

10.6.3: The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

10.7: Maintenance of training records: -

10.7.1: The secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual SMCEC members.

10.7.2: The copies will be filed in the individual members' files. The records regarding training copies of the secretariat will also be maintained in their respective files.

SOP 11-Informed consent Process

Purpose: An informed consent document (ICD) from each participant is essential to protect each individual's freedom of choice. This SOP explains the protocol of taking Informed consent from the participants involved in research.

Scope: The SOP explains the method of maintaining voluntary written informed consent document by the researcher which should contain both participant information sheet and informed consent form.

Responsibility: The researcher has to collect the ICD as per the standard protocol prescribed by SMCEC. During the review, ICD format prepared by the researcher should be submitted during the initial review by the SMCEC.

Process:

11.1:Informed consent is a continuous process involving three main components:

- Providing relevant information to potential participants
- Ensuring competence and comprehension of the information
- Voluntariness of participation

11.2: Researchers should only use the EC approved version of the consent form and its translation in local languages.

11.3: Informed consent should be voluntary and be signed by the participant after receiving information, understanding it and discussing with family/friends (if required).

11.4: Verbal/oral consent/waiver of consent/re-consent may be obtained only after approval by the EC.

11.5: Individual consent is important and required, even if the community gives permission for participation in a research study.

11.6: Electronic/online consent may be obtained for research involving sensitive topics while safeguarding information and data and also if required for regulatory clinical trials.

11.7: In case of research involving children, in addition to parental consent, verbal (7-12 years) or simplified written (>12 – 18 years) assent should also be taken from the participant.

11.8: TheLAR's consent is required in case a participant is incompetent (medically or legally).

11.9: SMCEC should carefully study the research where deception is being used

11.10: Conditions for waiver of consent:

1. Research cannot practically be carried out without the waiver and the waiver is scientifically justified
2. Retrospective studies, where the participants are de-identified or cannot be contacted
3. Research on anonymized biological samples/data
4. Certain types of public health studies/surveillance programs/program evaluation studies
5. Research on data available in the public domain
6. Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

ANNEXURES

Annexure 1: Appointment Proposal Letter

To:

Dr./Mr/Ms. ----------

Address: ----------

Sub: Constitution of SMCEC

Dear Sir /Madam,

I acknowledge your services and contribution to SIMS &RH. I request you to the member/Member Secretary/Chairperson of SMCEC for the next five years, effective from ---------- ----------. A detailed appointment letter will be issued once I receive acceptance letter from you. I request you to submit your recently updated, signed CV along with certificates of training on GCP, Bioethics and guidelines on biomedical and health science research.

With Regards,

Director, SIMS & RH

Annexure 2: Acceptance of appointment as a member of SMCEC

To:

The Director,
SIMS &RH
Tumkur

Dear Sir,

Sub: Acceptance of Appointment as a Member of SMCEC

Ref : Your Proposal Letter No. ----------, Dated. ---------- I am thankful to you for appointing me as a member of SMCEC with effect from ----------. I herewith accept my appointment. I am ready to undergo regular training on good clinical practice, ethical guidelines on biomedical and health science research and bioethics as required. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain the entire research project related information confidential. I shall sign the confidentiality agreement, and shall declare conflict of interest if any as and when applicable I am submitting my recently updated, signed CV and certificates of training as requested by you.

Thanking You,

Yours Sincerely,

Signature :

Name :

Designation and Department/Affiliations:

Date : Place :

Annexure 3: Appointment letter for chairperson

Shridevi Medical College Ethics Committee(SMCEC)

Date: ---------

To:

Sub: Appointment as Chairperson of SMCEC

Dear Sir/Madam,

I am pleased to appoint you as the Chairperson of SMCEC with effect from ----------. You will have tenure of five years from this date. As head of the institution, I assure you that SMCEC will be provided with all required infrastructure and facilities required for its effective functioning. The ethics committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution. You will be receiving an honorarium of Rs. --------- per sitting for the services rendered by you. Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of SMCEC.

Congratulations and all the best.

With Regards,

Director, SIMS &RH,Tumkur.

Terms and Conditions of Appointment

Roles and Responsibilities of Chairperson, SMCEC

1) As Chairperson of SMCEC, you shall conduct the meetings of SMCEC and ensure active participation of all members in the discussions and deliberations.

2) You are required to verify and approve the SOP of SMCEC in co ordination with the Member Secretary.

3) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the SMCEC.

4) You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain.

5) Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings.

6) To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and review and final decision making of research proposals.

7) You shall seek conflict of interest from members and ensure quorum and fair decision making.

8) You are the authorized and responsible for handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data.

9) You are the authority and responsible for approving the minutes of meetings.

10) You are the authority and responsible to review serious adverse events and take appropriate action as per guidelines .

11) You are the authority of SMCEC to discuss with members and recommend to the Director, SIMS & RH and the disqualification of members (if required) before the completion of their term.

12) You need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to lead the IEC team for onsite monitoring visits.

13) You shall not keep any literature or study related documents with you after the discussion and final review.

14) Be willing to undergo training or update programs on relevant guidelines and regulations, research ethics, and good clinical practice during your tenure in the SMCEC.

15) As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.

16) One month notice on either side will be necessary prior to resignation/termination of appointment.

17) You will be responsible for making any communications on behalf of the SMCEC to CDSCO and any other regulatory bodies. The Details of the roles and responsibilities of chairperson of SMCEC are mentioned in the policies and standard operating procedures of SMCEC.

Director, SIMS &RH

Annexure 4 Appointment letter as member secretary

Shridevi Medical College Ethics Committee (SMCEC)

Date: ---------

To :

Sub: Appointment as Member Secretary of SMCEC

Dear Sir/Madam,

I am pleased to appoint you as the Member Secretary of SMCEC with effect from ----------. You will have tenure of five years from this date. As head of the institution, I assure you that SMCEC will be provided with all required infrastructure and facilities required for its effective functioning. The ethics committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution. Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of SMCEC.

Congratulations and all the best.

With Regards,

Director, SIMS&RH

Terms and Conditions of Appointment

Roles and Responsibilities of Member Secretary, SMCEC

1) As Member Secretary, you are required to organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review; scheduling the meetings, preparing the agenda and minutes of meetings.

2) You are authorized and responsible to assess the need for exemption from review, expedited review or full review.

3) You are authorized to issue ethical approval letters, after approval from the committee.

4) You are required to do the needful for the revision of SOP of SMCEC in co ordination with the Chairperson.

5) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the SMCEC.

6) You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain.

7) Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings.

8) To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and review and final decision making of research proposals.

9) To organize IEC documentation, communication and archival 10) To arrange for training of IEC secretariat and members.

11) To ensure adherence of IEC functioning as per SOPs.

12) To prepare for and respond to audits and inspections.

13) You will be responsible for making communications on behalf of SMCEC, to investigators, members of SMCEC, sponsors and Head of the Institution.

14) You need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to participate in onsite monitoring visits.

15) You shall not keep any literature or study related documents with you after the discussion and final review.

16) Willing to undergo training or update programs on relevant guidelines and regulations, research ethics, and good clinical practice during your tenure in the SMCEC.

17) As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.

18) One month notice on either side will be necessary prior to resignation/termination of appointment. The Details of the roles and responsibilities of Member Secretary of SMCEC are mentioned in the policies and standard operating procedures of SMCEC.

Director, SIMS &RH

Annexure 5: Appointment letter as member

Shridevi Medical College Ethics Committee (SMCEC)

Date: ----------

To: ----------

Sub: Appointment as a Member of SMCEC

Category: Clinician/ Basic Medical Scientist/Lay Person/Social Scientist/Theologian/Legal Expert

Dear Sir/ Madam,

I am pleased to appoint you as a member of Shridevi Medical College Ethics Committee with effect from --------- ---. You will have tenure of five years from this date. You will be receiving an honorarium of Rs. ---------- per sitting for the services rendered by you. I request you to kindly extend your co-operation to the Chairperson and Member Secretary of SMCEC, in effective and efficient functioning. Please find the enclosed terms and conditions of your appointment, roles and responsibilities of Member and Chairperson. You will be issued a copy of the policies and standard operating procedures of SMCEC once you sign the consent letter and confidentiality agreement. You will have the voting rights in the IEC only after you receive the initial training on policies and standard operating procedures.

Congratulations and all the best.

With Regards,

Director, SIMS &RH

Terms and Conditions of Appointment,

Roles and Responsibilities of Member, SMCEC

1) As a member of SMCEC you need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to participate in onsite monitoring visits and review of serious adverse events as and when required. You are required to attend regular as well as emergency meetings of SMCEC. You are expected to participate actively in all discussions and deliberations of SMCEC.

2) You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the SMCEC.

3) You should be willing to place your full name, profession and affiliation to the ethics committee in the public.

4) Be willing to sign a confidentiality agreement, and to maintain confidentiality of the documents and deliberations of ethics committee meetings.

5) To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and review and final decision making of research proposals.

6) You shall not keep any literature or study related documents with you after the discussion and final review.

7) Be willing to undergo training or update programs on relevant guidelines and regulations, research ethics and good clinical practice during the tenure as ethics committee member.

8) As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.

9) One month notice on either side will be necessary prior to resignation/termination of appointment. The Details of the roles and responsibilities of a member of SMCEC are mentioned in the policies and standard operating procedures of SMCEC.

Director, SIMS &RH

Annexure 6: Consent Letter from Appointed Members

To:

Director,

SIMS & RH

Sub : Consent to be the Chairperson/Vice Chairperson/Member Secretary/Member of Shridevi Medical College ethics Committee.

Ref : Your letter No.----------; Dated ----------

Respected Sir,

In response to your letter, I give my consent to be the Chairperson/Member Secretary/Member of Shridevi Medical College Ethics Committee. I shall execute my roles and responsibilities as per the policies and standard operating procedures of SMCEC, and as mentioned in my appointment order. I shall maintain high ethical standards, and will not be unduly influenced in discharging my assigned work. I will sign the confidentiality agreement during my induction. I am aware of the conflict of interest policy of SMCEC, and I will declare conflict of interest (if any) during my induction as a member, review of research proposals and decision making in SMCEC.

Thanking You,

Yours Sincerely,

Signature :

Name :

Designation and Department/Affiliations:

Date :

Place :

Annexure 7: Confidentiality agreement to be signed by member of SMCEC

Name of the Member : Designation in SMCEC :

I have been appointed as a member of the SMCEC 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 standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines. The appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative neither of a home province, territory or community nor as a delegate of any organization. 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 and the undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate. This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the SMCEC. All Confidential information (and any copies and notes thereof) shall remain the sole property of the SMCEC. The undersigned agrees to hold all confidential 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. I have read and accept the aforementioned conditions as explained in this Agreement.

I acknowledge that I have received a copy of this agreement signed by the SMCEC chairperson and me.

Signature of the Member, with Date:

Chairperson's Signature and Date:

Annexure 8: Confidentiality agreement to be signed by secretariat staff of SMCEC

I, _____ (Staff's name and designation) herein referred to as the "undersigned", have been appointed as a staff of the IEC office. This agreement encompasses any information deemed confidential provided to the Undersigned in conjunction with the duties as a staff of the IEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the IEC. The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him or her during his tenure of service. I, _____ (name of the IEC office staff) have read and I accept the conditions as explained in this Agreement.

I confirm that I have received a copy of the confidentiality agreement signed by the Chairperson of SMCEC.

Name of the Member : Chairperson's Signature:

Signature :Date:

Date:

[The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to the Undersigned.]

Annexure 9: Conflict of Interest Declaration Form

To:

Chairperson

SMCEC

Dear Sir,

I am aware of the COI policy of SMCEC. I herewith declare my conflict of interest with regard to the following research proposal submitted to SMCEC for review.

Protocol No.

Study Title:

Name of Principal Investigator:

Type of COI (Personal/ Professional/Financial) and the Reason:

Hence, I stay away from reviewing this research proposal, any deliberations/discussions on this study, and refrain from any decision making.

Name and Signature of Member:

Date:

Name and Signature of Chairperson :

Date :

Annexure 10: Informed consent document(ICD)

Format for Participant Information Sheet and Informed Consent Form

Title of the Study :

Names of Researchers/Investigators:

Name of Organization :

Name of Sponsor (Grant agency):

Name of Project and Version:

Informed Consent Form has two parts: □

1. Information Sheet (to share information about the study with you) □

2. Certificate of Consent (for signatures if you agree to participate)

The participant information sheet should contain the following headings:

1. **Introduction:** Briefly state who you are and explain that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable about the research and that they can take time to reflect on whether they want to participate or not. Assure them that if they do not understand some of the words or concepts, they may ask questions now or later .

2. **Purpose**: Explain in**simple lay terms** why the research is being done and what is expected from the results. Explain why you need to conduct the research.

3. **Type of research intervention**: Briefly state the intervention.

4. **Selection of Participants**: State clearly why you have chosen them to participate in this study.

5. **Voluntary Participation:** Indicate clearly that they can choose to participate or not and reassure they will still receive all the services they usually do if they choose not to participate.. It is important to state clearly at the beginning of the form that **participation is voluntary** so that

the other information can be heard in this context. Participants may also be more alert at the beginning.

6. **Procedure:** Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

7. **Duration:** Include a statement about the time commitments of the study for them. Include both the duration of the study and follow-up.

8. **Explain:** Any risks or discomforts including any limits to confidentiality.

9. **Benefits:** Describe any benefits to them, to the community, or any benefits which are expected in the future as a result of the research.

10. **Reimbursements:** State clearly what you will provide the participants with as a result of their participation. You will not be entitled to any compensation beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost..

11. **Confidentiality:** Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

12. **Sharing of research findings:** Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details.

13. **Right to refuse or withdraw:** Explain again the voluntary nature of consent.

14. **Contact number and address of the researcher(s):**

15. **Mention** –This research project is reviewed and approved by Shridevi Medical College Ethics Committee. This is a committee whose task it is to make sure that research participants are protected from harm.

16. **Contact details of ethics committee:**

INFORMED CONSENT

I have read and understood the information/ it has been read to me and explained in an understandable language about the research project : ----------(title). I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant: _____

Signature of Participant: _____

Date: _____

If illiterate:

{A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.}

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____**AND** Thumb print of participant

Signature of witness: _____

Date: _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICD has been provided to the participant.

Name of Researcher/person taking the consent: _____

Signature of Researcher /person taking the consent:_____

Date: _____

Annexure 11: Informed Assent document for children(12-18 years age)

Names of principal investigator:

Name of Organization :

Name of Sponsor (Grant agency):

Name of Project and Version:

Informed Consent Form has two parts: □

1. Information Sheet (to share information about the study) □

2.Certificate of Consent (for signatures if agree to participate)

The participant information sheet should contain the following headings:

1. **Introduction:** Briefly state who you are and explain that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable about the research and that they can take time to reflect on whether they want to participate or not. Assure them that if they do not understand some of the words or concepts, they may ask questions now or later .

2. **Purpose**: Explain in**simple lay terms** why the research is being done and what is expected from the results. Explain why you need to conduct the research.

3. **Type of research intervention**: Briefly state the intervention.

4. **Selection of Participants**: State clearly why you have chosen them to participate in this study.

5. **Voluntary Participation:** Indicate clearly that they can choose to participate or not and reassure they will still receive all the services they usually do if they choose not to participate.. It is important to state clearly at the beginning of the form that **participation is voluntary** so that the other information can be heard in this context. Participants may also be more alert at the beginning.

6. **Procedure:** Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

7. **Duration:** Include a statement about the time commitments of the study for them. Include both the duration of the study and follow-up.

8. **Risks & discomfort:**If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

9. **Explain:** Any risks or discomforts including any limits to confidentiality.

10. **Benefits:** Describe any benefits to them, to the community, or any benefits which are expected in the future as a result of the research.

11. **Reimbursements:** State clearly what you will provide the participants with as a result of their participation. You will not be entitled to any compensation beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost..

12. **Confidentiality:** Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

13. **Sharing of research findings:** Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details.

14. **Right to refuse or withdraw:** Explain again the voluntary nature of consent.

15. Contact number and address of the researcher(s):

16. **Mention** –This research project is reviewed and approved by Shridevi Medical College Ethics Committee. This is a committee whose task it is to make sure that research participants are protected from harm.

17. **Contact details of ethics committee:**

INFORMED CONSENT

I have read and understood the information/ it has been read to me and explained in an understandable language about the research project : ----------(title). I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant: _____

Signature of Participant: _____

Date: _____

If illiterate:

{A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.}

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____ **AND** Thumb print of participant

Signature of witness: _____

Date: _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICD has been provided to the participant.

Name of Researcher/person taking the consent: _____

Signature of Researcher /person taking the consent:_____

Date: _____

Certificate of assent

Only if child assents.

I have read and understood the information/ it has been read to me and explained in an understandable language about the research project : ----------(title). I have had my questions answered and know that I can ask questions later if I have them. I agree to take part in the research. OR

If the child don't assent .

I do not wish to take part in the research and I have not signed the assent below._____(initialled by child/minor)

Name of child _____

Signature of child: _____

Date:_____

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness (not a parent):_____AND Thumbprint of participant

Signature of witness _____

Date _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

A copy of this assent form has been provided to the participant.

Name of researcher:_____

Signature of researcher: _____

Date:_____

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)

Informed parental consent form for research in children

Name of Principal Investigator :

Name of Organization :

Name of Sponsor :

Name of Proposal and version :

Informed Consent Form has two parts: Information Sheet and Certificate of Consent.

Part 1: In information sheet the information given to the parents should be described under the following headings:

1. **Introduction**: Briefly state who you are. and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them and they can ask questions now or later.

2. **Purpose**: Explain the problem/research question in lay terms which will clarify rather than confuse. Use clear,understandable, local and simplified terms for explanation. Recognize that parents' feelings about involving their children in research can be complicated.Give parents time to reflect on whether they will consent to have their child participate.

3. **Type of Research Intervention**: Briefly state the intervention if you have not already done so. 4. **Participant selection**:State clearly why you have chosen their child to participate in this study. Include a brief statement on why children, rather than adults, are being studied.

5.**Voluntary Participation**: It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.Indicate

clearly that they can choose to have their child participate or not and they will still receive all the services they usually do if they decide not to participate.

6.Procedure: Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

7.Duration: Include a statement about the time commitments of the study for them. Include both the duration of the study and follow-up.

8.Risks & discomfort: If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

9.Explain: Any risks or discomforts including any limits to confidentiality.

10.Benefits: Describe any benefits to them, to the community, or any benefits which are expected in the future as a result of the research.

11.Reimbursements: State clearly what you will provide the participants with as a result of their participation. You will not be entitled to any compensation beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost..

12.Confidentiality: Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

13.Sharing of research findings: Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details.

14.Right to refuse or withdraw: Explain again the voluntary nature of consent.

15.Contact number and address of the researcher(s):

16.Mention –This research project is reviewed and approved by Shridevi Medical College Ethics Committee. This is a committee whose task it is to make sure that research participants are protected from harm.

17.Contact details of ethics committee:

Part II: Consent form:

I have been invited to have my child participate in research of a new malaria vaccine. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Name of Participant: _____

Name of Parent or Guardian: _____

Signature of Parent or Guardian: _____

Date: _____

<u>If illiterate,</u>

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness:_____AND Thumb print of parent

Signature of witness: _____

Date: _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understood the things. I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent:____

Signature of Researcher /person taking the consent:_____

Date: _____

Annexure 12: Informed Consent For Case Reports

I , ----------(name of the patient/bystander of the patient/ parents or guardians of the patient) herewith give my consent to use the data/case details/photographs/ other details of the case ---------- ----------(clinical condition/disease) of mine /my child / my ----------(mention how the patient is related to you), for presentation or publication. The intended use of the case/data of mine is explained to me clearly, and I am aware that my name (my child's name) /personal identity will not be revealed in the presentations or publications. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction and I have voluntarily given my consent to the same.

Name of Patient/ Participant_____

Name of Parent or Guardian (as applicable):_____

Signature of patient/ participant/ bystander (or Parent/ Guardian as applicable):_____

Date: _____

If illiterate,

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well. I have witnessed the accurate reading of the consent form of the patient/ (include other categories of persons here from whomsoever the consent is proposed to be obtained) of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness:_____Thumb print of patient

Signature of witness: _____

Date: _____

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the parent / (include other categories of persons here from whomsoever the consent is proposed to be obtained) of the potential participant, and to the best of my ability made sure that the person understands procedures will be done. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by him/her been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent:_____

Signature of Researcher /person taking the consent:_____

Date: _____

Annexure 13: Definition of Risk (as per Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, 2017)

Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minor Increase Over Minimal Risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes

	indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
More than minimal risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

Annexure 14: Agenda format Meeting No. :

Date and Time of Meeting:

Venue of Meeting:

I. Ratification of the minutes of previous meeting:

II. List of Research proposals for full review:

III. List of proposals for expedited reviews

IV. List of proposals exempted from review

V. Protocol deviations/amendments

VI. Study completion /progress reports

VII. Reports of onsite monitoring

VIII. Reports of subcommittees

IX. Any other issues

Annexure-8.2: Format for Minutes of meeting:

Meeting No:

Date and Time:

Venue:

I. Members present and absent : list with designations

II. Guests or observers present : list with designations

III. Name of the individual who served as Chairperson

IV. Ensuring of quorum by the Chairperson

V. Ratification of the minutes of the previous meeting

VI. Research proposals for full review : The proceedings are recorded as follows ---

Protocol no.	Title of the study	Name of the PI	Remarks by members(opinion/suggestion/other remarks)	Approval status

VII. Research proposals for expedited review : The proceedings are recorded as follows ---

Protocol no.	Title of the study	Name of the PI	Members present during review with their remarks	Approval status

VIII. Research proposals for exemption from review : The proceedings are recorded as follows

Protocol no.	Title of the study	Name of the PI	New/revised submission	Approval status

IX. Discussion of Protocol Deviations/amendments and actions taken :

Protocol no.	Title of the study	Name of the PI	Protocol deviation/amendment	Approval status

IX. Discussion of reports of onsite monitoring

Protocol no.	Title of the study	Name of the PI	Deficiency observed during onsite monitoring	Approval status

X. Discussion of Progress Reports and Study Completion Reports :

Protocol no.	Title of the study	Name of the PI	Remarks on the submitted report	Approval status

Annexure 15: Decision letter

Shridevi Institute of Medical Sciences
& Research Hospital, Sira Road, Tumkur – 572106

Ref No: SIMSRH/IEC/2022-23/..... Date: .....

To,
Dr./Mr/Mrs. .....
Principal Investigator
Department of .....
Shridevi Institute of Medical Sciences & Research Hospital
Tumkur

Sub: Approval of Research project proposal by IEC

Your research project proposal entitled "....." has been done initial reviewed by Shridevi Medical College Ethics Committee and has taken the following decision.

a. Approved
b. Revision with minor modifications
c. Revision with major modifications for resubmission
d. Not approved

You can commence/cannot commence your work on your research project proposal with the following conditions:

1. Any other changes in methodology, Extension of Time, Changes in synopsis should be intimated and get the approval for the same.
2. It is mandatory that a half yearly interim review report of the status of the project to be submitted to IEC
3. On completion of the above Research project the Principal investigator is responsible for submitting a brief summary of the results obtained to the Member Secretary of IEC.
4. The publication format of your project must be sent to the IEC before sending it for publication.

Member Secretary

SMCEC

TUMKUR 572106.

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee(SMCEC)
Tumkur-572106

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

ADMINISTRATIVE DETAILS : Date of submission: [ ][ ] [ ][ ] [ ][ ]

1. Name of Principal Investigator: ---------

2. Department/Division:--------

3. Type of review requested[1]:

Exemption from review☐ Expedited review☐ Full committee review☐

4. Title of the study: .....

5. Acronym/ Short title, (If any): .....

6. Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

7. Duration of the study: .....

[1] Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review
[2] Include telephone/mobile, fax numbers and email id

8. Funding details and budget:

(a) Total estimated budget: ----------

(b) Funding method: Self-funding☐ Institutional funding☐ Funding agency (Specify)☐

SHRIDEVI INSTITUTE OF MEDICAL SCIENCES & RESEARCH HOSPITAL TUMKUR 572106

(c) If funding by agency, Specify the details:.....

SECTION B - RESEARCH RELATED INFORMATION

1. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words):

(b) Type of study:(click on the type of your study)

Basic Sciences ☐	Clinical☐	Cross Sectional☐
Retrospective☐	Epidemiological☐	Case Control☐
Prospective☐	Public Health☐	Cohort ☐
Qualitative☐	Socio-behavioural☐	Systematic Review☐
Quantitative☐	Biological samples/ Data☐	
Mixed Method☐	Any others *(Specify)*	

2. Methodology:

(a) Sample size/ number of participants (as applicable): --------

(b) Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation: (Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.)

(c) Any
External laboratory/outsourcing involved for investigations?[4] Yes☐ No☐ NA ☐

(d) Comments of scientific committee:

3. Type of participants in the study:

1.Healthy volunteers☐ 2. Patients☐ 3.Vulnerable persons/ Special groups ☑

4. Others *(Specify)*☐ .....

4. If vulnerable groups are involved, specify the type:

a. Children under 18 yrs age ☐ b. Pregnant or lactating women☐ c.Differently abled (Mental/Physical/both) ☐

d. Institutionalized employees/Students/Nurses/Staff/ Elderly☐

e. Economically and socially disadvantaged -Refugees/Migrants/Homeless☐

f.Terminally ill (stigmatized or rare diseases) ☐

g. Any other *(Specify)*☐:.....

5. Provide justification for inclusion/exclusion .....

6. Are there any additional safeguards to protect research participants?Yes☐ No☐

7. If yes, specify:.....

8. Is there any reimbursement to the participants?Yes☐ No☐

If yes, Monetary☐ Non-monetary☐ *Provide details*☐

.....

.....

(a) Are there any incentives to the participants?Yes ☐ No☐

If yes, Monetary ☐ Non-monetary☐ *Provide details*

.....

.....

(b) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

Yes ☐ No☐

If yes, Monetary☐ Non-monetary☐ *Provide details*

.....

.....

9. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants?

Yes ☐ No ☑

If yes, categorize the level of risk[5] :

Less than Minimal risk☐ Minimal risk☐

Minor increase over minimal risk or low risk☐ More than minimal risk or high risk☐

ii. Describe the risk management strategy: .....

....

(b) What are the potential benefits from the study?For the

	Yes	No	If yes,	Direct	Indirect
participant	☐	☐		☐	☐
For the society/community/	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐
	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

(c) Are adverse events expected in the study[6] ?Yes☐ No ☐ NA☐

(d)Are reporting procedures and management strategies described in the study?

Yes ☐ No☐ If Yes,
Specify .....

10. INFORMED CONSENT

(a) Are you seeking waiver of consent?Yes☐ No ☐ If yes, please specify reasons and skip to item no. 8

.....

.....

.....

.....

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(b) Version number and date of Participant Information Sheet (PIS):.....

Version number and date of Informed Consent Form (ICF):.....

(c) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent☐ Audio-Video (AV) consent☐

For children<7 yrs parental/LARconsent☐ Verbal assent fromminor (7-12 yrs) along with parental consent☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Consent from LAR☐ (If so, specify from whom).....

Other *(specify)* .....

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff☐ Other*(Specify)* ☐ .....

Any tools to be used .....

.....

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English☐ Local language☐

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

.....

.....

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language

Risks and discomforts

Alternatives to participation

Right to withdraw

Benefits

Purpose and procedure

Others(Specify)

Data/ Sample sharing

Need to recontact

Confidentiality

Storage of samples

Return of research results

Payment for participation

Compensation for study related injury

Statement that consent is voluntary

Commercialization/ Benefit sharing

Statement that study involves research

Use of photographs/ Identifying data

Contact information of PI and Member Secretary of EC

.....

.....

11. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

PI☐ Institution☐ Sponsor☐ Other agencies*(specify)*☐

.....

(b) Is there a provision for free treatment of research related injuries?Yes ☐ No☐ N/A☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE?Yes ☐ No☐ N/A☐

If yes, specify.

Sponsor☐ Institutional/Corpus fund☐ Project grant☐ Insurance☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? Yes ☐ No☐ N/A☐

If yes, specify.

.....

.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? Yes ☐ No☐ N/A☐

(f) If yes, please specify.

Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants2017, Page 54 in Section 5.8.
Enclose undertaking from PI confirming the same

12. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. Yes ☐ No☐ N/A☐

If Yes, specify

Anonymous/Unidentified ☐ Anonymized: Reversibly coded☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

.....

(b) Who will be maintaining the data pertaining to the study? .....

(c) Where will the data be analyzed? and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies?Yes☐ No☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?.....

.....

.....

SECTION D: OTHER ISSUES

13. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? Yes☐ No☐ NA☐ If yes, specify.

.....

.....

.....

.....

(b) Will you inform participants about the results of the study?Yes☐ No☐ NA☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? Yes☐ No☐ NA☐ If yes, describe in brief (Max 50 words)

.....

.....

.....

.....

(d) Is there any plan for post research benefit sharing with participants? Yes☐ No☐ NA ☐ . If yes, *specify*

.....

.....

(e) Is there any commercial value or a plan to patent/IPR issues? Yes☐ No☐ NA ☐ . If yes, please provide details

.....

.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere inthe form? Yes☐ No☐ If yes, provide details.

.....

.....

For example, a data entry room, a processed computer etc.

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
	I/We certify that the information provided in this application is complete and correct.
	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guide-lines.
	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and itsRules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions wherethis study will be conducted.
	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere tothe provisions of the EC approved protocol.
	I/We declare that the expenditure in case of injury related to the study will be taken care of.
	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviationsfrom protocols, progress reports and a final report and also participate in any audit of the study if needed.
	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict ofinterest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
	I/We have the following conflict of interest (PI/Co-I): 1. .... 2. ....
	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherev-er applicable.

Name of PI: .....

Signature: .....

Name of Co-PI: .....

Signature: .....

Name of Guide: .....

Signature: .....

Name of HOD: .....

Signature: .....

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter					
2	Brief CV of all Investigators					
3	Good Clinical Practice (GCP) training of investigators in last 3 years					
4	Approval of scientific committee					
5	EC clearance of other centers*					
6	Agreement between collaborating partners*					
7	MTA between collaborating partners*					
8	Insurance policy/certificate					
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification					
10	Copy of contract or agreement signed with the sponsor or donor agency					
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol					
PROPOSAL RELATED						
12	Copy of the detailed protocol[1]					
13	Investigators Brochure (If applicable for drug/biologicals/device trials)					
14	Participant Information Sheet (PIS) and Participant Informed ConsentForm (ICF)(English and translated)					
15	Assent form for minors (12-18 years) (English and Translated)					
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated)					
17	Advertisement/material to recruit participants (fliers, posters etc)					

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	CTRI					
19	DCGI					
20	HMSC					
21	NAC-SCRT					
22	ICSCR					
23	RCGM					
24	GEAC					
25	BARC					
26	Tribal Board					
27	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28						
29						

*For multicentre research.
MTA-Material transfer agreement, CTRI-Clinical Trial Registry-India, DCGI-Drug Controller General of India, HMSC- Health Ministry's Screening Committee, NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy, IC-SCR-Institutional committee for Stem Cell Research, RCGM-Review Com- mittee on Genetic Manipulation, GEAC- Genetic Engineering

Approval Committee, BARC - Bhabha Atomic Research Centre
[1]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

Application Form for Expedited Review

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why expedited review from EC is requested[12] ?
   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   ix. Any other (please specify) .....

   .....

2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[13] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

   .....

Signature of PI: ..... dd | mmm | yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd | mmm | yy

[□] Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2
[11] For details, refer to application for initial review, Section-C, 5(b)
* In case this is first submission, leave it blank

Application Form for Exemption from Review

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why exemption from ethics review is requested[14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[*] ☐
   - vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: .....

Comments of EC Secretariat: .....

Signature of Member Secretary: .....

[*]*Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[13]Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)

Continuing Review / Annual report format

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: dd mm yy — Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy — Proposed date of Completion: dd mm yy
   Period of Continuing Report: ---- to ------
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status - ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA☐

   (d) Any other remark.....

   .....

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐

   If yes, total number withdrawn and reasons: .....

   .....

   .....

4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

   .....

   .....

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐

   If yes, when / how: .....

   .....

   .....

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered*


TUMKUR
572109

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details: .....

.....

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's : ..... Type of SAE's: .....

.....

.....

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

.....

.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

.....

.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

.....

.....

Any other comments: .....

.....

Signature of PI: .....

Application/Notification form for Amendments

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [18]

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

[#]Location implies page number in the ICD/protocol where the amendment is proposed.

dd	mm	yy

Protocol Violation/Deviation Reporting Form (Reporting by case)

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval [dd][mm][yy] Date of start of study [dd][mm][yy]
2. Participant ID:..... Date of occurrence [dd][mm][yy]
3. Total number of deviations /violations reported till date in the study: .....
4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐
   SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others *(specify)*	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation: .....

.....

.....

.....

7. Corrective action taken by PI/Co-I: .....

.....

.....

.....

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

If yes, give details.....

.....

Signature of PI: ..... [dd][mm][yy]

SHRIDEVI INSTITUTE OF MEDICAL SCIENCES & RESEARCH HOSPITAL TUMKUR 572106

Serious Adverse Event Reporting Format (Biomedical Health Research)

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and ID	Age at the time of event	Gender	
.....	.....	Male ☐ Female ☐	Weight:.....(Kgs)
.....	.....		Height:.....(cms)

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event *:

.....

.....

.....

.....

.....

.....

.....

4. Details of suspected intervention causing SAE *

.....

.....

.....

.....

.....

.....

5. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

.....

.....

*Duration, setting, site, signs, symptoms, severity, criteria for regarding the event as serious

[#]Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

(Please list number of cases with details if available)

.....

.....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

.....

In case of death, state probable cause of death.....

C. No permanent/significant functional/cosmetic impairment ☐

Permanent/significant functional/cosmetic impairment ☐

Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

.....

11. Outcome of SAE

Fatal ☐ Recovered ☐

Continuing ☐ Unknown ☐

Recovering ☐ Other *(specify)* ☐

.....

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

.....

.....

.....

13. Provide details about PI's final assessment of SAE relatedness to research.

.....

.....

.....

Signature of PI: .....

Premature Termination/Suspension/ Discontinuation Report Format

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: .....

   .....

   .....

   .....

   Action taken post Termination/ Suspension/Discontinuation (if any): .....

   .....

   .....

   .....

5. Plans for post study follow up/withdrawal* (if any): .....

   .....

   .....

6. Details of study participants:

   Total participants to be recruited: ..... Screened: ..... Screen failures: .....

   Enrolled: ..... Consent Withdrawn: ..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI: ..... Reason(Give details): .....

   .....

[a] Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.

Active on treatment: ..... Completed treatment : ..... Participants on follow-up: .....

Participants lost to follow up: ..... Any other: ..... Number of drop outs: .....

Reasons for each drop-out: .....

.....

.....

.....

7. Total number of SAEs reported till date in the study: .....

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No ☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐

If yes, provide details: .....

.....

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐

If yes, have you implemented that suggestion? Yes ☐ No ☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No ☐

(e.g., making arrangements for medical care of research participants): If Yes, provide details

.....

.....

Summary of results (if any): .....

.....

.....

.....

.....

.....

Signature of PI: .....

Application Form for Clinical Trials

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number: ..... NABH accreditation number:..... EC registration number:.....

2. If regulatory trial, provide status of CDSCO permission letter

   Approved and letter attached ☐ Applied, under process ☐

   Not applied (State reason) ☐.....

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication	
Others (specify)	☐	or new route of administration	☐

.....

4. Trial design of the study

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others *(specify)*	☐	Equivalence trial	☐

.....

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

.....

.....

III. Describe the method of allocation concealment (blinding / masking), if applicable.

.....

INSTITUTE OF MEDICAL SCIENCES & RESEARCH TUMKUR 572106.

5. List the primary / secondary outcomes of the trial.

.....

.....

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐

If yes, Name and Contact details: .....

.....

.....

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others *(specify)*	☐

.....

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

.....

.....

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details. Yes ☐ No ☐ NA ☐

.....

.....

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

.....

.....

IV. Provide details of patent of the drug/s, device/s and biologics.

.....

.....

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100words).....

.....

.....

.....

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22]

.....

.....

.....

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?

If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

.....

.....

.....

11. Does the study use a placebo?

If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

.....

.....

.....

12. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐

If no, please justify.

.....

.....

.....

13. Are there any plans to withdraw standard therapy during the study? If yes, please justify. Yes ☐ No ☐ NA ☐

.....

.....

.....

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes ☐ No ☐ NA ☐

.....

.....

.....

.....

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

.....

.....

.....

- *In order to select participants for your protocol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐
(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

Other*(Specify)* ☐

.....

List the languages in which translations were done .....

Justify if translation not done.....

.....

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

.....

.....

.....

I. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?

Please provide details. Yes ☐ No ☐

.....

.....

II. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: ..... dd | mm | yy

Serious Adverse Event Reporting Format (Clinical trials)

Shridevi Institute of Medical Sciences and Research Hospital

Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and Case No./ Subject ID

.....

.....

Age at the time of event

.....

Gender

Male ☐

Female ☐

Weight:.....(Kgs)

Height:..... (cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐

By Sponsor – Related ☐ Unrelated ☐

By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy

Date of reporting: dd mm yy

5. Onset lag time after administration of intervention:

.....

Location of SAE (Clinic/Ward/Home/Other)

.....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy

Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

SHRIDEVI INSTITUTE OF MEDICAL SCIENCES & RESEARCH HOSPITAL TUMKUR 572106

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration: dd | mm | yy

.....

.....

II. Relevant test/laboratory data with dates: dd | mm | yy

.....

.....

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

.....

.....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

.....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

.....

Signature of PI: ..... dd | mm | yy

Study completion/Final report format

Shridevi Institute of Medical Sciences and Research Hospital

Shridevi Medical College Ethics Committee

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd | mm | yy
2. Date of start of study: dd | mm | yy Date of study completion: dd | mm | yy
3. Provide details of:

   a) Total number of study participants approved by the EC for recruitment: .....

   b) Total number of study participants recruited: .....

   c) Total number of participants withdrawn from the study (if any): .....

   Provide the reasons for withdrawal of participants[23] : .....

   .....

   .....

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....

   .....

   .....

5. Describe the main ethical issues encountered in the study (if any) .....

   .....

   .....

   .....

   .....

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

   Deviations: ..... Violation: ..... Amendments: .....

7. Describe in brief plans for archival of records / record retention: .....

   .....

   .....

   .....

   .....

SHRIDEVI INSTITUTE OF MEDICAL SCIENCES & RESEARCH TUMKUR 572106

[21] Explanation for the withdrawal of participants whether by self or by the PI

8. Is there a plan for post study follow-up? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

11. Describe results (summary) with Conclusion [#] : .....

.....

.....

.....

.....

12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ? Yes ☐ No☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No☐

If yes, provide details.....

.....

.....

.....

Signature of PI: .....

[#] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

Format for Curriculum Vitae for Investigators

Shridevi Institute of Medical Sciences and Research Hospital
Shridevi Medical College Ethics Committee

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration)*:
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations)*:

Projects undertaken in the last 5 years:

Relevant research training/experience in the area [25] :
Relevant publications *(Give references to all relevant publications in the last five years)*:

Signature	Date:

25 Details of any relevant training in the design or conduct of research, for example in the Ethics Training,

Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training.

REFERENCES

1. ICMR. National ethical guidelines for biomedical and health research involving human participants. Indian Council of Medical Research New Delhi: 2017.

2. New Drugs and Clinical Trial Rules, 2019. Department of Health and Family Welfare, New Delhi

3. FMIEC. Standard Operating Procedures (SOP) Father Muller Institutional Ethics Committee Revised Guidelines, Mangalore. 2019; Version 13: revision no.12.