Standard Operating Procedures
For
Institutional Ethics Committee

SRI VENKATESWRA INSTITUTE OF MEDICAL SCIENCES
TIRUPATI -517507

01/07/2024

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES:: TIRUPATI

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PREAMBLE

Someone said some time ago that if one has no regret for the past and no fear for the future, he or she is the one following the ethical and moral path in the present.

* * *

My dear colleague,

In the present days of medical practice with changing climate of health care reforms, modern technology, rapidly advancing procedural modifications, the health care provider and research worker is facing a challenging time. In the prevailing ambitious, goal oriented ambience with cutting edge competition, one should religiously adhere to best practice and research guidelines to protect oneself, the subject, a patient, organisation and society at large. One may wonder at this juncture what is meant by "Ethics". I surmise it is an esoteric principle, more an experience than an explanation and more a practice than a precept. Hence, at this juncture, let us all remember the exhortation from Rg Veda - AANO BHADRAH KRATAVO ENTU VISWATAH – "Let noble thoughts come to us from every side" and march forward with the only goal in mind "the universal good".

Our "Institutional Ethical Committee Guidelines" is a culmination of the efforts of one and all working in Academic & Examination Section. We sincerely place on record our acknowledgements to all the organisations cited as references in our book, for their valuable guidance. We submit that fulfilling a responsibility of this magnitude without an error is like trying to live without sin – worth the effort but probably impossible. However we did try our best.

"Everything should be made as simple as possible but not simpler - Albert Einstein"

From the Dean's desk

1. Short Title and Scope:

The following may be called as "Standard Operating Procedures for the Institutional Ethics Committee (IEC) of Sri Venkateswara Institute of Medical Sciences (SVIMS) Tirupati". The present SOP covers functioning of Ethics Committee reviewing all research on Human subjects done at SVIMS as well as those done at other locations under the aegis of a principle investigator/ co-investigator employed at SVIMS.

2. Name of the Ethics Committee:

Institutional Ethics Committee (IEC), Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati.

Address of the Office of the Ethics Committee
The Member Secretary
Institutional Ethics Committee
Sri Venkateswara Institute of Medical Sciences
Alipiri Road, TIRUPATI – 517 507.
Phone No: 0877-2287166
Fax No: 0877-2288002
Email ID: svimsregistrar@gmail.com

3. Objective:

The objective of this Standard Operating Procedures of the Institutional Ethics Committee (IEC) of SVIMS, Tirupati is to maintain effective functioning of the SVIMS-IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

4. **Terms of reference:** The Ethics Committee is mandated to examine research proposals where research is to be wholly or partially carried out at SVIMS to ensure that research is carried out in accordance with ethical principles.

To ensure that the research projects carried out at SVIMS

a. Are sound in design, have statistical validity and are conducted according to the ICMR and ICH / GCP guidelines.
b. Do not compromise safety of the patients or volunteers.
c. Are conducted under the supervision of medical persons with the required expertise.
d. Include solely, patients who have given voluntary and informed consent.

5. Authority under which the Ethics Committee has been constituted, Membership Requirements, Terms and conditions of appointment of EC members and the quorum required.

a. Authority under which the Ethics Committee has been constituted: The Academic Senate of Sri Venkateswara Institute of Medical Sciences, Tirupati, is the competent authority for constitution of the IEC. The Director cum Vice Chancellor is authorized to nominate members in consultation with the Chairperson of the IEC among those who possess the qualifications and experience as per the norms prescribed under Drugs and Cosmetics Rules.

b. Membership Requirements:

Institutional Ethics committee will be constituted with the following:

i. Chairperson, nominated by the Director –cum-VC, an expert- non-affiliated.
ii. Member secretary –Affiliated.
iii. Basic Medical scientist – non-affiliated
iv. Clinician - Affiliated.
v. Clinician –Affiliated.
vi. Clinician – non- affiliated
vii. Social Scientist–non-affiliated
viii. Philosopher/ethicist/theologian - non-affiliated
ix. Legal expert- non-affiliated
x. Layperson- non-affiliated
xi. Scientific Member – non-affiliated

5 (Five) woman are representing in the present committee.

Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

Members of EC	Definition/Description
Chairperson Non-affiliated	• ConductECmeetingsandbeaccountableforindependentandefficientfunctioningofthecommittee • Ensure active participation of all members in all discussions and deliberations • Ratify minutes of the previous meetings • Seek Conflict of Interest declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
Member Secretary Affiliated	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • EnsurecompletenessofdocumentationatthetimeofreceiptandtimelyinclusioninagendaforECreview. • Assess the need for expedited review/exemption from review or full review.
Basic Medical Scientist(s)	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics,

Affiliated / non-affiliated	continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
Clinician(s) Affiliated / non-affiliated	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol(SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
Legal expert/s Affiliated / non-affiliated	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
Social scientist / Philosopher/ ethicist / theologian Affiliated / non-affiliated	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
Layperson(s) Non-affiliated	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

c. Terms and conditions of appointment of EC members

i) The Director-cum-Vice Chancellor is appointing the chairperson and all members in the committee.
ii) The appointment order clearly specifies the role and responsibilities of the chairperson/members of the committee, conditions of appointment and duration.
iii) The term of Chairperson or member is 2 years from the date of appointment. The members may be reappointed. Members will retire in rotation at the end of the tenure.
iv) If regular member resigns or ceases to be a member due to disqualification, death/retirement a new member will be appointed for the remaining term.
v) They are paid honorarium as per the norms.
vi) The members appointed shall submit their recent CV signed, Certificate of training undergone in GCP.
vii) The members shall 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.

viii) The members are willing to undergo training or update their skills/knowledge during their tenure as an EC member.
ix) The members are aware of relevant guidelines and regulations.
x) The members are able to read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time.
xi) The members shall sign a confidentiality and conflict of interest agreement/s;
xii) The members shall be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
xiii) The members shall be committed and understanding to the need for research and for imparting protection
xiv) The Members are selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC. See Table 4.1 for further details.
xv) The Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. If the Chairperson is a social scientist, she or he can serve as both the social scientist and the Chairperson.

d. The quorum required:

A minimum of five members present in the meeting room.
The quorum should include both medical, non-medical or technical or/and non-technical members.
Minimum one non-affiliated member should be part of the quorum.
Preferably the lay person should be part of the quorum.
The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
No decision is valid without fulfillment of the quorum.

6. Type of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals, etc.,)

Drug trials, Prospective clinical studies, on both medical and surgical patients and blood and pathology specimens, epidemiological studies, retrospective studies.

7. Documents reviewed for every clinical trial protocol including informed consent documents.

(a) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for reaching sound conclusions with the smallest number of research participants.
(b) Consent form in English and local language (Telugu) case of studies on human subjects.
(c) Source of funding for the clinical trial.
(d) Description of the ethical consideration involved in the research.
(e) Case report forms, diary cards, proformas and other questionnaires intended for research participants.
(f) Investigator's curriculum vitae.
(g) A Statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
(h) A description of the arrangements for indemnity, if applicable.
(i) A description of the arrangements for insurance coverage for research participants, if applicable.

(j) A statement of agreement to comply with ethical principles set out in relevant guidelines.
(k) All previous IEC's decisions (e.g., those leading to a negative decision or modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.
(l) Justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
(m) The justification for use of control arms
(n) Criteria for prematurely withdrawing the research participants
(o) Criteria for suspending or terminating the research as a whole
(p) The adequacy of provisions made for monitoring and auditing the conduct of the research Including data safety monitoring committee
(q) The adequacy of the site, including the supporting staff, available facilities and emergency procedure.
(r) The manner in which the results of the research will be reported and published.

8. Procedure for submission of application for ethics review:

1) The Principal Investigator has to submit an application in a prescribed forma along with study protocol for the review of the IEC.
2) Application can be submitted to the office of the Chairman, IEC, Sri Venkateswara Institute of Medical Sciences, Tirupati, on any working day.
3) All the proposals and documents must be submitted in English language, at least 3 weeks in advance from the schedule date of IEC meeting.
4) Eleven (11) copies of study proposal (with all documents) must be submitted along with application form duly signed and dated by the investigator(s)
5) On receipt, the applications will be acknowledged with IEC registration number to be used for all future correspondence and reference.
6) Thesis of DM/M.Ch/MD/MS/Ph.D Courses involving ethical issues also need EC clearance.
7) Every application has to be routed through the concerned Head of the Department to the IEC.

9. The procedures (SOP) to be followed by the committee during meetings and while taking decisions:

(a) Meeting of the Ethics committee will be held monthly. Applicant, sponsor or investigator may be invited to make a slide presentation on the proposal or elaborate on specific issues.
(b) A decision will be taken only when sufficient time has been allowed to the Principal investigator for presentation of protocol and to the committee for review and discussion.
(c) The IEC will evaluate the possible risks to the subject with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
(d) A decision will only be taken at meetings where the quorum is complete. Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.
(e) Members will be given 10 days time in advance to review study proposals and the relevant documents.

(f) IEC meetings will be minuted and all the proceedings and deliberation will be documented.

(g) At the end of each IEC meeting, signatures from each member who has participated will be obtained on the final draft of the minutes of meeting.

(h) Decision will be taken only after reviewing a complete application with all the required documents necessary for the proposal.

(i) Only members who participated in review and discussion will participate in decision.

(j) Where ever possible, the decision will be arrived at through consensus not by vote, but when a consensus appears unlikely voting may be performed. Decision will be taken by simple majority of those attending.

(k) Member having the conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes.

(l) Where there is conflict of interest, member will withdraw from the decision making procedure

(m) In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and Re-review procedure.

(n) Negative decision will be supported clearly by stated reasons.

10. Conflict of interest

Conflict of interest (COI)is a set of conditions where professional judgment concerning a primary interest such as participants welfare or the validity of research tends to be undulyinfluencedbyasecondaryinterest,financialornon-financial.All the members are declaring COI and it is effectively manage.

a. The institution shall identify, mitigate conflicts of interest and educating the staff about such conflicts.

b. Researchers are informed to disclosure of interests that may affect the research.

c. EC should evaluate each study in light of any disclosed interest and ensure that appropriate means of mitigation are taken.

d. COI within the EC should be declared and managed in accordance with standard operating procedures (SOPs) of EC.

11. Policy on protection of vulnerable population:

a) Vulnerable populations have an equal right to be included in research and the benefits accruing from the research will be applied to them as well.

b) If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.

c) 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.

d) In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.

e) Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

f) If vulnerable populations are included in research, additional protection measures are taken to safe guard the dignity, rights, safety and well- being of these individuals.

g) Research on genetics should not lead to promotion of racialine qualities.

h) Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;

i) Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.

j) Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc., who have reduced autonomy as research subjects.

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

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

12. Procedure for communicating the decision of IEC to the applicant

The committee will give its opinion on the project in writing in one of the following ways;

Approval
Disapproval
Modification before approval
Discontinuation of previously approval project

The Chairman of the committee may provisionally approve without calling a full meeting in cases where only administrative amendment has been made. The Chairman will inform other members of the committee of the amendment and his decision. The decision will be ratified at the next full committee meeting and this will be minuted.

13. Procedure for expedited review:

Only to be performed when there is no or minimum risk to the trial participants.

1) Re-examination of a proposal already examined by the IEC.
2) Study of minor nature eg., examination of case records.
3) Similar study proposal for which IEC had already given approvals earlier.
4) An urgent proposal of national interest having minimum risk.
5) Proposals with minimum risk to be reviewed when it may not be possible to convene a main ethics committee meeting with quorum- as for example during natural disasters, lockdowns, epidemics etc

All expedited approvals will be given in a meeting with quorum of at least 3 members (nominated by the Chairman) of IEC. Quorum must have one expert or scientist having scientific knowledge in the field of proposal. It should also include either the Member Secretary or the Chairman or both.

Decision taken by the committee on expedited approval however will be brought to the notice of the main committee members for ratification.

14. Elements of Review:

Following are the elements to be reviewed by the IEC member.

A. Scientific design and conduct of the study:

1) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation),and the potential for reaching sound conclusions with the smallest number of research participants.

2) The appropriateness of clinical trial site in terms of facilities to conduct the intended research and to take clinical care of the patients as per their requirements. This shall include investigations, treatment facilities, supportive staff follow-up facilities etc.

3) The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.

4) The justification for the use of control arms.

5) Criteria for prematurely withdrawing the research participants

6) Criteria for suspending or terminating the research as a whole

7) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data and safety monitoring committee(DSMC).

8) The manner in which the results of the research will be reported and published.

B. Requirement of research participants:

1. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).
2. The means by which initial contact and recruitment is to be conducted.
3. The means by which full information is to be conveyed to potential research participants or their representatives.
4. Inclusion criteria for research participants.
5. Exclusion criteria for research participants.

C. Care and protection of research participants:

1 Any plans to withdraw or withhold standard therapies for the purpose of the justification for such action;

2. The medical care to be provided to research participants during and after the course of the research;

3. The adequacy of medical supervision and psycho-social support for the research participants.

4. Steps to be taken if research participants voluntarily withdraw during the course of the research.

5. The criteria for extended access to the emergency use of and/or the compassionate use of study products.

6. The arrangements, if appropriate for informing the research participants general

practitioner (family doctor), including procedures for seeking the participant's consent to do so.

7. A description of any plans to make the study product available to the research participants following the research.
8. A description of any financial costs to research participants.
9. The rewards and compensations for research participants (including money, services, and /or gifts.
10. The provisions for compensation/treatment in the case of the injury disability/ death of a research participant attributable to participation in the research.
11. The insurance and indemnity arrangements.
12. The ethics committee shall look into the details of the protocol for formation of a data and safety monitoring board. In the absence of any such provision in the protocol, the IEC may insist on the same prior to approval or recommend to the Director SVIMS to constitute a DSMB for monitoring the trial.

D. Protection of research participant confidentiality:

1) A description of the persons who will have access to personal data of the of the research participants, including medical records and biological samples;
2) The measures taken to ensure the confidentiality and security of personal information concerning research participants.

E. Informed consent process:

1. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.

2. Consent form in English and local language (Telugu) in case of studies on human subjects will be reviewed.
3. The adequacy, completeness, and understandability of written and oral information to be given to the research participants and when appropriate, their legally acceptable representative(s).
4. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
5. Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being).
6. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

F. Community considerations:

1) The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
2) The steps taken to consult with the concerned communities during the course of designing the research.
3) The influence of the community on the consent of individuals.
4) Proposed community consultation during the course of the research.
5) The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and the ability to respond to public health needs.
6) A description of the availability and affordability of any successful study product to the concerned communities following the research.

7) The manner in which the results of the research will be made available to the research participants and the concerned communities.

G. Selection of special groups as Research Subjects

i) Pregnant or nursing women: Pregnant or nursing women should in no circumstances be the subject of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

a. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessedexceptinthosestudieswherebreastfeedingisharmfultotheinfant.

b. Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made subjects for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

c. Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

ii) Children: Before undertaking trial in children the investigator must ensure that –

a. children will not be involved in research that could be carried out equally well with adults;
b. the purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. a parent or legal guardian of each child has given proxy consent;
d. the assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors, adolescents etc.;
e. research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child subject must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. the child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents/ guardian;
h. interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child subject as any available alternative interventions;

i. the risk presented by interventions not intended to benefit the individual child subject is low when compared to the importance of the knowledge that is to be gained.

H) **Appropriateness of investigator:** The ethics committee shall review the CV of the investigator, including qualifications, current designation and experience to determine whether he / she has appropriate capability to undertake the research in question (including clinical trials).

15. **Follow up procedure**:

1) IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2) Progress of all the research proposals will be followed at a regular intervals of at least once in 6 months. But in a special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3) The committee shall seek from the investigators:

- A progress report on six monthly basis or more frequently as the committee fee list.
- A report of each serious event when observed during the conduct of the study.
- To be kept informed of amendments to any study-related document.
- To be kept informed of study discontinuation with reasons.

4) With regard to Clinical trials, Data Safety Monitoring Board (DSMB) will be constituted by the Director SVIMS or by the trial investigators to review the clinical trial notifications and to report the adverse events if any to the Institutional Ethics Committee. The board will review the clinical trial records for serious adverse events and report periodically to the IEC. Also the investigators have to communicate the observations of DSMB to IEC periodically.
5) All the requirements and procedures for follow up review will be similar to that of initial and main review. Following instances and events will require the follow-up review

i) Protocol amendment, likely to affect, rights, safety or well being of research subject in conduct of study.
ii) Serious or unexpected adverse reaction related to study or product, action taken by investigator, sponsor and regulatory authority.
iii) Any event or information that may affect the benefit/risk ratio of the study.

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

IEC will also require the investigators to inform the committee about any SAE and payment of any compensation for the same. It shall also review the adequacy of treatment given to participants following an SAE.

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

Applicant must inform at the time of completion of study and must send the result summary to IEC.

IEC must receive a copy of final summary of study completed from the applicant.

16. Procedure for documentation and archiving:

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

17. Review of Performance of Ethics Committee:

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

18. Amendment of SOP:

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

APPENDIX-I

UNDERTAKING FROM PRINCIPAL INVESTIGATOR

Ref No: Date:

Name and Address of the Investigator (from SVIMS)

Chairperson/Member Secretary,

SVIMS Ethics Committee

Sri Venkateswara Institute of Medical

Sciences Tirupati – 517 507

Sub: Ethical clearance for research project entitled"_____

_____"

UNDERTAKING

With respect to the above said research/clinical trial/thesis (strike off whichever is not relevant) protocol involving human subjects for which the ethical clearance being sought, I am to state that I have gone through SVIMS Ethical Committee Guidelines and am aware of the rules governing the studies involving the human subjects. I am also aware that these guidelines are strictly to be followed while carrying out the above said research project involving human subjects.

Further, I also affirm that I will be responsible to keep the IEC informed of,

i. Any serious and unexpected adverse events and remedial steps taken to tackle them.

ii. Any new information that may influence the conduct of the study.

iii Any changes made in the consent form.

iv Under no circumstances I/we deviate from the original approval protocol without prior consent to that effect from the IEC. In the event of need to amend the original protocol approved by the EC, the proposed amendment shall be brought to the notice of EC for its consideration and approval.

Date: Name and Signature of the Principal Investigator

APPENDIX-II

SPECIMEN CONSENT FORM

Information to the participants:

This section should contain the information about the diagnosis made, if any, and also about the various modes of treatments available, Subject needs to be given the free choice of selection of the treatments that are available, including the one which is being considered for the research study. Even if there is scope for slightest risk involved in the proposed mode of treatment/procedure, the same needs to be clearly informed to the participant and/or guardian of the person participating in the study. Participant in the proposed study be clearly informed about his/her right to withdraw from the study without any reason, if he/she desire so, and that would not affect in any way his/her treatment or of his/herward/relative who is undergoing the treatment. Details regarding the scope of treatment in terms of duration, medications/procedures to be used and the clinical materials such as blood etc. that needs to be collected in terms of volume and periodicity be clearly stated in the information to be provided to the participant and/or the guardian. With this information made available to the participant in a language understandable to him/her, it needs to be followed by with the request and assurance, as enumerated below, from the investigator. i.e.,

Undertaking by the investigator:

Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving any reason. In such an event, you will still receive best possible alternative treatment, without any prejudice. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire (investigators Name with Telephone No. need to be furnished). **All the information/data collected from you will be kept in strict confidence.**

Date: **Name & Signature of Principal Investigator**

CONSENT FORM

I _____ {name} voluntarily give consent to participate in the study entitled **“”**. In doing so I affirm that:

- I have been given full information in my native language about the study and have understood the purpose and nature of the study and the potential risks to me resulting from my participation in the study.
- I have been given ample opportunity to ask questions, which have been answered to my satisfaction.
- I understand that my participation in the study is purely voluntary and that unwillingness/refusal to participate will not adversely affect the medical care due to me.
- I have been assured that there is no additional medical expenditure to be incurred by me on account of my participation in the study.
- That I faced no coercion to sign this consent form.
- I have been informed that notwithstanding my signing this consent, I can withdraw from the study at any point of time, without it compromising in any way, the medical care to which I am entitled.

Signature of patient	Signature of Witness	Signature of Investigator
Name of patient	Name of Witness	Name of Investigator
Date	Date	Date
Place	Place	Place

Pl. note: (1) The above format is only a guideline, which may need to be altered according to the situation as to whether the participant is a patient, or patient's guardian or a volunteer who may take part in studies involving the study of normal subjects. Further, where the participant is not proficient with English, he/she be provided with a consent form in a language in which he/she is proficient.

(2) Informed Consent Form in minimum 3 languages viz. English, Hindi, Telugu and other languages where needed required to be furnished.

(3) Suppose the study group deals with only English or any particular language speaking, patients, then an undertaking required to be furnished.

(4) A certificate from the translator stating that "the translated version of the informed consent form is the 'true' translation of the original version of the informed consent form" is required to be typed/printed at the end of the each translated version of the document. Further, the translator has to append is signature, name and address below the certificate.

APPENDIX -III

IEC Membership Acceptance:

To

The Director

Sri Venkateswara Institute of Medical Sciences

Tirupati – 517 507

Sub: Consent to be a member of Institutional Ethics Committee.

******

Sir,

I accept the invitation to become a member of IEC of Sri Venkateswara Institute of Medical Sciences, Tirupati. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

- I shall be willing to publicize my full name, profession and affiliation
- I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC.
- I shall not keep any literature or study related document with me after the discussion and final review.
- I shall maintain the confidentiality regarding IEC activities.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of Member_____ Date_____

Address

APPENDIX- IV

Application for Ethical Review of Biomedical Research Proposal

Date:

To
The Chairman
Institutional Ethics Committee
Sri Venkateswara Institute of Medical Sciences
Tirupati

Full name of applicant:_____Designation:

Complete Address:

Tel. No

Fax No:

E-mail:

Site of Study:

Protocol No. (if any) Date:

Amendment No. Date:

Title of Project:

Type of study:

Local/National/International Type of

Trial : single center / multi centre

Sponsor's Name:

Address :

	Name	Signature
Principal Investigator :		
Co-Investigator: 1)		
2)		
3)		

(Application must be submitted along with all essential documents for the review)

(See list of Documents)

List of documents to be submitted along with application for the IEC Review:

1. Signed and dated application form on prescribed format.
2. The protocol of the proposed research (clearly identified and dated), together with supporting documents and annexes.
3. A summary (as faras possible in non-technical language), synopsis, or diagrammatic representation (flowchart) of the protocol.
4. A description (usually included in the protocol) of the ethical considerations involved in the research.
5. Case report forms, diary cards and other questionnaires intended for research participants.
6. In case the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information).
7. Investigator(s) curriculum vitae (update, signed and dated).
8. Material to be used (including advertisements) for the requirement of potential research participants.
9. A description of the process to be used to obtain and document consent.
10. Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages.
11. Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and when required in other languages.
12. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
13. A description of the arrangements for indemnity, if applicable.
14. A description of the arrangements for insurance coverage for research participants, if applicable.
15. A statement of agreement to comply with ethical principles set out in relevant guidelines.
16. All previous IEC's decisions (e.g., those leading to a negative decision or modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.

APPENDIX - V

Institutional Ethics Committee

Sri Venkateswara Institute of Medical Sciences, Tirupati
Acknowledgement

Date:

Received_____Copies of study proposal.

Protocol No._____ Dated:

Amendment No. Dated:

Entitled_____

_____

From Dr._____

Designation_____

Address For ethical review.

For official use only

* Study Proposal Registration No. SVIMS-IEC/200 /

* Name of IEC Staff * Signature

Receiving application:

* Date:

(To be filled by the applicant in duplicate)

APPENDIX-VI

Institutional Ethics Committee

Sri Venkateswara Institute of Medical Sciences, Tirupati

Review letter No.IEC/SVIMS/ Date:

To

Ethics Committee of Sri Venkateswara Institute of Medical Sciences, Tirupati, in its Meeting held on_____athours in the meeting room _____reviewed and discussed the study proposed with Protocol No._____Dated_____

Entitled"_____

_____

_____

Submitted by Dr._____.

Members:

Name	**Affiliation**	**Gender**
1.		
2.		
3.		
4.		
5..		
6.		

Members reviewed the following documents(tick whichever is applicable):

1. Protocol ( )

2. Amendment ( )

3. Written informed consent ( )

4. Investigator's Brochure ( )

5. Available safety information ( )

6. Subject recruitment procedure ( )

7. Payments and compensation to subject ( )

8. Subject information sheet ( )

9. Investigator's C.V. ( )

10. Others: Specify_____( )

The members present, represented the quorum and having at least one medically qualified person and at least one layperson present from outside the Institute.

All the issues presented in the study proposal were thoroughly discussed and reviewed.

Of members present,_____voted for approval,_____ voted against and

_____Were absent.

After all considerations, the committee has decided to approve / not to approve / suggested resubmission after required modification / subject to.

Please provide the following clarifications / documents for re-review.

1.

2.

3.

4.

The present approval is valid only for one year, investigator must take the re- approval after one year.

The investigator is requested to submit the progress report after 6 months to IEC for review. Any change, modification or deviation in the protocol, or any adverse event must be informed to ethics committee. Any protocol modification or amendment must receive IEC approval. Investigator should conduct the study as per the recommended GCP guidelines.

Signature :

Date :

Name :

Chairman

Institutional Ethics Committee

APPENDIX-VII

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI
PROFORMA TO BE FILLED BY THE PRINCIPAL INVESTIGATORS SUBMITTING RESEARCH PROPOSALS THROUGH SVIMS FOR CONSIDERATION OF THE ETHICAL COMMITTEE

TITLE OF THE PROJECT _____

_____

PRINCIPAL INVESTIGATOR _____

DESIGNATION & DEPTT. _____

PART – I

(In vivo experiments on human subjects)

1. Whether the human subjects are

   Children (less than15years) Yes/No

   Elderly (More than60years) Yes/No

   Disabled (mentally or physically handicapped) Yes/No

   Prisoners/Restitutes Yes/No

2. Whether the human subjects are Suffering from illness Yes/No

   Normal individuals Yes/No

3. Whether the project involves

   Clinical trial with new drug(s)/ device(s) approved by DCI Yes/No

   Clinical trial with existing drug(s)/device(s) Approved by DCI Yes/No

   Clinical trial with traditional medicines from Ayurvedic /Unani/Homoeopathy/Tribal systems Yes/No

   None of the above Yes/No

(CAUTION: NO DRUG/DEVICE IS TO BE USED UNLESS APPROVED BY DRUG CONTROLLER OF INDIA)

If answer to 3.1 is yes, kindly furnish evidence of experimental and clinical safety of the drug (Use separate sheets)

4. Whether the project involves

Any invasive procedure which would otherwise not be performed for the management of the patient Yes/No

Use of in vivo radioactive material Yes/No

Use of radiation Yes/No

If answer to any of 4.1 or 4.2 or 4.3 is yes then answer 5, below.

5. Do you think that the procedural risk or the cumulative risk of exposure is below safety limits Yes/No

PART – II

(COLLECTION OF HUMAN MATERIAL OTHER THAN NORMALLY EXCRETED URINE, STOOL, SALIVA, SWEAT, WHICH WOULD OTHERWISE NOT BE COLLECTED FOR THE MANAGEMENT OF THE PATIENT)

6. If the human material to be collected is human tissue specify the tissue

(… .....)

It will be obtained by Operation/Biopsy/Abortion/Autopsy Other (Specify

_____)

Whether the procedure required to obtain the tissue is otherwise indicated for the management of the patient Yes/No

If answer to 6.2 is yes please explain the full procedure and justify collection and use of material (Use separate sheets)

7. Any other human material (Specify)

Yes/No If answer to 7 is yes then answer 7.1 and 7.2 below

Specify the method of collection (_____)

Specify the amount to be collected (_____)

PART – III (COLLECTION OF BLOOD)

8. Will it be collected in amounts in excess of which would otherwise be collected for the management of patients Yes/No

If answer to 8 is yes then specify the excess amount

_____ ml at a time

_____ ml total

Will it be collected by extra peripheral venous puncture which would otherwise be required for the management of the patient Yes/No

If answer to 8.1 is yes then specify the total number of peripheral venous punctures (_____)

Will it be collected by a method which would otherwise not be required for the management of the patient? Yes/No

If answer to 8.2 is yes then specify the method (_____)

PART – IV

(DECLARATION BY THE PRINCIPAL INVESTIGATOR)

9. I hereby declare that, Voluntary written informed consent of the human subject will be obtained.

In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/guardians will be obtained.

The probable risk involved in the project will be explained in full details to the subjects/parents/guardians.

Subjects/parent/guardians will be at liberty to opt out of the project at any time.

I will terminate the experiment at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgment required for me that continuation of the experiment is likely to result in injury, disability of death to the experimental subject.

PRINCIPAL INVESTIGATOR

DEPTT._____

PART – V

(DECLARATION BY THE PRINCIPAL INVESTIGATOR/HEAD OFTHE DEPT.)

1. Is the Dept./Institution ready to undertake the responsibility of the human subjects in case of injury Yes/No

   If yes, then will it include

   *Transportation charges Yes/No

   *Hospitalization charges Yes/No

2. Do you think that the experiments are so designed that they would yield meaningful results that could not be obtained by other methods. Yes/No

3. Do you think that the animal experiments carried out support the need for clinical experimentation Yes/No

4. Do you think that the experiments would be conducted in a manner to avoid all unnecessary physical and mental suffering and injury. Yes/No

5. Do you think the experiments have been planned in a manner so that the degree of risk to be taken would never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
   Yes/No

6. Do you think that proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. Yes/No

7. Do you think that safeguards have been taken to see that the experimentation would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research
   Yes/No

PRINCIPALINVESTIGATOR_____

HEAD OF THE DEPT._____

For drug trials the following are necessary before implementation;

1. Permission from DCG (I).
2. Memorandum of Understanding on Rs.100 Stamp paper (format given).
3. Indemnity agreement on Rs.100 Stamp paper (format given).

A

APPENDIX- VIII

MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding, (hereinafter called MoU) between Sri Venkateswara Institute of Medical Sciences, Tirupati, India (herein after called SVIMS) and (the Second Party)_____

_____(here after called_____

_____) entered in to this_____

(day)_____(month) _____(year). Preamble:

Whereas SVIMS is a super specialty hospital, established by Govt. of Andhra Pradesh, as a centre of excellence for providing medical care, education and research of high order and is chartered to function as a university under this State Act.

Whereas (the Second Party)

Whereas SVIMS and (the Second Party) _____

are willing to jointly participate in the development of_____

The coordinator of the project will be_____(name, designation of the faculty member responsible from SVIMS, Tirupati). The other Coordinator of the project will be_____(name, and designation of person responsible for second party).

Scope of MoU

This MoU will cover the joint efforts of Sri Venkateswara Institute ofMedical Sciences, Tirupati, and _(Second Party) in the area of

_____

(specify the area of work jointly to be done)

Furnish full details of the work to bed one:

1.

2.

3.

4.

5.

Responsibilities of SVIMS

1.

2.

3.

4.

5.

Responsibilities of Second Party

1.

2.

3.

4.

5.

Administration:

Overall responsibilities of the project will rest with Sri Venkateswara Institute of Medical Sciences, Tirupati &

_____

(identify the Institution/Organization and name of the persons)

Financial Arrangements:

Funds for the projects will be from_____(name the funding agency) and the proportion of the funds to be released to SVIMS will be Rs._____(specify the amount).

The following equipment/consumables/supplies will be provided to SVIMS by(SecondParty)._____

(This is for MoU involving grant of equipment/consumables/supplies)

1.

2.

3.

4.

5.

Intellectual Property Rights**:**

1. The R&D information generated shall be shared by both the collaborating parties.
2. Any publication shall be by mutual consent of the coordinators.
3. Patents and other benefits, arising out of the project if any, shall be shared between the collaborating parties.
4. For projects identified as having a distinct potential of generating know how leading to commercial applications *NRDC (National Research Development Corporation of India) Guidelines will be followed.

NRDC GUIDELINES

1. To bring to the notice of the Investigator, prospective user of the technology being developed.
2. To do market research about the product and bring out a comprehensive study about the market potential for attending entrepreneur.
3. For effective coordination between the laboratory generating the know how and the entrepreneur.
4. To take such other steps as may facilitate the communication of know how.
5. NRDC will retain 40% of the royalty/premia and the remaining 60% will be sent to the Institution generating the knowhow. The sharing of 40% between the Institute and the project investigator team may be decided by the Institute.

Duration of MOU

This MoU will be in force for a period of_____(Years) from the date of its signing).

Amendments to the MoU

Amendments if any, before the expiry of this MoU shall be made in writing by the Authorized representatives of SVIMS and_____(second party) after mutual agreement.

Resolution of Dispute:

Any dispute or difference between the collaboration parties shall be amicably resolved by either through mutual consultation or arbitration.

Seal of the Parties:

In witness thereof Parties hereto having signed this MoU on the day, month and year mentioned herein before.

Parties:

Signed and delivered for and behalf of SVIMS	Signed and delivered for and behalf of (Second Party)
Signature	Signature
Name Designation	Name Designation
Seal	Seal

APPENDIX-IX

INDEMNITY AGREEMENT

This indemnity agreement is between Sri Venkateswara Institute of Medical Sciences, Tirupati, India (hereinafter SVIMS)and_____

_____

(Name of the second party/ sponsor)

(herein after SPONSOR)

Whereas SVIMS engages in medical research that involves experimental and investigational products, drugs, devices or therapy and

Whereas SPONSOR owns or has right to such experimental or investigational products, drugs, devices specifically as it relates to this agreement, products, devices, drugs shall mean the following.

1.

2.

3.

4.

5.

Whereas SVIMS and SPONSOR have agreed that SVIMS will use SPONSOR'S experimental and investigational products, drugs, devices for research purpose.

Now therefore, the parties agree as follows:

1. Undesirable side effects, injuries, illness or reactions.

The SPONSOR agrees to indemnify, protect, defend and hold harmless SVIMS, its officers, employees against cost or expenses associated with the diagnosis and treatment of undesirable side effects, injuries, illness or reactions that arise specifically from SPONSOR's products, devices, drugs.

2. Loss, Damage or Liability.

The SPONSOR agrees to indemnify, protect, defend and hold harmless SVIMS, its officers, employees from any loss, damage or liability they may suffer or incur as a result of claim or demands made against them that arise specifically from research involving SPONSOR's products, devices, drugs.

3. Insurance

The SPONSOR agrees to maintain in force at its sole cost and expense with reputable insurance companies, Insurance of a type and in amounts equal to at least_____per

(specify the amount of money)

occurrence combined single limit and_____annual

(specify the amount of money)

SVIMS shall have the right to request the appropriate certificates of insurance from SPONSOR for purposes of ascertaining the sufficiency of coverage.

4. Attorneys and legal coverage.

The SPONSOR agrees to provide, at its own expenses, attorneys to defend against any claims made or action filed against SVIMS, its officers, employees. The SPONSOR also agrees to pay any settlement amounts or judgments levied against SVIMS or any losses or expenses incurred by SVIMS resulting from such claims or action.

5. Cooperation of parties.

SVIMS agrees to notify promptly, SPONSOR in writing when any undesirable side effect, injury, illness or reaction arises from research involving SPONSOR's products, devices, drugs, SVIMS agrees to cooperate with SPONSOR in defending any claim or action covered by this agreement. The SPONSOR agrees to consult on a regular basis with SVIMS regarding the defense or settlement of any claim or action. Neither party will compromise or settle any claim or action without prior written consent of the other party.

6. Other.

This indemnity agreement does not displace, super cede or in any way limit any other agreements between the parties.

SVIMS

Name_____

Signature_____
Date_____

Seal_____

REFERENCES

1. Ethics Committee guidelines of AIIMS, New Delhi.
2. Ethics Committee guidelines of SGPGIMS, Lucknow.
3. Ethics Committee guidelines of NIMHANS, Bangalore.
4. Ethics Committee guidelines of NIMS, Hyderabad.
5. Ethics Committee guidelines of CMC & Hospital, Vellore.
6. Ethical guidelines of ICMR, New Delhi.
7. Rajiv Gandhi University of Health Sciences, Karnataka

i) Undertaking Form by Principal Investigator - NIMHANS, Bangalore
ii) Specimen consent form - -do-
iii) IEC Membership Acceptance Form - NIMS, Hyderabad
iv) Application for Ethical Review Biomedical Research Proposal - -do-
v) List of documents to be submitted - -do-
vi) IEC acknowledgement Form-do-
vii) IEC Review Letter - -do-
viii) Proforma to be filled by the Principal Investigator - SGPGIMS, Lucknow
ix) MOU for drug trials -do-
x) Indemnity agreement for drug trials - -do-