



# Shri Sathya Sai Medical College & Research Institute

(Affiliated to Sri Balaji Vidyapeeth University, Puducherry)

## Institutional Ethics Committee (Human Studies)

## Standard Operating Procedures

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## **Establishing and Constituting the Institutional Ethics Committee (IEC)**

### **PROCEDURE**

- \* The Dean will select and nominate the Chairman, Members and Member Secretary for IEC, SSSMC&RI.
- \* The Dean will invite the members to join ethics committee by sending official request letter (Doc 1)
- \* Members will confirm their acceptance to the Dean by providing all the required information for membership (Doc 2)
- \* The Dean will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and Principles of communities they serve (Doc 3)
- \* The Dean will designate and instruct Chairman of IEC or his representative to conduct the regular proceedings of IEC for the Institute.
- \* At regular intervals, Dean will review the functioning of IEC

### **Organisation of the IEC**

1. Chairman – from outside the institution
2. one-two persons from basic medical science area
3. One –two clinicians from various institutions
4. One legal expert or retired judge
5. One social scientist /representative of NGO
6. One philosopher/ethicist/theologian
7. One lay person from the community
8. Member secretary

## **Procedure for appointing members for the IEC**

### **PROCEDURE**

1. Dean in consultation with Chairman will nominate the members of IEC, who have the qualification and experience to review and evaluate the scientific, medical and ethical aspects of the proposed study.
2. When needed, IEC will invite subject experts to offer their views.
3. The appointment of an IEC member will be for 3 years.
4. Dean may renew the appointment on the basis of the member's contribution.
5. During the term, Dean in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.
6. Member will have the right to discontinue from membership of IEC after giving written notice at least three months in advance.
7. Dean can replace the member of IEC as and when required.
8. Each member is required to sign the declaration and Confidentiality agreement regarding IEC activities (Doc 2).
9. Dean can nominate IEC members to undergo orientation programme in national and international developments in ethics.

## Procedure for convening and conducting IEC meetings

### PROCEDURE

- The Member Secretary in consultation with the Chairman may convene the IEC meeting once in every three months or earlier if minimum of ten scientific proposals are forwarded.
- Additional review meetings can also be held with short notice as and when required.
- Meetings will be planned in accordance with the need of the work load.
- All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.
- All the proposals will be received at least three weeks before the meeting, checked for completeness as per the check list initially by the office clerk(Form II), subsequently by the member secretary (through a nominated person) using the evaluation form (Form III).
- Members will be given not less than 10 days time in advance to review study proposals and the relevant documents.
- Minutes of the IEC meetings, all the proceedings and deliberation will be documented.
- Signatures of the Chairman and the Member Secretary will be obtained on the minutes of the meeting document. The minutes will be circulated to all the guides /HODs in case of student proposals.
- Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.
- Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement. They will not have a role in decision making.

**Procedure for submission of research project for review by Ethics  
(Regular and Sub) Committee**

1. Applicable to Principal Investigators from SSSMC&RI.
2. All investigators are responsible for implementing this SOP. Every protocol submitted for review to IEC must contain number, version and date. All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review.

**PROCEDURE**

- I. The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC (Form No: IA or IB). All research proposals must be submitted in English language only.
- II. Application can be submitted to the office of the Member Secretary, IEC, SSSMC&RI.
- III. All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting
- IV. Ten copies of study proposal (with all documents) must be submitted for Regular Ethics Committee along with application form duly signed and dated by the investigator(s).
- V. Receipt of the application will be acknowledged by the IEC office.
- VI. Every application will be allotted an IEC registration number to be used for all future correspondence and reference

## **Procedure for initial scrutiny of proposals**

### **PROCEDURE**

- I. Every proposal will be collected and compiled by the Institute Ethics Committee office.
- II. An office staff nominated by the Member Secretary will verify the proposals for completeness as per the checklist (Form II).
- III. In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary corrections and to resubmit.

## **Procedure for reviewing the research proposals**

### **PROCEDURE**

- I. Every proposal will be sent not less than 10 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review.
- II. All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
- III. The IEC review will be done through formal meetings.
- IV. However in case of a proposal awaiting review on an urgent basis, review may be considered for decision through circulation of proposals to members after obtaining prior permission from the Chairperson regarding the same.
- V. Expert opinion of additional members would be obtained if necessary



## **Procedure for expedited review of research project by Ethics Sub-Committee**

### **PROCEDURE**

- I. IEC will receive and consider the proposals for expedited review and approval for the studies having/involving:
  - i. No or minimum risk to the trial participants.
  - ii. Re-examination of a proposal already examined by the IEC.
  - iii. Study of minor nature like the examination of case records.
  - iv. Similar study proposal for which IEC had already given approvals earlier.
  - v. An urgent proposal of national interest having minimum risk.
  - vi. All ICMR student projects and post graduate proposals.
- II. All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.
- III. All expedited approvals will be given in a meeting of the Sub-Committee of three members (nominated by the Chairman). All the three members including the Member Secretary should be present for the meeting.
- IV. Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IEC.

## **Procedure for decision making regarding the research project**

### **PROCEDURE**

In making decision on application for the ethical review of any research proposal, IEC will consider the following:

1. Member having a conflict of interest will indicate to the Chairman prior to the review of application and same will be recorded in the minutes.
2. Where there is a conflict of interest, member will withdraw from the decision making procedure.
3. A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non-members (e.g. Investigator) from the meeting.
4. Decision will only be taken at meetings where a quorum (seven in a committee of 13) is complete.
5. Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.
6. Only IEC members who participated in review and discussion will participate in decision making.
7. Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.
8. Decision will specify the conditional decision if any, with clear suggestions and re-review procedure
9. Rejection of proposal will be supported by clearly stated reasons.

## **Procedure for communicating the decision of IEC to the Investigator**

### **PROCEDURE**

A decision of the IEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format(Doc4). A certificate of approval will be sent to the applicant within 2 weeks (Document-5). All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

The communication of the decision will include:

- A. Name and address of IEC.
- B. The date and place of decision.
- C. The name and designation of the applicant.
- D. Title of the research proposal reviewed.
- E. The clear identification of protocol no., version no., date, amendment no., date.
- F. A clear statement of decision reached.
- G. Any advice by the IEC to the applicant.
- H. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
- I. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
- J. Signature of the member secretary with date.

## **Procedure for follow-up of research projects by Ethics Committee**

### **PROCEDURE**

- 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.
- Progress of all the research proposals will be followed at a regular interval of at least once a year.
- But in special situations, IEC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
- 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. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
  - II. Serious or unexpected ADR 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 the applicant indicating modification/suspension/termination /continuation of the project.
  - In case of premature suspension /termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.
  - Applicant must inform 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.

## **Procedure for documentation and archiving of documents and communications of IEC**

### **PROCEDURE**

- All the documents and communications of IEC will be dated, filed and archived in a secure place.
- Only persons, who are authorized by the Chairman of IEC will have the access to the various documents.
- All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
- No document (except agenda) will be retained by any IEC member.
- At the end of each meeting, every member must return all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.
- Following documents will be filed and archived with proper label on the top of file for easy identification of proposal
- The constitution, written standard operating procedures of the IEC, and regular (annual) reports.
- The curriculum vitae of all IEC members.
  - a) A record of all income and expenses if any, of the IEC, including allowances and reimbursements made to the secretariat and IEC members.
  - b) The published guidelines for submission established by the IEC.
  - c) The agenda of the IEC meetings.
  - d) The minutes of the IEC meetings.
  - e) One copy of all material submitted by an applicant.
  - f) A copy of the decision and any advice or requirements sent to an applicant.

- g) All written documentation received during the follow-up.
- h) The notification of completion, premature suspension, or premature termination of study
- i) The final summary or final report of the study

Document 1

Letter ref No/

From,

The Dean,  
SSSMC&RI.

To,

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Sub: Constitution of Institute Ethics Committee (Human studies) – Reg

Dear Sir / Madam,

On behalf of SSSMC&RI, a Medical College approved for conducting clinical research in human subjects, I request your concurrence for possible appointment as a member of Institute Ethics Committee of this institute. Kindly send your written acceptance in the enclosed format and provide the necessary information requested. On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

Signature

Name

Seal

Document 2

Letter ref No/

From,

-----  
-----  
-----

To,

The Dean,  
SSSMC&RI.

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) – Reg

Ref: Your Letter No:

Dated:

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of SSSMC&RI. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall be willing for my name, profession and affiliation to be published. I shall not keep any literature or study related document with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel. I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature





Copy to :

- 1.The Dean,SSSMC&RI.
- 2.File

Document 4

**Shri Sathya Sai Medical College & Research Institute,  
Ammappettai-603108**

Review letter No. IEC/ SSSMC&RI/  
Date:

To,

\_\_\_\_\_

\_\_\_\_\_

The ..... meeting of the Institute Ethics Committee (Human Studies) for the year..... was held in \_\_\_\_\_, SSSMC&RI on \_\_\_\_\_ under the chairmanship of \_\_\_\_\_. Besides the Chairman, \_\_\_\_\_ (Member Secretary), \_\_\_\_\_ (Member), \_\_\_\_\_ (Member), attended the meeting.

After the proceedings, the proposals listed for the meeting were taken up for discussion. After deliberations, the following decisions were arrived:

No. of proposals reviewed - \_\_\_\_\_

No. of proposals approved - \_\_\_\_\_

No. of proposals approved subject to corrections - \_\_\_\_\_

The recommendations made by the committee are given below.

The investigators whose proposals need minor modifications are required to send Three copies of revised proposals to \_\_\_\_\_, Member-Secretary. If the revision is satisfactory, the approval certificate will be issued after consulting the Chairman of committee.

The recommendations of the committee to each proposal are detailed below:

Sl no. Regm no	Name of the student/Princi pal Investigator	Title of dissertation	Name of Guide/co- Guide	Recommendations of the committee

Any change, modification or deviation in the protocol, or any serious adverse event must be informed to ethics committee within fourteen days. Any protocol modification or amendment must receive IEC approval. Investigator should conduct the study as per the recommended GCP/GLP guidelines. It is also confirmed that our ethics committee is constituted and functions as per Good Clinical Practice guidelines issued by Central Drugs Standard Control Organisation and Ethical Guidelines for Biomedical research on Human Subjects, issued by Indian Council of Medical Research.

Member Secretary  
Institute Ethics Committee  
(Human studies)

Chairman  
Institute Ethics committee  
(Human Studies)

Name :

Signature

Date :

Document 5

**Shri Sathya Sai Medical College and Research Institute**  
**Ammamet ,Kancheepuram, 603 108**

**Decision of the Institutional Ethics Committee (IEC)**

IEC No: 2012/

<b>Protocol title:</b>
<b>Principal Investigator:</b>
<b>Name &amp; Address of Institution:</b>
<input type="checkbox"/> New review <input type="checkbox"/> Revised review <input type="checkbox"/> Expedited review
<b>Date of review (D/M/Y):</b>
<b>Decision of the IEC:</b>  <input type="checkbox"/> <b>Recommended</b> <input type="checkbox"/> <b>Recommended with suggestions</b>  <input type="checkbox"/> <b>Revision</b> <input type="checkbox"/> <b>Rejected</b>
<b>Suggestions/ Reasons/ Remarks:</b>  <p align="center"><b>A report on the status of this study should be submitted to the IEC at the end of the _____ months from the date of issue.</b></p>
<b>Recommended for a period of :</b>

**Please note \***

- Inform IEC immediately in case of any adverse events.
- Inform IEC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above. Completion report to be submitted to IEC.
- Members of IEC have right to monitor the trial with prior intimation.

Signature of The Chairman,  
Institutional Ethics Committee.

Document 6

**Form I**

**Shri Sathya Sai Medical College and Research Institute**  
**Ammamet ,Kancheepuram, 603 108**

**Format for submission of Research proposal to Institutional Ethics Committee**  
**(IEC) \***

**Serial No (IEC Office):**  
**IEC/2012/**

**Date of submission:**

1. Title of the research project:
2. Brief Biodata of the principal investigator and co-investigator/s

*A. Principal Investigator*

Name	Designation	Department	Educational Qualification	Research experience	Address & Tel.no. Email/ Fax

*B. Co-investigator/s (If any)*

Name	Designation	Department	Educational Qualification	Research experience	Address & Tel.no. Email/ Fax

3. Department/s involved:
4. Expected duration of the project:

**5. Attach typed copy of Research Protocol** under following headings:  
(This protocol , which need not exceed 5 pages, must clearly define your role in your project and must have sufficient detail to permit review to the research committee) – **Please also submit a soft copy of the Research Protocol**

- **Title of the Research Project:**
- **Objectives:** (please enumerate)
- **Review of Literature (with references)** pertaining to the project (in less than 100 words)
  
- **Rationale of the study** (in less than 100 words)
- **Research design & methodology** (This will be the most detailed portion of the proposal.) Please include number of subjects, describe the study design, research methods and/or procedures that will be used for estimation and procedures to be employed for statistical analysis. Attach all relevant enclosures like proforma, case report form, questionnaires etc. Informed consent process, including patient information sheet and informed consent form in local language, if applicable. For any drug / device trial, mention all relevant pre-clinical animal data and clinical trial data from other centres within the country /other countries, if available- If applicable
- **Name and signature of Principal Investigator and co-investigator/s** on research protocol with date.

**6. Checklist for attached documents:**

- 1.Project proposal – 10 Copies
- 2.Curriculum Vitae of Investigators
- 3.Brief description of proposal
- 4.Patient information sheet
- 5.Informed Consent form
- 6.Investigator’s brochure for recruiting subject
- 7.Copy of advertisements/Information brochures
- 8.Copy of questionnaire / data collection sheet

Place: \_\_\_\_\_ Signature & Designation of PI/Co-PI/Collaborator

Date: \_\_\_\_\_

7. HOD’s remark with Name & Signature:

(Research proposal can be submitted in the office of Secretary, IEC, SSSMC&RI)

Document 7

## Form II

### Informed Consent form

“Title: \_\_\_\_\_”

Name of the participant:.....

Name of the Principal investigator: .....

Name of the Institution:.....

Documentation of the informed consent:

I,.....was explained in my language about the project in detail, which I have understood. I was free to ask any questions and they have been answered. I am over 18 years of age and exercising my free power of choice, hereby give my consent to be included as a participant in this study,“  
.....”

- 1) I have read and understood this consent form and the information provided to me
- 2) I have had the consent document explained to me
- 3) I have been explained about the nature of the study
- 4) My rights and responsibilities have been explained to me by the investigator
- 5) I have been advised about the risks associated with my participation in the study
- 6) I agree to cooperate with the investigator and I will inform him immediately if I suffer unusual symptoms
- 7) I have not participated in any research study within the past ...12. Months
- 8) I am aware of the fact that I can opt out of the study at any time without giving any reason.
- 9) I am also aware that the investigators may terminate my participation in the study at any time for any reason without my consent.
- 10) I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the ethics committee.
- 11) My identity will be kept confidential if my data are publicly presented.
- 12) I have had my questions answered to my satisfaction
- 13) I have decided to be in the research study

I am aware, that if I have any questions during this study, I should contact any one of the addresses listed. By signing this consent form, I attest that the information given in this document has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

Participant's initial.....

(Translated in vernacular language may be used whenever applicable)

Document 8

### Form III

#### Information to participants

Protocol No : .....

Investigator : ..... **{PI} complete address with contact No.**

..... **{Co- investigator}**

Title : “ .....”

You are invited to take part in this research study .The information on this document is meant to help you decide whether you want to participate or not. Please feel free to ask if you have any queries or concerns.

You are asked to participate in this study that is to be conducted in Shri Sathya Sai Medical College &RI because you satisfy our eligibility criteria:

1. ....
2. ....
3. ....
4. ....
5. ....
6. ....

**What is the purpose of research?**

**The study design**

**Study procedures**

**Possible risks to you**

**Possible benefits to you**

**Possible benefits to other people**

**The Alternatives you have**

**What should you do in case of injury or a medical problem during this research study?**

**Confidentiality of the information obtained from you**

**How will your decision not to participate in the study affect you?**

**Can you decide to stop participating in the study once you start?**

**Can the investigator take you off the study?  
Right to new information**

Participant's initial.....

(Explanation under each above said title in easy language should be made and a copy in English and local language should be included )

**Acknowledgements:**

- 1.ICMR,New Delhi
- 2.JIPMER, Puducherry
- 3.PGIMER,Chandigarh.