

## **PREAMBLE**

**Someone said sometime 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**

# INTRODUCTION

## **Responsibility:**

### **To ensure that the research projects carried out at SVIMS**

- are sound in design, have statistical validity and are conducted according to the ICMR and ICH/GCP guidelines.
- do not compromise safety of the patients or volunteers.
- are Conducted under the supervision of medical persons with the required expertise.
- include solely, patients who have given voluntary and informed consent.

## **The committee expects from the investigators:**

- A progress report on six monthly basis or more frequently as the committee feels it.
- 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.

# STRUCTURE OF INSTITUTIONAL ETHICS COMMITTEE

## Committee Composition:

Ethics committee of SVIMS will be multidisciplinary and multisectorial in composition with at least one lady member.

Establishing and Constituting Authority - Director

Chairperson - Outside Expert

Member - Dean

Member Secretary - Registrar

Members of IEC (including at least one lady Member)

MEMBER	NUMBER OF PERSONS
Medical Scientists from - SVIMS	2
Medical Scientists from - others	1
Non-Medical Scientists* :	2
Lay Person	1
Legal Expert / Judge	1

\* For animal research approval, the ethical committee should have Veterinary Scientist and Animal House In charge as members.

**Chairperson:**

- a. The Chairperson of the Committee should be preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee.
- b. The Chairperson is responsible for conducting all committee meetings, and leads all discussions and deliberations pertinent to the review of research proposals.
- c. The Chairperson presides overall administrative matters pertinent to the committee's functions.
- d. In case of anticipated absence, the Chairperson nominates a committee member as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

**Member Secretary:**

- a. The Member Secretary who generally belongs to the same Institution should conduct the business of the committee. So the Registrar will be the Member secretary to IEC.
- b. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions.
  1. Receiving all research proposals.
  2. Forwarding all materials for review by the committee members.
  3. Preparation and dissemination of agenda for all committee meetings (10 days prior to the meeting date).
  4. Inviting special attendees/expert, from relevant specialities to the scheduled meetings, if needed.
  5. Preparation and circulation of minutes (within 14 days of the meeting).
  6. Notification of review outcome to Principal Investigator of research proposals.
  7. Retention and safekeeping of all records and documentation.
  8. Performance of other duties assigned by the Chairperson.

**Procedure for appointment of Members:**

Director, in consultation with the Chairperson, will nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

1. The normal term for IEC member will be for 24 months.
2. Director can renew the appointment of the member on the basis of Contribution.
3. During the term, Director can disqualify any member if the contribution is not adequate and, or there is long period of (member) non availability.
4. Member can discontinue from membership of IEC after giving at least 1 month advance notice.
5. Director can replace the member of IEC as and when required.
6. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.

INSTITUTIONAL ETHICS COMMITTEE  
SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI  
II. IEC WORKING MANUAL

### **Procedure for submission of application for ethical review:**

- 1) The Principal Investigator has to submit an application in a prescribed format 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.

### **Review Procedure:**

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.

The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal.

### **Quorum Requirements:**

1. Minimum 5 members are required to compose the quorum
2. No quorum should consist entirely of members of one profession. Quorum will include at least one member as non scientific (lay person), at least one who is independent of the Sri Venkateswara Institute of Medical Sciences and at least one medical scientist.
3. In case of animal research, Veterinary Scientist should be one of the quorum
4. Legal expert should always be the member in any quorum.

## **Meeting Requirements:**

- All the IEC meetings on dates that are announced and notified in advance. 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.
- Member will be given 10 days time in advance to review study proposals and the relevant documents.
- IEC meetings will be minuted and all the proceedings and deliberation will be documented.
- Signatures of all the members who have participated in the meeting will be obtained.
- 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.
- Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.
- Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

## **Procedure for decision making:**

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

- Member having the conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes.
- Where there is conflict of interest, member will withdraw from the decision making procedure.
- A decision will only be taken when sufficient time has been allowed for the review and discussion of an application and in absence of non members.
- Decision will only be taken at meetings where a quorum is complete.
- Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal, consideration has been examined by IEC.
- Only members who participated in review and discussion will participate in decision.
- Wherever possible, the decision will be arrived through consensus not by vote, but when a consensus appears unlikely voting can be performed.
- Decision procedure will specify the conditional decision, with clear suggestions and re-review procedure.
- Negative decision will be supported by clearly stated reasons.

## **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 justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- 3) The justification for the use of control arms.
- 4) Criteria for prematurely withdrawing the research participants
- 5) Criteria for suspending or terminating the research as a whole
- 6) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring committee (DSMC).
- 7) The adequacy of the site, including the supporting staff, available facilities and emergency procedures.
- 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 The suitability of the investigator(s)'s qualifications and experience for the proposed study.
2. Any plans to withdraw or withhold standard therapies for the purpose of the justification for such action;
3. The medical care to be provided to research participants during and after the course of the research;
4. The adequacy of medical supervision and psycho-social support for the research participants.
5. Steps to be taken if research participants voluntarily withdraw during the course of the research.



6. The criteria for extended access to the emergency use of and/or the compassionate use of study products.
7. The arrangements, if appropriate for informing the research participants general practitioner (family doctor), including procedures for seeking the participant's consent to do so.
8. A description of any plans to make the study product available to the research participants following the research.
9. A description of any financial costs to research participants.
10. The rewards and compensations for research participants (including money, services, and /or gifts).
11. The provisions for compensation/treatment in the case of the injury disability/ death of a research participant attributable to participation in the research.
12. The insurance and indemnity arrangements.

**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. 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).
3. 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.
4. 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).
5. 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 assessed except in those studies where breast feeding is harmful to the infant.
- 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.

**iii) Vulnerable groups:** Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

- a. research on genetics should not lead to **racial inequalities**.
- b. persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them;
- c. 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;
- d. 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.

**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.

### **Procedure for expedited review:**

IEC will receive and consider the proposal for the expedited approval for the studies having

- 1) No or minimum risk to the trial participants.
- 2) Re-examination of a proposal already examined by the IEC.
- 3) Study of minor nature eg., examination of case records.
- 4) Similar study proposal for which IEC had already given approvals earlier.
- 5) An urgent proposal of national interest having minimum risk.

All expedited approvals will be given in a meeting with quorum of at least 3 members (nominated by the chairman) of IEC present. Quorum must have one expert or scientist having scientific knowledge in the field of proposal.

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

## **Follow up 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 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.
- 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.

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.

## **Procedure for documentation and archiving:**

All the documents and communications of IEC will be dated, filed and archived in a secured place.

Only the person, who is 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 5 years in the Institute, following the completion of the study.

No documents (except agenda) will be retained by any IEC member.

At the end of each meeting every member will return all the research proposal documents to IEC office staff.

## **Scope for amendments:**

Guidelines in this document may be subjected to amendments as and when the need arise. 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. Amended version of the document will be put before the Executive Board of SVIMS for its consideration and approval.

## 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

# 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/her ward/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:**

I have been informed about the procedures of the study. The possible risks too have been explained to me as stated in the information. I have understood that I have the right to refuse my consent or withdraw it any time during the study without adversely affecting my/my ward's treatment. I am aware that by subjecting to this investigation, I will have to give more time for assessments by the investigating team and that these assessments do not interfere with the benefits.

I,....., the undersigned, give my consent to be a participant of this investigation/study program/clinical trial, entitled" \_\_\_\_\_

\_\_\_\_\_”

**Signature of the patient/  
guardian**

guardian

(Name and address)

Signature of the Doctor/investigator:

Name and Designation

Date:

**Signature of the witness**

(Name and address)

Place:

**PI.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 his signature, name and address below the certificate.

## **IEC Membership Acceptance:**

To

The Director

Sri Venkateswara Institute of Medical Sciences

Tirupati – 517 507

Sub: Consent to be a member of IEC

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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





**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 far as 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.

**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.

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**For official use only**

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

\* Name of IEC Staff

\* Signature

Receiving application:

\* Date:

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**( To be filled by the applicant in duplicate)**

# 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 \_\_\_\_\_ at \_\_\_\_\_ hours in the meeting room \_\_\_\_\_ reviewed and discussed the study proposed with Protocol No. \_\_\_\_\_ Dated \_\_\_\_\_

Entitled" \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Submitted by Dr. \_\_\_\_\_.

## Members:

Name	Affiliation	Gender
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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 atleast one medically qualified person and atleast 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**

**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
  - 1.1 Children (less than 15 years) Yes/No
  - 1.2 Elderly (More than 60 years) Yes/No
  - 1.3 Disabled (mentally or physically handicapped) Yes/No
  - 1.4 Prisoners/Restitutes Yes/No
2. Whether the human subjects are
  - 2.1 Suffering from illness Yes/No
  - 2.2 Normal individuals Yes/No
3. Whether the project involves
  - 3.1 Clinical trial with new drug(s)/ device(s)  
approved by DCI Yes/No
  - 3.2 Clinical trial with existing drug(s)/device(s)  
approved by DCI Yes/No
  - 3.3 Clinical trial with traditional medicines from  
Ayurvedic/Unani/Homoeopathy/Tribal systems Yes/No

3.4 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

4.1 Any invasive procedure which would otherwise  
not be performed for the management of the  
patient

Yes/No

4.2 Use of invivo radioactive material

Yes/No

4.3 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 (...  
.....)

6.1 It will be obtained by

Operation/Biopsy/Abortion/Autopsy

Other (Specify\_\_\_\_\_)

6.2 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

7.1 Specify the method of collection(\_\_\_\_\_)  
\_\_\_\_\_)

7.2 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

8.1 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(\_\_\_\_\_) )

8.2 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

9.1. Voluntary written informed consent of the human subject will be obtained.

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

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

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

9.5 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 judgement 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 OF THE DEPTT.)**

1. Is the Deptt/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

**PRINCIPAL INVESTIGATOR**

**HEAD OF THE DEPTT.**

**For drug trials the following are necessary before implementation;**

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

## 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 into this \_\_\_\_\_

(day) \_\_\_\_\_ (month) \_\_\_\_\_ (year).

Preamble:

Whereas SVIMS is a superspeciality 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)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Where as 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 of Medical 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 be done:

- 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 (Second Party). \_\_\_\_\_

(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 know how. 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

Name

Designation

Designation

Seal

Seal

**INDEMNITY AGREEMENT**

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

\_\_\_\_\_  
(Name of the second party/ sponsor)

(hereinafter 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 atleast \_\_\_\_\_ per

(specify the amount of money)

occurrence combined single limit and \_\_\_\_\_ annual  
(specify the amount of money)

aggregate. 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, supercede or in any way limit any other agreements between the parties.

**SVIMS**

Name\_\_\_\_\_

Signature\_\_\_\_\_

Seal\_\_\_\_\_

Date\_\_\_\_\_

**SPONSOR**

Name\_\_\_\_\_

Signature\_\_\_\_\_

Seal\_\_\_\_\_

Date\_\_\_\_\_

## INSTITUTIONAL ANIMAL ETHICS COMMITTEE

### **Role of the IAEC**

All scientists who use animals in research must be aware that any and all use of animals must be first reviewed and approved by the Institutional Animal Ethics Committee. All proposed use of laboratory animals should be subject to review, to determine whether such use appears to be scientifically and ethically justifiable. In some circumstances, the “alternative” may simply be not to undertake the animal procedure at all. Where the necessity of conducting certain animal procedure cannot be justified sufficiently on scientific or ethical grounds, the project proposal should be rejected.

A research project involving animal subjects should take place only when it can be shown:

- that the aim of the project is worthwhile;
- that the design of the project is such that there is the strong possibility that it will achieve the aim.
- that the aim could not be achieved using morally more-acceptable and scientifically no less-acceptable alternative subjects and procedures; and
- that the likely benefits of the project are substantial enough in relation to the suffering likely to be caused to the animals used (that is, the likely benefits of the research should be 'weighed' against the 'costs' to the animals involved).

These four main points, which includes the need to consider the potential for using alternative methods, should be addressed to the satisfaction of the reviewers.

### Guidelines for project designing

1. In designing a project the investigator should first consider whether the aims of the project could be realized by using *in vitro* techniques or less sentient animal species, such as insects or nematodes. The replacement of one animal species with another, particularly if the species, which is then used, is non-vertebrate, could also be considered to be an alternative method. Therefore, the model selected should be the lowest phylogenetic species, and also the least sentient species, which will allow the scientific objective to be realized. If the use of living vertebrates is considered to be essential, the aim should be to use the minimum possible number of animals and to use strategies, which will ensure that the animals, which must be used, are subject to the minimum discomfort.
2. **Reduction alternatives** are methods for obtaining comparable levels of information from the use of fewer animals in scientific procedures, or for obtaining more information from a given number of animals, so that, in the long run, fewer animals are needed to complete a given research project or test. The greater the number of animals used in an experiment, the greater will be the overall costs, in terms of animal suffering. Thus, the numbers of animals used should be the minimum, which is consistent with the aims of the experiment.
3. **Research Strategy** is also important and should be given due consideration. For example *in vitro* systems, may be readily used for the random screening of potential new pharmaceutical agents.
4. **Small pilot studies** which can be reviewed before committing animals and resources to major experiments.
5. In view of the importance of **good experimental design** and **appropriate statistical analysis** in underpinning high quality research, and the potential savings in terms of

the numbers of animals which are used, due consideration should be given to optimum experimental design and statistical input.

6. **Refinement alternatives** encompass those methods which alleviate or minimize potential pain and distress, and which enhance animal well-being. "Distress" is an aversive state in which an animal is unable to adapt completely to stressors and the resulting stress, and therefore shows maladaptive behaviours. The stressors may induce physiological, psychological or environmental stress. "Pain" results from potential or actual tissue damage, such as that caused by injury, surgery or disease, and can lead to distress.
  
7. Pain and distress can result from both experimental and non-experimental causes. Potential sources of experimental pain and distress include: improper or prolonged restraint, experimental infections, chemical induced toxic effects, surgical and experimental procedures, post-operative pain, and improper euthanasia techniques. Non-experimental sources include: naturally occurring infectious and non-infectious diseases, sub optimal environmental conditions, improper handling, stressful housing situations, injuries sustained during fighting, and injuries associated with the housing or caging.

Much potential pain and distress can be avoided or at least alleviated with the proper use of anesthetics, analgesics and tranquilizers, which is a critical component of any comprehensive programme of adequate veterinary care. Such a programme provides for frequent observation of the animals by trained veterinary staff, to detect and appropriately relieve pain and distress. However, a substantial number of animals used in research and testing experience unrelieved pain or distress. All experimental protocols should be sufficiently detailed with regard to the type and severity of likely adverse effects, the times of peak occurrence, humane endpoints, and the remedial actions to be taken.

**Replacement alternative** methods and approaches includes the following:

- The improved storage, exchange and use of information about animal experiments already carried out, so that unnecessary repetition of animal procedures can be avoided.
  
- The use of physical and chemical techniques, and of predictions based on the physical and chemical properties of molecules.
  
- The use of mathematical and computer models, including:
  - modeling of quantitative structure - activity relationships, i.e taking advantage of correlations between molecular structure and biological activity in the prediction of the potential desired and undesired effects of series of related chemicals;

- molecular modeling and the use of computer graphics, for example in actively designing drugs and other chemicals for specific purposes; and
  - modeling of biochemical, physiological, pharmacological, toxicological and behavioural systems and processes.
- The use of “lower” organisms with limited sentience, including invertebrates, plants and microorganisms; for example, the use of bacteria in genotoxicity testing.
  - The use of the early developmental stages of vertebrates before they reach the point at which their use in experiments and other scientific procedures is regulated.
  - The use of *in vitro* methods, including sub cellular fractions, short-term maintenance of tissue slices, cell suspensions, and perfused organs, and tissue culture proper (cell and organotypic culture), including human tissue culture.
  - Human studies, including the use of human volunteers, post-marketing surveillance and epidemiology; for example, skin patch testing in humans before marketing, and monitoring consumer response after marketing, as alternatives to the animal testing of cosmetic products.

In many areas of the biomedical sciences, *in vitro* methods are increasingly used as the methods of choice in place of animal studies, not because they provide precisely the same information, but because they offer the best scientific approach to tackling the questions being asked. An example of this would be the use of tissue, cell and sub cellular preparations, *in vitro* for screening candidate compounds for pharmacological activity.

## **Powers and Duties of the Members of the IAEC**

1. Every member of the IAEC shall scrutinize the protocols and justify the need for the use of animals and the methodology detailed.
2. Whenever a nominee of CPCSEA as any Institutional Animal Ethics Committee disagrees with the proposal for experimentation on animals, which comes before the concerned Institutional Animal Ethics Committee, then the Institutional Animal Ethics Committee will not be empowered to give permission for pursuing that experiment. Such proposal should be referred to the Expert Consultant in the office of CPCSEA for placing the proposal before the sub-committee. The expert consultant will communicate the decision of the sub-committee to the organization for experimentation and only then experimentation can be commenced. If the organization has any disagreement with the decision of the sub-committee in this regard, it may appeal to CPCSEA for reconsideration, CPCSEA's decision will, however, be final.

3. Institutional Animal Ethics Committee will give permission to conduct experiments on only small laboratory bred animals viz. guinea-pigs, rabbits, rats, mice, hamster and invertebrate animals.
  
4. The nominee of CPCSEA on the IAEC is authorized to make surprise visits to the animal houses and places of experimentation on animals at any time, including holidays tensure the well being of the animals. (Section 18, PCA, Act 1960).

## APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to be sent either to the CPCSEA or Institutional Animal Ethics Committee (IAEC)

### Part A

1. \* Name and Address of establishment
  
2. \* Registration number and date of registration
  
3. Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C
  
4. Place where the animals are presently kept (or proposed to be kept)
  
5. Place where the experiment is to be performed
  
6. Date on which the experiment is to commence and duration of experiment

(The appropriate protocol for the research proposal – part B in the case of experiments using animals other than non human primates, part C for use of non-human primates – to be duly filled in, signed and appended to this form)

Signature

Name and designation of Chief Investigator

Date:

Place:

\*Applicable only for application to be submitted to CPCSEA



## PART B

Protocol for research proposals to be submitted to the committee/Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

1. Project title.
2. Chief Investigator
  - a. Name
  - b. Designation
  - c. Dept/Div/Lab
  - d. Telephone No.
3. List of names of all individuals authorized to conduct procedures under this proposal
4. Funding source
5. Duration of the project
  - a. Number of months
  - b. Date of initiation
  - c. Date of completion
6. If date by which approval is needed is less than six weeks from date of submission, justification for the same.
7. Study objectives [the aims of study (and why they are important) to be explained briefly using non-technical terms as far as possible]
8. Animal required
  - a. Species
  - b. Age / weight / size
  - c. Gender
  - d. Number to be used (Year-wise breakups and total figures needed to be given)
  - e. Number of days each animal will be housed.

9. Rationale for animal usage

- a. Why is animal usage necessary for these studies?
- b. Why are the particular species selected required?
- c. Why is the estimated number of animals essential?
- d. Similar experiments conducted in the past. If so, the number of animals used and results obtained in brief.
- e. If yes, why new experiment is required?
- f. Have similar experiments been made by any other organization agency? If so, their results in your knowledge.

10. Description of procedures to be used.

(List and description of all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiment, indication of the frequency for all procedures where appropriate. The following specific issues are also to be addressed when relevant-injections (substances, doses, sites and volumes), blood withdrawal (volumes and sites, radiation (dosage and schedules), all anesthetics and/or analgesics (dosage and routes,), mechanical methods of restraint, animal identification methods of non-survival surgical procedures and experimental end-point criteria (required when pathological changes are expected to be caused).

11. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection, or blood withdrawal)

If Yes, explanation and justification

12. Will survival surgery be done?

If Yes, the following to be described.

- a. List and description of all such surgical procedures (including methods of asepsis)
- b. Names, qualifications and experience levels of operators
- c. Description of post-operative care
- d. Justification if major survival surgery is to be performed more than once on a single individual animal.

13. Methods of disposal post-experimentation

Rehabilitation/Euthanasia (in case of euthanasia, justification for not undertaking rehabilitation and drug dosage and route for anesthesia, where appropriate, as well as methods of carcass disposal)

14. Animal transportation methods if extra-institutional transport is envisaged
  
15. Use of hazardous agents [use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Bio-safety Committee (IBC)]. For each category, the agents and the bio-safety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified)
  - (a) Radionuclide
  - (b) Biological Agents
  - (c) Hazardous chemicals or drugs
  - (d) Recombinant DNA
  - (e) Any other (give name)

Copy of IBC approval to be attached in case hazardous agents are used

**Investigator's declaration.**

1. I certify that I have determined that the research proposal herein is not unnecessarily duplicative of previously reported research.
  
2. I certify that all individuals working on this proposal, and experimenting on the animals, have been trained in animal handling procedures.
  
3. For procedures listed under item 11, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
  
4. I will obtain approval from the IAEC/CPCSEA before initiating any significant changes in this study.
  
5. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee / funding agency / other body (to be named)).
  
6. Institutional Bio-safety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents or human pathogens).
  
7. I shall maintain all the records as per format (Form D)

Signature

Date:

Name of the Investigator

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(for IAEC / CPCSEA usage)

Proposal Number

Date first Received

Date received after modification (if any)

Date received after second modification (if any)

Approval date

Expiry date

Name of IAEC / CPCSEA Chairperson.

Date:

Signature

### Form C

Record of animals bred/acquired: (to be maintained by the breeder/establishment)

Date of entry	No.of Animals (specify species, sex &age)	No.of Animals bred (Specify date of birth, species & sex)	No.of Animals acquired (Specify date of acquisition species, sex & age)	Name, address, date & from whom acquired	No.of animals transferred (Specify date, Species,sex) &Voucher/bill No.	Name, Address and registration No. of the Establishment To whom transferred	Signature
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### Form D

**Record of Animals Acquired and Experiments performed: (to be maintained by the Investigator)**

Date of entry	No.of Animals acquired- (specify species, sex& age)	Name, address and Registration No. of the breeder from whom acquired with voucher/ bill No.	Date & particular of order of grant of permission by the committee	Date/ Period of Expt.	Name and address of the person authorizing the experiment	Certification of th investigator authorizin the experiment that a conditions specified fc such an experiment hav been complied wit (Signature)
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# 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<br>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-                 |
| xi)   | IAEC guidelines  | - R.G.U.H.S, Bangalore |