

Institutional Ethics Committee

Standard Operating Procedures

Icfai Foundation for Higher Education

Deemed-to-be-University under section 3 of UGC ACT 1956.

Donthanapally, Shankarpally Road, Hyderabad, India



S. Vijayalakshmi

REGISTRAR

ICFAI FOUNDATION FOR HIGHER EDUCATION
(Deemed-to-be-University establishes under section 3 of UGC Act 1956.)

Standard Operating Procedures
for
Institutional Ethics Committee of Icfai Foundation for Higher Education,
Hyderabad, India

The Institutional Ethics Committee (IEC), IFHE Hyderabad, India. was constituted by the Honourable Vice Chancellor, IFHE Hyderabad, according to guideline of UGC for a period of three years.

S.No.	Name	Address	Designation
1.	Prof. J Mahender Reddy	Vice Chancellor	Chairman
2.	Dr. S Venkata Sessaiah	Director, IBS	Member
3.	Dr. M Srinivasa Reddy	Director, FST	Member
4.	Dr. A V Narsimha Rao	Director, FoL	Member
5.	Prof. V N Reddy	Adjunct Professor	Member
6.	Prof. Pratap Reddy K	Adjunct Professor	Member
7.	Dr. V V Bhanoji Rao,	Adjunct Professor	Member
8.	Dr. C. S Shylajan	Dean, IBS	Member

I. Short Description of SOP:

The following may be called as “Standard Operating Procedures for the Institutional ethics committee (IEC) of IFHE Hyderabad, ”.

II. Objective:

The objective of this SOP is to contribute to the effective functioning of the IEC-IFHE so that a quality and consistent ethical review mechanism for research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for research.

III. Role of IEC-IFHE:

IEC-IFHE will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the ethical issues related to research.

The IEC-IFHE will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The SOPs will be updated periodically based on the changing requirements.

The mandate of the IECs will be to review all research projects involving prototypes, materials and subjects to be conducted at the Institute, irrespective of the funding agency.

IV. Composition of IEC-IFHE:

IEC-IFHE should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IEC-IFHE.

The number of persons in an ethical committee should be kept fairly small (7-9 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a Committee will make it difficult in reaching consensus opinions. 12-15 is the maximum recommended number.

The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who generally belongs to the same Institution should conduct the business of the Committee. Other members should be a mix of Engineering / Management and non- scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows :-

1. Chairperson
2. 1-2 scientists/professors.
3. 1-2 Professors from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

V. Authority under which IEC-IFHE is constituted:

The Institutional Head, Hon'ble Vice Chancellor, IFHE Hyderabad, will constitute the IEC-IFHE.

Membership requirements:

- a. The duration of appointment is initially for a period of 3 years.
- b. At the end of 3 years, as the case may be, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.
- c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member. .
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting.
- f. Members of Ethics committee will declare conflict of interest with proponent and/or projects at the initiation of meeting. They will not be part of deliberations on projects submitted by self, siblings, spouse, children, parents and first degree relatives. In case they abstain from participation for other reasons they have to agree with the decisions of the Ethics Committee.

VI. Frequency of meetings:

The Ethics committee will meet about once in 6 months or as per the requirement.

VII. Quorum requirements:

The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

VIII. Offices:

The Chairperson will conduct all meetings of the IEC-IFHE. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairperson before communicating to the researchers with the approval of the appropriate authority.

Independent consultants:

IEC-IFHE may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in thrust areas. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC-IFHE.

IX. Application Procedures:

- a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation
- b. All relevant documents should be enclosed with application form (**Annexure I**)
- c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ethics committee.
- d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
- e. The decision will be communicated in writing. If revision is to be made, the **revised document** in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting. (**Annexure II**)

X. Documentation:

All Research proposals (6 copies along with 1 CD/DVD) shall be submitted along with the information and documents as specified in **Annexure III** to the Member Secretary, Institutional Ethics Committee at the IEC office, IFHE, .

Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project. Efforts taken to minimize the 'risks'. For trials, proposed compensation and reimbursement of incidental expenses and management of research related and unrelated risks during and after research period. Description of the arrangements for indemnity, if applicable in study-related risks and description of the arrangements for insurance coverage for research participants, if applicable. (**Annexure IV** and **Annexure V**)

XI. Review procedures:.

- a. The meeting of the IEC-IFHE should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.
- b. The proposals will be sent to members at least 2 weeks in advance.
- c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
- d. Researchers will be invited to offer clarifications if need be.
- e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed. The Chair may direct the secretary to obtain review by an expert prior to consideration for ethical approval by the EC. The reviewer has to give comments in writing on scientific merit and feasibility to assist in the decision of the EC. Chairperson will identify

the name of the external reviewer. Members of EC can suggest names of external reviewers to the chair for approval.

- f. The decisions will be minuted and Chairperson's approval taken in writing.

XII. Distribution of Review work:

a. New Proposal:

Review proposals have to come to full committee.

b. Revised Proposal:

In case of minor amendments the investigators will state what changes have been made. This will be subject to approval by the Chair. If there are major modifications the Chair may place the proposal before full committee for approval.

c. Special Case

The sponsors will have to submit project for review by Institutional Ethics Committee.

XIII. Element of review:

- a. Scientific design and conduct of the study.
- b. Approval of appropriate scientific review committees.
- c. Examination of predictable risks/harms.
- d. Examination of potential benefits. .
- e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
- f. Management of research related risks, adverse events.
- g. Compensation provisions.
- h. Availability of products after the study, if applicable.
- i. Patient information sheet and informed consent form in local language.
- j. Protection of privacy and confidentiality.
- k. Involvement of the community, wherever necessary.
- l. Plans for data analysis and reporting
- m. Adherence to all regulatory requirements and applicable guidelines
- n. Competence of investigators, research and supporting staff
- o. Facilities and infrastructure of study sites
- p. Criteria for withdrawal of patients, suspending or terminating the study

(Annexure VI to VIII)

XIV. Expedited review:

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairperson to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review can be done by circulation and there must be an immediate response (7 days).

XV. Decision Process:

- a. Members will discuss the various issues before arriving at a consensus decision.
- b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- c. Decisions will be made only in meetings where quorum is complete.
- d. Only members can make the decision. The expert consultants will only offer their opinions.

XVI. Suggested decisions made by committee:

For all new proposals reviewed the committee will come to one of the following decisions:

- a. Approval as submitted
- b. Withheld approval contingent upon specific revisions – Chair alone will approve the revisions.
- c. Tabled for substantive change – Full EC will approve changes.
- d. Disapproved

If a proposal has been disapproved then the person could resubmit it for review to the committee.

XVII. Communicating the decision:

- a. Chairperson will sign the final minutes.
- b. Decision will be communicated by the Member Secretary in writing to the PI/Research scholar within two weeks after the meeting at which the decision was taken. All the approvals will be valid for three years or for the duration of the project.
- c. Suggestions for modifications, if any, should be sent by IEC-IFHE.
- d. Reasons for rejection should be informed to the researchers.
- e. The schedule / plan of ongoing review by the IEC-IFHE should be communicated to the PI.

XVIII. Follow up procedures:

- a. Annual progress report will be reported in a standardized format. (**Annexure IX**)
- b. Reports should be submitted at prescribed intervals for review.
- c. Final report should be submitted at the end of study.
- d. All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated.
- e. Protocol deviation, if any, should be informed with adequate justifications.
- f. Any amendment to the protocol should be resubmitted for renewed approval.
- g. Any new information related to the study should be communicated.
- h. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

- i. Change of investigators / sites should be informed.

XIX. Record keeping and Archiving:

- a. Curriculum Vitae (CV) of all members of IEC-IFHE.
- b. SOPs of IEC-IFHE
- c. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
- d. Minutes of all meetings duly signed by the Chairperson.
- e. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
- f. Copy of all correspondence with members, researchers and other regulatory bodies.
- g. Final report of the approved projects.
- h. 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.

XX. Updating IEC-IFHE members:

- a. All relevant new guidelines should be brought to the attention of the members.
- b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

Annexure- I

Application for Ethical Committee Approval

To,
The Chairperson/Member Secretary
Institutional Ethics Committee IFHE Hyderabad,

Subject : Regarding submission of Research Proposal for Ethical Approval.

Dear Sir/Madam,

My topic of research project is
".....
.....
.....
....." I am submitting this

research project for the ethical clearance certificate approval from Institutional Ethics
Committee of IFHE Hyderabad, .

Kindly do the needful.

Date :

With regard

Encl. 1. CV of
PI/CoPI/Collaborators
2. Related annexures

Name and Signature of
PI/Co PI/ Collaborator with
Address.....
.....

Annexure - II**Standard Format for Submission of revised/additional Document**

Format for *submission of revised/additional documents, protocols and information regarding already approved projects* to be submitted by the Principal Investigator (PI) (Two copies of this form along with the revised documents to be submitted)

1. **IEC Reference No:**
2. **Approval Date and Number:**
3. **Title:**
4. **Principal Investigator:**
5. **Purpose of this submission:**
6. **New documents being submitted:** Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:

Signature PI/Collaborator

Date:

Name:

Annexure – III

Standard Format for Executive Summary
to be submitted for Ethical Approval
(up to 5 pages)

1. Title of Project:
2. Investigators (Name & Affiliation):
3. Collaborators (if any):
4. Potential Funding Agency:
5. Background and Brief Review of Literature with references:
6. Hypothesis and Objectives:
7. Study design and methods:
8. Intervention:
9. Inclusion and exclusion criteria:
10. Sample size for primary outcomes:
11. Data Management and Analysis:
12. Ethical clearances:
13. Time Line:

Signature of Principal Investigator: _____

Date: _____

Annexure – IV

MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding (hereinafter called MOU) between Icfai Foundation for Higher Education, India, through Registrar, IEC-IFHE, (herein after called IFHE, Hyderabad), the Principal investigator of the Project (the Second Party _____ (herein after called _____)) and the sponsoring Agency (the third Party _____ (herein after called _____)) of the Project entered into on this _____ (day) _____ (month) _____ (year).

Preamble :

Whereas IFHE is a deemed to be University, established under Section 3 of UGC Act 1956 for providing education and research of high order.

Whereas (the third Party) _____

Whereas IFHE and (the second party) _____
_____ are willing to jointly
participate in the development of _____

The coordinator of the project will be

_____ (name and designation of
the faculty member responsible from IFHE,) (Second Party). The other coordinator of the project
will be

_____ (name and designation of person responsible for
third _____ party).

Scope of MOU

This MOU will cover the joint efforts of Icfai Foundation for Higher Education, , (First Party), the Principal investigator of the Project (Second Party) and _____ (third 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 IFHE,

- 1.
- 2.
- 3.
- 4.
- 5.

Responsibilities of Second Party

- 1.
- 2.
- 3.
- 4.
- 5.

Responsibilities of Third Party

- 1.
- 2.
- 3.
- 4.
- 5.

Administration:

Joint responsibilities of the project will be with Icfai Foundation of Higher Education, Hyderabad., (first Party), the Principal investigator of the Project (Second Party) and _____(third party)

Financial Arrangements:

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

The following equipment/consumables/supplies will be provided to IFHE, by (third Party) _____

(This is for MOU's 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 second and third party.
3. Patents and other benefits, arising out of the project if any, shall be shared between all three 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 IFHE, , generating the knowhow. The sharing of 60% between the IFHE, and the project investigator team may be decided by the IFHE, .

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 IFHE, and _____(third 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. The Vice Chancellor, Icfai Foundation for Higher Education, India. will be the arbitrator and the decision of the arbitrator shall be final.

Jurisdiction and Courts:

The MOU shall be governed by Laws of India and the parties agree to be subject to jurisdiction of competent courts at Telangana i.e. High Court and Subordinate courts at in addition to other places in India only.

Seal of the Parties:

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

Parties:

(1) Signed and delivered for
and behalf of IFHE, (First Party) and

(2) Signed and delivered for
behalf of (Second Party)

Signature

Name

Designation

Seal

Signature

Name

Designation

Seal

(3) Sign and delivered for and behalf of (Third Party)

Signature

Name

Designation

Seal

Note : This is to be written on stamp of Rs. 100/-

Annexure – V

INDEMNITY AGREEMENT

The indemnity agreement is between Icfai Foundation for Higher Education, Telangana., India (hereinafter IFHE,) through Principal Investigator and

_____ the authorized Signatory of Second party

(Name of the second party/sponsor)

(hereinafter SPONSOR)

whereas IFHE, 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 IFHE, and SPONSOR have agreed that IFHE, will use SPONSOR's experimental and investigational products, devices, drugs for research purposes.

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

3. ***Insurance:***

The SPONSOR agrees to maintain inforce at its sole cost and expense with reputable insurance companies, Insurance of a type and in amounts equal to atleast ____per occurrence combined (*specify the amount of money*) single limit and__annual (*specify the amount of money*) aggregate. IFHE, 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 expense, attorneys to defend against any claims made or action filed against IFHE, its officers, employees. The SPONSOR also agrees to pay any settlement amounts or judgments levied against IFHE, or any losses or expenses incurred by IFHE, resulting from such claims or action.

5. ***Cooperation of parties***

IFHE, (Principal Investigator) agrees to notify promptly, SPONSOR in writing when any undesirable side effect, risks arises from research involving SPONSOR's products, devices, drugs. IFHE, 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 IFHE, 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. ***Institutional Overhead***

10% of total budget (less the cost of equipment) be provided as institutional overhead.

7. ***Other***

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

Indian agents can sign on behalf of foreign sponsor.

Tripartite agreement is needed.

Signed for and on behalf of IFHE,

Name_____

Signature_____

Seal_____

Date_____

Signed for and on behalf of SPONSOR

Name_____

Signature_____

Seal_____

Date_____

Note : Indemnity Agreement is to be written on stamp of Rs. 100/-

Annexure -VI

Standard Format Informed Consent Form in English & Hindi

Title of Project:

Investigators (Name & Affiliation):

Collaborators (if any):

Potential funding agency:

Patient/Parent/Guardian Consent

PART 1

1. Purpose of the study
2. Study procedures
3. Risk from the study
4. Benefits from the study
5. Complications
6. Compensation
7. Confidentiality
8. Rights of the participants
9. Alternatives to participation in the study

PART 2

Patient/Parent/Guardian Consent

I have had the study explained to me and have read the contents of this form/had the contents of this form read to me. I have been given the opportunity to ask question and have them answered to my satisfaction.

I am willing for my child to be enrolled in the study

Name of subject:

Signature of Patient/Parent/Guardian:

Name of Patient/Parent/Guardian:

Date:

Relationship to subject :

Investigator's statement:-

I, the undersigned have explained to the parent/guardian in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signature of the Investigator:

Date:

Name of the Investigator:

Signature of the Witness:

Date:

Name of the Witness:

Annexure -VII

PARTICIPANT INFORMED CONSENT FORM (PICF)

(For the Subject / Patient)

The advantages and disadvantages of the research in which I am expected to participate, for which I have to donate _____ sample has been explained to me.

I willingly, under no pressure from the researcher –

(i) agree to take part in this research and agree participate in all investigation which will help acquire knowledge for the benefit of the mankind.

(ii) agree to donate my

My consent is explicitly not for disclosing any personal information. For disclosing any such personal information obtained from the investigations conducted on my project, further consent should be obtained.

I have been informed that researcher (_____) will take my prior consent before they draw benefits from research based on my project.

Name -	Subject/Patient	Witness	Principal Investigator
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Signatures -	Subject/Patient	Witness	Principal Investigator
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Annexure-VIII

IFHE Hyderabad,

*Check List for submitting Research Proposals for clearance of Ethical Committee***PART I**

1. Title of the Project : _____

2. Investigator's Name & Department : _____

3. Source of Funding : _____

4. Check List

S.No.	Particulars	Yes	No	If No (Give Reason)
a.	Executive Summary (Proposal/Modification)			
b.	New Proposal for Modification			
c.	Informed Consent Form	(a) English		
		(b) Hindi		
d.	Budget			
e.	Memorandum of Understanding (Industry Sponsored Projects)			

5. Whether the project involves

- 5.1 Experimental work/prototype building Yes ☐ No ☐
- 5.2 Study oriented Yes ☐ No ☐
- 5.3 Programming Yes ☐ No ☐
- 5.4 Note of the above Yes ☐ No ☐

PART II

(DECLARATION BY THE PRINCIPAL INVESTIGATOR)

I hereby declare that :

1. Voluntary written consent of the project from respective department will be obtained.
2. In case of students involved in experimental then consent of the parents/guardians will be obtained.
3. The probable risk involved in the project will be explained in full detail to the parents/guardians.
4. Parents/guardians will be at liberty to opt out of the project at any time.
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 high risk, to the people involved and to the institution.

Date : _____

(Name & Signature of Principal Investigator)

Dept. _____

PART III

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

1. Is the Department/University ready to undertake the responsibility of the prototype preparation/experimental work? Yes ☐ No ☐
If yes, then will it include
 - Transportation Charges Yes ☐ No ☐
 - Consumable 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 the other method? Yes ☐ No ☐
3. Do you think that the experiments carried put support the need for 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 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 investigators 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 ☐

(Signature of Principal Investigator)

(Signature of Head of the Dept.)

Name of PI

Name of HOD

Date of Receiving _____

(Signature)
On behalf of IEC

Annexure - IX

Standard Format for Annual Progress Report
(up to 5 pages)

1. Institute Ethics Committee Reference No. _____
2. Title of Project: _____

3. Investigators (Name & Affiliation): _____

4. Collaborators (if any):
5. Potential Funding Agency:
6. Hypothesis and objectives
7. Duration of the Study:
8. Date of Starting of the study:
9. Period of Annual progress report: From _____ to _____

Progress:

Side Effects if any:

Amendments if Any:

Discontinuation reasons:

Signature of Principal Investigator _____

Name of PI _____

Date: _____



S. V. Gayala
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