

Standard Operating Procedures

for

Institute Ethics Committee (Human Studies)



2010



**Jawaharlal Institute of Postgraduate
Medical Education and Research
Puducherry - 605 006**

*Institution of National Importance under
Ministry of Health and Family Welfare,
Government of India*

Jawaharlal Institute of Postgraduate Medical Education and Research Puducherry - 605 006

*Institution of National Importance under Ministry of Health and
Family Welfare, Government of India*



2010

**Standard Operating Procedures for
Institute Ethics Committee (Human Studies)**

PREFACE

JIPMER was established in 1964 as a regional medical centre with an attached tertiary care hospital. Since then it has been functioning to impart quality education in under-graduate and post-graduate medical and paramedical courses while offering patient care of high order.

JIPMER has now attained the status of “Institution of National Importance” (an autonomous body) under the Ministry of Health and Family Welfare, Government of India. It is now in a better position to augment research in a large scale besides teaching, training and patient care. The institute is also active in research in various fields of modern medicine & health and medical education. A research council at institute level looks after the research activities and there is a scientific society which provides forum for presentation of the research work. Funds for research come from mural and extramural sources like ICMR, UGC, DBT, WHO, etc. A number of research papers are published by faculty and residents every year in journals of national and international repute. There is an independent Institute Ethics Committee for research on humans which reviews all the research proposals by investigators who conduct research in this institute. As Ethics Committee plays a major role in guiding research while protecting participants, Standard Operating Procedures (SOP) for Ethics Committee is an important document for any educational institute involving in research.

I congratulate Dr. C. Adithan, Professor and Head of Department of Pharmacology, JIPMER and Dr. M. Jayanthi, Senior Resident, Department of Pharmacology, JIPMER for bringing out this SOP. This SOP states the procedures for constituting the Human Ethics Committee as well as the responsibilities of both the members as well as the principal investigators.

I am confident that this SOP booklet will help all the researchers for preparing the research protocols and ensure smooth functioning of the Institute Ethics Committee (Human Studies).



Dr. K.S.V.K. Subba Rao
Director, JIPMER

Editors' Note

The major responsibility of the Institute Ethics Committee (IEC) is to protect rights, safety and well being of the research participants. JIPMER is one of the earliest Institutions in India to establish the Institute (Human) Ethics Committee. It regularly meets to review and approve all research proposals involving human participants. However, it is not having a manual of standard operating procedure (SOP) which is needed to ensure quality, consistency, reliability and uniformity of the process being followed by Ethics Committee. This deficiency is corrected with the publication of this booklet. It is designed to suit the administrative structure of this Institute conforming to the guidelines put forth by the Indian Council of Medical Research in 2006. This SOP will reinforce the optimum standards in the composition of the IEC and also the operational procedures followed by them. It would help to protect rights, safety and well being of the research participants through best possible ethics review.

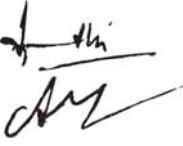
We thank Director, JIPMER for his advice and encouragement in preparation of the SOP. The SOP was written with valuable advice and guidance from Honorable Shri.S.Nadamuni, Retired Judge and Chairman of IEC. Dr.R.Ravi, member of IEC provided valuable suggestions in the preparation of the patient information sheet. Several suggestions received from the members of the IEC are also incorporated in this SOP.

In preparation of this booklet several SOPs and guidelines served as references. The important publications that were consulted by us include ICMR Ethical Guidelines for Biomedical Research on Human Subjects (2006), Nizam's Institute of Medical Sciences SOPs, Hyderabad (2004) and WHO Ethics Review Committee Guidelines (2007). We received editorial assistance from Dr.A.Surendiran, Dr.Shahid Akhtar, Dr.S.E.Damodaran and Dr.S.Madhan, Department of Pharmacology, JIPMER.

Dr.C.Adithan
Dr.M.Jayanthi

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Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 1 of 25
	Title : Establishing and Constituting the Institutional Ethics Committee (IEC)	Revision 1	Category IECH

1. PURPOSE

To establish and constitute the Ethics Committee for JIPMER.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

Director (Head of the Institute) is responsible for implementing this SOP.

4. PROCEDURE

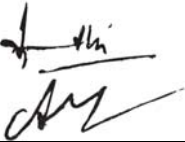

- 4.1. Director will select and nominate the Chairman and Member Secretary for JIPMER IEC.
- 4.2. The IEC will be constituted by the Director in consultation with the Chairman.
- 4.3. Director will invite the members to join ethics committee by sending the official request letter (Document 1)
- 4.4. Members will confirm their acceptance to the Director by providing all the required information for membership (Document 2)
- 4.5. The Director will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve (Document 3)
- 4.6. Director will designate and instruct Chairman of IEC or his representative to conduct the regular proceedings of IEC for the institute
- 4.7. At regular intervals, Director will review the functioning of IEC.


Approved by:


Chairman, IEC (Human)

29.03.2010

Date

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature:	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 2 of 25
	Title : Procedure for appointing members for the IEC	Revision 1	Category IECH
<p>1. PURPOSE</p> <p>To appoint suitable members for the IEC, JIPMER.</p> <p>2. SCOPE</p> <p>Applicable to JIPMER.</p> <p>3. RESPONSIBILITY</p> <p>Director (Head of the Institute) and Chairman are responsible for implementing this SOP.</p> <p>4. PROCEDURE</p> <p>4.1. Director in consultation with Chairman will nominate the members of IEC, who have the qualification and experience to review and evaluate the scientific, medical and ethical aspects of the proposed study.</p> <p>4.2. When needed, IEC will invite subject experts to offer their views.</p> <p>4.3. The appointment of an IEC member will be for 3 years.</p> <p>4.4. Director may renew the appointment on the basis of the member's contribution.</p> <p>4.5. During the term, Director in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.</p> <p>4.6. Member will have the right to discontinue from membership of IEC after giving written notice at least one month in advance.</p> <p>4.7. Director can replace the member of IEC as and when required.</p> <p>4.8. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Document 2)</p> <p>4.9. Director can nominate IEC members to undergo orientation programme in national and international developments in ethics</p>			
Approved by:	 <hr/> Chairman, IEC (Human)		29.03.2010 <hr/> Date

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 3 of 25
	Title : Procedure for convening and conducting IEC meetings	Revision 1	Category IECH

1. PURPOSE

To hold regular Ethics Committee meetings.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

The Chairman and Member Secretary are responsible for implementing this SOP.

4. PROCEDURE

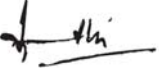

- 4.1. The Member Secretary in consultation with the Chairman may convene the IEC meeting once in every four months.
- 4.2. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
- 4.3. All the IEC meetings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

Approved by:


Chairman, IEC (Human)
29.03.2010

Date

CODE NO.: JIPMER-IECH 001

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature:  	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 4 of 25
	Title : Procedure for submission of research project for review by Ethics (Regular and Sub) Committee	Revision 1	Category IECH

1. PURPOSE

To submit a research proposal for review by IEC.

2. SCOPE

Applicable to Principal Investigators from JIPMER or other institutes where there is no independent Human Ethics Committee.

3. RESPONSIBILITY

All investigators are responsible for implementing this SOP. Every protocol or amendment submitted for review to IEC must contain number, version and date. All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review. Proposals may be submitted for review only after the approval of Institute Research Council/Scientific Advisory Committee/PG Committee/Doctoral Committee. Proof of approval needs to be submitted.#

4. PROCEDURE

- 4.1. The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC (Form No: IA or IB). All research proposals must be submitted in English language only.
- 4.2. Application can be submitted to the office of the Member Secretary, IEC, JIPMER, Pondicherry on any working day.
- 4.3. All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting
- 4.4. Fifteen copies of study proposal (with all documents) must be submitted for Regular Ethic Committee review and five copies for ethics Sub-Committee review along with application form duly signed and dated by the investigator(s). A soft copy of the proposal must also be submitted in a CD.
- 4.5. Receipt of the application will be acknowledged by the IEC office.
- 4.6. Every application will be allotted an IEC registration number to be used for all future correspondence and reference.

Approved by:




Chairman, IEC (Human)

29.03.2010

Date

CODE NO.: JIPMER-IECH 001

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 5 of 25
	Title : Procedure for initial scrutiny of proposals	Revision 1	Category IECH

1. PURPOSE

To check the research proposals submitted by the investigators for completeness.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

The office of Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

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

Approved by:





Chairman, IEC (Human)

29.03.2010

Date

CODE NO.: JIPMER-IECH 001

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature:  	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 6 of 25
	Title : Procedure for reviewing the research proposals	Revision 1	Category IECH

1. PURPOSE

To review the research proposals submitted by the investigators both scientifically and ethically.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

4. PROCEDURE

4.1. Every proposal will be sent not less than 10 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review.

4.2. All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

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

4.4. Expert opinion of additional members would be obtained if necessary.

Approved by:





Chairman, IEC (Human)

29.03.2010

Date

CODE NO.: JIPMER-IECH 001

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature:  	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 7 of 25
	Title : Procedure for expedited review of research project by Ethics Sub-Committee	Revision 1	Category IECH

1. PURPOSE

To provide expedited review and approval of a research proposal.

2. SCOPE

Applicable to the members of IEC of JIPMER.

3. RESPONSIBILITY

All members of Ethics Sub-Committee are responsible for implementing this SOP.

4. PROCEDURE

4.1 IEC will receive and consider the proposals for expedited review and approval for the studies having/involving:

- i. No or minimum risk to the trial participants.
- ii. Re examination of a proposal already examined by the IEC.
- iii. Study of minor nature like the examination of case records.
- iv. Similar study proposal for which IEC had already given approvals earlier.
- v. An urgent proposal of national interest having minimum risk.
- vi. All ICMR student projects and post graduate proposals.

All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

4.2 All expedited approvals will be given in a meeting of the Sub-Committee of three members (nominated by the Chairman). All the three members including the Member Secretary should be present for the meeting.

4.3 Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IEC.

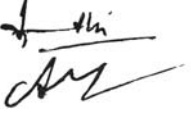
Approved by:



Chairman, IEC (Human)

29.03.2010

Date

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 8 of 25
	Title : Procedure for decision making regarding the research project	Revision 1	Category IECH

1. PURPOSE

To make a decision regarding approval of the submitted research proposal.

2. SCOPE

Applicable to the IEC of JIPMER.

3. RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

4. PROCEDURE

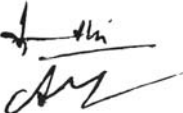
4.1. In making decision on application for the ethical review of any research proposal, IEC will consider the following:

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

Approved by:


Chairman, IEC (Human)
29.03.2010

Date

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 9 of 25
	Title : Procedure for communicating the decision of IEC to the Investigator	Revision 1	Category IECH

1. PURPOSE

To communicate the decision of IEC to the applicant.

2. SCOPE

Applicable to the IEC of JIPMER.

3. RESPONSIBILITY

Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

4.1. A decision of the IEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format (Document-4). A certificate of approval will be sent to the applicant within 2 weeks (Document-5). All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

4.2. The communication of the decision will include:

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

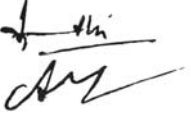
Approved by:



Chairman, IEC (Human)

29.03.2010

Date

Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 10 of 25
	Title : Procedure for follow-up of research projects by Ethics Committee	Revision 1	Category IECH

1. PURPOSE

To carry out follow-up of the research proposals.

2. SCOPE


Applicable to the IEC of JIPMER.

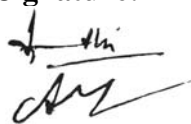

3. RESPONSIBILITY

All members of the IEC and the investigators are responsible for implementing this SOP.

4. PROCEDURE

- 4.1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
- 4.2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
- 4.3. All the requirements and procedures for follow up review will be similar to that of initial and main review.
- 4.4. Following instances and events will require the follow-up review:
 - 4.4.1. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
 - 4.4.2. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
 - 4.4.3. Any event or information that may affect the benefit/risk ratio of the study.
- 4.5. A decision of a follow up review will be issued and communicated to the applicant indicating modification/suspension/termination /continuation of the project.
- 4.6. In case of premature suspension /termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.
- 4.7. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

Approved by:  <hr/> Chairman, IEC (Human)	29.03.2010 <hr/> Date
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Prepared by: Dr. M. Jayanthi Dr. C. Adithan Signature: 	Institute Ethics Committee (Human Studies) JIPMER Standard Operating Procedure	Date	Page 11 of 25
	Title : Procedure for documentation and archiving of documents and communications of IEC	Revision 1	Category IECH
<p>1. PURPOSE To archive the study related documents, proceedings and communications.</p> <p>2. SCOPE Applicable to the IEC of JIPMER.</p> <p>3. RESPONSIBILITY The Member Secretary is responsible for implementing this SOP.</p> <p>4. PROCEDURE</p> <p>4.1. All the documents and communications of IEC will be dated, filed and archived in a secure place.</p> <p>4.2. Only persons, who are authorized by the Chairman of IEC will have the access to the various documents.</p> <p>4.3. 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.</p> <p>4.4. No document (except agenda) will be retained by any IEC member.</p> <p>4.5. At the end of each meeting, every member must return all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.</p> <p>4.6. Following documents will be filed and archived with proper label on the top of file for easy identification of proposal.</p> <p>4.6.1. The constitution, written standard operating procedures of the IEC, and regular (annual) reports.</p> <p>4.6.2. The curriculum vitae of all IEC members.</p> <p>4.6.3. A record of all income and expenses if any, of the IEC, including allowances and reimbursements made to the secretariat and IEC members.</p> <p>4.6.4. The published guidelines for submission established by the IEC.</p> <p>4.6.5. The agenda of the IEC meetings.</p> <p>4.6.6. The minutes of the IEC meetings.</p> <p>4.6.7. One copy of all material submitted by an applicant.</p> <p>4.6.8. A copy of the decision and any advice or requirements sent to an applicant.</p> <p>4.6.9. All written documentation received during the follow-up.</p> <p>4.6.10. The notification of completion, premature suspension, or premature termination of study.</p> <p>4.6.11. The final summary or final report of the study.</p>			
Approved by:	 <hr/> Chairman, IEC (Human)	29.03.2010 <hr/> Date	

Letter Ref. No:

Date:

From

Director
JIPMER
Puducherry.

To

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

* * * *

Dear Sir / Madam,

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

Yours sincerely,

Signature:

Name:

From,

To

The Director
JIPMER
Puducherry-6.

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

Ref: Your Letter No:

dated:

* * * *

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of JIPMER. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of the Member _____

Date:

Address:

Telephone No: (Off)

(Res)

email:

JIP-IEC Ref. No.:

Date:

OFFICE ORDER

I herewith establish and constitute an Ethics Committee of Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, to ensure a competent review of all ethical aspects of project proposal received and execute the same free from any bias and influence that could affect the objective.

The following members will constitute the Institutional Ethics Committee (Human studies)

1. Chairman_____
- Designation_____ Affiliation
2. Member secretary(Convener)
- Designation_____ Affiliation
3. Member
- Designation_____ Affiliation
4. Member
- Designation_____ Affiliation
5. Member
- Designation_____ Affiliation
6. Member
- Designation_____ Affiliation
7. Member
- Designation_____ Affiliation
8. Member
- Designation_____ Affiliation
9. Member
- Designation_____ Affiliation
10. Member
- Designation_____ Affiliation
11. Member
- Designation_____ Affiliation
12. Member
- Designation_____ Affiliation
13. Member
- Designation_____ Affiliation

The tenure of this membership will be for a period of 3 years from the date of appointment.

Signature
Director, JIPMER

Institute Ethics Committee (Human Studies)
JIPMER

Review letter No. IEC/JIP/

Date: _____

To,

The _____ meeting of the Institute Ethics Committee (Human Studies) for the year _____ was held in _____, JIPMER on _____ under the chairmanship of _____. Besides the Chairman, _____ (Member Secretary), _____ (Member), _____ (Member), attended the meeting.

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

No. of proposals reviewed - _____

No. of proposals approved - _____

No. of proposals approved subject to corrections - _____

The recommendations made by the committee are given below.

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

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

DEPARTMENT _____

Sl No.	Reg. No.	Name of the student/Principal Investigator	Title of dissertation	Name of Guide/co-Guide	Recommendations of the committee

Any change, modification or deviation in the protocol, or any serious adverse event must be informed to ethics committee within fourteen days. Any protocol modification or amendment must receive IEC approval. Investigator should conduct the study as per the recommended GCP/GLP guidelines.

It is also confirmed that our ethics committee is constituted and functions as per Good Clinical Practice guidelines issued by Central Drugs Standard Control Organisation and Ethical Guidelines for Biomedical research on Human Subjects, issued by Indian Council of Medical Research.

Member Secretary
Institute Ethics Committee
(Human studies)

Chairman
Institute Ethics Committee
(Human studies)

Name:

Signature:

Date:



JAWAHARLAL INSTITUTE OF POST GRADUATE MEDICAL EDUCATION
AND RESEARCH (JIPMER) PUDUCHERRY-605 006

(Institution of National Importance under Ministry of Health and Family Welfare, Government of India)

No. IEC. -----

Date: -----

CERTIFICATE

This is to certify that the project No. -----, entitled "-----"
submitted by -----, has been approved by the Institute Ethics Committee/Sub-
Committee (Human Studies), at its meeting held on -----, under the following terms and
conditions.

This approval is valid for three years or the duration of the project whichever is less.

Member Secretary
Institute Ethics Committee (Human studies)
JIPMER

Form IA

Proforma to be submitted to the Institute Ethics Committee (Human Studies) (for projects other than those mentioned in Form I B)

Kindly submit 15 copies of proforma and consent forms in 2 parts (in English and Tamil) to the Member Secretary, Institute Ethics Committee (Human Studies), JIPMER, Puducherry

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Number of projects already with the investigators/co-investigators:
4. Date of approval by JIPMER Research Council:
5. Sources of funding:
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc:
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Costs involved (Appx. in Rs.)
 - a) Investigations
 - b) Disposables
 - c) Implants
 - d) Drugs/Contrast MediaWho will bear the costs of the requirements? 1. Patient 2. Project 3. Exempted
4. Other Agencies (Name)
11. Ethical issues involved in the study:
less than minimal risk / minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines - at JIPMER website)
12. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications.
13. Whether Consent forms part 1 and 2 in English and in local language are enclosed?
14. Documents attached
 - (a) Brief CV of investigators (including no. of projects with him/her) - Needed only for Investigator/s from outside JIPMER
 - (b) Investigator's Brochure
 - (c) Others
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
16. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigators:

Date :

Signature of the Head of the Department

Date:

(Note: The proforma must be accompanied by Consent forms I & II in English and Tamil. Consent form I is equivalent to Patient Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

Form IB

Proforma to be submitted to the JIPMER Institute Ethics Sub-Committee (Human Studies) for MD/MS/DM/M.Ch/Ph.D/MSc Students (for Thesis or Dissertation)/MBBS student projects

Kindly submit 5 copies of proforma and consent forms in 2 parts (in English and Tamil) to the Member Secretary, Ethics (Human) committee, JIPMER, Puducherry

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by Institute Research Council/ Scientific Advisory Committee/ PG committee/ Doctoral committee:
5. Sources of funding
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Ethical issues involved in the study:
less than minimal risk/ minimal risk/ more than minimal risk to the study subjects (for guidance please consult ICMR guidelines - at JIPMER website)
11. Do you need exemption from obtaining Informed Consent from study subjects – if so give justifications
12. Whether Consent forms part 1 and 2 in English and in local language are enclosed?
13. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
14. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigators:

Date :

Signature of the Head of the Department

Date:

(Note: The proforma must be accompanied by Consent forms I & II in English and Tamil. Consent form I is equivalent to Patient Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

CONSENT FORM

PART 1 of 2

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The patient information sheet must be duly signed by the investigator

CONSENT FORM

PART 2 of 2- Participant consent form

Participant's name:

Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Note: Consent form II should be appropriately worded for adults and children (less than 18 years) e.g. If the participant is less than 18 years of age, instead of 'my participation', 'my child's/ward's participation' needs to be replaced.

Form II

Initial Check list to verify completeness of documents submitted

For official use only

Proposal No. _____

1. Fifteen copies of the proposal for regular ethics committee along with a soft copy in CD format
2. Five (for PG dissertation/PhD thesis/ICMR studentship) copies of proposal for ethics sub-committee meeting along with a soft copy in CD format
3. Proforma and consent forms (English) matching with those given in JIPMER web site
4. Proforma completely filled with all the questions answered in complete sentences
5. Proforma duly signed by the investigator(s), guides, co-guides and Head of concerned departments, with date
6. Consent forms I and II in both English language and the local language (Tamil)
7. Consent form I completely filled with all the questions answered in complete sentences and in simple language. (abbreviations to be avoided)
8. Consent form I written in dialogue format addressing the patient/participant
9. Complete address and phone number of the investigator/guide provided in the appropriate place in consent form I
10. Consent form II appropriately worded for adults and children (less than 18 years) e.g. Instead of 'my participation', 'my child's/ward's participation' to be replaced.

Form III

Check list for verification of proposals submitted to Institute Ethics committee (Human studies)

For official use only

Proposal No. _____

	Yes	No	NA	Comments
Is all the documentation provided?				
Scientific importance and validity				
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert, policy maker or statistical expert? (If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person)				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Are the investigators qualifications, competence and experience appropriate to conduct the study?				
10. Are the facilities at the site adequate to support the study?				
11. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risks/Benefits				
1. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
4. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
5. Is there provision for compensation for participants who sustain injuries?				

	Yes	No	NA	Comments
6. Have adequate provisions been made for dealing with and reporting adverse effects?				
7. Have adequate provisions been made for safety monitoring and termination of the research project?				
Respect for the dignity of the research participants				
<i>Informed consent</i>				
1. Is the process for obtaining informed consent appropriate?				
2. Are the participants competent to give consent?				
3. Is the justification adequate for the intention to include individuals who cannot consent?				
4. Will dissent be respected?				
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
<i>Confidentiality</i>				
1. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
<i>Rights of the participants</i>				
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?				
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
3. Is there provision for the subjects to be informed of results of clinical research?				
Fair participant selection				
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favour any group?				

	Yes	No	NA	Comments
5. Is the research conducted on vulnerable individuals or groups?				
6. Is the research externally sponsored?				
7. Is the research a community research?				
8. Is the research a clinical trial?				
Responsibilities of the researcher				
1. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher obtained permission from the relevant authorities?				
3. Are there any conflicts of interest, including payments and other rewards?				
4. Are there any other ethical / legal/ social /financial issues in the study?				

Additional Comments:

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Recommendation: Approve [] Reject [] Conditional Approval (please state the conditions)

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Name of Reviewer:

Signature :

Date :

Acknowledgements

- 1. WHO Ethics review committee guidelines (2007)**
- 2. ICMR Ethical Guidelines for Biomedical research on Human Subjects(2006)**
- 3. All India Institute of Medical Sciences, New Delhi**
- 4. Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad**

