DIVISION OF RESEARCH, JIPMER

CIRCULAR

Guidelines for Sponsored Clinical Trials of Drugs and New Devices

1. **Preamble:**

Clinical research is essential for development of safer new drugs. India is emerging as a global hub for clinical research. JIPMER being the premier research Institute, having dedicated and experienced doctors and patients with variety of illnesses, has the responsibility to actively participate in new drug development and new devices. JIPMER is receiving several proposals from pharmaceutical industries, medical companies, contract research organisations for conducting studies with new drugs and new medical devices. The present guidelines will provide the necessary information for screening, evaluating, accepting and carryout the sponsored clinical trial of drugs and new devices at JIPMER

2. **Purpose and Scope:**

The proposed study should aim to

2.1 develop a new chemical entity or new drug which includes pre-clinical and clinical studies – all phases of clinical trial
2.2 investigate a new use/indication of the existing drug
2.3 develop and/or testing new medical devices to be clinically used
2.4 develop and / or advanced technology for patient care, teaching and research

3. **Scientific merit:** The study should be directed towards development of newer therapeutic strategies including new drugs & molecules, new biological agents, vaccines, new medical devices, newer uses of available drugs and devices. It should be targeted towards addressing national health problems, priority areas identified by Govt. of India, ICMR, WHO and similar organisations.
4. **Sponsors of the study:**
   a. Government, semi-Government and private research & development organisations in India and abroad
   b. Original manufacturers of medical devices, drug molecules and investigational new drugs

Contract Research Organisations (CRO) can not sign agreement with the Investigator/Institute. However the original sponsors of the study/trial can operate through authorised CROs. The details should be mentioned in the agreement form.

5. **Initiation of the Proposal:** The agency/industry interested in a clinical trial/project at JIPMER, may approach the concerned department HOD/Faculty member with a request to conduct the trial. The concerned faculty will be the Principal Investigator and submit the proposal for Director's permission through Clinical research committee.

6. **Responsibility of Principal investigator (PI)**

   The PI is responsible for preparing and execution of Institute Sponsor Agreement, detailing any commitment of institutional resources, and submitting the proposal to the Clinical Trial Research Committee and the Institute Ethics Committee JIPMER for approval. He is authorised to withdraw the money after due permission from the Director's office, spend the money as per the agreement and submit audited statement of account to the Director office at the end of the study. Once the study has been executed, he should submit the final report to the sponsor as per the institute sponsor agreement with a copy to the Director office through the Head of the Department.

   The PI for the trial/project is permitted to negotiate the terms and conditions of the trial/project with the funding agencies on behalf of the Institute. The PI and other investigators are also permitted to attend the "Investigators' Meeting" with regard to development of methodologies and protocol of the clinical trial/project. They will be given special casual leave as per the Institute policy.

   It is the responsibility of the Principal Investigator to get the trial registered with Clinical Trial Registry of India.

7. **Institute Sponsor Agreement (ISA):** The sponsor and the investigator should enter into an agreement before initiating the study. The ISA should include the details of sponsors and investigators, obligations and responsibilities of sponsor and investigators, funding, Ethics committee and informed consent, duration of the study and agreement, protocol, subject enrolment, study conduct, study data, biological samples, study records, disclosure required by law, confidentiality agreement, monitoring, inspection and audit, issues related to invention, patents, intellectual property rights, publication rights, indemnification, liability and insurance, conditions for termination of project, governing law or any relevant details.

8. **Clinical Trial Research Committee (CTRC) approval:** The 5 member Clinical Trial Research Committee will be appointed by the Director. Dean will be the chairman of the committee. The other members will be Member Secretary – Institute Human Ethics Committee, Head of the Department of Medicine, Head of the Department of Surgery and Head of the Department of Clinical pharmacology (Member Secretary). The Chairman can co-opt upto 2 subject experts related to the project. CTRC will have monthly meeting on first Thursday of the month. It will exclusively consider, discuss and approve proposals submitted for clinical trial of new drugs and new medical devices.
9. **Ethics committee approval:** The ethics committee will take up proposals approved by CTRC. The study and the informed consent form should be approved by the Institute (Human) Ethics Committee before starting the study. The Principal Investigator and Co-investigators will submit a six monthly progress report to Institute Ethics Committee. They will report any serious adverse event (SAE) to the Institute Ethics Committee within 24 hours of occurrence.
10. **Drug Controller General of India (DCGI) permission:** The sponsoring agents should submit drug controller's permission along with their proposal, wherever needed.
11. **Health Ministry Screening Committee (HMSC) Permission:** The approval from the HMSC, Govt. Of India should be obtained for multinational studies, wherever necessary.
12. **Funding:** The details of funding including head-wise proposed expenditure, overhead charges for the institute, subject compensation should be submitted. All payment should be sent in the name of "The Director, JIPMER" .
13. **Institute fee (Institute overhead charges):** It shall be 25 % of the total cost of the project to be done at JIPMER. Fifty percent of the overhead charges will be provided to the principal investigator's department, at the discretion of the Director. The Principal investigator will use this money exclusively for research and academic purpose and for the infrastructure development of the parent and collaborating departments. The institute fee for the Government sponsored projects (e.g., DBT, ICMR etc) will be as per their norms.
14. **Eligibility of investigators:** The principal investigator should have a postgraduate degree in the concerned speciality and be a permanent employee of the Institute
15. **Appointment of project staff:** The Principal Investigator will appoint project staff as per the norms laid by JIPMER.

16. **Clinical pharmacology department:** It is recommended that Department of Clinical Pharmacology, JIPMER may be consulted for advice and execution of clinical trials
17. **Insurance:** The ISA should clearly state the liabilities of the sponsor and also insurance details of all study participants against any anticipated or unforeseen injuries, illnesses etc related to the study.
18. **Utilization of unspent balance:** The Principal Investigator may refund the unspent balance to the funding agency. In case he/she desires to utilize the unspent balance for a pilot study of another research project, he/she needs to obtain approval from the CTRC, JIPMER. However, in no case the unspent fund will be utilized for travel or any other personal benefit. The unspent money could also be donated to JIPMER for other purposes such as care of poor patients or research if a written letter of permission from the funding firm/industry is received. The Director, JIPMER, in consultation with CTRC will take a final decision on such unspent money for any other welfare measure in JIPMER.
19. **Closure of the study:** At the time of closure of study, the Principal investigator should submit project completion report and also audited statement of accounts to the Director office through Clinical Trial Research Committee, within 4 months of completion of the study.
20. In case of any dispute related to clinical trial, the Director, JIPMER decision is final.
21. **Legal aspects:** The ISA shall be governed by and interpreted in accordance with the laws of India and both Parties consent to the exclusive jurisdiction of the Courts at Pondicherry/Chennai, India.

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RESEARCH PROPOSAL REGISTRATION FORM

(Eight copies to be submitted to the Member Secretary, Clinical Trial Research Committee)

CTRC NO:_____

(FOR OFFICE USE)

1. Name of the Investigator :
2. Department/Division :
3. Designation :
4. Name of Co-Investigators : 1.
   (Qualification, Designation & Department)

2.

3.

4.

5. Title of the project :

6. Year of start of the study :

7. Year of proposed termination of study :

7. Sponsor's Name : Self ☐

8. Ethics Committee approval received : Yes ☐ No ☐ NA ☐

9. If yes, approval No and date :

APPLICATION FOR PROJECT PROPOSAL APPROVAL

(Eight copies to be submitted to the Member Secretary, Clinical Trial Research Committee)

CTRC NO:_____

(FOR OFFICE USE)

1. Title of the project :
2. Principal Investigator :
3. Designation :
4. Department :
5. Sponsor's Name and Address :
6. Proposed date of starting project :
7. Duration of project :
8. Budget details / Plan :

S. No.	BUDGET HEADS	AMOUNT (LAKH Rs)
1.	Equipment	
2.	Equipment maintenance charges	
3.	Salaries	
4.	Hospital expenses (Investigation, hospital stay charges etc)	
5.	Subject compensation (transport, means etc)	
6.	Travel (investigator's meet, conferences, project work etc)	
7.	Contingencies (Xerox, stationary, postage, telephone, fax etc)	
8.	Consumables	
9.	Miscellaneous	
10.	Others	
11.	Insurance charges (for investigators, patients/volunteers)	
	TOTAL COST OF STUDY CONDUCT	
12.	Institutional over heads (25%)	
	GRAND TOTAL	

10. Enclosures :

(For list of enclosures see on next page)

CTRC NO:_____
(FOR OFFICE USE)

Check list for enclosures:

1.	Research proposal Registration form	Enclosed	Yes/No
2.	Application For Project Proposal Approval including Budget Details	Enclosed	Yes/No
3.	Short summary (synopsis) of research proposal	Enclosed	Yes/No
3.	Request letter from sponsor (if applicable)	Enclosed	Yes/No
4.	Ethics committee approval	Enclosed	Yes/No
5.	DCGI approval (if applicable)	Enclosed	Yes/No
6.	Institute Sponsor Agreement (ISA)	Enclosed	Yes/No
7.	HMSC permission (if applicable)	Enclosed	Yes/No
8.	Any other documents enclosed (give details):		

11. Signatures of the investigators:

Name	Department	Designation	Signature

Principal Investigator

1.

Co-Investigators

1.

2., etc

Date:

(For official use)

CTRC NO:_____

Date:

Project Title:

Principle Investigator:

Comments/suggestions:

Decision: Approved / not approved

DEAN
(Chairman, CTRC)

DIRECTOR
(Financial authority)