Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)

Puducherry

Sponsored Clinical Trial Research Committee (SCTRC)

JIPMER

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Standard Operating Procedures for the review, approval and conduct of sponsored clinical trials in JIPMER

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2. Changes from previous version of the SOP

Not applicable. This is the first version of the SOP.

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3. Purpose

This document describes the overall process of approval and conduct of sponsored clinical trials at JIPMER, including the procedure for the review of proposals for such trials by the Sponsored Clinical Trials Research Committee (SCTRC), in order to guide the investigators who wish to conduct such trials.

4. Constitution of the SCTRC

The SCTRC will consist of 7-10 members, with Dean (Research) as the ex-officio Chairman, and Law Officer as an ex-officio member. The other members will be appointed by the Director from among faculty members at the Institute. While choosing these members, an attempt will be made to ensure that various skill-sets required are adequately represented in the committee (e.g. expertise related to conduct of clinical trials, and knowledge in the fields of medical, surgical, public health, and pediatric streams, etc.). Half the members will be changed every 3 years.

The Chairman may co-opt up to 2 subject experts (including from outside the institute – in consultation with the Director) for discussion on a particular project, if deemed necessary.

The current members (Admin/II/ Committee/2020 dt. 29 Jun 2020) are as follows:

Name, Designation	Role
Dr. R. Raveendran, Professor (Sr. Scale), Dean Research, JIPMER	Chairperson
Dr. Gautam Roy, Prof (Sr. Scale), Preventive and Social Medicine	Member*
Dr. L. N Dorairajan, Professor (Sr. Scale) and Head, Urology	Member
Dr. B Adhisivam, Addl. Prof of Pediatrics and Head, Neonatology	Member*
Dr. Rashmi Kumari, Addl. Prof and Head, Dermatology and STD	Member*
Dr. Vikas Menon, Addl. Prof, Psychiatry	Member and Alternate Member Secretary
Mr. Mathivathanan, Law Officer, JIPMER	Member
Dr Prasanth Ganesan, Addl. Prof and Head, Medical Oncology	Member Secretary

The persons marked with * will continue till 30 June 2023, and the others till 30 June 2026.

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5. Roles and responsibilities

Role	Responsibilities
Chairman	a. Overall in-charge b. Deciding on dates for meetings c. Final approval of minutes of meetings d. Issue of the final approval certificate from SCTRC after verifying the checklist and recommendation submitted by the Member-Secretary (CO-5)
Member Secretary	Besides his/her role as a member, s/he will: a. Receive new proposals from principal investigators (PIs) b. Maintain all records pertaining to the SCTRC, including of all meetings, in coordination with the office of Dean (Research) c. Fix dates for and organize meetings in consultation with the Chairman d. Prepare and circulate minutes of each meeting and respond to PIs (CO-3) e. Forward a copy of each new proposal to the Law Officer for obtaining his comments on the Clinical Trial Agreement (CTA) f. Help investigators in processing of sponsored trials through SCTRC g. Issue the initial certificate (CO-4) for submission of proposal to IEC h. Scrutinize each proposal for approval from all committees, using the pre-trial checklist, and forward these with his recommendation to the Chairman for issue of certificate to start the study
Alternate Member Secretary	Besides his/her role as a member, s/he will act as Member-Secretary: a. In the absence of the Member Secretary b. For projects where the Member Secretary is the PI/co-investigator, s/he will also maintain and circulate the minutes of the meeting for discussions involving the above projects c. Document conflict of interest of the mem sec in the minutes in the above situation
Law Officer, Member	a. Review legal aspects of the CTA, including ensuring that all the required elements are represented and that interests of are preserved. For this, each CTA will be sent to him/her and his comments will be presented and reviewed in the next meeting b. Representing JIPMER and the PI at any legal proceedings during or after the clinical trial
Members	Review of scientific content of all protocols for sponsored clinical trials, including doing a risk vs benefit analysis, and the feasibility of doing the study at JIPMER.

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6. Scope

SCTRC will review all proposals for research projects sponsored by industry and undertaken with an intent or having potential for submission of data for regulatory purposes. All such proposals must be approved by the SCTRC before these can be submitted to the Institute Ethics Committee.

These will include studies using:

i. a new chemical entity, including a biosimilar and generic product
ii. a new indication for an existing drug, with a regulatory intent
iii. a new device
iv. a new route of administration for a previously-approved drug
v. a new technology for research, patient care or teaching

Multi-centric research projects or clinical trials involving academic institutions and those of non-regulatory nature, or those projects funded by government agencies (including Foreign Government) but excluding public sector undertakings ***will not be reviewed by SCTRC.***

The committee shall also consider any other matter that may be referred to it by Director, JIPMER.

7. Conduct of meetings

a. *Calling for meetings:* The Chairman will decide the date and time for each meeting, and the Member-Secretary will circulate this information to the members. The committee will generally meet once a month, if any projects are available for discussion. Quorum would be considered met if at least 50% of the members are present for a meeting.

b. *Procedure:* Each proposal to be discussed will be sent to all the members ahead of the meeting. Three members will be chosen as primary discussants for each project who will give their comments in the prescribed format. (SCTRC-F-15). These comments and observations will be discussed during the meeting and the response of the PI will be noted. These comments will be made available in the records.

c. *Minutes:* The Member-Secretary will prepare minutes of each meeting and circulate these to all the members. Based on comments from the members, the final minutes will be prepared which will be approved by the Chairman. These will be finally presented at the next meeting and formally approved.

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8. Work-flow for sponsored clinical research

1. Receipt of proposal and review by PI
1A. PI receives proposal for sponsored trial
1B. PI signs CDA and obtains the trial documents
1C. Instruct the sponsor to pay the SCTRC sitting fee (Appendix 1)
1D. PI reviews the trial and CTA using guidelines (PI-1A,PI-1F)

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2. Submission to SCTRC for review
2A. Submission of trial documents to SCTRC (Format: PI-1A to PI-1F)
2B. Simultaneous submission of CTA to law officer with checklist(PI-1F)

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3. Protocol circulation and review
3A. Review comments by primary reviewers(Format: CO-1)
3B .Law officer provides comments (Format: CO-2)
3C. Conduct of the SCTRC meeting and presentation by PI- detailed review of proposal

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4. Providing comments to the PI
4A. Minutes circulated within SCTRC and approved by chairman
4B. comments provided to PI (CO-3)

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5. PI modification as per SCTRC and resubmission
5A. PI discusses SCTRC comments with the sponsor, makes changes as needed
5B. Resubmits to SCTRC (Format: PI-02)

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6. Review of resubmission by SCTRC
6A. Modifications are reviewed by Member secretary and Chairman
6B. if accepted, SCTRC provides ***initial*** approval letter (CO-4)

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7. EC submission and approval
7A. PI submits the proposal to Ethics committee (EC)
7B. Obtain EC approval

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8. Final CTA approval
8A. Submit the CTA to Director for approval with changes as per SCTRC and EC and all changes highlighted [Forwarded by Dean(R)] (Format: PI-3)
8B. CTA approval and signature by PI, Director and sponsor
8C. Submit copy of CTA to Dean (R)

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9. Start-up funds
9A. Discuss with sponsor to provide initial Start up funds
9B. Funds are transferred to Research account

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10. Errors and omissions policy for the trial
10A. Request to Dean(Research) to include trial in SFACTS (Format: PI-4)
10B. Once funds are available, obtain errors and omissions policy if required

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11. Pre-trial checklist and Final approval
11A. Resubmit to Dean (Research) with pre-trial check list (Format: PI-5)
11B. Final approval to start project by Dean (Research)(CO-5)

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12. Initiation and conduct of the trial
12A. Initiation of trial
12B. Annual report and End of study reports to SCTRC (PI-6)

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9. Steps in the approval of sponsored clinical trials

9.1 Confidentiality Disclosure Agreement (CDA)

a. A prospective sponsor wishing to conduct a clinical trial/ project at JIPMER may approach a head of the department/ or a faculty member and discuss the idea.

b. Faculty members may discuss ideas for clinical trials with prospective sponsors, may sign the CDA if it is required. While signing the CDA, the SCTRC may be informed but no formal permission is needed.

c. The signature of the Director/ Dean (Research) is not required in the CDA and PI will take responsibility for the provisions of the CDA.

9.2. Submission of proposals

a. Once the trial protocol is received the PI must submit a proposal to the SCTRC in the specified format (PI-1A to PI-1F), along with all the supporting documents and undertaking as a soft copy attachment to the email jipmersctrc@gmail.com

b. One hard copy of all documents and an additional hard copy of the CTA must be submitted to the office of the Dean (Research).

9.3. Sitting Fees- SCTRC

a. The sponsor must pay a sitting fee of Rs. 25,000/- (Rupees twenty-five thousand only) for each proposal. It may be paid online through JIPMER website http://jipmer.edu.in/online-payments/ by selecting the category DIV OF RESEARCH SCTRC and after filling the necessary details. The payment receipt will serve as proof of payment.

b. Alternatively, a challan form can be downloaded after filling the details online and the amount can be paid at any branch of State Bank of India. The PAN no for this account is AAAJJ0846M. The proof of payment of this fee must be enclosed along with the submission.

c. This payment must be made prior to the meeting of the SCTRC and proof of payment can be submitted prior to the meeting, if not provided prior to submission itself.

d. Payment by cheque, demand draft, NEFT RTGS or by cash is not acceptable.

9.4 Actions to be taken by the Principal investigator (PI)

Eligibility: The principal investigator should have a postgraduate / postdoctoral degree in the specialty concerned and he/ she must be a permanent employee of the Institute. The PI will be responsible for the following steps:

a. Signing of CDA

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b. Preparing and submitting the documents to SCTRC in the prescribed format
c. Ensuring that the study will be started only after final approval by the Dean (Research) and the Institute Ethics Committee, and the execution of the Clinical Trial Agreement (CTA)/ Institute Sponsor Agreement (ISA)
d. The investigator must understand that any drug or device under investigation must be administered or implanted, as the case may be, only by the investigator or a co-investigator or a person authorized by him in writing as part of the protocol.
e. The PI is authorized to withdraw the money after due permission from the Director's office, spend the money as per the agreement and submit a statement of account to the Director office at the end of the study.
f. Submit a final report to the office of the Dean (Research) in the prescribed format (PI-6) soon after completion of the study
g. Negotiate the terms and conditions of the trial/project with the sponsor
h. The PI and other investigators may attend "Investigators' Meeting" for the development of protocol and standardization of methods of the clinical trial/project. They will be given leave as per the Institute policy. No honorarium can be received for this purpose. Any expense for travel and accommodation will be borne by the sponsor.
i. PI should ensure that trial is registered with Clinical Trial Registry of India before starting the study and that the CTRI website is regularly updated about any amendments made as well as the progress of the study

9.5. Clinical Trial Agreement (CTA)/ Institute Sponsor Agreement (ISA)

Before the trial commences, a tripartite agreement (CTA/ISA) involving the sponsor, PI and JIPMER (Director, JIPMER) has to be signed with the following details(PI should check these clauses and can negotiate these with the sponsor *prior* to initial submission):

a. Contact names and addresses of sponsors and investigators
b. Obligations and responsibilities of sponsor and investigators
c. Funding mechanism and budget
d. Duration of the study and of the agreement
e. Disclosures as required by law
f. Statement on adherence to the laws governing clinical trials in India
g. Confidentiality clauses, if any

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h. Monitoring mechanisms for the study
i. Inspection and audit related clauses
j. Issues related to invention, patents, intellectual property rights and publication rights
k. Clinical trial insurance: sponsor or his authorized representative takes responsibility for providing insurance to cover compensation for patients who suffer injury or death as a result of trial participation
l. Indemnification, liability and insurance: professional liability of health care providers involved in the clinical trial is covered by the sponsor due to issues arising from the trial participation. Alternatively, the PI and the study team should have an errors and omissions policy in place to cover for professional liability as part of the trial.
m. Conditions for termination of project
n. Dispute resolution: Arbitration clause must be present
o. Statement that all disputes 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
p. If biological specimens are being sent outside JIPMER, assurance that these will be used only for such tests as mentioned in the protocol and for no other purpose and residual samples will not be retained but be discarded at the end of the study

9.6. Other regulatory approvals and steps

a. *Institute Ethics Committee* (Interventional): Each study should be approved by the Institute (Human) Ethics Committee before it starts and serious adverse events (SAE) must be reported to the Institute Ethics Committee within 24 hours of occurrence
b. *Drug Controller General of India* (DCGI): The sponsoring agents should obtain permission from the Drug Controller General of India (DCGI) for the study and the site and submit these prior to study commencement
c. *Registration in Clinical Trial Registry of India (CTRI)*: Trial should be registered with CTRI and JIPMER site should be included
d. *Health Ministry Screening Committee* (HMSC) Permission: Approval of the HMSC should be obtained for international funding, wherever necessary.

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9.7. Decision on proposals

a. After initial review, the SCTRC may provide comments to the PI. These will be conveyed to the PI by the member secretary after the approval of the Chairman in the format CO-3.
b. The PI may discuss with the sponsor and give a point-by-point response to the comments given by the SCTRC (PI-2)
c. If the SCTRC is satisfied with the response from the PI, the member secretary will convey a "Initial approval" to the PI (CO-4) to allow the PI to submit the proposal to the EC.
d. However, the trial can start only after a ***final approval*** is issued by Dean (research) Form (CO-5). For this, the PI should submit the final checklist (PI-5) to the SCTRC and the member secretary will verify and provide recommendations to the Dean (R).

9.8. Submission of reports

The PI will submit reports in the prescribed format (PI-6) as follows:

a. **Annual report**: *within three months of completion of each year* of the trial
b. **Project Completion Report**: *within three months* of completion of the trial.

10. **Policy on laboratory tests on biological material**

a. In general, all laboratory tests must be done in JIPMER
b. When biological samples are sent to a laboratory outside JIPMER because a particular test cannot be done in JIPMER, or to maintain uniformity in test procedure, the sponsor/ laboratory must provide that the samples will be used only for the tests as mentioned in the protocol and for no other purpose, and residual samples be discarded at the end of the study
c. When samples are to be sent abroad, the sponsor must give an assurance the guidelines on the transfer of human biological material, issued by the Ministry of Health and Family Welfare, Govt. of India, New Delhi, vide O.M. No.L.19015/53/97-IH (Pt.) dated 19th Nov. 1997 will be complied with

11. **Policy on document archiving and handover of documents**

a. All regulatory documents submitted by the PI shall be the retained by the Dean (Research) office in a single file for each trial
b. The other study related documents relating to individual participants etc. will be retained by the PI

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