ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

Guidelines/SOP for Industry Sponsored Clinical Trials of Drugs and New Devices

Research Section

AIIMS, Jodhpur

1. **Preamble:**

Clinical trial conducted in the AIIMS Jodhpur should follows the highest standard of ethics as per the national and international norms. The research should be in sync with the disease burden of the India.

2. **Purpose and Scope:**
   - The proposed study should aim to
   - Develop a new chemical entity or new drug which includes pre-clinical and clinical studies – all phases of clinical trial
   - Investigate a new use/indication of the existing drug.
   - Develop and/or testing new medical devices/ techniques and investigations to be used clinically.
   - Develop and /or advanced technology for patient care, teaching and research.

3. **Scientific merit: The study should be conducted to develop new** drugs & molecules or newer uses of available drugs, new biological agents, vaccines and new medical devices. Clinical trial should be done preferably for the diseases common in the India as mentioned in the thrust areas identified by Govt. of India, ICMR, WHO and similar organisations.

4. **Sponsors of the study:**
   - Original manufacturers of medical devices, drug molecules and investigational new drugs.
   - Government, semi-Government and private research & development organisations in India and abroad.

Original sponsors of the trial execute the contract through authorized Contract Research Organisations (CRO) but CRO independently will not negotiate the agreement. Relevant details should be mentioned in the agreement form.

5. **Initiation of the Proposal:** Authorized person of the industry/agency interested in a clinical trial/project at AIIMS Jodhpur, 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 through proper channel.

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

The PI will be responsible and accountable for all scientific and financial aspects of project. He/she will be responsible for preparing and execution of the agreement between Institute and sponsoring agency and submitting the proposal to the Clinical Trial Research Committee and the

Institute Ethics Committee AIIMS Jodhpur for approval. Any query or communication with the Institute authorities will be done by the PI only.

The Principal Investigator can maintain a current A/C jointly with the Co-I on the name of Trial where an advance of not more than 25% can be transferred with a justification and after that the next amount shall only be released after the submission of Utilization Certificate of the earlier amount.

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. It is preferable to retain the publication rights with the PI. 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. The finance for any activity of the project will not be borne by the Institution.

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:** CTRC (Clinical Trial Research Committee) must ensure the study is conducted with respect to good clinical compliance and patient safety. The 5 member Clinical Trial Research Committee will be appointed by the Director (1.Committee constitution).

   Dean (Research) will be the chairman of the committee. The committee constitution will be decided by the Director, with preferably member of the Department of Pharmacology as (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 (or any other day as seems suitable

to all). 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. A fee of INR 20,000/- shall be levied upon the Sponsoring agency as fee for considering the proposal in IEC. 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. **Constitution of Subcommittee for serious adverse events SAE/ data safety monitoring committee (DSMC**): Serious adverse events should be submitted to IEC and sponsor within 24 hours. To assess the IEC for monitoring of adverse events in clinical trials, a subcommittee for SAE termed as data safety monitoring committee DSMC will be constituted as IEC. Its function includes giving opinion on causality of SAE and submit it to DCGI within 14 days of occurrence with intimation to IEC. It will also decide the amount of compensation to be given to the patients with trial related injury along with monitoring of clinical trial. DSMC will prepare its own SOP which has to be ratified by IEC before implementation. The subcommittee should review the SAE during trial. When the risk is found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physician must assess whether to continue, modify or immediately stop the study). Protocol of reporting has to be prepared

11. **Drug Controller General of India (DCGI) permission:** The sponsoring agents should submit drug controller's permission along with their proposal, wherever needed.

12. **Health Ministry Screening Committee (HMSC) Permission:** The approval from the HMSC, Govt. Of India should be obtained for multinational studies, wherever necessary.

13. **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, AIIMS Jodhpur".

14. **Institute fee (Institute overhead charges):** For the projects with a total budget of up to INR five lakhs, the Institute Overhead charges would be 10% of the overall budget, whereas for the proposals with a budget of more than five lakhs it shall be 25% of the total cost of the project. Fifty percent of the overhead charges will be provided to the principal investigator. The Principal Investigator in consultation with the Head of Department and

other faculty members 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.

15. **Eligibility of investigators:** The principal investigator should have a postgraduate degree in the concerned speciality and be a permanent employee of the Institute

16. **Appointment of project staff:** The Principal Investigator will appoint project staff as per the norms.

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 shall refund all the unspent money to the funding agency.

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, AIIMS, Jodhpur 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 Jodhpur, Rajasthan, India.**

Version-01, Approved by Dean Research Committee in meeting on 16th September, 2017.