"CLINICAL TRIAL SCREENING COMMITTEE"
SMS MEDICAL COLLEGE & ATTACHED HOSPITALS, JAIPUR

STANDARD OPERATING PROCEDURE

Composition of Clinical Trial Screening Committee:

As per Principal office order No. MC/GS/07/16510 dated 4 June, 2007 and No. MC/GS/2007/16644 dated 7 June, 2007 & No. 1131/F3(68) MC /GS/2007 dated: 16/01/2008, order no 31286-9 dated 1/11/2008 and 29662 dated 18/09/2009, order No. F3(68)/MC/GS/2007/28450 dated 08/11/2011 , order No. F3(68)/MC/GS/2007/32502 dated 09/12/2011 and order No. F.5( )/MC/GS/2014/244 dated: 03-01-2014, order No. F.5( )/MC/GS/2014/6728 dated: 04/03/2015, No. F.5 (112)/MC/GS/2015/26593 dated: 22/09/2018.

Clinical Trial Screening Committee of this Medical College is hereby re-constituted consisting of the following officers:

1. **Dr. Rambabu Sharma,** Additional Principal , SMSMC, Jaipur.**(Chairman)**
2. **Dr. C.L. Nawal,** PHOD, Department of Medicine, SMSMC, Jaipur.**(Co - Chairman)**
3. **Dr. Arun Chougule,** PHOD, Department of Radiological Physics, SMSMC Jaipur. **(Nodal Officer)**
4. **Dr. R.K. Pokharna,** Professor, Department of Gastroenterology, SMSMC, Jaipur.**(Member)**
5. **Dr. M.L. Gupata,** Professor, Department of Pediatrics, SMSMC, Jaipur.**(Member)**
6. **Dr. Sandeep K. Mathur,** PHOD, Department of Endocrinology, , SMSMC, Jaipur **.(Member)**
7. **Member/ Representative** of Pharmaco-vigilance committee **(Member)**

The Clinical Trial Screening Committee Meeting will be held on third Thursday of every month, if holiday is falling on third Thursday, meeting will be held on next working day. If needed, additional meeting may be called with 7days notice. At least 50% of the members of the Clinical Trial Screening Committee (Minimum 4 members) have to be present to constitute a quorum. If quorum is not complete, The Chairman will convene the adjourned meeting after 20 minutes and will complete the scheduled task.

The Clinical Trial Screening Committee will examine the feasibility of the project and evaluate the infrastructure available with Principal Investigator for carrying out the project.

The Principal Investigator will provide following information to Clinical Trial Screening Committee:

1. The Principal Investigator will submit seven copies of the project in a standard format along with abstract and flow chart format (Six copies to Dr. Arun Chougule, Nodal Officer & one copy to Dr. Rambabu Sharma, Chairman) **at least 10 days prior** to the schedule meeting.
2. Furnish information regarding feasibility and objectiveness of the project.
3. The Principal Investigator should furnish information regarding other ongoing projects and their current status. The project related to drug trial of Principal Investigator having more than 03 Industry/Pharma sponsored clinical/ drug trials ongoing at a time will not be considered.
4. The Principal Investigator should furnish information regarding infra-structural facilities including subject qualified manpower available in the institute for carrying out the project.
5. Submission of Contract/Memorandum of understanding (Clinical Trial Agreement) signed between the Principal investigator & The Sponsoring Institute/Agency.
6. The Principal Investigator or nominee should appear personally before the committee. In case, he is unable to do so, then he/she should inform the convener prior to the meeting and should make alternative arrangement.
7. Principal Investigator should also send 16 copies of the project to Ethics Committee (EC).
   After evaluation, Clinical Trial Screening Committee will send its report to Principal & Controller, SMS Medical College, Jaipur for further necessary action.

(Dr. Rambabu Sharma)
Chairman

(Dr. Arun Chougule)
Nodal Officer

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY CLINICAL TRIAL SCREENING COMMITTEE (CTSC), S.M.S. MEDICAL COLLEGE & ATTACHED HOSPITAL'S JAIPUR

6 Copies of the Research Project along with Covering letter with the following information to be submitted to **Prof. Arun Chougule, Nodal Officer**, Clinical Trial Screening Committee, PHOD, Department of Radiological Physics, SMSMC, Jaipur. Ext. No. 638 and one copy **Dr. Rambabu Sharma, Chairman**, Clinical Trial Screening Committee, Additional Principal, SMSMC, Jaipur. The Principal Investigator must submit **Protocol written by him through Head of the Department who ensures that the project has been wetted both from the scientific and ethical point of view.**

The submission must be accompanied with Informed Consent and Patient Information Sheet in both English and Hindi (with validation certified), copy of insurance policy, copy of financial agreement, copy of DCGI permission and investigators undertaking.

Project Submission Time: Projects will be received on all working days. Proposals received till 10th of any month will be processed in the same months Clinical Trial Screening Committee meeting and those received after 10th will be processed in the next Clinical Trial Screening Committee meeting. All meeting of Clinical Trial Screening Committee will be held preferably on every **3rd Thursday of the month** if holiday falls on that day meeting will be held on next working day with convenience.

The research projects proposal submitted should be as follow:

<table>
<tr><td>1. Full Title of Study:</td><td colspan="2"></td></tr>
<tr><td>2. Name of Investigators/Co-investigators (permanent SMS Faculty with designation and department)
2.1 _____
2.2 _____
2.3 _____
2.4 _____
2.5 _____
(Expand if more co-investigators)</td><td>Signature

2.1 _____
2.2 _____
2.3 _____
2.4 _____
2.5 _____</td><td>No. of projects already with investigators</td></tr>
<tr><td>3. Objective of the study</td><td colspan="2">3.1 _____
3.2 _____
3.3 _____
3.4 _____
3.5 _____</td></tr>
<tr><td>4. Justification for conduct of this study</td><td colspan="2"></td></tr>
<tr><td>5. Methodology</td><td colspan="2">5.1. Number of Patients:

5.2. Inclusion criteria
a). _____
b). _____
c). _____
d). _____
5.3. Exclusion criteria
a). _____
b). _____
c). _____
d). _____
5.4. Control (S) _____</td></tr>
</table>

	5.5. Study design _____ 5.6. Dosages of drug _____ 5.7. Duration of treatment _____ 5.8. Investigation _____ 5.9. Others _____
6. Permission from drug controller General of India (DCGI)	1 Required 2 Not required 3 Received 4 Applied When: _____
7. Permission from DGFT if applicable	1 Required 2 Not required 3 Received 4 Applied When: _____
8. **a)** Safety measures for proposed interventions **b)** Result of relevant laboratory tests **c)** Results of studies in human	a) _____ b) _____ c) _____
9. Plans to withdraw standard therapy during conduct of research	Yes No Remarks: _____
10. Plan for provision of coverage for medical risk (s) / insurance of patient during the study period	
11. How you will maintain confidentiality of subject?	
12. **Total Budget (Approx. in Rupees)** who will bear the cost of investigation/implants drugs/contrasts?	1 Patient 2 Project - Sponsor 3 S Exempted 4 Other Agencies (Name)
13. Attached documents **a.** Financial agreement **b.** DCGI Permission **c.** DGFT Permission **d.** Any other documents	13.1Brief CV of Investigators (including No. of projects with him 13.2Investigator's Brochure 13.3_____ 13.4_____
Conflict of interest for any other investigators(s) if yes , please explain in brief	1 _____ Yes No 2 _____ Yes No 3 _____ Yes No 4 _____ Yes No

I agree to deposit the EC/Institutional fees as per rule.

SIGNATURE
PRINCIPAL INVESTIGATOR

Comments Head of the department.

SIGNATURE

HEAD OF THE DEPARTMENT

CHECK LIST FOR CLINICAL TRIAL SCREENING COMMITTEE

1. STANDARD FORMAT FORWARDED BY HOD ☐
2. SUMMARY OF STUDY ☐
3. FLOW CHART ☐
4. INSURANCE ☐
5. DCGI PERMISSION ☐
6. CLINICAL TRIAL AGREEMENT ☐
7. DGFT PERMISSION ☐
8. PATIENT INFORMED CONSENT FORM HINDI & ENGLISH ☐
9. NO. OF PROJECTS RUNNING & FEASIBILITY ☐
10. AVAILABILITY OF INFRASTRUCTURE & STAFF FOR PROPOSED WORK. ☐

Signature of Principal Investigator