Copyright Office
Government of India

सत्यमेव जयते

Extracts from the Register of Copyrights

Dated : 16/08/2021

1.	Registration Number	:	**L-106467/2021**
2.	Name, address and nationality of the applicant	:	SANTOSH DEEMED TO BE UNIVERSITY [INDIAN INSTITUTE] , GHAZIABAD, UTTAR PRADESH-201009 INDIAN
3.	Nature of the applicant's interest in the copyright of the work	:	OWNER
4.	Class and description of the work	:	LITERARY/ DRAMATIC WORK
5.	Title of the work	:	OPERATIONAL GUIDELINES FOR MANAGEMENT OF CLINICAL TRIALS IN A HEALTH SCIENCES UNIVERSITY
6.	Language of the work	:	ENGLISH
7.	Name, address and nationality of the author and if the author is deceased, date of his decease	:	DR. JYOTI BATRA , SANTOSH DEEMED TO BE UNIVERSITY GHAZIABAD, UTTAR PRADESH-201009 INDIAN DR. TRIPTA BHAGAT , SANTOSH DEEMED TO BE UNIVERSITY GHAZIABAD, UTTAR PRADESH-201009 INDIAN
8.	Whether the work is published or unpublished	:	UNPUBLISHED
9.	Year and country of first publication and name, address and nationality of the publisher	:	N.A.
10.	Years and countries of subsequent publications, if any, and names, addresses and nationalities of the publishers	:	N.A.
11.	Names, addresses and nationalities of the owners of various rights comprising the copyright in the work and the extent of rights held by each, together with particulars of assignments and licences, if any	:	SANTOSH DEEMED TO BE UNIVERSITY [INDIAN INSTITUTE] , GHAZIABAD, UTTAR PRADESH-201009 INDIAN
12.	Names, addresses and nationalities of other persons, if any, authorised to assign or licence of rights comprising the copyright	:	N.A.
13.	If the work is an 'Artistic work', the location of the original work, including name, address and nationality of the person in possession of the work. (In the case of an architectural work, the year of completion of the work should also be shown).	:	N.A.
14.	If the work is an 'Artistic work' which is used or capable of being used in relation to any goods or services, the application should include a certification from the Registrar of Trade Marks in terms of the provision to Sub-Section (i) of Section 45 of the Copyright Act, 1957	:	N.A.
15.	If the work is an 'Artistic work', whether it is registered under the Designs Act 2000 if yes give details.	:	N.A.
16.	If the work is an 'Artistic work', capable of being registered as a design under the Designs Act 2000.whether it has been applied to an article though an industrial process and ,if yes ,the number of times it is reproduced.	:	N.A.
17.	Remarks, if any	:	

Diary Number : 15142/2021-CO/L
Date of Application : 07/07/2021
Date of Receipt : 07/07/2021

TITLE: - OPERATIONAL GUIDELINES FOR MANAGEMENT OF CLINICAL TRIALS IN A HEALTH SCIENCES UNIVERSITY

AUTHORS: DR. JYOTI BATRA & DR. TRIPTA BHAGAT

SANTOSH DEEMED TO BE UNIVERSITY,

GHAZIABAD, UTTAR PRADESH- 201009

Clinical Trials is complex process involving various stakeholders from the fields of scientific, medical and translational research background. In India, the process for conducting clinical trials has been involved very much in last decade at par with international standards. Clinical Trials are regulated and governed in India by national regulatory authority, i.e, CDSCO and Ethics Committees.

The standards and requirements for conducting clinical trials have been laid out in New Drugs & Clinical Trials Rules 2019, Drugs & Cosmetics Rules 1945 and Good Clinical Practice guidelines. These standards clearly delineate the responsibilities and expectations from various stakeholders involved in the trial such as Principal Investigator, Institution, Study Team, Clinical Research Organisation & Sponsor involved in such studies.

To conduct a clinical trial at any Hospital it is essential that the Study site is equipped with adequate resources and infrastructure to address the needs of study protocol. Upon completion of feasibility, the staff and Investigators involved in trial should be imparted adequate training and should possess requisite background to participate in such studies.

Clinical Trials which happen as per required standards not only bring scientific and academic value for the institution and investigators who participate but also provide the source of an additional revenue stream for them to compensate for the resources used in such studies. Considering the time sensitive requirements of clinical trials and involvement of financial revenue, it is advised by experts across the world that such clinical studies should be conducted planned and administered through a process which allows for fair and equitable distribution of resources and revenue from such studies while ensuring that the factors

which may cause coercion and undue influence to any stakeholder are removed at beginning of any such clinical study.

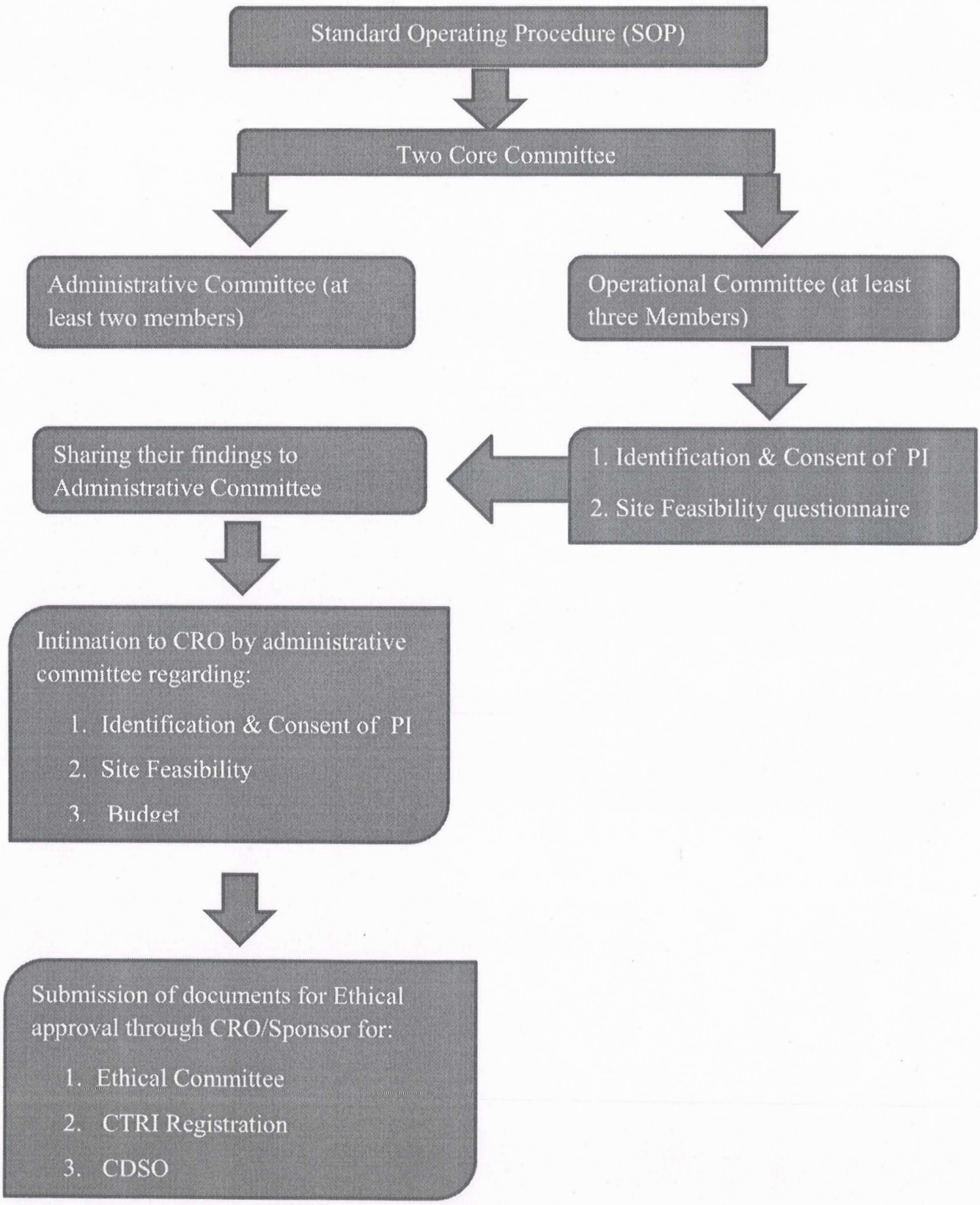
To comply with national / international standards while ensuring timely completion of such studies, an operational process / guideline has been prepared which will be used to plan, allocation, monitoring and conduct of such clinical studies:

1. Two Core committees (Operational Committee & Administrative Committee) to be constituted with clearly defined responsibilities & scope which will be responsible for activities related to clinical trials.
2. Each committee to consist of at least two members and should meet on weekly basis to assess the progress of ongoing clinical trials and to decide way forward for new/upcoming projects
3. The **Operational committee** should consist of at least three members, namely, Head of Institution, One Member with experience in clinical trials and One Representative from Management. The role of operational committee will be to guide and handhold the stakeholders of clinical trials for:
    a. Setting up of clinical trial projects
    b. Training and guidance to new prospective PI's on the relevance and benefits of clinical research for PI and Institution
    c. Handholding & guidance in devising strategies for early execution & completion of clinical trial projects
    d. Support to Administrative Committee in conducting feasibility & due diligence at the time of taking up new projects
    e. Providing suggestions for prospective PI who can take up the study
    f. Troubleshooting activities and support in resolution of hurdles which will allow for faster execution of trials

4. The **Administrative Committee** should comprise of at least two members with representation of Institute (preferably Head of Institute) and one

representative from Management. The scope of activities of Administrative committee will be as follows:

a. Conduct Preliminary discussions with Sponsor / CRO regarding feasibility of upcoming clinical trial projects
b. Risk-benefit assessment of each clinical trial prior to initiation project considering the factors such as scientific / academic value of the clinical trial and prospective risks involved vis-a-vis financial benefits for PI/Institute.
c. Verification of necessary legal & statutory compliances such as regulatory & Ethics Committee Approvals, Mechanism for Indemnification for PI/Institute from Sponsor/CRO to safeguard the PI/Institute
d. Suggest Prospective PI after discussion with Operational Committee & PI consent for participation
e. Execution of Clinical Trial Agreement between PI, Institute & Sponsor/CRO as per prescribed format.
f. Budget negotiation & finalization of study budgets with Sponsor / CRO & PI
g. Distribution / Allocation of study related revenue to appropriate PI / Institute Accounts
h. Monitor and review the progress of ongoing trials and track the payment of outstanding dues to the Institute / PI in timely manner
i. Plan, develop and execute strategies to bring more clinical trial projects
j. Provide overall monitoring and support to operational team and PI in cases where there may be delay in starting new projects.


Standard Operating Procedure (SOP)
Two Core Committee
Administrative Committee (at least two members)
Operational Committee (at least three Members)
1. Identification & Consent of PI
2. Site Feasibility questionnaire
Sharing their findings to Administrative Committee
Intimation to CRO by administrative committee regarding:
1. Identification & Consent of PI
2. Site Feasibility
3. Budget
Submission of documents for Ethical approval through CRO/Sponsor for:
1. Ethical Committee
2. CTRI Registration
3. CDSO

20/8/21

Santosh Deemed to be University

Place ...Ghaziabad

Dated.....

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NEW DELHI
Reg. No. L-106467/2021
Date 16/8/2021

SANTOSH DEEMED TO BE UNIVERSITY
REGISTRAR
GHAZIABAD, NCR DELHI

उप पंजीयन अधिकारी/प्रतिलिप्याधिकार
DEPUTY REGISTRAR OF COPYRIGHT

Diary Number : **15142/2021-CO/L**
Ministry of Commerce & Industry
Department For Promotion of Industry & Internal Trade
Copyright Office
(Tele: 011-28032496

Boudhik Sampada Bhawan,
Plot No. 32, Sector 14, Dwarka,
New Delhi-110075
Dated :**16/08/2021**

To,

REGISTRAR
SANTOSH DEEMED TO BE UNIVERSITY GHAZIABAD, UTTAR PRADESH ,
201009

Subject : Copyright Registration Certificate - forwarding of.

With reference to your application dated **07/07/2021**, I have the honour to send herewith a copy of the extract from the Register of Copyrights with regard to the work
OPERATIONAL GUIDELINES FOR MANAGEMENT OF CLINICAL TRIALS IN A HEALTH SCIENCES UNIVERSITY
particulars of which have been entered in the Register of Copyrights.

Kindly acknowledge receipt of this letter.

DEPUTY REGISTRAR OF COPYRIGHTS

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GOVT OF INDIA

28-8-21

Deem / Re