

RESEARCH COMMITTEE

Standard Operating Procedure of Research Committee

Introduction

The purpose of developing Standard Operating Procedure (SOP) of the Research Committee at Late Shri Lakhiram Agrawal Memorial Government Medical College is to give a clear idea to undergraduate/post-graduate/faculty researchers about its proposal processing pathway.

The LSLAM Medical College and Hospital consists of faculties from pre-clinical, Para-clinical and clinical Departments. A detail of the committee members is attached.

This Committee **aims** for timely and complete critical appraisal of the submitted research proposals.

The review of the submitted research proposals is an in-house exercise, where an article is reviewed for its feasibility, to improve relevance to the local context, technical quality and ethical aspects. (To be dealt in detail by the ethical committee).

Meeting and quorum requirement

The members of the committee will be meeting quarterly i.e. once in three months. However the meetings are flexible depending on the number of projects submitted or the need to review any proposal urgently.

Recording of the discussion

The minutes of the meetings are recorded. The members are given a template to note down their comments. Later the proposals are compiled and communicated to the concerned investigators.

The investigators are advised to develop their proposals as per the pre-specified checklist. The protocol has to be made under the following titles

Introduction

The proposal should have an “Introduction” section which states the ‘need’ for the present study. It should have a brief scientific description on the given topic and what ‘new’ will be added by doing the present study. It should state as how this study is going to be used in the state of practice/medical care/education etc.

A brief review of literature

It should include some known facts and some existing gaps in the knowledge. It is better to review the recent articles from the beginning of the plan to start research. Attempt should be made to know as what is happening at international level, national level and regional level. It should preferably also include limitations in the previously reported studies which will be a part of the ongoing study.

Objectives

‘Objectives (Primary and Secondary) should be clearly defined.

Material and Methods

In this section please define:

- Area of the study (Laboratory/hospital/community/college).
- Study design.
- Study subject (Human/Animals/Laboratory samples/Secondary data).
- Sample size
 - (In quantitative research, sample size should be worked out on the basis of a ‘primary outcome’ of the study and justify a feasible sample/convenient sample in quantitative research as it affects its external validity.
 - In qualitative research, type should be worked out and described), sampling technique (Once the sample size is decided, then that sample should be selected from a suitable ‘sampling frame’ by using some procedure where every study participant has equal probability of getting into the study. Sampling procedures and the study period of clinical trials, the details related to ‘Phase’ of the trial, randomization and blinding should be given.
- Measurement (Develop a tool which is reliable and valid i.e. It measures what you want to measure more accurately. Follow standard practices. Please check copyright/permission issues if you are using a standard questionnaire. The details of study participants etc. should be mentioned).

- Ethical issues (Please mention the ethical issues you are expected to face and your strategy to minimize any potential harm. Please follow the Clinical Practice guidelines while conducting clinical trials and The Committee for the purpose of Control and Supervision of Experiments on Animals guidelines in the conduct of animal experiments).
- The study on human subjects should have an informed consent form as per national ethical committee guidelines. Please follow Reporting Qualitative Research for conducting and reporting qualitative researches (Tong A, 2007). We encourage detailed research issues in the proposed research and try to address it in its design and data collection).
- Analysis (The details of the study variables to be measured and the appropriate statistics (test of significance, level of significance.) applied. Research plan should be clearly worked out at the time of proposal development. Please mention the name of statistical software used in the proposed study data. Please consult and acknowledge the biostatistician or epidemiologist during the phase of proposal development).

AUTHORSHIP GUIDELINES

The reason for this authorship guideline is to offer technical information and promote good authorship practices among researchers at LSLAM Medical College and to avoid duplicacy.

It is based on the recommendations of the International Committee of Journal Editors, Journal of American Medical Association guideline for authorship, International Committee of Medical Journal Editors (ICMJE), also known as Vancouver group, 2001, states that – Authorship to be given on:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be published

Conditions 1, 2, 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group justify authorship.

To reduce the incidence of authorship problem, we encourage following tips for all the researchers at LSLAM Medical College.

1. **Encourage a culture of ethical authorship** – Good authorship practices should reduce the incidence of such dilemma. Researchers should have a book on publication ethics and there should one seminar on publication ethics (For post graduate Students)
2. **Start discussion on authorship when you plan your research** – It is better to decide the team to begin with all the members and if possible discuss authorship at a face-to-face meeting. Continue to discuss ideas about authorship especially if new people get involved. Keep a written record of your discussion and decision
3. **Decide authorship before you start writing each article/case report** – Ensure good communication to avoid miscommunications. Ideally there should be a face-to-face meeting where it is confirmed who will do what – and by when of changes, if any
4. **Review by Research and Ethics Committee** – Please ensure the clearance of your research proposals from the Ethics Committee of LSLAM Medical College (If required). It is expected to strengthen technical and ethical dimensions of your research proposal
5. **Informed consent** – Please obtain informed consent and retain its details. In a case report, consent for publication must be obtained from the patients. Please prepare your consent forms as per the national ethical committee guidelines.

Processing of the Research Proposal by the committee (FLOWCHART)

Submission of the Research proposal to the chairman of Research Committee



Presentation at the Research Committee Meeting



RC members to review the research proposal



Investigators make changes as per comments of the RC members



Submission of the revised proposal to the chairman of RC



RC members review the research proposals again



Reviewed proposals are forwarded to the Investigating team

The research project investigator team has to submit the following:-

1. One hardcopy of the research protocol in prescribed format [**Annexure A**] to Chairperson, Scientific Research Committee).
2. Soft copy of the protocol with attachments, if any, to be sent to the co-coordinator of the scientific research committee on their email ID i.e. dr.sofia.noor@gmail.com.
3. All protocol to be reviewed in details by at least one member of the SRC depending upon the topic chosen (department concerned). It is open to all other members for their views and opinions.
4. Statistical consideration will be addressed by the assigned statistician.
5. The SRC encourages the investigators to submit the hardcopy of protocol printed back to back and not on single side of page to save paper. The text can in Times New Roman Font size 12 with line spacing 1.15 or 1.5.
6. At the research protocols review committee meeting following guidelines to be followed by the investigators.
 - A. The medium of presentation will be **Power-Point Presentation**.
 - B. Ordinarily the **principal investigator would present** the study protocol on PPT before the scientific research committee. The Co-Investigators / Guides are also encouraged to remain present at the time when their protocol is being discussed during the meeting.
 - C. The time allotted for each **presentation would be ten minutes**.
 - D. **Investigators are advised to keep the length of PPT reasonable so that the presentation can be completed in around 10 minutes.** [Find in the **Annexure B** General guidelines on how to distribute the topics across the PPT slides] The additional materials such as intervention and evaluation protocol, questionnaires should be hyper-linked in the PPT and such additional material should also be forwarded through e-mail.
5. Based on these comments the SRC will either issue an approval letter or issue a modification advice. In case of modification advice a follow up meeting will be held after 10 days of the last meeting.
6. The research proposal approved by the scientific committee will then processed through the IEC. A copy of the list of approved projects will be communicated to the Coordinator IEC.
7. In case of academic clinical trials, mandatory registration with the clinical trials registry - India.

Protocol Submission Format (Annexure A)

Project Title:

Name & designation of Principal Investigator with Co investigators/Name PG student with guide (contact details) (whichever is applicable)

Name of Department:

Project Description:

1. Introduction
2. Objectives/ Research Question
 - A. Primary objective
 - B. Secondary objective/s
3. Materials & Methods
 - A. Research design
 - B. Study area
 - C. Subjects to study – inclusion/ exclusion criteria
 - D. Sample size & Sampling method
 - E. Data collection method
 - F. Intervention
 - G. Ethical issues

Outline of PPT for presentation at SRC meeting (Annexure B)

Slide 1:

1. Title of the study,
2. Name of the Investigator/Candidate, Name of the Co-Investigators/Guide & Co-Guide(s).
3. Designation of principal investigator
4. Department

Slide 2: Objectives of the study – primary / secondary (if any).

Slide 3 onwards: Methodology: Study Design / Study area / Study sample (inclusion/exclusion criteria) / Sample Size / Intervention & Evaluation plan / Outcome measures / Statistical analysis.

Final decision of the scientific research committee will be according to the following

1. **Approved for submission to the ethical committee.**
2. **Require minor revision for approval** - scientifically sound but requires minor clarification on the part of the principal investigator on specific points. A revised copy to be submitted to the chairperson for expedited review and approval.
3. **Require major revision for approval** - scientifically sound but requires major clarification on the part of the principal investigator on specific points. A revised copy to be submitted to the chairperson for expedited review and approval.
4. **Disapproved-** Not scientifically sound, not accepted by majority of the scientific research committee members. Ethical issue beyond the acceptance of chairperson.



कार्यालय अधिष्ठाता,
स्व. श्री लखीराम अग्रवाल स्मृति शासकीय चिकित्सा महाविद्यालय, रायगढ़ (छ0ग0)

(दूरभाष क्र. 07762-220741, वेबसाइट- www.gmcraigarh.in ई-मेल gmcraigarh.2013@gmail.com)

क्रमांक / शा.चि.म. / स्था. / 2019 / 10152

रायगढ़, दिनांक 19/3/19

// आदेश //

स्व. श्री लखीराम अग्रवाल स्मृति चिकित्सा महाविद्यालय रायगढ़ के आदेश क्रं / चिकि / स्था / 2017 / 8134 रायगढ़ दिनांक 02 / 03 / 2017 में आंशिक संशोधन करते हुये रिसर्च कमेटी का पुर्नगठन निम्नानुसार किया जाता है :-

// RESEARCH COMMITTEE //

क्रमांक	पद	पदनाम एवं विभाग	अधिकारियों के नाम
1.	अध्यक्ष	अधिष्ठाता	डॉ. पी. एम. लूका
2.	उपाध्यक्ष	प्राध्यापक एवं विभागाध्यक्ष, पैथोलॉजी विभाग	डॉ. एम. के. मिंज
3.	समन्वयक	प्राध्यापक एवं विभागाध्यक्ष, कम्प्यूनिटी मेडिसीन विभाग	डॉ. सोफिया नूर
4.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, एनाटॉमी विभाग	डॉ. जयदेव उघाड़े
5.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, फिजियोलॉजी विभाग	डॉ. अर्ध्य सूर
6.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, बायोकेमिस्ट्री विभाग	डॉ. हेमोन्तिका चक्रवर्ती
7.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, फार्माकोलॉजी विभाग	डॉ. पूर्णिमा राज
8.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, ई.एन.टी. विभाग	डॉ. वाय. किशोर कुमार
9.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, मेडिसीन विभाग	डॉ. यास्मिन खान
10.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, निश्चेतना विभाग	डॉ. ए. एम. लकड़ा
11.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, सर्जरी विभाग	डॉ. के. एन. चौधरी
12.	सदस्य	प्राध्यापक एवं विभागाध्यक्ष, प्रसूति एवं स्त्रीरोग विभाग	डॉ. पी. सुधीर बाबू
13.	सदस्य	सहायक प्राध्यापक एवं विभागाध्यक्ष, अस्थिरोग विभाग	डॉ. पी. के. जांगड़े
	सदस्य	सहायक प्राध्यापक, अस्थिरोग विभाग	डॉ. एस. सी. अवस्थी
14.	सदस्य	सहायक प्राध्यापक एवं विभागाध्यक्ष, शिशुरोग विभाग	डॉ. लक्ष्मणेश्वर सोनी
	सदस्य	सहायक प्राध्यापक, शिशुरोग विभाग	डॉ. जे. विभा मिंज
15.	सदस्य	सह प्राध्यापक एवं विभागाध्यक्ष, मनोरोग विभाग	डॉ. राजेश अजगल्ले
	सदस्य	सहायक प्राध्यापक, मनोरोग विभाग	डॉ. विमलचन्द्र भगत
16.	सदस्य	सह प्राध्यापक एवं विभागाध्यक्ष, चर्म एवं रतिजरोग विभाग	डॉ. दिलीप कुमार साँ
	सदस्य	सहायक प्राध्यापक, चर्म एवं रतिजरोग विभाग	डॉ. अखिलेख बेहरा
17.	सदस्य	स्टेटिशियन, कम्प्यूनिटी मेडिसीन विभाग	डॉ. एस. पी. सिंह
18.	सदस्य	उप संचालक, पशु चिकित्सा सेवायें, जिला-रायगढ़	पदेन
19.	सदस्य	अधिष्ठाता, शासकीय कृषि महाविद्यालय, रायगढ़	पदेन
20.	सदस्य	विभागाध्यक्ष, रसायन शास्त्र विभाग, किरोड़ीमल शासकीय कला एवं विज्ञान महाविद्यालय, रायगढ़	पदेन
21.	सदस्य	असिस्टेंट सर्जन, पशु चिकित्सा सेवायें, जिला-रायगढ़	पदेन

• यह आदेश तत्काल प्रभाव से लागू किया जाता है।

अधिष्ठाता

स्व. श्री लखीराम अग्रवाल स्मृति,
चिकित्सा महाविद्यालय, रायगढ़

क्रमशः.....

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पृ० क्रमांक / चिकि. / स्था. / 2019 / 10183-87

रायगढ़, दिनांक 19/3/19

प्रतिलिपि:-

1. संचालक, चिकित्सा शिक्षा, छत्तीसगढ़, रायपुर की ओर सूचनार्थ।
2. संयुक्त संचालक सह चिकित्सा अधीक्षक, स्व. श्री लखीराम अग्रवाल स्मृति शा. चिकित्सा महाविद्यालय संबद्ध किरोड़ीमल शा. चिकित्सालय, रायगढ़ (छ.ग.) की ओर सूचनार्थ।
3. प्रशासकीय अधिकारी, स्व. श्री लखीराम अग्रवाल स्मृति शा. चिकित्सा महाविद्यालय, रायगढ़ की ओर सूचनार्थ।
4. संबंधित की ओर सूचनार्थ एवं पालनार्थ।
5. कार्यालय नस्ती।



अधिष्ठाता

स्व. श्री लखीराम अग्रवाल स्मृति,
चिकित्सा महाविद्यालय, रायगढ़