Scientific Research Committee

Standard Operating Procedures for Health Research involving Human Participants

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Standard Operating Procedures for Scientific Research Committee, Chhattisgarh Dental College & Research Institute, Rajnandgaon

I. Standard Operating Procedures (SOPs)

CDCRI SRC SOP Version: 2.0 w.e.f: 06.01.2021

II. SOPs prepared by:

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Scientific Research Committee, Chhattisgarh Dental College and Research Institute, Rajnandgaon

Standard Operating Procedure of Scientific Research Committee

1. Introduction:

The purpose of developing Standard Operating Procedure (SOP) of the Scientific Research Committee, Chhattisgarh Dental College and Research Institute, Rajnandgaon (SRC, CDCRI) is to give a clear idea to undergraduate/post-graduate/faculty researchers about its proposal processing pathway. The Scientific Research Committee, Chhattisgarh Dental College and Research Institute consists of faculties from pre-clinical, Para-clinical and clinical disciplines. The Scientific Research Committee aims to offer timely and complete critical appraisal to the submitted research proposals and offer technical guidance to those who submit their proposals for its review. The review of the submitted research proposals is an in-house exercise, where an attempt is made to assess its feasibility, to improve relevance to the local context, technical quality and ethical aspects of proposed research.

We encourage Good Clinical Practice and Good Authorship Practices at Chhattisgarh Dental College and Research Institute. Hence, SOP is developed with a following objective –

A. To ensure that the proposed research has relevance in the present context and that it is technically sound and meets ethical standards.

B. In order to achieve the above mentioned objective, following activities are done to –

   a. Develop the procedures for processing the submitted research proposals.
   b. To offer guidance to RC members and investigators as how to review and receive comments respectively.
   c. Conduct periodic research methodology trainings to empower students and faculty on relevance, technical quality and ethical aspect of the research.
   d. Define a policy for funding institutional research at Chhattisgarh Dental College and Research Institute.

e. Workout authorship guidelines for researchers at Chhattisgarh Dental College and Research Institute.

2. Composition of the Research Committee

The Scientific research committee should be multidisciplinary and multisectorial in composition, the committee consist of members from various clinical, pre-clinical and para-clinical departments of Chhattisgarh Dental College & Research Institute. The number of persons in a research committee should be kept fairly small (7-10 members). It is generally accepted that a minimum of five persons is required to compose a quorum.

The Chairperson of the Scientific Research Committee and the Member Secretary who generally belongs to the same Institution should conduct the business of the committee should be nominated by the Head of the Institute.

The Committee will ensure that their members receive initial and continued education in research ethics and science, and are kept aware of current issues and developments in the broad area of ethics and science.

The composition may be as follows:

1. Chairperson
2. Member Secretory
3. 2-3 basic medical scientists.
4. 3-4 clinicians from different specialities of the institute
5. Epidemiologist
6. Biostatistician

3. Membership requirements:

1. The duration of appointment is initially for a period of 2-3 years
2. At the end of 2-3 years, as the case may be, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.
3. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

4. A member can tender resignation from the committee with proper reasons to do so.
5. All members should maintain absolute confidentiality of all discussions during the meeting.
6. Conflict of interest should be declared by members of the RC.

4. Meeting, quorum requirement and MOM:

The meetings of SRC, CDCRI will occur on 1st Monday of January, March, May, July, September and November. If 1st Monday is holiday the meeting will be conducted on coming working day. But in case of urgency to review research proposal emergency meeting can be called by member secretory with the permission of chairman.

The minimum 50% of members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals to members by any means. (e.g.: email, whatsapp etc)

The Chairperson will conduct all meetings of the SRC. If for any reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected from the members by the Chairperson with prior approval from Director/Dean, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned persons. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

5. Independent consultants

SRC, CDCRI may call upon subject/field experts as independent consultants who may provide special review of selected research protocols, if needed. These experts may be a specialist in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, ethnic minorities etc. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC.

6. **Guidance for the Investigators:**

How to develop the research proposal for submission to SRC, CDCRI.

All the investigators/ Researchers are advised to develop their proposals as per the pre-specified format (**Annexure 1**). The proposal should be developed under the following Headings.

A. Introduction

The research proposal should have an "Introduction' section which states the 'need' for the present study. It should have a brief note on what is known to the science 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 benefit the current state of practice/medical care/education etc.

B. A brief review of literature

It should include some known facts and some existing gaps in the knowledge based on the literature review. It is better to review the most recent articles from the indexed journals. Always an attempt should be made to know as what is going on at international level, national level and also at regional level. It should also explore the strengths and limitations in the previous studies.

C. **Aims & Objectives**

'Aims & Objectives (Primary and Secondary) of the students' should be clearly defined.

D. **Material and Methods**

In material section mention all the materials being used along with the manufacture information. In the 'Methods' section, please define the setting (Laboratory/ hospital/community/college) in which the present study will be done. Also, specify under which Department the proposed study will be done.

E. **Study design**

Please specify the study design

All the Study participants/subjects

Human/Animals/Laboratory samples/Secondary data

F. **Sample size**

In quantitative research, sample size should be defined on the basis of a 'primary outcome' of the study and justified. It is better to avoid feasible sample/convenient sample in

quantitative research as it affects its external validity. In qualitative research, type of sample and sampling should be worked out and described.

G. **Sampling procedure**

Once the sample size is decided, then that sample should be selected from a suitable 'sampling frame' by using some random selection methods, where every study participant has equal probability of getting into the study. Sampling procedures and the study period should be defined. In case of clinical trials, the details related to 'Phase' of the trial, randomization and blinding should be given.

H. **Measurement**

Develop a tool which is reliable and valid i.e. It measures what you want to measure more accurately. Follow standard questionnaire development practices. Please check copyright/permission issues if you are using a standard questionnaire. The details of study participants such as age, gender etc. should be mentioned.

I. **Ethical issues**

Please mention the ethical issues you are expected to face and your strategy to minimize any potential harm. Please follow guidelines on Good Clinical Practice (GCP) while conducting clinical trials and Committee for the Purpose of Control And Supervision of Experiments on Animals (CPCSEA) guidelines in the conduct of animal experiments. The consent forms for research on human subjects should have an informed consent form as per given template (**Annexure 2 & 3**). Please follow Consolidated Criteria for Reporting Qualitative Research for conducting and reporting qualitative researches (Tong A, 2007). We encourage researchers to anticipate ethical issues in the proposed research and try to address it in its design and data collection.

J. **Analysis**

The details of the study variables to be measured and the appropriate statistics (test of significance, level of significance) should be given. Analysis plan should be clearly worked out at the time of proposal development. Please mention the name of statistical software to be used for analysis of proposed study data. Please consult and acknowledge the biostatistician or epidemiologist during the phase of proposal development.

7. How to submit the research proposals?

Please submit one hard copy of research proposal with the completed checklist and a covering letter (**Annexure 4**) to the member secretary of Scientific Research Committee, CDCRI.

Please check the content of proposals as per points in the checklist and then check the box

Also, submit a soft copy of the proposal as a single file (either word file or PDF file) to email ID – **researchcommitteecdcri@gmail.com**

Please make sure that a soft copy of the proposal is submitted before the submission of hard copy to the member secretary of Scientific Research Committee

8. Decision on proposal at SRC meeting

The decision on a research proposal will be made by members in SRC meeting. The SRC members will review the research proposal in SRC meeting, and the changes required will be informed to principal investigator in order to make necessary changes in their research proposal.

9. How to submit the revised proposals?

Investigators have to revise their proposals in the light of comments by the SRC members and make the corresponding changes in the proposal. The revised proposal has to be submitted to SRC for re-review.

10. Policy for Research Scholarships at CDCRI, Rajnandgaon

a. **Purpose of the Research Funding:** The purpose of research scholarships is to promote research leading to publication of original research papers by students and faculties in indexed scientific bio-medical/health journals. However, we encourage students, post-graduates and faculties to apply for funding at various regional, national and international level.

b. **Research by the undergraduate students:** Undergraduate investigator who have obtained clearance from the Scientific research committee, CDCRI, and the ethics committee and those who did not get funding under ICMR- STS program may apply for funding. The maximum funding amount will be 25% or 10,000 INR whichever is

more and 20% amount will be released after the publication of the article (based on work done) in an indexed Journal

Projects will be shortlisted depending on its scientific merit and publication potential and student's academic level and calibre will also be taken in to consideration by the committee. Investigators will have to submit their completed project report and publications related to work done to coordinator of the Scientific Research Committee.

c. **Research by the postgraduate:** No scholarship for mandatory assignments such post-graduate dissertation will be offered. Any research project, apart from thesis work and mandatory requirements will be considered for a scholarship which is subject to clearance from the Scientific Research committee and the ethics committee. The maximum funding amount will be 50% or 20,000 INR whichever is more and 20% amount will be released after the publication of the article (based on work done) in an indexed Journal

Projects will be shortlisted for funding based on its scientific merit, compliance to comments given by research committee members and its publication potential Investigators have to submit their completed project report and related publications to coordinator of Scientific Research Committee.

d. **Research by the teaching Faculties:** The maximum funding amount will be 25,000 INR where 20 % amount will be released after the publication of the article (based on work done) in an indexed Journal. Scholarship is subject to clearance from the Scientific research committee and the ethics committee. Projects will be shortlisted for funding based on its scientific merit, national or regional, or local relevance of topics, compliance to comments given by research committee members and its publication potential

Investigators have to submit their completed project report and related publications to coordinator of the Scientific Research Committee.

The Scientific Research Committee, CDCRI, Rajnandgaon will recommend the shortlisted projects for funding approval by Management of CDCRI, Rajnandgaon. Acknowledgement for

funding should be mentioned in all the publications. Refer to Annexure 5 for application to seek funding.

11. Authorship Guidelines for Researchers at CDCRI, Rajnandgaon

The authorship guideline is to offer technical information and promote good authorship practices among researchers at CDCRI, Rajnandgaon and avoid duplication of efforts.

It is based on the recommendations of the International Committee of Journal Editors, Journal of American Medical Association and FAIMER guideline for authorship.

International Committee of Medical Journal Editors (ICMJE), also known as Vancouver group, 2001, states that – Authorship credit should be based 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; and
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, by themselves, do not justify authorship.

To reduce the incidence of authorship problem, we encourage following tips for all the researchers at CDCRI, Rajnandgaon (COPE report, 2003).

1. **Encourage a culture of ethical authorship** – Good authorship practices should reduce the incidence of such dilemmas. Each department library should have a book on publication ethics and there should one post-graduate seminar on publication ethics
2. **Start discussion on authorship when you plan your research** – It is better to decide the team to begin with and gather views of all team members and if possible discuss authorship at a face-to-face meeting. Continue to discuss ideas about authorship as research work progresses, 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 misplaced expectations and poor communications. Ideally there

should be a face-to-face meeting where it is confirmed who will do what – and by when. Keep everyone informed of changes, if any

4. **Review by Research and Ethics Committee** – Please ensure the clearance of your research proposals from the Research Committee and the Ethics Committee of CDCRI, Rajnandgaon. It is expected to strengthen technical and ethical dimensions of your research proposals
5. **Informed consent** – Please obtain informed consent and retain its details. In a case report, consent for publication in print and electronically must be obtained from the patients. Please prepare your consent forms in the prescribed format as recommended by the Research and Ethics Committee of CDCRI, Rajnandgaon.
6. **Consider author contribution** – All authors must have made an individual contribution to the writing of the article and not just been involved with the patient's care
7. Individuals just involved in the patient's care (including diagnosis and management) should be listed in the acknowledgements.

12. Authorship disputes – how to handle it?

The team should have a written authorship agreement before the article is written. We recommend authors to follow authorship criteria followed by The Journal of American Medical Association, July 2007 to decide authorship. We also recommend to follow a rubric provided by Francois Cilliers, 2007 to decide the order of co-authorship. Disagreement about authorship can be classified into two types: those that do not break ICMJE guidelines (disputes) and those that do (misconduct).

a. **Disputes** – It is a question of interpretation. In this case, you may discuss with the people involved and the supervisor/any senior person involved in the study/Head of the Department. Consider or support your discussion or opinion with the evidences such as laboratory notebooks, manuscripts, ICMJE statement, Instructions to Authors etc. If you remain unhappy with the supervisor's decision, you may approach to the Scientific Research Committee at CDCRI, Rajnandgaon. But you should do this in exceptional circumstances only and other researchers are well informed about what you're intending to do.

b. **Misconduct** – If you notice or experience some scientific misconduct, please bring it to the notice of the Scientific Research Committee of CDCRI, Rajnandgaon.

13. Authorship Criteria

Rubric provided by Francois Cilliers, 2007

Authorship of any work resulting from this research will be determined by means of the following authorship index.

Co-authorship scoring system: Each co-author (s) completes a self-assessment form indicating individual contribution and is encouraged to complete a form for each member of the team.

Intellectual Input (Planning/designing/interpretation)		**Literary Input (Contribution to first complete draft of manuscript)**	
No contribution	0	No contribution	0
One detailed discussion/ correspondence	5	Edited others' material	5
Several detailed discussions/ correspondences	10	Contributed small sections	10
Longer meeting/ correspondence	15	Contributed moderate proportion	15
Substantial liaisons	20	Contributed majority	20
Closest possible involvement	25	Contributed virtually all	25

Practical Input (setting up/ observing/ recoding/ abstracting)		**Specialist Input from Related Fields**	
No contribution	0	No contribution	0
Small contribution	5	Brief or routine advice	5
Moderate indirect contribution	10	Specially-tailored assistance	10
Moderate direct contribution	15	Whole basis of approach	15
Major indirect contribution	20		
Major direct contribution	25		

Practical Input: Beyond Data Capture (data processing/organization)	
No contribution	0
Minor or brief assistance	5
Substantial or prolonged assistance	10

Whoever achieves a total of 25 points will be offered joint authorship in rank order of total score. In the event of ties, recent near misses will be considered. If none exists, alphabetical order may be used.

Note for authorship in case report: In the past, it was acceptable to include as authors those contributing to the management of the patient, but this is no longer true. Currently, it is expected that the authors contribute significantly to the intellectual content of the case report.

14. Acknowledgement

We are very much thankful Dr. Hema Suryawanshi (Dean & Chanrman, SRC) and to all the members of the Scientific Research Committee for giving their valuable opinion to improve these guidelines.

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