STANDARD OPERATIVE PROCEDURES

INSTITUTIONAL RESEARCH COMMITTEE

PUNJAB INSTITUTE OF MEDICAL SCIENCES

GARHA ROAD, JALANDHAR

STANDARD OPERATIVE PROCEDURES

INSTITUTIONAL RESEARCH COMMITTEE
PUNJAB INSTITUTE OF MEDICAL SCIENCES
GARHA ROAD, JALANDHAR

AUTHORISED BY

DR. RAJIV ARORA

DIRECTOR PRINCIPAL

PIMS, JALANDHAR

DATED:

Foreword

Punjab Institute of Medical Sciences (PIMS), a premier medical institute is devoted to clinical excellence, research and ethical practice. It instills the best values and ethos among the undergraduates in their quest for knowledge. With the vision to provide benevolent patient care PIMS hospital is equipped with advanced facilities and dedicated health professionals.

The Institutional Research Committee (IRC) of PIMS constituted under the chairmanship of Director Principal ensures high scientific research standards and offers technical guidance and complete critical appraisal to the submitted research proposals.

INDEX

Introduction

CODE SOP01/V1

Description of SOP

Standard Operating Procedures for the Institutional research committee of Punjab Institute of Medical Sciences (PIMS), Jalandhar has been adopted to ensure the highest scientific standards of research, in biomedical, experimental and behavioral research in accordance with the ICMR guidelines.

Objectives of SOP

To maintain effective functioning of the PIMS-IRC and to ensure quality, technical excellence and consistent review of all the submitted research proposals.

Authority for constituting the PIMS IRC

The Director Principal, Chairperson of IRC will appoint all the committee members based on their competence, experience and integrity.

Purpose, Role and Responsibilities of PIMS - IRC

IRC will go through the research protocol / proposal and state whether or not it is acceptable. IRC of PIMS is committed to:

- Evaluate all the scientific aspects of research proposals. Review and approve proposals for basic and clinical research projects
- Develop and implement education and training programs. Create awareness by conducting seminars and workshops amongst hospital faculty and staff regarding clinical practice and research along with IEC (Institutional Ethics Committee).
- Development and implementation of guidelines for smooth functioning of IRC

Composition

CODE SOP02/V1

Composition of PIMS-IRC

PIMS-IRC is a multidisciplinary body consisting of 8 members. The chairperson, IRC is the Director Principal of the Institution who will appoint Member Secretary and other members. Members include medical / non-medical persons and may invite subject experts to take their views, whenever it is needed.

The PIMS-IRC (Revised vide Ref. No. PIMS/DP/Gen.50/6338-6362 dated 17/05/2022)

1. Dr. Rajiv Arora, Director Principal of the institute, Chairman.
2. Dr. Sandeep Kaushal, Dean Academic, DMC Ludhiana, (Chairman IEC PIMS) Member
3. Dr. Harwinder Kaur Cheema, Professor & Head, Obs & Gynae, Member Secretary.
4. Dr. Ravjit Kaur Sabharwal, Professor & Head Biochemistry, Member
5. Dr. Sheevani, Professor, Microbiology, Member.
6. Dr. Pushpendra Magon, Professor, Pediatrics, Member.
7. Dr. Tania Moudgil, Professor, Ophthalmology, Member.
8. Dr. Rakesh Kumar, Professor, Pharmacology, Member.
9. Dr. Mohit Sharma, AP, Community Medicine, Member
10. Mrs. Prabhjot Kaur, Statistician cum Lecturer, Community Medicine, Member

Requirements for IRC Membership

- All members will serve for a period of 3 years on renewable basis. New members will be included in the IRC as per the experience and requirement.
- Director Principal, Chairman of IRC can disqualify and replace any member if the contribution to IRC work is not adequate/ ineffective/ not available for long time/insane/behaves inappropriately in IRC meetings. The Director Principal has the power to dissolve the IRC or reappoint IRC.

- A member can tender resignation of his office of membership from the IRC to the Director Principal after serving one month advance notice.
- Each member is required to sign the declaration and confidentiality agreement regarding IRC activities
- All IRC members must be conversant with ICMR Guidelines for Research involving Human Subjects, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.
- The IRC members will be encouraged to receive ongoing training by attending workshops at least once every year.

Quorum requirements

Minimum of 6 members are required to constitute the quorum for the meeting. All decisions will be taken in meetings.

MANAGEMENT OF RESEARCH STUDY SUBMISSION

CODE SOP03/V1

Conduct of PIMS- IRC meetings

1. The Chairperson will conduct all meetings of the PIMS- IRC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. The IRC members will receive the soft copies of all research proposals on their respective email IDs. The member secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. The IRC meetings will be conducted in the third week every three months in a year. The Chairman can hold the meeting at any time if the need arises.

Participation of Independent consultants

The Chairman may invite the subject experts as an independent consultants to provide special review of selected research protocols, if need be. They will be required to give their specialized views but should not take part in the decision making process.

Aspects to be considered by IRC during review of research proposal

The IRC will consider issues like study design, relevance of sample size, statistical correlation, experimental details and its feasibility, conduct of the study, risk benefit analysis, enrollment procedure, outcome of the proposal, facilities & infrastructure and plans for data analysis during the review process.

Process of decision-making

- Decision will be made only in meetings where quorum is complete. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived, the decision of the Chairperson will be final.

- Decision may be to approve, reject or revise the proposals. Specific suggestions and reasons for modifications and reasons for rejection will be given.
- A member cannot participate in the review and approval process for any project in which he or she is a PI, Co-PI or has any other potential conflict of interest. A member will withdraw from the meeting during the decision, concerning an application where a conflict of interest arises and this will be indicated to the chairperson prior to the review of the application and recorded in the minutes.

Application, Review and Decision of Study Protocol

CODE SOP04/V1

Application procedures and Review

1. The Principal investigator must discuss the research proposal with his departmental research committee consisting of all the faculty members and head of department who is also the head of Departmental Research Committee. After approval from the head of Departmental Research Committee, the duly signed research proposal will be submitted to the Member Secretary of Institutional Research Committee.
2. The Principal investigator should submit one hard copy and one soft copy (irc@pimsj.com) of complete research proposal along with required annexure to the Member Secretary at least 10 days before the next scheduled meeting.
3. The PI or the Co-PI has to present the proposal in PPT (Power Point Presentation) format and should be able to clarify the queries raised by the members. The PPT must include brief introduction, Aims & Objectives, Material and Methods and Justification of the study with appropriate references.
4. After approval from the research committee the research protocol will be forwarded to the Institutional Ethics committee for final approval.
5. No research project will be allowed to start unless IEC clearance is obtained. No retrospective/ post facto ethical clearance can be provided to research projects.
6. No processing fees will be charged from any research proposals submitted with IRC.

Decisions

After thorough review and discussion of submitted study protocols, IRC will give any one of the following decision

- Approved without suggestions
- Revision with minor amendments - approval of revised version is given by member secretary
- Revision with major amendments - approval of revised protocol is given after repeat review by full committee

- Not approved - the clear cut reasons for not approving

The researcher will modify the proposal as per suggestions of IRC and resubmit revised proposal within 7 days of issuing of decision.

Record keeping and archiving at the office of PIMS IRC

- All the documents and communications of IRC will be dated, filed and archived in IRC office.
- Only the member secretary or persons, who are authorized by the Chairman of IRC will have the access to various documents.
- No document (except agenda) will be retained by any IRC member.
- Final report of the approved projects.

Submission of Research Proposal to Member Secretary IRC

Presentation at Research Committee meeting (Power Point presentation)

Review by IRC members

PI makes changes as per suggestions of IRC members

Submission of revised proposal to Member Secretary IRC

Review by IRC members again

Approved proposal by IRC will be forwarded to IEC for final approval

Steps in Processing the Research Proposal at IRC

Format of Research Proposal

CODE SOP05/V1

The proposal should be developed under the following titles:

Introduction:

This section state "Why did you start" the present study. It zooms in from the broad general information related to the topic to specifically acknowledge the gap that needs to be addressed as a part of study. It provides information that justifies that why present study needs to be done. It should state 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. It should also explore the strengths and limitations in the previously reported studies.

It usually ends with statement of Objectives. The objectives may be primary and secondary and should be clearly defined.

Methods:

In this section state "What did you do" in the present study in simple terms. It provides key information on study settings, study design, sampling strategy, sample size, study procedures, operational definitions, data management, and human participation protection.

References:

In Vancouver style