srivenkateshwaraa
Medical College Hospital and Research Centre
CREATING HEALTHIER SOCIETY
Ariyur, Puducherry 605 102.

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ISO 21001

SCIENTIFIC RESEARCH COMMITTEE (SRC)

STANDARD OPERATING PROCEDURE (SOP)

1. PURPOSE AND SCOPE

1.1 Purpose

This Standard Operating Procedure (SOP) establishes the framework for the functioning of the Scientific Research Committee (SRC) at Sri Venkateshwaraa Medical College Hospital and Research Centre to ensure:

- Scientific validity and rigor of all research proposals
- Methodological soundness before ethical review
- Feasibility and resource optimization
- Protection of research participants through scientifically sound research
- Compliance with ICMR guidelines and national regulations

1.2 Scope

This SOP applies to:

- All research involving human participants conducted at the institution
- Student research (UG, PG)
- Faculty-initiated research
- Short-term student projects (STS)
- Industry-sponsored clinical trials
- Collaborative multi-centre studies (National / International)
- NGO/ Self Sponsored Clinical Trials

2. DEFINITIONS

2.1 Definitions

1. Scientific Research Committee (SRC): A multidisciplinary committee established to evaluate the scientific merit, methodology, and feasibility of research proposals before submission to the Institutional Ethics Committee (IEC).
2. Principal Investigator (PI): The researcher who has primary responsibility for the design and conduct of the research study.
3. Co-Investigator (Co-PI): A researcher who collaborates with the PI in conducting the study.
Research Protocol: A comprehensive document describing the rationale, objectives, design, methodology, statistical considerations, and organization of a research study.
4. Scientific Review: The process of evaluating research proposals for scientific merit, methodological soundness, statistical validity, and feasibility.

3. AUTHORITY AND REGULATORY FRAMEWORK

3.1 Establishment Authority

The Scientific Research Committee is established by the authority of:

- Sri Venkateshwaraa Medical College Hospital and Research Centre - In accordance with Institutional research policy
- As per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

Prepared by	Reviewed by	Approved by
Dr. M. Priyatharshini SRC Chairperson	Dr. Papa Dasari Dean Research	Dr. S. Ratnasamy Director

SCIENTIFIC REVIEW COMMITTEE Chairman

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3.2 Relationship with IEC

- SRC review precedes IEC review
- Scientific soundness is a prerequisite for ethical approval
- IEC may refer proposals back to SRC for clarification
- Both committees work collaboratively to ensure quality research

4. COMPOSITION OF SCIENTIFIC RESEARCH COMMITTEE THE COMMITTEE WORKS UNDER SUPERVISION OF DEAN RESEARCH/DIRECTOR

4.1 Membership Structure

The SRC shall consist of members as follows:

1. Chairperson: 1 Senior faculty with extensive research experience
2. Member Secretary: 1 Faculty with administrative and research experience
3. Basic Medical Scientists: 2-3 From pre and para clinical departments
4. Clinicians: 3-4 From various clinical departments
5. Biostatistician: 1-2 Expert in research methodology and statistics
6. Laboratory Medicine Expert: 1 From Pathology/Biochemistry/Microbiology
7. Community Medicine Expert: 1 Expertise in epidemiology and public health research
8. Clinical Pharmacologist: 1 For clinical trial review

4.2 Term of Appointment

- Duration: 3 years (renewable once)
- Rotation: 30% members rotated every year to ensure continuity
- Extension: Possible for another term based on performance

4.3 Appointment Process

- Members nominated by Dean Research/ Director of the Institute based on expertise
- Appointment letter issued specifying roles and responsibilities
- Orientation provided to new members

4.4 Resignation and Replacement

- Written resignation accepted by Chairperson/ Dean Research/ Director
- Replacement nominated within 30 days
- Substitute member may be appointed for temporary absence

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4.5 Removal

Members may be removed for:

- Missing three consecutive meetings without valid reason
- Serious breach of confidentiality
- Conflict of interest not disclosed
- Upon recommendation of Chairperson with Dean's approval

5. ROLES AND RESPONSIBILITIES

5.1 Responsibilities of the SRC

Primary Responsibilities:

The Scientific Research Committee shall:

1. Review all research proposals for scientific merit and methodological soundness
2. Assess statistical validity and sample size justification
3. Evaluate feasibility of considering available resources
4. Ensure research questions are relevant and answerable
5. Verify adequacy of literature review
6. Assess competence of investigators
7. Recommend modifications for improvement
8. Provide guidance to investigators on scientific issues
9. Monitor ongoing research for scientific integrity
10. Report serious deviations to appropriate authorities

Additional Responsibilities:

- Develop and update institutional research guidelines
- Conduct training programs for researchers
- Promote research culture in the institution
- Maintain registry of approved research
- Coordinate with IEC and other institutional committees IAEC, NABH,
- Annual report preparation on research activities

6. MEETING SCHEDULE AND QUORUM

6.1 Meeting Frequency

Regular Meetings:

- Frequency :Six (6) meetings per year (Bi-monthly schedule)
  Each meeting may be conducted 2 or more days depending on the number of projects
  During PG admission for thesis Protocols there may be more frequent meetings
- Tentative schedule: February, April, June, August, October, December
  (It may be changed to monthly if the projects are more in future)
- Annual calendar prepared in December for next year
- Circulated to all members and departments

Emergency Meetings:

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- Called by Chairperson when urgent review required
- Minimum 3 days notice
- For time-sensitive studies or serious issues

6.2 Meeting Schedule

As per Annual Research Calendar:

6.3 Quorum Requirements

Minimum Quorum: Seven (7) members including:
- Chairperson OR Member Secretary (mandatory)
- At least one (1) Biostatistician (mandatory)
- At least one (1) Basic Medical Scientist
- At least one (1) Clinician
- Remaining three from any category

Special Considerations:
- For clinical trials: Clinical Pharmacologist presence preferred
- For laboratory-based research: Laboratory medicine expert recommended
- For community-based studies: Community medicine expert recommended

Quorum Not Met:
- Meeting postponed to alternate date
- Investigators informed immediately
- Rescheduled within 2 weeks

6.4 Meeting Conduct

Meeting Duration: minimum 01 day (depending on number of proposals)

Meeting Process:
1. Call to order by Chairperson
2. Confirmation of quorum
3. Approval of previous meeting minutes
4. Matters arising from previous meeting
5. Review of new proposals
6. Continuing review items
7. Any other matter

Discussion Protocol:
- Each proposal allocated 15-20 minutes
- Primary presentation by PI (10 minutes)
- Open discussion (7-10 minutes)
- Decision
- Recommendations documented

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7. TYPES OF RESEARCH REQUIRING SRC REVIEW

7.1 Mandatory SRC Review

All research proposals involving:

1, - Observational studies (cross-sectional, case-control, cohort)
- Clinical audits with research component
- Diagnostic test evaluation
- Surgical/procedural technique evaluation

2. Clinical Trials
- Phase I to Phase IV trials
- Drug trials
- Device trials
- Vaccine trials
- Investigational medicinal products

3. Laboratory-Based Research
- Studies using human biological samples
- In-vitro studies with clinical implications
- Genomic/proteomic research

4. Community-Based Research
- Epidemiological studies
- Health surveys
- Intervention studies in community
- Implementation research
- Operational research

5. Student Research
- Undergraduate projects
- Postgraduate theses (MD/MS/DNB)
- Short-term studentship projects (STS)

6. Multi-Centre Studies
- As participating centre
- As coordinating centre

7. Industry-Sponsored Research
- Pharmaceutical industry trials
- Device company studies
- CRO-coordinated studies

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Expedited Review
May be considered for:
- Research with prior NIH/ICMR/DST funding approval (peer-reviewed)
- Minimal risk studies
- Minor modifications to approved protocols
- Amendment not affecting scientific validity
- Extension of timeline without changes

Expedited Review Process:
- Reviewed by Chairperson + 2 designated members + Biostatistician
- Decision within 2 weeks
- Reported in next full committee meeting

8. SUBMISSION PROCESS

8.1 Pre-Submission Requirements

Step 1: Departmental Review
- Submit to Departmental Research Committee (DRC)
- Obtain DRC certificate (signed by HOD)

Step 2: Document Preparation
- Complete research proposal as per template (modified from ICMR)
- Collect all required documents
- Self-check using submission checklist

8.2 Submission Documents Checklist

PART A: Mandatory Documents

1 Covering Letter Signed by PI, Co-PI, and HOD ; Email ID and Mobile number for contact
2 Title Page With all investigators' details and their sinatures
3 Type of Project STS/UG/PG/Thesis/Faculty/Clinical Trial
4 Problem Statement Background and context
5 Rationale Justification for the study
6 Research Question/Hypothesis Clear, specific, answerable
7 Objectives Primary and secondary (SMART)
8 Literature Review Table format with recent references
9 Methodology Complete methodology section
- Study Design Appropriate design specified
- Study Area/Setting Location and setting
- Study Duration Start and end dates
- Sample Size Calculation with formula
- Sampling Technique Method of participant selection
- Inclusion Criteria Clearly defined

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- Exclusion Criteria Clearly defined
- Procedure/Flowchart Step-by-step methodology
- Statistical Analysis Methods relevant to objectives

10 Implementation Plan Timeline and Gantt chart
11 Expected Outcomes Anticipated results and impact
12 Intellectual Property Declaration of IP rights
13 Data Collection Forms All proformas, questionnaires

PART B: Additional Documents

14 Preliminary Work If pilot study conducted
15 Facilities Required Resource requirements
16 Laboratory Facilities Lab requirements and availability
17 Budget Proforma Detailed budget breakdown
18 DRC Certificate Mandatory for all
22 Permissions from collaborating departments/institutions
23 Funding Details If externally funded (Certificate to be enclosed)
24 CTRI Registration For clinical trials (if registered)
25 Insurance Certificate For clinical trials
26 Investigator Brochure For drug/device trials

Check List to be enclosed. … To be checked and signed by Office Steno/Secretary

8.3 Submission Method

Physical Submission:

- Submit one (1) hard copy
- Addressed to: Chairman, SRC
- Submit at: Research Section/SRC Office

Electronic Submission:

- Email to: src@svmchrc.ac.in
- All documents in single PDF
- Subject line: "SRC Submission - [PI Name] - [Month-Year]"

Submission Deadline:

- As mentioned in the research calendar/ SRC circular
- Late submissions deferred to next meeting
- Emergency review requests to Chairperson

8.4 Screening Process

Member Secretary Screening (within 3 days):

✓ Complete Checklist Review:

- All mandatory documents present
- DRC certificate valid
- HOD signatures present
- Forms properly filled

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✓ Basic Completeness Check:
- Sample size calculation present
- Statistical methods specified
- Timeline realistic
- Resources identified

Outcomes:
1. Complete: Submission Accepted for review
2. Incomplete: Submission documents Returned stating the deficiency
   - PI given 2 days to resubmit if it is to be included in the upcoming meeting
3. Require Clarification: Minor queries sent to PI

9. REVIEW PROCESS AND SCRUTINY GUIDELINES

9.1 Review Framework

The SRC shall evaluate proposals based on the following criteria:

9.1.1 Scientific Merit

Assessment Criteria:
- Relevance: Does the research address an important problem?
- Novelty: Does it add new knowledge or validate existing?
- Significance: What is the potential impact?
- Rationale: Is the need for the research clearly justified?

Questions to Consider:
- Is the research question clinically/scientifically important?
- Will the results help to/support to advance the knowledge in the field?
- Is there adequate review of existing literature?
- Are the gaps in knowledge clearly identified?

9.1.2 Methodological Soundness

Study Design:
- Is the design appropriate to answer research question?
- Are there better alternative designs?
- Are confounders considered?
- Is randomization/blinding applicable and addressed?

Sample Size and Sampling:
- Is sample size adequately calculated?
- Is the formula correct?
- Are assumptions stated (effect size, power, alpha)?
- Is sampling method appropriate?
- Is the sample representative of the target population?

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Data Collection:

Data collection Proforma

- Are tools validated/standardized?
- Is data collection feasible?
- Are variables clearly defined?
- Is there risk of bias? How minimized?

9.1.3 Statistical Validity

Biostatistician Review:

- Sample size calculation accuracy
- Appropriateness of statistical tests
- Plan for handling missing data
- Interim analysis (if applicable)
- Multiplicity adjustment (multiple outcomes)
- Statistical software specified

9.1.4 Feasibility

Resource Assessment:

- Are required facilities available?
- Is necessary equipment accessible?
- Are laboratory facilities adequate?
- Is trained manpower available?

Timeline Evaluation:

- Is the timeline realistic?
- Adequate time for recruitment?
- Does timeline match academic requirements (for students)?
- Are potential delays considered?

Financial Aspects:

- Is budget reasonable and justified?
- Source of funding confirmed?
- Patient cost implications considered?

Investigator Competency:

- Does PI have necessary expertise?
- Is research team adequate?
- Are co-investigators appropriately qualified?
- For students: Is supervisor experienced?

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9.1.5 Ethical Considerations

Note: Detailed ethical review by IEC, but SRC flags obvious issues:

- Risk to participants minimized? Risk calculation as per ICMR guidelines
- Informed consent process adequate?
- Privacy and confidentiality addressed?
- Vulnerable population protection considered?
- Risk-benefit ratio acceptable?

9.2 Specific Guidelines for Different Study Types

9.2.1 Clinical Trials

Additional Scrutiny:

1. Protocol Compliance:
   - GCP principles followed
   - CTRI registration status
   - CDSCO approval (if required)
2. Safety Aspects:
   - Adequate safety monitoring plan
   - SAE reporting mechanism
   - Data Safety Monitoring Board (if needed)
   - Stopping the research rules defined

3. Compensation:
   - Compensation plan as per CDSCO guidelines
   - Insurance coverage adequate
   - Free treatment provision clear

4. Sponsor Requirements:
   - Sponsor credentials verified
   - Agreement terms reasonable
   - Intellectual property rights clear
   - Publication rights protected

5. Trial Design:
   - Phase appropriate
   - Control arm justified
   - Placebo use ethical (if applicable)
   - Rescue medication available

CONDUCT OF SRC MEETING:

- All meetings are Physical
- 50% of the SRC members to be present (to be signed on Attendance sheet)
- Preferably PI should present the Protocol
- Guide . Co-guide to be present for Student (UG/PG) projects
- Comments should be cordial and no ragging is allowed by the committee members
- Constructive criticism to be given to improve the Project scientifically

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- In case of Conflicts or diffence of opinion among members subject expert from external source may be invited and the protocol to be presented in the next meeting
- The opinion of Chairman/ Dean Research/Director is final after due discussions and clarifications by PI/Guide/external expert
- Members who scrutinised the protocol initially should contribute scientificallyto the discussions . A special meeting for the discussions may be arranged with Dean Research/Director

10. DECISION CATEGORIES AND TIMELINES

10.1 Decision Categories

The SRC may make one of the following decisions:

10.1.1 APPROVED

Criteria: (Agreed by more than 50% 0f the committee members)
- All scientific criteria met
- No major concerns
- Minor concerns acceptable

Communication:
- Approval certificate issued within 7 days: Hard copy will be sent to the Faculty/ Students to the concerned departmental Office.

Soft copy will be mailed to the PI
- Validity: 3 years/ study duration mentioned at the time of presentationfrom approval date
- Copy to HOD, PI, CO_ PI and IEC
- Conditions (if any) clearly stated

10.1.2 APPROVED WITH MODIFICATIONS (Minor)

Criteria:
- Overall scientifically sound
- Major/minor revisions needed as per the SRC members advice
- Changes do not affect core methodology
- Can be addressed through written response

Examples of Minor Modifications:
- Clarify operational definitions
- Add specific statistical test
- Minor rewording of objectives
- Addition of quality control measure
- Correction of calculation errors
- Format corrections

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Process:
- Modifications/ comments will be sent to PI within 7 days
- PI responds in writing within 2 weeks (Response to Comments)
  Revised submission to SRC highlighting the changes
- Chairperson -final approval after scrutiny by Member Secretary
- Approval if satisfactory

10.1.3 CONDITIONAL APPROVAL (Major Modifications)

Criteria:
- Good potential but significant issues
- Major methodological concerns
- Substantial changes required
- Requires re-review by committee

Examples of Major Modifications:
- Change in study design
- Inadequate sample size requiring recalculation
- Major addition to methodology
- Significant change in outcomes
- Statistical method redesign
- Addition of quality assurance measures

Process:
- Detailed modifications letter will be sent to PI within 7 days-by mail
- PI revises and resubmits within 4 weeks
- Resubmission reviewed in next meeting
- May require primary reviewer presentation again

10.1.4 DEFERRED

Criteria:
- Substantial information missing
- Cannot be reviewed without key information
- Needs major reworking

Reasons for Deferral:
- Incomplete proposal
- Lack of essential documents
- Major clarity issues
- Pilot work needed
- Need for expert consultation

Process:
- Deferral letter with specific requirements
- PI may resubmit when ready (any meeting)
- Treated as fresh submission

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10.1.5 REJECTED

Criteria:
- Scientifically unsound
- Unethical research question
- Not feasible
- Duplicate research without justification
- Investigator not qualified

Reasons for Rejection:
- Fundamental scientific flaws
- Research Question not answered adequately
- Methodology cannot answer Research question
- Serious safety concerns
- Resources not available

Process:
- Detailed rejection letter with reasons will be sent by mail to PI
- Option to re-apply with major changes
- Appeal process available

10.1.6 WITHDRAWN

Criteria:
- PI withdraws before decision
- PI does not respond to queries
- PI not present for presentation

Process:
- Recorded in minutes
- Can reapply later

10.2 Timelines

Standard Timeline:
Submission deadline 10 days before the scheduled meeting
Screening and assignment ----- 3 days
SRC meeting As per calendar
Decision communication Within 2 days of meeting
PI response (minor modification) Within 3 days
PI response (major modification) Within 5 days
Final approval Within 7 days of satisfactory response

10.3 Communication of Decisions

Approval Certificate Contents:
- SRC reference number
- Study title and PI name
- Decision and date

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- Validity period
- Conditions (if any)
- Next steps (IEC submission)
- Reporting requirements
- Signatures

11. CONTINUING REVIEW AND MONITORING

11.1 Protocol Amendments

Amendment Categories:

Major Amendments (Require SRC approval):

- Change in objectives
- Change in study design
- Sample size modification
- Addition of procedures
- Change in statistical methods
- Extension beyond 1 year
- Change of PI

Minor Amendments (Notification only):

- Change in co-investigator
- Minor timeline adjustment (<3 months)
- Administrative changes
- Format corrections

Amendment Submission:

- Amendment request form
- Revised sections of protocol
- Justification for change
- Approval from previous committee (if applicable)

Amendment Review:

- Major: Full committee review
- Minor: Chairperson approval
- Timeline: Within 2 weeks for major, 1 week for minor modifications

11.2 Serious Adverse Event (SAE) Reporting

For Clinical Trials:

- SAE reporting as per regulatory requirements
- SRC informed within 24 hours
- Review of causality assessment
- Decision on study continuation
- CDSCO/DCGI reporting ensured

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12. RECORD KEEPING AND DOCUMENTATION

12.1 Essential Documents

SRC Office Shall Maintain:

1. Meeting Records:
   - Attendance sheets
   - Agenda
   - Minutes of meetings
   - Decision register

2. Proposal Files:
   - Submitted protocols
   - Review forms
   - Correspondence
   - Amendment records
   - Progress reports
   - Completion reports

3. Administrative Records:
   - SRC constitution document
   - Member appointment letters
   - Training records
   - SOP and updates
   - Annual reports

12.2 Document Retention

Retention Period:

- Active studies: Until 3 years after completion
- Completed studies: Minimum 5 years after completion
- Clinical trials: As per regulatory requirements (usually 15 years)
- Minutes and decisions: Permanent record
- Administrative documents: Permanent record

12.3 Confidentiality

Confidentiality Requirements:

- All proposals treated as confidential
- Members sign confidentiality agreement
- No discussion outside meetings
- Secure storage of documents
- Password-protected electronic files
- Restricted access to SRC office

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