SRM UNIVERSITY – *AP*, ANDHRA PRADESH

SRMAP / Reg. Off / Notification /83/2023-24 **11th March 2024**

NOTIFICATION

Sub: Standard and Operational Procedures (SOP) of the Institutional Ethics Committee (IEC) – SRM University – *AP* - Reg.

Standard and Operational Procedures (SOP)

of

The Institutional Ethics Committee (IEC) - SRM University - *AP*

List of Acronyms

SRMAP	SRM University - *AP*
IEC	Institutional Ethics Committee
SOP	Standard Operating Procedures
MOM	Minutes of meeting

I. Overview of the Ethics Review Board

The Standard Operating Procedures (SOP) delineate the structure, functions, and process to be followed by the Institute Ethics Review Board of the SRM University-*AP* (SRMAP), established through the Andhra Pradesh Private Universities (Establishment and Regulation) Act, 2016, for ethical review of research proposals submitted to it.

I. A. The Purpose of Institutional Ethics Committee (IEC)-SRMAP

The key functions of IEC-SRMAP will include:

1. To make sure the research involving human and animal subjects carried out at SRMAP or the projects funded by SRMAP should meet the ethical standards in terms of
   i) Respect for the research subjects, animals, and humans
   i) Beneficence and
   ii) Justices
2. To make sure that the proposed research designed is scientifically sound, pertinent to addressing the research question and will not expose the subjects to unwarranted risks.

I. B. Fundamental Ethical Standards

The SOP of IEC-SRMAP is formulated in accordance with the ICMR guidelines 2006 and World Medical Association in Declaration of Helsinki 2013. This SOP is subject to modifications whenever a new guideline formulated by ICMR or any other competent authorities of government of India.

II. IEC-SRMAP Structure

II. A. Members

The Committee shall consist of at least ten members excluding Member Secretary of IEC-SRMAP. The honorarium will be paid to the external members of the committee as per the norms of the SRMAP.

II. B. Appointment and removal of Members

The Vice Chancellor of SRMAP shall appoint the members of the committee for a stipulated period. The Member Secretary of the committee can also be an ex-officio member of the Committee.

1. The members will be appointed based on the following criteria:
   i. Their willingness to serve as a member of the committee and also to efficiently carry out their committee responsibilities.
   ii. Their expert knowledge in biological sciences, natural sciences, humanities & social sciences, and medical sciences, or relevant to any other appropriate domains.

iii. Their willingness to update the knowledge of the research ethics.

2. The Vice Chancellor of SRMAP can replace any members of the committee who is unable to function as a member of the committee.
3. Members may submit a resignation letter to the Vice Chancellor, SRMAP by providing advance intimation (at least 14 working days) to the member secretary.

II. C. Appointment and responsibilities of Chairperson

1. The Chairperson of the committee shall be appointed by Vice Chancellor, SRMAP and he/she shall serve for a maximum of two renewable terms of three years each.
2. The roles and responsibilities of the Chairperson are as follows:
   i. Preside over Committee meetings.
   ii. Authorized to sign the IEC approval letter.
   iii. Appoint subcommittees or ad hoc committees based on the required inquiry.
   iv. Functions as liaison between IEC and Vice Chancellor SRMAP.
   v. Recommend potential new IEC members to the Vice Chancellor, SRMAP.

II. D. Appointment and responsibilities of Member Secretary

1. The Member Secretary of the Committee shall be a Faculty from SRM-AP nominated by the Vice Chancellor, SRMAP.
2. The Member Secretary shall be assisted by an administrative staff based on the requirement.
3. Serve as an ex-officio member of the Committee.
4. Point of contact for providing information on standard procedures and to conduct orientation/training on ethical issues pertaining to research involving human and animal subjects.
5. Maintain a registry (both hard and soft copy) of research proposals received by the IEC, proceedings, and recommendations of the Committee.
6. The other responsibilities of the member secretary are as follows:
   i. Acts as a liaison with the Chairperson and the Committee members on conducting IEC-SRMAP meetings.
   ii. Scrutinize the submitted research proposal to IEC and liaise with investigators to ensure the order and correctness of the documents.
   iii. Maintain minutes of the meeting (MOM) conducted by IEC.
7. Maintaining and archiving the following documentation:
   i. a copy of the Standard Operating Procedure (SOP) and any amendments.
   ii. an up-to-date list and curriculum vitae of all Committee members.
   iii. Archive a complete set of minutes of Committee meetings with all additional detailed records.
   iv. Maintain all the research proposals in various stages right from submission, review, exempt from review, approvals, modifications, and rejections.

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v. Maintain copies (both hard and soft copy) of comments from any scientific or technical bodies and any other research ethics committees on all research proposals.

8. Duration of the document maintenance:

i. Project-related documents shall be retained for a minimum period of three years after the closure of the research project.

ii. Secretariat-related documentation (meeting agenda, minutes of meetings, annual reports, reports etc.) for at least for a minimum period of five years after the completion of the project.

iii. Biological samples-investigators shall be advised to retain the samples for a minimum period of ten years after the publication of result.

II. E. Ad hoc Committee Members

The committee may involve any external experts as and when required for a particular project. Any such Ad hoc members can review the process and provide recommendations. However, their attendance will not contribute to the quorum of the meeting.

III. Committee Meetings

III. A. Frequency

1. The secretary will convene the IEC-SRMAP meeting as and when required.
2. The IEC-SRMAP will convene the committee meeting within three months of receipt of the research proposal.
3. The Member Secretary will provide the members with a copy of the proposal and relevant materials at least 15 days before the meeting.

III. B. Attendance

1. The committee members should inform the member secretary of their willingness or inability to attend the meetings well in advance.
2. The Chairperson will invite the Investigator and/or co-investigator for a presentation and justification of the research proposal.
3. If required, the Chairperson may invite additional internal/external experts to review and provide input on the research proposal.

III. C. Confidentiality

1. The committee members and invited experts are bound to maintain the confidentiality of the documentation and deliberations of the committee.
2. The member secretary must summarize the minutes of the meeting and other records based on the collective decision of the committee, without attributing it to the opinions of the individual members.
3. All the communications and details of the research proposals should be maintained confidential in a manner that does not influence the decisions of the committee.

III. D. Quorum

A minimum 60% quorum is required to commence and continue the committee meeting. Invited internal/external experts do not count towards the quorum.

III. E. Meeting records

The Member Secretary shall circulate the minutes of the meeting to the members of the IEC-SRMAP with the approval of the Chairperson.

IV. Submission of Research Proposals to IEC-SRMAP

IV. A. Submission protocol

1. The researcher(s), investigator(s) is/are required to submit the research proposal in the prescribed format (both hard copy and soft copy to the IEC Secretary iec@srmap.edu.in). The person submitting will be the only contact point for further communications.
2. Documents needed to be submitted-
    i. Cover letter (1 page) – addressed to Chairman, IEC-SRMAP - forwarded through Head of the Department
    ii. An abstract (less than 500 words) – should include study objectives, methodology, risks and potential benefits and outcomes of the study.
    iii. A complete proposal (background of the study, objectives, methodology, limitations, novelty, significance, outcome of the study, Outline strategies for disseminating the research findings, Budget and timelines, References) in the prescribed format.
3. Informed consent documentation and research subject information sheet should be submitted for approval along with the proposal.

The following should take place during the consent process:

a. review of recruitment materials.
b. verbal instructions.
c. written material (when appropriate).
d. questions and answer sessions; and
e. agreement by documented signature when appropriate (most situations). Participants must be informed that it is their right to withdraw from a study at any time. The consent form must be communicated in suitable and effective ways to any participant, including those with disabilities. Children and other vulnerable subjects may need information presented as simply and straightforwardly as possible. In cases in which the potential participants cannot read the consent form, it must be read to the individual and a witness' signature is required on the form, indicating that he or she was present during the reading and interpreting of the consent form and that it was presented in a manner that was comprehensible to the subject. If for any reason the informed consent process is waived a clear justification must be provided as well as any alternative arrangements.

4. A copy of ethical committee approval/comments from the collaborative institution should

be submitted as and when it is issued.

5. A complete Curriculum vitae of the Investigator(s).
6. Any other relevant documents.

V. Review of Research Proposals received to IEC-SRMAP

V. A. What is Subject to Review: Scope of Review

Research that involves human and animal subjects and pertaining interventions be it therapeutic, diagnostic, and preventive needs to be reviewed and approved by the committee. The studies involving vulnerable population, drug testing and invasive procedures must be reviewed and approved. Research work in the field of humanities and social sciences involving deception and sensitive questions for collecting data that could lead to stereotyping, prejudice, discrimination, and stigmatization needs to be reviewed and approved.

The committee may exempt or include the research work for review process that involves, a) Health care data collected from public domain or public/ government officials. b) Naturalistic observation or surveillance studies. c) Periodic health care surveys conducted by the government organizations.

V. B. Review and Approval Process

1. The Chairperson and the committee members will decide after the initial screening of the proposal, either to exempt or to consider for the review process. The proposal will be classified as "review required" or "review not required". In the latter case, an official letter with a brief explanation with the reason for exemption will be issued to the concerned scientist. In case of non-consensus among the committee, the decision would be based on majority, whether to exempt or include for review and approval process. If there exists a tie on any research proposal, the proposal will be taken for review.

2. A meeting will be convened to review the proposals. All the members of the committee shall be informed about the proposals in order to participate in the discussion and decision-making process. The approval would be based on the consensus of the committee, but in case of any disagreement within the committee, the investigator may be asked to explain and if required, an expert opinion might be sought before making a decision.

3. The committee will follow the guidelines issued by ICMR (2017) and Helsinki declaration.

4. The decision of the committee may be one of the following, a) Approved, b) Approved with conditions, c) Exempted from Review, and d) Not Approved.

5. The member secretary will issue a letter on the decision of the committee to the investigator.

6. Any substantial changes in the approved proposal should be duly intimated to the

committee for further review and reapproval.

7. In case of multi centric/ multi-institutional projects, where SRMAP is the lead institute, the approval of the ethical committees of the participating centers must be submitted along with the proposal for review. In case of SRM AP being a collaborator, the usual standard procedure to secure approval needs to be followed.
8. ***Nested Studies***: The nested studies should also be reviewed in accordance with the university's IEC procedures.

V. C. Continuing Oversight and Monitoring

1. Any serious violation and deviation from the approved procedures and guidelines in the approved project will be liable for the withdrawal of the IEC-SRMAP approval.
2. Any deviation from the approved procedures and guidelines in the approved project should be brought to the IEC for reviewing and approval. During the pending period, the altered part of the project should not be executed.
3. The second or subsequent approval for the revised procedures should be obtained in a timely manner.
4. Any serious adverse events including deaths that occur to participants during their participation in any approved research project shall be reported immediately to the IEC, funding agencies and university authorities.
5. The committee will review and determine the action plan as per the ICMR and other national guidelines either in the next IEC meeting or an extraordinary committee meeting if required. The decision of such meeting will be conveyed to the principal investigator of the project.
6. Upon completion of the approved project, the PI shall submit a closure report to the IEC.

VI. Conflicts of Interest

The committee should ensure there is no bias towards the investigators and project received for the ethical review and approval from IEC-SRMAP. The committee should maintain no conflict of interest between committee members and investigators.

1. The committee members and investigators should refrain from situations and biases that could influence the objectives of the study, review of the proposals and recommendations.

2. The Committee must ensure that any potential conflict of interest should be resolved amicably and plans for avoiding reoccurrence of conflict of interest of the same nature.

3. In projects where conflict of interest is revealed but not significant enough to reject the project, the committee will decide the description that should be included in concerned documents to be collected from the participants in the research.

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VI. A. Conflict of interest Investigator(s)

1. Every investigator of the proposed research project should clearly state that they have no conflict of interest in the cover page of the proposal.
2. The Investigator should not have any material conflict of interest that could influence the scientific objective of the project.
3. The Committee shall approve only those projects which include no conflict-of-interest declaration. The committee should make sure that the conflict of interests, if any, should not influence the scientific objectivity of the project.

VI. B. Committee members: Financial Conflict

The Vice Chancellor of SRMAP must duly be intimated by the investigator(s) and the members of IEC-SRMAP if they or their spouses or dependents have any financial interests in SRMAP any other collaborating organizations. The same should also be documented by the IEC-secretary. The same rules also applied for the external IEC members.

VI. C. Committee members Conflicts

A committee member who is connected to a submitted proposal in any capacity should be declared as conflict of interest and refrained from the entire review process for that concerned project.

VI. D. Resolution of Conflict

1. Any committee member having a financial interest or conflicting role to their proposal should clearly disclose such a conflict and decline to be a part of the review process.

2. The conflict of interest of any members should be announced in the meeting and the proceedings should be duly recorded in the minutes of the meeting.

3. The chairman may request any committee member having a financial benefit or conflict of interest on a particular project, to comment on the subject matter of the submitted proposal. The chairman may instruct such committee member to leave the meeting while the proposal is taken for discussion or when the decision is being made.

4. In case the Chairperson has a financial interest or conflict of interest, he/she shall transfer his/her responsibility to another member of the IEC-SRMAP. The minutes of the discussion and resolution of the conflict of interest should be meticulously recorded.

VII. Evaluation and Improvement

1. The university can access the documents and files of ethical committee proceedings for the review by a special committee constituted for the purpose by the VC of the university.
2. Any amendments in the national ethical guidelines will be included as described elsewhere in the SOP.

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VIII. Adoption and Amendment of the Standard Operating Procedures

1. The SOP will be approved by the Vice Chancellor, SRMAP for adoption by the Committee.

2. Any amendment in the SOPs will be adopted by a majority of the Committee members voting. The amendment shall come into effect once approved by the Vice Chancellor, SRMAP.

Glossary

Annexure A: **Form 1A** - Format of application for human ethics clearance for UG/PG/PhD/Faculty research.

Annexure B: Information for participants in the study.

Annexure C: Participant consent form.

Annexure D: Institutional ethics review board - Checklist.

All the applications should fulfill the following requirements:

1. A cover letter - forwarded by Head of the department.
2. Two sets of hard copies of the application in the format given in **Annexure A (Form 1A)**, duly signed by investigators and Head of the Department.
3. Information collection sheet, questionnaire if any.
4. Research proposal.
5. Consent forms if any (**Annexure B and C**).
6. Soft copy of the complete set in PDF format through email.

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Registrar
11/3/24

Registrar
SRM UNIVERSITY-AP
Andhra Pradesh-522 240

Institutional Ethics Committee (IEC)

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IMPORTANT NOTES:

- The researchers/investigator(s) should submit two hard copies of the IEC application (available in University website) at least four weeks before the commencement of the IEC meeting.
- The following documents should be submitted: cover letter (forwarded by Head of the department), application format given Annexure A (Form 1A), Consent forms if any (Annexure B and C), information collection sheet, questionnaire if any, research proposal.
- Soft copy of the complete set in PDF format through email to secretary of IEC.
- The committee will meet **three times** in a year (tentatively in the **first week of January, May, and September**).
- Extraordinary meetings may be conducted depending on the need.
- The minutes of the meeting will be prepared and recorded.
- The member secretary will communicate the decision of the IEC and/or will request additional documents if needed.
- The schedule of review by the IEC-SRMAP will be communicated to the investigator/supervisor.

Annexure - A
Form - 1A

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Format of application for human ethics clearance for UG/PG/PhD/Faculty research

1. Title of the project:
2. Name and Designation of Research Supervisor/Guide with full address:
3. Name of Investigator (UG/PG/PhD/Postdoc) and Address:
4. Name and Designation of Co-Investigator(s) and Address (if any):
5. Institution/Place where the research will be carried out:
6. Name of the Funding Agency and Address:
7. Duration of the scheme:
8. Objectives of the study: (can be given in bulletin points)
9. Brief review of the proposed project:
10. Summary of the methods and the sample size including controls:
11. Inclusion and exclusion criteria for admission of subjects in the study:
12. Research subject information sheet (The Research subject information sheet must include the following information in a simple language which can be understand by them
    a. Aims and methods of the research.
    b. Expected duration of the subject participation.
    c. The benefits that might reasonably be expected from the outcome of research to the subject or to others.
    d. Any risk to the subject associated with the study.
    e. Maintenance of confidentiality of records.
    f. Incentives to the research subjects
    g. Provision of free treatment for research related injury.
    h. Compensation of the subjects for disability and death occurs due to the study.
    i. Freedom of individual to participate and withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
13. Informed consent and the procedure for obtaining it:

I (We), the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements approved guidelines.

(signature should be signed in ink)

Name and Signature of the Investigator(s) **Signature of Supervisor/Guide**

Forwarding by the IIead of the Department

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Annexure B

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INFORMATION FOR PARTICIPANTS OF THE STUDY

Study Title:

Institution (s):

Name of the Investigator(s):

Informed Consent of Participants in accordance with the guidelines of ICMR/other national bodies should be enclosed by the investigator(s).

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Annexure C

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PARTICIPANT CONSENT FORM

Participant information sheet in accordance with the guidelines of ICMR/other national bodies should be enclosed by the investigator(s).

Annexure D

INSTITUTIONAL ETHICS REVIEW BOARD
SRM UNIVERSITY -ANDHRA PRADESH, Amaravati- 522502

Checklist

Name of the Ethics Committee: IEC-SRMAP **IEC Ref. No.:**

Title of the Proposal:
Funding Agency:
Name & Address of the investigator:
Name & Address of the Co-investigator:

FOR OFFICIAL USE

The following item [√] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[ ] Cover letter
[ ] Study Protocol application as per the **recommended** format
[ ] Participant Information Sheet
[ ] Participant Consent Form
[ ] Summary of Change Document (in case of a revision)
And have been:
[ ] Approved
[ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
[ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Date of the decision:

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Member Secretary IEC-SRMAP