

CREATING HEALTHIER SOCIETY

RESEARCH POLICY

Policy for Promotion of Research

Research and extension activities are integral to teaching. Education is a dynamic process. It requires constant updating. This updating is only possible with a vibrant research aptitude. Research makes it possible to create knowledge, innovation and newer insights that make extension activities and teaching more vibrant and scientific.

The objective of the Institute shall be to disseminate and advance knowledge by providing instructional and research facilities in such branches of learning as it may deem fit and by the example of its corporate life, and, in particular, to make special provisions for studies in French and for integrated courses for Humanities and Science in the educational programmes of the Institute and to take appropriate measures for promoting inter-disciplinary studies and research in the Institute.

Promotion of Research in SVMCH&RC

In order to promote research activities, this Medical College has established Project Cell that deals with all research projects funded by various funding agencies. In order to facilitate other research and development activities like conferences, collaborations and establishing networking with other institutes in India and outside India, has established Planning and Development Section headed by an officer of a rank of Chief Operating Officer aided by a Research Coordinator.

SVMCH&RC encourages its faculty to apply for research projects from International and national funding agencies apart from local bodies, industries and other funding sources for research projects. In accordance with the NMC and IGC norms, high standards of research output are one of the main criteria for the recruitment and promotion of faculty. So as to hasten the process of administrative issues related to research, the post of Dean of Research has been created as singly point for coordination. Optimal decentralization of procedures related to research is in place to support researchers. Detailed procedures for simplifying the research project implementation have been developed to help the faculty handling the research projects.

Teachers in particular in pre, para clinical disciplines without PhD are encouraged to pursue and complete their PhD by providing study leave with salary benefits.

Encouraging faculty members to pursue Post-Doctoral research, national collaborative, research projects and fellowships by providing study leave to spend their time in research activities the Institution itself or in other Institutions in permitting external candidates.

Eligible faculties are encouraged to guide PhD research scholars in accordance with PhD Regulation of Pondicherry University to which SVMCH&RC affiliated according to PhD Regulations of the University, Professors and Associate Professors are automatically recognized as PhD guides, and eligible Assistant Professors are given recognition to supervise PhD scholars as per University PhD regulations.



Universities encourages faculty to establish network with other Universities within India as well as abroad and go for MoUs for the benefit of faculty and students for research activities.

Periodically every year the research output of faculty is collected and published in 'Annual Report', which would be shared with members of the Governing Body of SVMCH&RC.

Ethics in Research

SVMCH&RC plays utmost importance in encouraging its faculty for following ethical guidelines established by appropriate bodies in carrying out the research activities.

The Institution has separate statutory Institutional Ethics Committee for research involving human subjects as well as animal subjects, and research proposals have to undergo these committees before carrying out the research. The process of having a Biosafety Committee is in progress.

As per University guidelines highest importance to IPR and ethical publishing is given. All the PhD thesis before submission must be checked by authentic plagiarism checking software and certificate to be submitted with signatures of both research scholar and the concerned research guide. Plagiarism software has been provided to the entire faculty for checking their research articles, research proposals and research project reports besides using plagiarism check to regulate the student assignments. All the PhD thesis of the PhD scholars gets uploaded to the Shodhganga-INFLIBNET repository thro' Pondicherry University.

SVMCH&RC encourages various departments to conduct workshops in research methodology where ethics in research is an integral part of these workshops. Awareness is also created to faculty members by invited talks on ethics in research. Ethics in research is also taught for PhD research scholars as part of their course work, where ethics is an essential part. In addition, collaborative research is undertaken with Research Institutions in Pondicherry via, Vector Control Research Centre MoUs.

IPR

The research output in the form of innovation, creativity and patents filing are encouraged through Pondicherry University IPR policy and a separate IPR Cell for facilitating the said activities has been established.

Policy for consultancy and revenue sharing

A detailed policy has been drafted in dealing with matters relating to consultancy and revenue sharing with our copyright and patent consultants.

Note:

Being an affiliated college to Pondicherry Central University, it is ensured that policy for research at SVMCH&RC and regulations are in line with that University.



CREATING HEALTHIER SOCIETY

<u>DFA</u>

Discussion with COO, SVGI

Date: _____

ROADMAP for Research @ SVMCH&RC/SVGI

Research Advisory Committee

- Streamline research activities
- Formulate various research workshops
- Organize research related Programmes
- Plan activities of IFU
- Institutional Biosafety Committee
- Sponsored Clinical Trials Research Committee
- PhD Research Monitoring Committee
- ✤ PG Research Monitoring Committee
- Plagiarism checking Committee
- **♦** Innovation Facilitation Unit (IFU)
- ***** Research Mentors... for UGs

Already Available Committees

- Scientific Advisory Committee
- **Institute Ethics Committee**
- Institute Animal Ethics Committee

Central Research Lab

Enable Coordination among Faculty and Facilitate inter-departmental research activities and between other Institutes as well.



Innovation Facilitation Unit (IFU)

- Innovation ideas for affordable Health Care and protect the same as Intellectual Property (IP) of SVMCH&RC.

Manpower:

- <u>Short Term Road Map</u> aims at capacity Building in defined (Target) areas. This can be facilitated by identifying committed Faculty and designate them as Associate Dean(Research). The numbers not to exceed four with Coordinators department wise for augmenting interdisciplinary research workforce.
- <u>Long Term Road Map</u> aims at procuring extramural funding with Institutional seedmoney to establish state-of-art research facilities.

<u>Training:</u>

- Research Advisory Committee (RAC) identifies priority areas for health research and formus "theme-based", multi-disciplinary teams. The Associate Deans would develop procedures, guidelines and SOPs, for biannual review by RAC.
- Training workshops will be a regular annual feature run by departments as part of their research initiatives.

Epilogue:

Research till date at SVMCH&RC is limited to PG Students' dissertation presentation to SAC and IEC and Faculty presenting some interesting cases at their conferences. Whether this has motivated research among students or Faculty for good ethical and best medical practices remains to be seen. (Preparing a committee for NABH / NAC purposes will only be a short term goal may not create a research aptitude or climate).



INTERNAL MEMBERS

- Prof. Dr. S. Mahadevan, MD., Ph.D., MNAMS (Critical Care Pediatrics) DEAN(Res. & PG Studies), SVMCH&RC.
- Prof. Dr. S. S. Rajasekar, MS, Ph.D., FAIMER, FIMSA, HOD, Department of Anatomy, SVMCH&RC, President, IIC (SVGI).
- Dr. P. Suresh, M.Sc., Ph.D. (Medical Biochemistry) Assoc. Prof. in Dept. of Biochemistry & Central Lab In-charge, SVMCH&RC

EXTERNAL MEMBERS

 Professor R. SAJITH KUMAR MD, PhD.
 Chief Infectious Diseases, Govt. Med. College Kerala Govt. Med. Edu. Services Kottayam - 686 008.
 Dr. ASHOKKA BALAKRISHNAN, MD, FANZCA MHPE CONSULTANT ANESTHESIOLOGIST,

National University, Singapore.

Tel.: +6597118855, email: <u>ashokka_balakrishnan@nuhs.edu.sg</u>

3. DR. RAMALINGAM .B, PhD Scientist E/DBT Ramalingaswami Fellow, Department of Immunology, ICMR-NIRT, Chetpet. Chennai – 600 031. Tel.: +91 9677074680, email: bramalingam@gmail.com



CREATING HEALTHIER SOCIETY

RESEARCH ADVISORY COUNSIL (SVGI)

Tenure:

- 2 (two) years
- Will meet at least twice a year and as and when required.

Terms of Reference:

- Advise SVGI on matters of Research Policy and strategy.
- Clearing and Certifying Authority of Studies after due scrutiny.
- Identify priority research areas relevant locally, nationally and temporarly.
- Ensure supportive supervision for the various committees.

MEMBERS	Total: 2	20 (+) or (-) 1	17+3 Total	: 13	
CHAIRPERSON	1				
CO-CHAIRPERSON	1				
INTERNAL MEMBERS	1	2	3		
EXTERNAL MEMBERS	1	2	3		
INTERNATIONAL ADVISORS					

Biosafety Considerations: Institutional Biosafety Committee (IBSC)

Generally Modified Organisms (GMOs) and products thereof are regulated as per the "Rules for the manufacture, use / import / export and storage of hazardous microorganisms / genetically engineered organism or cells 1989" (Referred as Rules 1989) notified by Ministry of Environment and forests (MOE) GOT under Environment Protection Act (1986).

Each IBSC is a registered and accredited committee of DBT.

Streamlines and Facilitates Research dealing with GMOs, Living Modified Organisms (LMOs) and recombinant-DNA (r-DNA) materials. This is relevant while handling Live Vaccines studies.



Research Mentorship Program for UGs in all SVGI:

To promote interest and aptitude for research among UG students by associate them with a Faculty-Mentor familiarize with research methodology with a faculty in their mutual area of interest.

They will facilitate to develop communication skills to present research findings in various specific scientific platforms.

DRIVERS OF RESEARCH FOR SVMCH&RC

- Curiosity driven
- Opportunity driven for funding from ICMR, DST, DBT, International bodies.
- Multi Centre International Research
- Industry Sponsored
- Small Projects by single or small groups of Investigators.
- Need driven as in COVID-19.
- Academic regulations driven e.g., PG dissertations / NMC requirements.

Document prepared by	Document reviewed by	Document authorized by

* * * * *

accordance with regulatory and GCP provisions. I will fully cooperative with any study related audit conducted by regulatory officials or authorized representative sponsors. I agree to promptly report to the Ethics Committee all the changes in the clinical trial activities

- and all unanticipated problems involve in risks to human subjects or others. g.
- h. I agree to inform all unexpected serious adverse events to the Sponsor as well as the Ethics Committee within seven days of their occurrence.
- i. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- j. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in clinical trials.

Signature of the Principal Investigators:

Signature of the Co-Investigator:(If applicable)

Signature of the Guide : (with seal)

(If applicable) Signature of the Co-Guide : (with seal)

Signature of the Head of the Department (with seal)

Date :

Date :

Date :

Date :

Date:



SRI-VENKATESHWARAA MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE Ariyur, Puducherry, Ph.0413-2644435, 2644482

Undertaking by the Investigator

1. Full name, address of the investigator:

2. Name and address of the Medical college, Hospital or other Facility where the clinical trial will be contacted.

Education, Training and Experience that qualify the Investigator for the clinical trial:

Name and address of all clinical laboratory to be used in the study:

4. Name and address of the ethical committee that is responsible for approval and continuing review of the study:

Institutional Ethical Committee,

Sri Venkateshwaraa Medical College Hospital and Research Centre, Ariyur, Puducherry.

5. Name of the other members of the Research team, who will be assisting the Investigator in the conduct of the Investigation(s): Co-Guide: Guide:

6. Protocol Title:

7. Commitments:

- a. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- b. I agree conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the sponsor and prior review and documented approval/ favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial subjects or when the change(s) involved are only logistical or administrative in nature.
- c. 1 agree to personally conduct and/ or supervise the clinical trial at my site.
- d. I agree myself that I will not use the blood sample for stem cell culture.
- e. I agree to ensure that all associates, Colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligation in meeting their commitments in the trial.
- f. I agree to maintain adequate and accurate records and to make those records available for audit/ Inspection by the Ethics Committee, Licensing Authority or their authorized representatives, in

VENKATESHWARAA MEDICAL COLLEGE HOSPITAL RESEARCH CENTRE r, Puducherry. Ph.0413-2644435, 2644482

TITLE PAGE

Title of the study :

Name of the Investigator

UG/PG/Faculty

(Signature with date)

Year of study / Department

Sri Venkateshwaraa Medical College

Hospital & Research Centre, Ariyur, Puducherry.

Name of the Co-investigator : If applicable

(Signature with date)

Name of the Guide

Designation

:Name

: Name

(Signature with date& seal) Department

Sri Venkateshwaraa MedicalCollege

Hospital & Research Centre, Ariyur, Puducherry.

Name of co-guide

:If applicable

(Signature with date& seal)



SOP CODE: SOP 03/V02

5. Annexure

Annexure 1 AX 01/SOP 03/V2 - Conflict of Interest Form for IEC, SVMCH.

6. Reference

- 1. Part 560institution review boards, subpart B-Organization and personnel, Sec 56.107 1RB membership, 45 CFR 46.107 (e) and 21 CFR
- Forum for Ethics review committees in India (FERCI). Standard operating of Institutional Ethics Committee (cited22nd October 2018). Available from:http://www/ferci.orp/sop/
- Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research Available from: http://www.icmr.nic.in/guidelines/ICMR-Ethical-Guidelines-2017.pdf



Effective Date: 01/06/2020

- Types of COI
- A Personal COI is said to exist when
 - There is immediate family relationship (spouse, parent or parent of a spouse, child or child of spouse, sibling of spouse, or a dependent who resides with an EC member or consultant or who receives 50% or more support from an EC member, regardless of age) or other close personal relationship ("step" relationships included) with the investigator, or with co-investigators.
 - EC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financer.
 - Research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)
- A Professional COI means the EC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
- A Financial COI for EC members and immediate family exists when the EC member or the spouse or dependent of a member receives monetary benefits including, but not limited to salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

Mandate

G.S.R. 12(E)Chapter III & IV, New drugs and clinical trials, Rule 2019.dated 19th March 2019

There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

"A member must voluntarily withdraw from the ethics committee proceedings while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairman prior to the review and should be recorded so in the minutes. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed".

"No Institutional Ethics Committee (IEC) may have a member participate in the ethics committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. [45CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 IEC membership".

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Effective Date: 01/06/2020

SOP CODE:

- c) If an EC member has a COI for review of research study at a meeting, he or she will inform
- the Chairman and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer question about the research. This is applicable also for EC meetings at which discussion on serious adverse events, deviations/violations, amendments/continuing review reports related to studies are discussed.
- d) Recusal EC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal,

EC Chairman would ask the members, at the beginning of each meeting to disclose any COI concerning any of the items on the agenda. During the meeting, EC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.

If the Chairman has a conflict of interest for a particular project, this should be so declared

and determination is done by EC member with the help of EC Chairman/Member Secretary. The EC Chairman has the final authority to determine whether a COI has been managed or

eliminated appropriately for research participant protection. The EC shall not approve a research study proposal where a COI is not managed or eliminated.

Management of CO I

In case of a COI,

- EC members will disclose the COI as discussed above EC members will not serve as reviewers.
- EC members will not influence the discussion and decision making of concerned study by staying away during the EC meeting.
- EC Member Secretary and the Secretariat will record the points related to disclosure and

management of COI of EC members in the EC minutes. Definition and mandate

Definitions:

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Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain [http://icmr.nic.in/ethical_guidelines.pdf accessed on 23rd Nov 2015].

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SOP CODE: SOP 03/V02

Title: Handling Conflict of Interest among Ethics Committee Members

1. Purpose

The purpose of this SOP is to describe the process to identify and manage conflict of interest among Institutional Ethics Committee (IEC), members, SVMCH.

2. Scope

This SOP covers the policy related to identification, declaration and management of Conflict of Interest and is applicable to all Institutional Ethics Committee (IEC) members.

3. Responsibility

It is responsibility of each members of IEC to read, understand, accept and sign the agreement contained in the Conflict of Interest (COI) Form, at the beginning of the tenure of his/her

It is the responsibility of the guest/observers/ Independent Consultant (IC) intending to attend a meeting to read, understand, accept and sign the agreement contained in the Conflict of Interest form

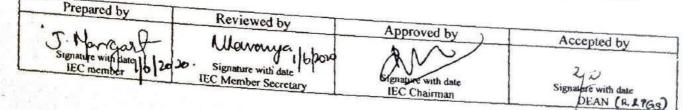
The Chairman would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

4.Detailed Instruction

Voluntary disclosure regarding COI by EC member - The EC member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest

EC member should not participate in discussing, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full - board) when they have conflicts of interest, except to provide information requested by the EC.

- a) If an EC member has a COI for review outside a meeting he or she should notify the EC
- b) If an EC member has a COI for a study for which he or she has been assigned as a primary. reviewer, he or she will inform the EC secretariat so that the review is reassigned to other



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3

SRI VENKATESHWARAA MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE

Annexure 1: AX 01/SOP01/V2 List of SOPs of the Institutional Ethics Committee

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S.No	Title of the Standard Operating Procedures (SOPs)		
1	Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)		
	Ethics Committee (IEC)	SOP 01	
2	Establishing and Constituting Institution Establishing		
3	Handling Conflict of Interest among Ethics committee members	SOP 02	
		SOP 03	
4	Selection and Responsibilities of Independent Consultants for IEC, SVMCH		
5		SOP 04	
. 6	Wastagement of Research Protocol Submissions	SOP 05	
7	Categorization of Research Protocol	SOP 06	
8	Full Board Review of Submitted Protocol	1	
9	Expedited Review of Research Protocol	SOP 07-A	
10	Exemption from the Ethics Review for Research Protocol	SOP 07-B	
11	Review of Resubmission of Amended Protocols	SOP 07-C	
12	Review of Research protocol involving vulnerable population	SOP 07-D	
13	Agenda Preparation, meeting procedures and recording of minutes		
14	Continuing Review of Study Protocols		
15	Review of Protocols		
16	Review of Protocol Deviation/Violation		
17	Review of Serious Adverse Events (SAE) Reports and Unexpected Adverse Events	SOP 11	
. /	Review of Study Completion Report	SOP 12	
18	Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation		
19	Request for Waiver of Written / Verbal Informed Consent	SOP 14	
20	Site Monitoring Visit and Post Monitoring activities	SOP 15	
21	Management of Research Participant's Request or Complaints	SOP 16	
22	Archiving and Retrieving Documents	SOP 17	
23	Preparation of IEC for Audit / Inspection	SOP 18	
24	Review of Biomedical and Health Research during Covid-19 pandemic	SOP 19	



Effective Da 01/06/2020

SOP CODE:

SOP 01/V02

When the revised version is implemented one copy of the earlier version will be filed centrally in the file ٠ entitled 'Past SOPs of the IEC' by the Secretariat of the IEC in the IEC office. .

The Secretariat will review the SOPs at least once in every two years and record the dates of review on the SOP Master file. .

As per the findings and opinion of the Secretariat, the Member-Secretary will inform the Chairman about the result of review process.

5. Annexure

Annexure 1 AX01/SOP 01/V2 List of SOPs of IEC Annexure 2 AX02/SOP 01/V2 Template for Standard Operating Procedures Annexure 3 AX03/SOP 01/V2 Document History of the SOP Annexure 4 AX04/SOP 01/V2 Log of IEC members receiving SOP

6. References

- 1. Forum for Ethics review committees in India (FERCI). Standard operating of Institutional Ethics Committee (cited22nd October 2018). Available from: http://www.ferci.orp.sop
- 2. Ethical guidelines for biomedical research on human participants. (2019). Indian Council of Medical Research Available from: http://www.icmr.nic.in/guidelines/ICMR-I thical -Guidelines-2017 pdf



Effective Date: 01/06/2020

SOP CODE: SOP 01/V02

4.4 Design a format and layout

- Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format <u>SOP xx/Vy</u> will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version.
- Each annexure will be given unique code number with the format AX pp/SOP xx/Vy. AX refers to annexure form; pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version.
- Each SOP will be prepared according to the standard template in AX 02/SOP01/V2. Each page of the SOP will bear the header with effective date i.e. the date of approval and validity of the SOPs, the SOP number on the right side upper corner and page number (as page of total pages) on the bottom of the page. The first page of each SOP document will be signed and dated by the authors, the IEC members who have reviewed the SOPs and the IEC Chairman.

4.5 Write and review a new/revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form AX 03/SOP01/V2
- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairman.

4.6 Preparation and submission of final draft

- IEC Members will review the revised draft SOP at a special meeting.
- The suggestions that are agreed upon by the IEC members present at the special meeting will be discussed and incorporated in the revised draft SOP and the final draft of the SOP will be formulated.
 - The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP

4.7Approve a new / revised SOP

- The final version will be presented to the Chairman for review and approval.
- The authors, reviewers and the Chairman sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from where by the SOP will be implemented.

4.8 Ensure Implementation and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat of the IEC in the office of Institutional Ethics Committee.



Effective D. 01/06/2020

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- Draft the SOP/modify SOP in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairman

3.3 Chairman of the IEC will:

- Appoint one or more SOP Teams
- Approve the SOPs
- Sign and date the approved SOPs

3.4 IEC members and involved administrative staff will:

- Sign and date the approved SOP when they receive it.
- Maintain a file of all SOPs received.

4. Detailed instructions:

4.1 Identify the need for new or amendment of current SOP

Any member of the IEC or Secretariat who would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his/her request by written letter or by email to the IEC Chairman. The SOPs will be updated regularly at the interval of 2 years or if there are major changes whichever

The Chairman will inform all the IEC members about this request in a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairman and designated the task to proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, no further action will be taken. The Chairman will inform the person/ IEC member who made the request in writing about the decision

4.2 Appoint the SOP Team(s)

- The Chairman will constitute an SOP Committee(s) consisting of the member-secretary and two or more members of the IEC who have a thorough understanding of the ethical review
- The SOP writing team will carry out the subsequent steps. (5.3-5.7)

4.3 List all relevant SOPs

- Write down step by step all the procedures of the Institutional Ethics Committee. Organize, divide and name each process (AX01/SOP01/V2)



1

Title: Preparation of Standard Operating Procedures for Institutional Ethics Committee (Human studies)

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committee (IEC). The SOPs provide clear, unambiguous instructions with the intention that the related activities of the committee are conducted in accordance with Indian laws and relevant National and International Guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the Institutional Ethics Committee (IEC), SVMCH&RC.

3. Responsibility

It is the responsibility of the Member Secretary in consultation with Chairman of the IEC to appoint the SOP Team to formulate and make amendments in the SOPs. The SOP Team shall do this by following the same procedures, format and coding system when drafting or editing any SOP of the Institutional Ethics Committee. The Head of the Institute (Dean / Director) is responsible for implementing this SOP.

The responsibilities of Members, Member Secretary and Chairman of the committee is given below

3.1 Secretariat of the Institutional Ethics Committee will

- Assist Member Secretary to form the SOP team
- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and the list of SOPs
- · Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain an upto date distribution list of SOPs distributed to the IEC members

3.2 SOP Team (will contain Member Secretary and at least two other members) will:

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairman
- Propose new / modified SOPs as needed
- Select the format and coding system for SOPs

Prepared by	Reviewed by	Approved by	Accepted by
J Margant Significate with dare 6 20. IEC member	20 Mlavorya 16 por Spr. M. LAVAN TA Signature with date IEC Member Secretary	ijenature with date IEC Chairman	Signature with date DEAN (RSPGS)

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- IC will attend an EC meeting for providing additional information or clarification, if invited by Member Secretary/Chairman. However, the IC will not participate in the decision making process on the research study.
- IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

Independent Consultant:

An independent consultant is a subject expert in a specified filed who gives advice, comments and suggestion upon review of the study protocols, He/she has no affiliation to the investigators, proposing the research protocols.

5. Annexure

Annexure 1: AX 01 /SOP 04/V2 Confidentiality agreement AX 02 /SOP 04/V2-Conflict of interest document AX 03/SOP 04/V2 – Study Assessment form for IC

5. Reference

- 1. Part 560 institution review boards, subpart B-Organization and personnel, Sec 56.107 1RB membership, 45 CFR 46.107 (e) and 21 CFR
- Forum for Ethics review committees in India (FERCI). Standard operating of Institutional Ethics Committee (cited22nd October 2018). Available from:http://www/ferci.orp/sop/
- 3. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research Available from: http://www.icmr.nic.in/guidelines/ICMR-Ethical-Guidelines-2017.pdf





SOP CODE: SOP 04/V02

(those outside roster) for EC records and future reference.

- The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign
 confidentiality and conflict of interest agreements.
- The Member Secretary will provide explanations / clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairman/Legal expert/EC members.

4.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The subject expert will sign and date the Confidentiality and Conflict of Interest Agreement document.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairman.
- The Chairman will sign and date the Confidentiality and Conflict of Interest Agreements The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to subject expert.
- The subject expert is expected to implement the clauses of the signed Confidentiality Agreement Form AX 04/SOP 03/V6.

4.5 Reviewing documents pertaining to research project

- The Secretariat will provide study protocol documents along with the Study Assessment Form for subject experts AX 03/SOP 04/V2 to the subject expert after Confidentiality and Conflict of Interest documents have been signed by subject expert and Chairman and received by the IEC. The subject expert will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the subject expert becomes a permanent part of the study file.

4.6 Tenure of services of IC

- The roster of ICs maintained at the EC office will be updated every 3 years
- For IC appointed for a particular study, the service of IC get automatically terminated once the final decision regarding the study is taken by EC. The EC will document he termination of the services of IC by providing a letter thanking the IC for the services rended.

4.7 Responsibilities of IC

- If IC agrees to review a research proposal, he/she will comply with EC requirement of signing confidentiality and conflict of interest agreements.
- IC will review the research study and complete the Assessment from (duty signed and dated) within a stipulated period or by a stipulated date.



Effective Date: 01/06/2020

SOP CODE:

SOP 04/V02

Title: Selection and Responsibilities of Independent Consultants for IEC SVMCH

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide procedures for obtaining the expertise of a professional as an Independent Consultant(IC) / subject expert, either affiliated or non-affiliated, to the Institutional Ethics Committee (IEC).

2. Scope

If the Chairman, Member Secretary or the IEC determine that a study involves procedures or information that is not within the collective expertise of the IEC members, the Chairman/Member Secretary on behalf of the IEC will invite individual(s) with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to that / those available with the IEC.

3. Responsibility

Upon the advice or recommendation of the secretariat or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special ICs / subject experts and be endorsed by the Chairman for the given project.

4. Detailed instructions

4.1 Recommendation of name of ICs

- The IEC will select a panel of subject experts from the different specialties of Medicine and the chairman will issue an appointment letter to the subject experts.
- An IEC member/ Chairman may suggest that the opinion be sought from one or more subject experts and may suggest the name of a particular IC / subject expert from the roster of subject experts.

4.2 Consulting an IC during review process

- An EC member /Member Secretary Chairman may suggest that the opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the roster of ICs maintained by the EC or from outside the roster, if during the review process of any given research study if it is felt that the study involves procedures or information that is not within the area of collective expertise of the EC members.
- The Member Secretary in consultation with Chairman will decide, identify and select the ICs to be invited

4.3 Communication with ICs

Prepared by	t may request a copy of the upda Reviewed by	Approved by	Accepted by
Signature with date 46/2	20. Marray 1 2020 Signature with date IEC Member Secretary	Signature with date IEC Chairman	Zy N Signature with date DEAN (R2PGS

Page 1 of 3



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SRI VENKATESHWARAA MEDICAL COLLEGE HONPHAL AND RESEARCH CENTRE

Annexure 1

AX 04/SOP 05/V2

Confidentiality Agreement Form for Subject Experts/ advisory committee/ board member

(Affiliated / nonaffiliated to the institution)

(Name and Designation) as a non-member of Institutional

Ethics Committee (IEC), understand that the copy/ copies given to me by the IEC, is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Signature of the recipient	Date
Chairman of IEC	Date

I,______(name) acknowledge that I have received a copy of this Agreement signed by the Chairman of the IEC and me.

Signature

Date

(Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC))



Effective 01/06/202

SOP CODE: SOP 05/V02

4.4 Signing up Confidentiality Agreement Form

- The guest/observe will sign and date the document before a member of the Secretariat.
- He/she will return the signed form to the Secretariat.
- The Secretariat will obtain the signature of the EC Chairman on the Confidentiality/Agreement Form.
- The Secretariat will provide guest observe for EC a photocopy of the Confidentiality Agreement Form for their records (duty signed and dated by them and EC Chairman) and Knowledge the receipt of agreement by their signature.
- The Secretariat will keep the original copy of the signed Agreements at the EC office in the files entitled 'Confidentiality Agreement file for guests/observes, Independent Consultants (IC)'.

4.5 Keep the Agreement in mind.

The IEC, members/Guests /observers for Institutional Ethics Committee meetings/Independent Consultants must implement the clauses of the signed Confidentiality Agreement Form as in AX 03A/SOP 02/V2, AX 01/SOP 05/V2and AX 01/SOP 04/V2 respectively.

5. Annexure:

Annexure : AX 01 /SOP 05/V2

6. References

- 1. Forum for Ethics review committees in India (FERCI). Standard operating of Institutional Ethics Committee (cited22nd October 2018). Available from:http://www/ferci.orp/sop/
- 2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research Available from: http://www.iemr.nie.in guidelines IC MR-1 thical-





Effective Date: 01/06/2020

SOP CODE: SOP 05/V02

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Title: Procedures for allowing Guest /Observer to visit IEC - SVMCH

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure adequate protection of confidentiality of information related to research studies, when the Guest / Observer visits the IEC office or observe the IEC meeting.

2. Scope

This SOP describe procedures to be followed by the Institutional Ethics Committee (IEC) in allowing the Guest / Observer to visit the IEC office or observe the IEC meeting.

3. Responsibility

- It is the responsibility of the Member Secretary in consultation with the Chairman to decide on allowing the Guest / Observer to visit the IEC office or observe the IEC meeting.
- Guests / Observers should read, understand, accept and sign the confidentiality agreement form prior to visiting / observing IEC meeting.

4. Detailed instructions

4. 1 Receiving request from guest/observer to visit or attend IEC meeting

- On receiving a written or verbal request from a guest regarding visiting the EC office or to observe an EC meeting, the EC member/Member Secretary/Secretarial will obtain permission from Chairman
- The date and time of the visit to EC or for EC meeting will be informed to the guest/observe preferable in writing/email.
- The request letter/email will be filEd in EC records by the secretatriat.

4.2 Filling up of Confidentiality Agreement Form

- Confidentiality Agreement Form (AX 01/SOP 05/V2) will be provided to the guest attendee/observer on the day of visit/at the time of meeting,
- The guest/observer will read the form carefully before visit visit/or before commencement of the
- He/she will fill up the details in the form.

4.3 Ask question, if any

If there are any doubts, the guest/observer will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and/or

Prepared by Reviewed by		
	Approved by	Accepted by
Signature with date IEC member IEC Member Secretary	Signature with date IEC Chairman	Signature with date DEAN (R&F65)





A CALL

- 3. Detailed Instructions:
 - The Research Proposal should be submitted electronically in ICMR Common Forms for Ethics Review (http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx) with supporting documents (Informed Consent, Brief CV of PI/ Co PIs, Questionnaire/ Case report form, Approval/ Comments of scientific committee, CTRI/CDSCO/HMSC/MTA/MoU/ insurance coverage) as applicable.
 - Once received, the secretariat will verify protocol for completeness (if not ask PI) and number.
 - Member Secretary to categorise research into full review, expedited review or exemption from review.
 - Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.
 - The project for full review will be included in agenda of virtual full-committee meeting to be scheduled at the earliest (48 hrs) by the Member Secretary in consultation with the Chairperson.
 - The members will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.
 - Quorum requirements for review will be applicable as per Section 4.8.4 ICMR National Ethical Guidelines, 2017.
 Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics
- Annexures:

AX01/SOP19/01: Application form for Initial review (electronic format)

5. References ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants

Prepared by Rev	iewed by		
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Pristing the states	nber Secretary	IEC Chairman	C2-Signature with date DEAN
Plat gill		Prs. M	AHADEVAN, MD., DCH., MNAMS., PhD
• . · 9 a · · · · · · · · · · ·			DEAN Research & PG Studies)
		P	rofessor (SS) Pediatri -e



Effective Date. 02/07/2020 /

SOP CODE:

SOP 19/V01

Title: SOP for Review of Biomedical and Health Research during COVID-19 Pandemic

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

2. Procedures & Responsibilities:

SN	Procedure	Responsibility
1.19		
8.	Submit research proposal (electronically)	and the first state of the second state of the
b.		Researchers
0.	Receive, record, verify completeness and allot reference no.	Secretariat/ Member Secretary
C.	Categorize depending on risk (Exempt/ Expedited, Full committee), identify need for review by experts/ independent consultants/ patient /others, designate reviewers	Member Secretary in consultation with Chairperson
d.	Perform Initial review of documents as described in Table 4.3 of ICMR National Ethical Guidelines, fill study evaluation form	Primary/ secondary Reviewers
e.	Schedule virtual Meeting, Prepare Agenda, invite members (Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson).	Secretariat / Member Secretary
f.	Open the meeting, determine quorum (Section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries Agenda	Chairperson
g.	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (optional) %
h.	Present observations on item reviewed	Primary/ secondary Reviewers
i.	Discuss further on the item and reach consensus	EC members
j.	Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda	Secretariat / Member Secretary
k.	Record minutes of meeting, ratify approved decisions of exemption/expedited review before closing meeting	Member Secretary/ Chairperson
	Post meeting activities	
_	Communication of decision and maintaining records.	Secretariat/ Member Secretary
1.	B	been blan hat intentioer beeretary

Prepared by	Reviewed by	Approved by	Accepted by
Signature onth date 2/3/ IEC member	Signature with date ² 17/2020 IEC Member Secretary	- Signature with date IEC Chairman	2/am - 13
n an an Anna an Anna an Anna an Anna Anna Anna		1 DRS.	MAHADEVAN, ND., OCH., MNAMS., Ph DEAN (Research & PG Studies) Professor (SS) Perdiatric



SRI VENKATESHWARAA MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE Ariyur, Puducherry. Ph.0413-2644435, 2644482



CONSENT FORM II

Informed Consent Form

Participant's name:

Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant:	Date:
Signature of the witness:	Date:
Signature of the investigator:	Date:

(Note: Consent form II should be appropriately worded for adults and children (less than 18 years)

eg if the participant is less than 18 years of age, instead of 'my participation', 'my child's/ward's participation' needs to be replaced.)



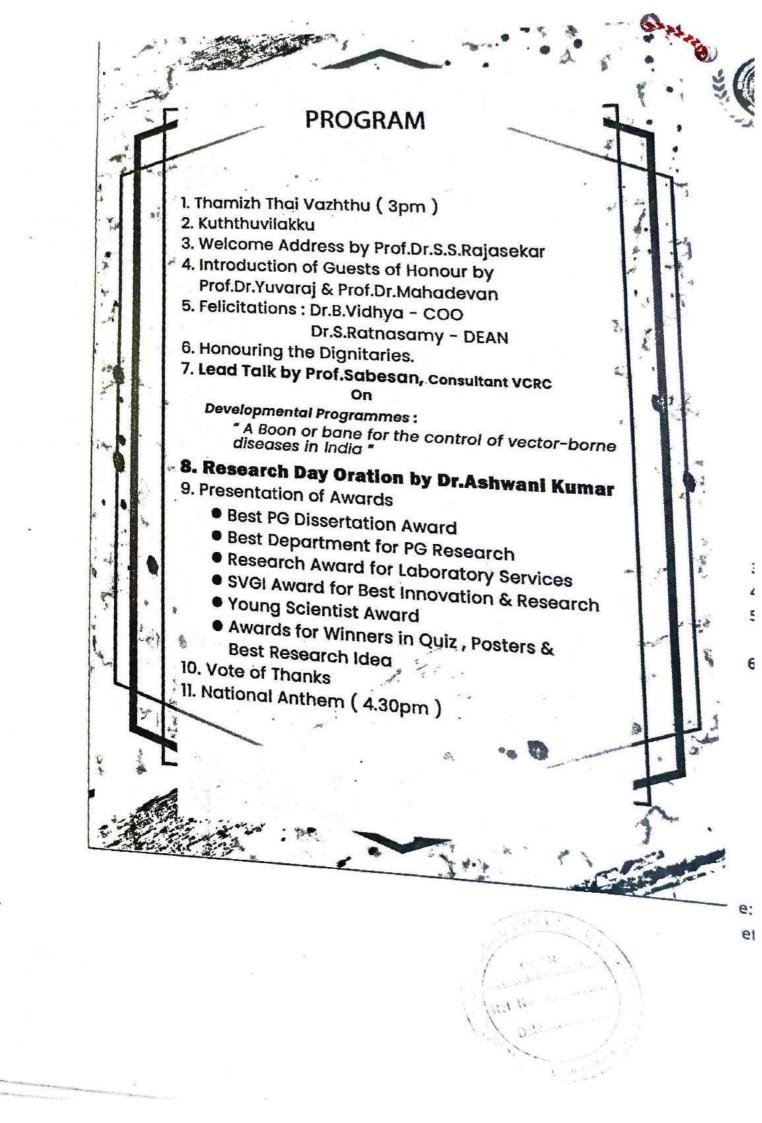
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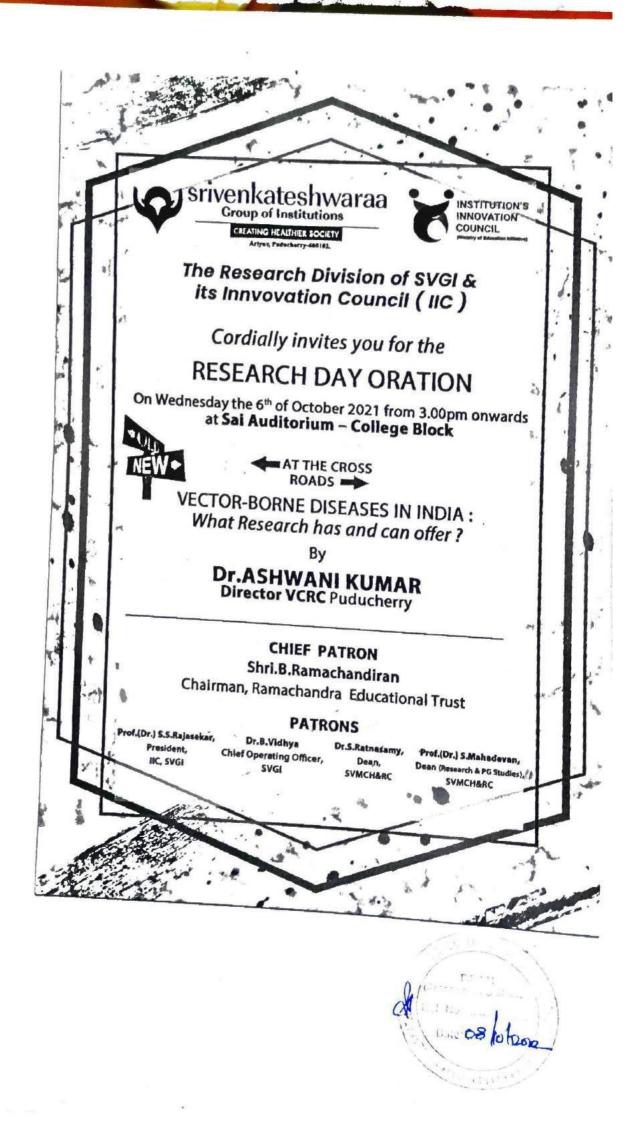
INSTITUITIONAL ETHICS COMMITTEE (HUMAN STUDIES)

INSTRUCTIONS FOR SUBMISSION OF RESEARCH PROPOSALS FOR IEC CLEARANCE

- 1. Read the Handbook on National Ethical guidelines for biomedical & Health Research, ICMR 2018
- 2. Submit the research proposal along with the following documents in the same order
 - a. Covering letter
 - b. Title page
 - c. SRC approval certificate copy
 - d. Research proposal with case proforma / Questionnaire
 - e. IEC protocol submission form
 - f. Undertaking by the Investigator
 - g. Consent forms in English and Tamil
 - i. Participant information Sheet
 - ii. Informed Consent Form
- 3. Signatures with date and seal has to be obtained wherever necessary
- 4. Research proposal with Case proforma / Questionnaire to be attached
- IEC protocol submission must be duly filled. Select the risk category of your study by referring to risk category document (ICMR Ethical guidelines, 2017)
- 6. Participant Information Sheet (PIS) and Informed consent form
 - a. Should be addressed to the participants of the study
 - **b.** Depending upon the nature of the individual project, the details provided to the participant may vary
 - c. PIS must be prepared for patient / test group and controlseparately, if applicable
 - d. Should be written in simple layman language
 - e. Tamil translation should be appropriate (Do not use Google translate)
 - f. Obtain back translation certificate

Note: The soft copy of formats of the above documents can be obtained from the Member Secretary, IEC.







* Required

1. Name of the Post-graduate *

2. Year of joining *

3. Department *

4. 1. What is the current status of work on your dissertation *

5. 2. Difficulties faced in your dissertation work. *

 3. How many journal/ seminar presentations presented so far? who was the moderator *



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	2.	Year *
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	3.	Department *
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		2. Which component of PG interaction/ training in your department may require some fine- tuning? *
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Research	h Gatekeeping Sheet (RGKS)								
S.No	Name of the Research	her UG/ PG/ Facu	Name of Princip Ity Investigator	pai Name of the Guide (if an		Date of Approv	al Date of Approv by IEC	al Title of the Project Duration	Current status of the study
- A).	1 Dr. D R. Vedapriya	Faculty	Dr. D R. Vedapri Prof & HOD, Comm. Med	уа -	Dr. N. Bhuvaneswari Asst. Prof, Comm. Mec Dr. K. Nirupama 3rd yr PG, Comm. Med	and the second second	07.12.2021	Prevalence of COVID 19 among Diabetic patients in Puducherry- A Community based cross sectional study	Data collection
Ĵ.	2 Dr. S. Vijayalakshmi	Faculty	Dr. S. Vijayalakst Assoc. Prof Comm. Med	im. -	Dr. R. Surendar Asso. Prof Comm. Med Dr. D R. Vedapriya Prof & HOD Comm. Med	26.06.2021	07.12.2021	Challenges in implementing re	wise Data collection
	3 Dr. Marie Gilbert Majella	Faculty	Dr. Marie Gilbert M Asst. Prof Comm. Med	Λε -	Dr. D.R. Vedapriya Prof & HOD Comm. Med Dr. N. Bhuvaneswari Assr. Prof Comm. Med	11.11.2021	To be applied	Mapping of Tobacco Retailer in the neighbourhood of Education	
	4 Ms. Janani S	Faculty	Ms. Janani S Tutor cum Statistic Comm. Med	ù .	Dr. R. Surendar Asso. Prof Comm. Med		19.11.2020	Effectiveness of online learning its satisfaction level among sture of a medical college in Puduche	syn
	5 Ms. Janani S	Faculty	Ms. Janani S Tutor cum Statistici Comm. Med	•	Dr. C. Ananda Vayaravel Principal, SVCPMS	05.04.2020	29.08.2020	Effect of webinar process during C 01 year	Sent for Publication
	6 Dr. K. Nirupama	PG	Dr. K. Nirupama 3rd Yr PG, Comm. I	Prof & HOD, Comm. Med	Dr. R. Surendar Asso, Prof Comm. Med in Dr. K. Karthick Anand Asso, Prof Dept. of Orthopedics			A Study on preve of a medical colle 6 months	
	7 Dr. J. Thamizhmathi	100000	2nd yr PG	Dr. D R. Vedapri Prof & HOD, Comm. Med	Dr. Marie Gilbert Majella Asst. Prof Comm. Med	07.12.2021 0		Prevalence and c among elderly in of Puducherry- A 06 months	
	8 Dr. J. Thamizhmathi	10-0211		Prof & HOD,	Dr. E. Suganya Asst. Prof Comm. Med	21.08.2021 av		A cross sectional phone addiction : with sleep quality medical students 6 months	
_	9 Ms. Divya K		is. Divya K A	sso. Prof	Dr. S. Vijayalakshmi Asso. Prof Comm. Med			Awareness of Po group in the Urba area of Puduchei 6 months	

Received

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RGKS - Template

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1 20	1	ekeeping Sheet (RGKS)	LICIDALE	Name of Principal	Name of the	Name of the	Date of Approval	Date of Approval	Title of the Project	Duration	Current sta of the stud
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	Clinical										
	Medicine	Surgery	Anesthesiology	Pediatrics	Ophthalmology	Orthopedics	ENT				
	Psychiatry	DVL	OBG	Pulmonary Medicine	Radio-diagnosis	Physiotheraphy					
	Non-Clinical	O's shawlates	Dhusialogy	Pathology	Pharmacology	Forensic Medicine	Community Medicine				
	Anatomy	Biochemistry	Physiology	Pathology	Pharmacology	Porensic wedicine	Community Medicine				

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