Sri MANAKULA VINAYAGAR Nursing College

SOP Code: SOP 09/V1	Preparation of Standard Operating Procedures for Sri Manakula Vinayagar Nursing College Ethics Committee (SMVNC-EC)	Effective Date: 11.10.2023

Title: Preparation of Standard Operating Procedures (SOP) to be followed by the committee for Vulnerable Population

1. Purpose

The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of the SMVNC-EC. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with ICMR guidelines (Indian regulations) and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPS to be followed by the committee for Vulnerable Population of the SMVNC-EC

Title: Checklist: Requirements for Research Involving Pregnancy

Name of Principal Investigator:

Study Title:

For the principal investigator		**IEC Office**
RISK DETERMINATION	**BENEFIT ASSESSMENT**	**IEC ACTION**
Minimal	Direct benefit	Approvable
	No direct benefit	
Greater than minimal risk	Potential benefit to pregnancy	Approvable

Greater than minimal risk	No direct benefit, offer knowledge about pregnant woman condition/disorder	Approvable on case-by-case basis**

Minimal risk means that the probability and magnitude of harmer discomfort anticipated in the research or not greater than those ordinarily encounter in daily life or occurring during the performance of routine physical or psychological examinations or tests.

**Consent of both parents may be needed as applicable.

Annexure 1: AX 01/SOP 09/V1

When Research involves Pregnant Women

Sl. No.	Requirements	Yes	No	NA
1.	Where scientifically appropriate preclinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risk to pregnant women?			
2.	Is the risk to the pregnant women not greater than minimal, or any risk which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman?			
3.	Any risk that is the least possible for achieving the objectives of the research			
4.	Is the woman's consent or the consent of her legally authorized representative obtained in			

	accordance with the informed consent provisions, unless altered or waived?			
5.	Is the woman legally accepted for examination?			
6.	Is there any risk to the pregnant woman by giving intervention or during procedures?			
7.	Does the pregnant woman give the acceptance the information given by nursing personnel?			
8.	Is the woman's consent or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the pregnant woman?			
9.	Will any incentive, monetary or otherwise, be offered to terminate a pregnancy?			
10.	Does the pregnant woman have the rights to withdrawal at any stage during the study?			
11.	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?			
12.	Do individuals engaged in the research have a part in determining the high risk pregnancy?			

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Annexure 2: AX 02/SOP 09/V1

When Research involves Children and Neonate

Name of Principal Investigator:

Study Title:

For the principal investigator		**IEC Office**
Risk Determination	**Benefit Assessment**	**IEC Action**
Minimal	Direct benefit	Approvable
	No direct benefit	
Greater than minimal risk	Potential benefit to child	Approvable
Greater than minimal risk	No direct benefit, offer knowledge about child's condition/disorder	Approvable on case-by-case basis**

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research or not greater than those ordinarily encounter in daily life or occurring during the performance of routine physical or psychological examinations or tests.

**Consent of both parents may be needed as applicable.

Sl. No.	**Requirements**	**Yes**	**No**	**NA**
1.	Does the research pose greater than minimal risk to children?			
2.	If yes: Are convincing scientific and ethical justifications given?			
3.	If yes: Are adequate safeguards in place to minimize these risks?			
4.	Does the adequate measures to safeguard the dignity rights, safety and well-being of the children			

5.	Does the research assess the additional safety measures and examine the risk minimization strategies			
6.	Is the intervention risk to children?			
7.	Does the study involve healthy children?			
8.	a) If yes: Is the inclusion of healthy children justified?			
9.	Are the studies conducted on animals and adults appropriate and justified?			
10.	Will older children be enrolled before younger ones?			
11.	Is permission of both parents necessary?			
12.	a) If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
13.	b) If Yes: Are the conditions acceptable?			
14.	Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
15.	Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
16.	Are their parents and guardians involved in decision making including consent and withdrawal of consent			
17.	Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
18.	Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			

19.	Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?			
20.	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
21.	Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis)			
22.	If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
23.	Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

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Annexure 3: AX 03/SOP 09/V1

When Research involves Adults

SL. No	Requirements	Yes	No	NA
1.	• Explain rules and regulations to patient's attendants and get signed as per the protocol. • Adult patient above 18 years - Take consent of the patient only. • Take consent for every invasive procedure. • Informed consent regarding various treatment procedures should be obtained from the patient/party by the treating physician.			
2.	Dignity and privacy of patients to be maintained at a highest level.			
3.	Determine and communicate whether patient is ambulatory or will require a stretcher transport.			
4.	The Nurse must perform the initial assessment. This to be further assessed by the doctor.			
5.	Explain to the patient the reason for his/her involvement in the study.			
6.	• All important information regarding patients to be written on the information board and updated on time. • Documentation and record to be maintained properly and strictly.			
7.	Facilitate the protection of patient's rights in relation to confidentiality, privacy, beliefs, values, and wishes.			

8.	Adhere to the Principles of Aseptic Technique and infection control and waste management guideline.			
9.	If the patient condition is serious, like in ET intubated, Cardiac arrest, profound shock, eclampsia etc., high risk consent must be taken.			
10.	Format Clearly. As well as being careful with language, process documentation should always use intuitive formatting.			
11.	SOPs describe each critical and sequential step of a task to ensure its expected result.			
12.	Patient Care Record (PCR) to be maintained which include patient vital medical parameters and details of drugs and disposables consumed.			
13.	Fill the medical and consumable details consumed for particular patient.			

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Annexure 4: AX 04/SOP 09/V1

When Research involves Elderly People

Sl. No.	Requirements	Yes	No	NA
1.	Is the recruitment of participants justified considering the rationale and objectives of the study.			
2.	The risk is justified by the anticipated benefits to the participants.			
3.	The relation of anticipated benefits to the risk is at least as favourable to the participants as that presented by available alternative approaches.			
4.	The proposed plan for the assessment of the capacity to consent is adequate.			
5.	Consent will be taken from participants/care givers capable of being consulted.			
6.	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted.			
7.	Have the risk to subjects been minimized?			
8.	Have subjects been assured that participation is voluntary .			
9.	Have the subject been assured that confidentiality will be protected and maintained.			
10.	The Subject has the full freedom to quit the study at any point.			
11.	At any point the subject of the study is affected, he/she will be compensated with money/continuation of treatment.			

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Annexure 5: AX 05/SOP 09/V1

When Research involves Physically/ Emotionally Disabled

SL. No.	Requirements	Yes	No	NA
1.	Build rapport, greet participant with warm introduction to feel free to explore the data			
2.	The informed consent need to receive before partipate in the study to the participants.			
3.	The assent of the child should be obtained those who are minor (below 6 yrs to 18 yrs)			
4.	The parent or guardian of participants has given proxy consent (those who minor)			
5.	Research should be conducted in nearer setting where the participants & family members can easily reach and accessible.			
6.	Use simple words and short sentences during sharing information as well as convey one point at a time.			
7.	Often presented as a “yes or no” based questions only.			
8.	The IEC policy should be under protection of human subjects requires.			
9.	The additional safequards have been included in this study to protect the rights and welfare of the subjects.			
10.	Researchers should strongly consider a participatory approach when conducting disability research, whereby appropriate engagement with prospective participants			

	and relevant stakeholders.			
11.	Researchers should ensure that people are equally eligible to participate, regardless of their disability or any other aspect of their identity.			
12.	Researchers should ensure that they disseminate their research findings in a way which reaches the group they are engaging with			
13.	The study participants can withdraw from the study at any point of time.			
14.	The researcher can review the disability certificate from the participants.			
15.	If any harm occurs the participants will receive a compensation from the researcher in the form of money settlement or treatment based.			

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Annexure 6: AX 06/SOP 09/V1

When Research involves Students, Employees or Residents

Subjects who are students, employees or residents require special considerations.

Investigator: **IEC Ref:**

Study Title: ……

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Sl. No.	Requirements	Yes	No	NA
1.	Does the employer or supervisor of the research subject need to be aware of the research project?			
2.	Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?			
3.	Have the risks to subjects been minimized?			
4.	Have subjects been assured that participation is voluntary (no signs of coercion)?			
5.	Have subjects been assured that confidentiality will be protected or maintained?			
6.	Does the subject if need withdraw from the study?			
7.	Have the subjects have any compensation if there is risk in this study?			

References

1. Forum for Ethics Review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http://www.ferci.org/sops/
2. Ethical Guidelines for biomedical Research on Human Participants (2017). India Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

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