Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

RESEARCH PROPOSAL

1.	**Name of the Principal Investigator** Designation: Email ID: Contact no:	
2.	**Name of Co- Investigator/s** Designation: Email ID: Contact no:	
3.	**Department/s Involved**	
4.	**Title of the Topic**:	
5.	**BRIEF RESUME OF THE INTENDED WORK** **Introduction and Background:** **Review of Literature:**	

	Objectives of the study:
6.	**MATERIALS AND METHODS**: Study Design: Sample Size: Study Duration: Inclusion criteria: Exclusion criteria: Sampling method: Method of collection of data: Statistical method used: Study procedure:

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

7.	**Does the study require any investigation or interventions to be conducted on patients or other humans or animals? If so, please describe briefly.**	
8.	**Ethical considerations:**	
9.	**Funding sources (if any):**	
10.	**Conflict of interest (if any):**	
11.	**Plans for publication:**	
12.	**List of references:**	
13.	**Participant information sheet & Informed consent document attached: YES/NO**	
14.	**Signature of the Principal Investigator**	
15.	**Signature/s of Co-Investigator/s**	

16.	**Signature of Head of the Department**	
17.	**Signature of the Principal**	

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

Annexure 1

Informed consent form

1. Study Title:

2. Study Number:

3. Participant's Name:

4. Date of birth/ Age:

5. Address of the participant:

7. Qualification:

8. Occupation:

9. Annual Income:

10. Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

Place Initial box (Subject) [ ]
(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) 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 my medical care or legal rights being affected. [ ].

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) 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 purposes [ ]

(v) I agree to take part in the above study. [ ]

Note: Three copies should be made, one each for 1. Patient 2. Researcher/ PI 3. IEC

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

Signature (or Thumb impression) of the Subject/ Legally acceptable representative:

Date: _____

Signatory's Name: _____

Signature of the Investigator: _____ Date: _____

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: _____

Name of the Witness: _____

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

1.ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ:

2. ಅಧ್ಯಯನ ಸಂಖ್ಯೆ:

3. ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

4. ಹುಟ್ಟಿದ ದಿನಾಂಕ/ ವಯಸ್ಸು:

5. ಭಾಗವಹಿಸುವವರ ವಿಳಾಸ:

6. ವಿದ್ಯಾರ್ಹತೆ

7. ಉದ್ಯೋಗ:

8. ವಾರ್ಷಿಕ ಆದಾಯ:

9. ನಾಮನಿರ್ದೇಶಿತ ಸದಸ್ಯನ ಹೆಸರು, ವಿಳಾಸ ಮತ್ತು ಭಾಗವಹಿಸುವವರೊಂದಿಗಿನ ಸಂಬಂಧ (ಪರಿಹಾರದ ಉದ್ದೇಶಕ್ಕಾಗಿ)
ಭಾಗವಹಿಸುವವರ ಕ್ರಮ ಸಂಖ್ಯೆ [ ]

(i) ಮೇಲಿನ ಅಧ್ಯಯನಕ್ಕಾಗಿ ನಾನು _____ ದಿನಾಂಕದ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಹಾಗೂ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶವನ್ನು ಹೊಂದಿದ್ದೇನೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ. [ ]

(ii) ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ [ ] ಮತ್ತು ಯಾವುದೇ ಕಾರಣವನ್ನು ನೀಡದೆ, ನನ್ನ ವೈದ್ಯಕೀಯ ಆರೈಕೆ ಅಥವಾ ಕಾನೂನು ಹಕ್ಕುಗಳಿಗೆ ಧಕ್ಕೆಯಾಗದಂತೆ ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂಪಡೆಯಲು ಮುಕ್ತನಾಗಿದ್ದೇನೆ. [ ].

(iii) ಕ್ಲಿನಿಕಲ್ ಪ್ರಯೋಗದ ಪ್ರಾಯೋಜಕರು, ಪ್ರಾಯೋಜಕರ ಪರವಾಗಿ ಕೆಲಸ ಮಾಡುವ ಇತರರು, ನೈತಿಕ ಸಮಿತಿ ಮತ್ತು ನಿಯಂತ್ರಕ ಅಧಿಕಾರಿಗಳು ಪ್ರಸ್ತುತ ಅಧ್ಯಯನ ಮತ್ತು ಯಾವುದೇ ಹೆಚ್ಚಿನ ಸಂಶೋಧನೆಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ನನ್ನ ಆರೋಗ್ಯ ದಾಖಲೆಗಳನ್ನು ನೋಡಲು ನನ್ನ ಅನುಮತಿಯ ಅಗತ್ಯವಿಲ್ಲ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ. ನಾನು ವಿಚಾರಣೆಯಿಂದ ಹಿಂದೆ ಸರಿದರೂ ಅದಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಪ್ರಯೋಗವನ್ನು ಮುಂದುವರಿಸಬಹುದು. ಆದಾಗ್ಯೂ, ಮೂರನೇ ವ್ಯಕ್ತಿಗಳಿಗೆ ಬಿಡುಗಡೆ ಮಾಡಲಾದ ಅಥವಾ ಪ್ರಕಟಿಸಿದ ಯಾವುದೇ ಮಾಹಿತಿಯಲ್ಲಿ ನನ್ನ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ ಎಂದು ನಾನು ತಿಳಿದುಕೊಂಡಿದ್ದೇನೆ. [ ]

(iv) ಈ ಅಧ್ಯಯನದಿಂದ ಉಂಟಾಗುವ ಯಾವುದೇ ಫಲಿತಾಂಶಗಳ ಬಳಕೆಯನ್ನು ನಿರ್ಬಂಧಿಸದಿರಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ ಹಾಗೂ ಅಂತಹ ಬಳಕೆಯನ್ನು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಗಳಿಗಾಗಿ ಮಾತ್ರ ಬಳಸಲಾಗುವುದೆಂದು ನನಗೆ ತಿಳಿದಿದೆ. [ ]

(v) ಮೇಲಿನ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ. [ ]

ವಿಷಯ/ಕಾನೂನುಬದ್ಧವಾಗಿ ಸ್ವೀಕಾರಾರ್ಹ ಪ್ರತಿನಿಧಿಯ ಸಹಿ (ಅಥವಾ ಹೆಬ್ಬೆರಳು ಗುರುತು):

ದಿನಾಂಕ: _____

ಸಹಿ ಮಾಡಿದವರ ಹೆಸರು: _____

ತನಿಖಾಧಿಕಾರಿಯ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಅಧ್ಯಯನದ ತನಿಖಾಧಿಕಾರಿಯ ಹೆಸರು: _____

ಸಾಕ್ಷಿಯ ಸಹಿ: _____ ದಿನಾಂಕ: _____

ಸಾಕ್ಷಿಯ ಹೆಸರು: _____

ಗಮನಿಸಿ:– ಒಂದು ಪ್ರತಿ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುತ್ತಿರುವವರಿಗೆ ಮತ್ತೊಂದು ಸಂಶೋಧಕರಿಗೆ ಹಾಗು ಇನ್ನೊಂದು ಇನ್‌ಸ್ಟಿಟ್ಯೂಷನಲ್ ಎಥಿಕ್ಸ್ ಕಮಿಟಿ (IEC)ಗೆ ಕೊಡತಕ್ಕದ್ದು

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

Annexure 2

Participant Information Sheet

The project must be submitted along with Participant Information Sheet (PIS) addressed to the patient or participant or parent/ legal guardian, in case of minor. The PIS must be in a simple layman's (vernacular) language which is easily understandable.

The PIS must include the following details;

1. Title of the study:

2. Aims and methods of the research study:

3. Statement that the study involves research and explanation of the purpose of the research: In simple language.

4. Expected duration of the participation of subject.

5. Description of the procedures to be followed, including all invasive procedures.

6. Description of any reasonably foreseeable risks or discomforts to the subject.

7. Description of any benefits to the participant or others reasonably expected from research. If no benefit is expected participants should be made aware of this.

8. Disclosure of specific appropriate alternative procedures or therapies available to the participant.

9. Statement describing the extent to which confidentiality of records identifying the participant will be maintained and who will have access to participant's medical records.

10. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).

11. Statement describing the financial compensation and the medical management as under: (a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. (b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or center, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

12. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.

13. The anticipated prorated payment, if any, to the participant for participating in the trial.

14. Responsibilities of subject on participation in the trial.

15. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

16. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

17. Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

18. Amount of blood/ biological sample (quantity in ml/ mg) to be taken

19. In case of a drug trial: a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned b. Initial bioequivalence study of the drug/ references should be provided

20. Self-certification should be given that the translation to vernacular language is correct.

21. Any other pertinent information.

Additional elements, which may be required:

(a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

(b) Additional costs to the participant that may result from participation in the study.

(c) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

(d) Statement that the Participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation will be provided.

(e) A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of participants enrolled in the study. Date Signature of Principal investigator.

Date : Signature of Principal Investigator

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

Guidelines to fill the Research Proposal format

Introduction and Background (Upto 250 words)

- Rationale for conducting the research in the light of current knowledge.
- Statement of need/problem that is the basis of the project.
- Cause of this problem
- Possible solutions.

The purpose of an introduction is to provide the rationale behind the work, so that the reader may understand and appreciate your objectives. Please describe the importance (significance) of the study. Provide a rationale and describe the reasoning that led you to select the study design and objectives. Very briefly describe the experimental design and how it accomplished the stated objectives. Try to provide appropriate references wherever necessary. Present background information and analyse the research work done in the particular topic and identify the gaps in knowledge for which you would like to seek an answer.

Review of literature (Upto 500 words)

- Most important studies to least
- Earliest to recent studies
- Known and unknown aspects of the study topic
- Should help in generating research question

The literature review is a critical look at the existing research that is significant to the work that you are carrying out. You must do a thorough literature search on the topic of your research in order to understand the current status of knowledge on the particular subject which is published in National as well as international journals. You may carry out a PUBMED or MEDLINE search complemented by taking out the full research papers from the library and carefully reading them in order to obtain the most recent and relevant information. When you have taken out the original articles from the Internet/ Library, you need to summarize relevant research, by first evaluating the particular work, show the relationships between different works, and show how it relates to your work. In other words, you cannot simply give a concise description of other people's work! So analyze and take only the relevant information and present that in your report.

Please Note:

- When you do a literature search remember to keep all references as you would need to put in the References when you prepare your report.

- Do not provide the well-known textbook information with textbook references (unless essential), rather give the latest status of research on the topic by quoting recent research papers/ articles on the subject published in journals.

Objectives (Upto 50 words):

The action(s) you will take in order to achieve the aim. Objectives are formed from the research question stated. You may write primary and secondary objectives if needed.

Primary: Based on the main focus of the research proposal

Secondary: Other aspects of the research proposal which needs to be answered.

The objectives should be, Specific, Relevant Measurable, Time bound, Achievable.

Materials and Methods (Upto 500 words):

Methodology may be reported under separate sub-headings or incorporated together.

- Study design: Prospective/ Retrospective, Cross sectional/ Longitudinal, Observational/ Experimental
- Sample Size
- Study Duration
- Inclusion criteria
- Exclusion criteria
- Sampling method
- Method of collection of data
- Statistical method used: Details of data entry and data analysis, Statistical software used, Statistical tests planned

Study procedure:

Report the methodology and procedure employed. Describe the methodology completely, including recruitment of study subjects, informed consent process, methods of data collection, types of data collected from subjects, examinations

performed, biological samples collected, processing of samples, lab analysis (if any). Provide information on interventions if any in detail. Attach format of any questionnaires or data collection forms if used, and also a blank format of Informed consent form (ICF) and Case report form (CRF) in English and mother tongue.

Ethical considerations (Upto 80 words):

- Any ethical issues in the study
- Ethical guidelines followed for conduct of the study
- Informed consent planned or not
- How frequently the progress of the study will be reported
- What is the action plan in case of premature termination of the study

Funding:

Any funding agencies or sponsors involved in study

Conflict of interest:

Any conflicts which may affect the ethical conduct of the study to be declared

Plans for publication:

Mention plan of publication in International Journals/ National Journals / CMEs/ Conferences / Paper or Poster presentation.

Publications to be preferably sent to NMC indexed journals as amended from time to time.

References:

Referencing (also called citing or documenting) your sources mean systematically showing what information or ideas you are quoting in your text and where they come from by indicating their source. Give references in your text whenever you state any information from any other source than your own work. All these references should be as per standard **Vancouver format**. Minimum of 6 references needed.

Siddaganga Medical College and Research Institute
Dr. Sree Sree Shivakumara Swamiji Road, Tumakuru – 572 102
Institutional Research Committee
Email:irc@smcri.edu.in

Participant information sheet:

English and Mother tongue

Relevant details of the study

Details of data needed/ Physical examination performed/ Investigations done/ Blood or tissue sample/ Radiological investigations/ Interventions applied (New drug / others)

Expected harm/ benefits

Emergency contact persons

Note : The duly filled form should be emailed to irc@smcri.edu.in. Further information contact Dr. Rashmi M V Professor & HOD, Dept of Pathology, SMCRI, Tumakuru, Ph: 0816-2602200

For ethical clearance contact Dr. Priyadarshini Bai G, Professor & HOD, Dept of Pharmacology, SMCRI, Tumakuru, Ph : 0816-2602200