- *Ensure that the title is clear & concise and conveys what and who is being studied.*
- *The tile can be in the form of a declarative, informative or an interrogative statement.*
- *Avoid abbreviations. (Delete after entering the title)*

THIS IS THE TITLE OF YOUR DISSERTATION PROTOCOL TO BE SUBMITTED FOR SCIENTIFIC AND ETHICAL REVIEW (THREE LINES MAX)

DR. YOUR NAME IN FULL – CLICK TO REPLACE

REG. NO: SB09153 | MONTH/YR OF ADMISSION | MONTH/YR OF EXAMINATION

COURSE OF STUDY (E.G.: MD., PEDIATRICS), MGMCRI

CANDIDATE

- Candidate Name : YOUR NAME IN FULL
- Course of Study : MD/MS - SPECIALITY
- University Identity No : 1234567890
- Mobile Phone No : +911234567890
- E-mail Address : Email@domain.com
- Month/Yr of Admission : AUGUST 2015
- Month/Yr of Examination : APRIL 2018

GUIDES

- GUIDE: DR. GUIDE'S FULL NAME
    - Professor / Associate Professor / Assistant Professor
    - Department of Specialty
    - Contact Number
    - Email
- CO GUIDE: DR. CO-GUIDE'S FULL NAME
    - Professor / Associate Professor / Assistant Professor
    - Department of Specialty
    - Contact Number
    - Email
- CO GUIDE: DR. CO-GUIDE'S FULL NAME
    - Professor / Associate Professor / Assistant Professor
    - Department of Specialty
    - Contact Number
    - Email

Check list for submission to Ethics committee

S.No	Element	Page number in which written
1.	Scientific background and explanation of rationale	
2.	Specific objectives or hypotheses	
3.	Study Population	
4.	How sample size was determined	
5.	Description of study design	
6.	Eligibility criteria for participants / volunteers	
7.	Settings and locations where the data will be collected	
8.	The interventions for each group with sufficient details to allow replication, including how and when they will actually be administered	
For Randomised trial		
9.	Method that will be used to generate the random allocation sequence	
10.	Type of randomization; details of any restriction (such as blocking and block size)	
11.	Mechanism that will be used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
For blinded trials		
12.	Who will generate the random allocation sequence, who will enrol the participants, and who will assign participants to interventions	
13.	If done, who will be blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
For Analytical / Observational Studies (STROBE Guidelines)		
14.	*a) Cohort study*—The eligibility criteria, and the sources and methods of selection of participants. *b)* Methods of follow-up	
15.	*Case-control study*— a) The eligibility criteria, and the sources and methods of case ascertainment and control selection.	

	b) The rationale for the choice of cases and controls	
16.	*Cross-sectional study—* *a)* The eligibility criteria, and the sources and methods of selection of participants	
17.	*Cohort study—* *a)* For matched studies, matching criteria and number of exposed and unexposed	
18.	*Case-control study—* *a)* For matched studies, matching criteria and the number of controls per case	
For Qualitative Studies (McMaster University)		
19.	A theoretical perspective is identified	
20.	The process of purposeful selection is described	
21.	Is sampling done until redundancy in data is reached?	
22.	Is Procedural rigor used in data collection strategies?	
23.	Is there evidence of the four components of trustworthiness? Credibility, Transferability, Dependability, Confirmability	
Outcomes		
24.	Completely defined primary and secondary outcome measures, including how and when they will be assessed	
Statistical methods		
25.	Statistical methods that will be used to compare groups for primary and secondary outcomes	
26.	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Consort flow chart		
27	Consort flow chart	
28.	Ethical issues	
29.	Consent form	
30.	Patient information sheet in Tamil	

Signature of the PG Signature of Guide

PART II – THE PROTOCOL

1 INTRODUCTION

- *Introduces the reader to the general area / topic that is going to be studied.*
- *Conveys the current state of knowledge in the study area, identifying possible scientific lacunae (gaps in knowledge) through a brief review of existing studies.*
- *The section ends with justifying why this research study is needed and leads to the next section of Aims and Objectives.*
- *(Delete after entering the introduction)*

2 AIMS AND OBJECTIVES

- *"Aim" is a broad statement of what the research aims to find out or achieve.*
- *"Objectives" are clear-cut statements that state what and how we are planning to do*
- *(Delete after entering the Aims and Objectives)*

1. Aim
2. Objectives:
    a.

3 REVIEW OF LITERATURE

- *Is comprehensive and up to date; Shows a command of the literature*
- *Contextualizes the problem; Gives an overview of the selected literature in chronological order*
- *Includes a discussion that is selective, synthetic, analytical, and thematic*

- *Avoids cut and paste of a series of articles; Has paraphrased the articles coherently*

4 RESEARCH QUESTION OR HYPOTHESIS

- *"Hypothesis" is a statement, the truthfulness of which we intend to test by the study*
- *"Research Question" is what we are trying to answer by conducting the research study*

(Enter either a Research question or a Hypothesis. Delete irrelevant portion)

5 SUBJECTS AND METHODS

- *Describes the study population – for whom the findings of the study would apply and the study subjects – on whom the study is actually conducted*
- *Describes the duration and time period of the proposed study*

Study design in detail which should include the following:

- *Describes in detail the type of study – qualitative, descriptive, analytical, Interventional*
- *Describes the method of sample size calculation appropriate to the study design (not just a formula)*
- *Describes the sampling method by which the study subjects would be selected*
- *Describes the eligibility or inclusion and exclusion criteria*
- *Describes clearly the study groups, the method of allocation to the groups, binding procedure if the study is a blinded trial, study variables and if blinded, the rescue in case of adverse event*
- *Describes clearly the methods of data collection*
- *Describes the study tools (questionnaire, proforma, tests, procedures) and parameters*
- *Describes the methods of data collection in detail*

(After entering the Methodology, use the above checklist to make sure all elements are covered and then delete this section in Red)

5.1 USES A FLOW-CHART TO SUMMARIZE THE SEQUENCE OF EVENTS

5.1.1 PROCUREMENT OF INVESTIGATIONAL DRUGS, STORAGE, DISPENSING, ETC.

Click to replace with Text

5.2 STUDY TERMINATION

Click to specify study termination

6 STUDY VARIABLES

- *Lists the "Operational Definitions" of the variables being studied for clarity and interoperability*
- *Describe the method of data collection (Data will be collected using predefined data capture form / schedule / questionnaire.)*
- *Describes the data type, listing out the dependant and independent variables*
- *Mentions the appropriate statistical tests that would be used*
- *Mentions the statistical software that would be used*
- *Mentions methods for data safety and confidentiality*

S. No	Name of the dependent / independent variables	Scale of measurement (Quantitative / qualitative)	Descriptive / Inferential Statistics to be used

7 REFERENCES

- *References quoted in the introduction and review of literature should find a place here*

- *Follows Vancouver style of citing references*

8 PRELIMINARY WORK DONE ALREADY

Fill if appropriate, any work already done in regard to the Dissertation such as preparation of Questionnaire, collection of patient details, etc.

9 ETHICAL ISSUES

- *Describes in detail the ethical issues expected when carrying out the study*
- *Describes the process of getting informed consent / ascent*
    - *Attach the informed consent / ascent form*

Attach the patient information sheet in local language

10 INFORMED CONSENT PROCEDURE

Please click to give detailed procedure involved for obtaining informed consent from the participant or guardian & assent from the children

11 QUALITY CONTROL

Please give Quality Control and Assurance Procedures if applicable

Name of Officer designated by the department for quality control:

Name here (Head of the Department or other Professor in case if the HOD is the Chief Investigator or Guide)

Designation:

Telephone No:

E-mail:

12 SPONSORSHIPS

a. Sponsors for the study, if any (with address, contact number and email)

b. Outside funding, if any

13 INVESTIGATORS DECLARATION

This is to certify that the protocol entitled "**FULL TITLE OF YOUR DISSERTATION PROTOCOL**" was reviewed by us for submission to the SBV Institutional Ethics Committee and certified that this protocol represents an accurate and complete description of the proposed research. We have read the ICMR guidelines, ICP-GCP guidelines/CPCSEA guidelines/and other applicable guidelines and undertake to ensure that the rights and welfare of the study subjects are protected.

The study will be performed as per the approved protocol only. If any deviation is warranted, the same will be presented to the ethical committee and permission will be sought. We assure that the study will be terminated immediately in case of any unforeseen adverse consequences and we will inform the same to the ethical committee immediately.

Dr. PRIMARY GUIDE
Professor and Head of
Department of Speciality
Guide ..... DD/MM/YYYY

Dr. CO GUIDE ONE
Associate Professor of Speciality
Co-guide ..... DD/MM/YYYY

Dr. YOUR NAME
Department of
CANDIDATE/PI ..... DD/MM/YYYY

Dr. Head of Department
Head of Department of Speciality
with Dept. Seal ..... DD/MM/YYYY

Appendix 1 List of Ethical issues to be considered. This is only for guidance. Detail the ethical issue in section 9 in protocol.

Delete this section before submission

Does the Study Involve:

1. Young Subjects under the age of 18 (see Note).
2. Young Subjects studing in a School or Institutional Setting
3. Collection of Blood or any other Biological Sample such as Saliva, Semen, Biopsy, Placenta, etc.
4. Storage of Biological Samples, bodily fluids, tissues, cells, etc
5. Pregnant or Lactating Women
6. Patients of Geriatric Age Group
7. Patients in the ICU or highly dependent on medical care
8. Patients in Unconscious State/Coma/Low Glasgow Scale or otherwise unable to understand Verbal Instructions and/or give consent
9. Ionising Radiation (X-Rays, CT Scans, Radioisotopes, etc)
10. Procedures involving Reproductivity / Infertility / Contraception (ART, IUD, etc)
11. Approved Drugs being investigated for additional or newer indications
12. Approved Drugs with non-standard Doses, Routes of Administration, Duration of treatment?
13. Innovative Therapy or Intervention or Novel Procedure in the therapy or management of patients in a clinical setting?

14. Any form of physically invasive procedure such as blood collection, endoscopy, exercise regimens or physical examination, and which is not part of clinical management?
15. Physical pain, beyond mild discomfort
16. Personal questions, such as regarding intimacy/sexual relationships/promiscuousness, domestic violence, potentially embarrassing habits, etc
17. Direct Interviewing in a home or public setting with other people around.
18. Questions related to suicidal tendencies, thoughts, etc
19. Questions regarding Alcoholism, Drug Abuse, etc that the subject would otherwise wish to keep confidential.
20. Retrospective study of Pathological/other Samples that might reveal new information or modify/nullify previous information.
21. Information about deceased persons
22. Covert observation or recording
23. Data that was not collected explicitly/implicitly for research purpose (e.g. from other Databases
24. Human Genetic Material (Spermatozoa/Ova)
25. Human Stem Cells, Biologics (IG cells, cancer cell lines, etc)
26. Repetitive visits to the Hospital/interviews solely for the purpose of the Study
27. Any perceived, possible or actual conflicts of interest.
28. Use of Students of SBV University/Any person associated in any way with SBV University as participants.

29. Use of any participants with which the researcher has a relationship such as teacher-student, family members, etc.
30. Restricted or Specific populations in terms of religion, caste, socio-economic groups, professions, etc.

If you have answered YES to any one or more of the above questions, Explain the issue in words for ethics committee to consider in section 8.

Other Ethical Issues: If the Study is foreseen to have any other ethical issue than the above mentioned, please include it here

Note: In India, 'majority' is achieved at an age of 18 years and considered a legal age for giving a valid consent for treatment as per Indian Majority Act, Guardian and Wards Act, and Indian Contract Act. A child below 12 years (minor) cannot give consent, and parents/guardian can consent for their medical/surgical procedures. A child between 12-18 years can give consent only for medical examination but not for any procedure.

If you have any subject below the age of 18 or unable to give fully informed independent consent, give details below: