* *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.YOURNAMEINFULL–CLICKTOREPLACE

**R EG . N O : S B 0 9 1 5 3 | M O N T H /Y R O F A D M I S S I O N | M O N T H /Y R O F**

**E X A M I N A T I O N**

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

**Version: (the revised version protocol number)**

**Protocol No:**

**GENERAL INFORMATION**

|  |
| --- |
| CANDIDATE |
| * Candidate Name : YOUR NAME INFULL * Course of Study : MD/MS -SPECIALITY * University Identity No : 1234567890   ◼Mobile/Phone No : +911234567890   * E-mail Address : [Email@domain.com](mailto:Email@domain.com) * Month/Yr of Admission : AUGUST 2015 * Month/Yr of Examination: APRIL2018 |
| GUIDES |
| * GUIDE: DR. GUIDE’S FULLNAME   + Professor / Associate Professor / Assistant Professor   + Department of Specialty   + Contact Number   + Email * CO GUIDE: DR. CO-GUIDE’S FULLNAME   + Professor / Associate Professor / Assistant Professor   + Department of Specialty   + Contact Number   + Email * CO GUIDE: DR. CO-GUIDE’S FULLNAME   + Professor / Associate Professor / Assistant Professor   + Department of Specialty   + Contact Number   + Email |

* State whether it is Intradepartmental or Interdepartmental

If the study is interdepartmental

1. State the name of collaborating departments
2. State whether consent has been obtained from them

#### Check list for submission to Ethics committee

|  |  |  |  |
| --- | --- | --- | --- |
| **S. No** | **Items** | **Yes/No** | **Page No** |
| 1 | Exact title as approved by Preliminary Review Committee (PGRC/IRC/etc..) |  |  |
| 2 | Date of Preliminary Review Committee approval mentioned in proper format (dd/mm/yyyy) |  |  |
| 2 | Source of funding mentioned |  |  |
| 3 | Adequate literature review with justification for the study mentioned |  |  |
| 4 | Detailed description about methodology (Study design, number of groups, sample size etc) |  |  |
| 5 | No mirror statement in Inclusion/Exclusion criteria  (Ex: Age <18 in inclusion & Age>18 in exclusion) |  |  |
| **6. For Randomized Trial:** | | | |
| a. | Method that will be used to generate the random allocation sequence |  |  |
| b. | Type of randomization; details of any restriction (such as blocking and block size) |  |  |
| c. | Mechanism that will be used to implement the random allocation sequence (such as sequentially numbered containers0, describing any steps taken to conceal the sequence until interventions were assigned |  |  |
| **7. For Analytical/Observational Studies (STROBE Guidelines)** | | | |
| 1. C | * Cohort study – the eligibility criteria, sources and methods of selection of participants * Methods of follow-up |  |  |
|  | * Case-Control Study – eligibility criteria, sources and methods of case ascertainment and control selection * The rationale for the choice of cases and controls |  |  |
|  | * Cross-sectional study – eligibility criteria, sources and methods of selection of participants |  |  |
|  | * Cohort study – for matched studies, matching criteria and number of exposed and unexposed |  |  |
|  | * Case-control study – for matched studies, matching criteria and number of controls per case |  |  |
| 8. | Outcomes – completely defined primary and secondary outcome measures, including how and when they will be assessed |  |  |
| **9.Statistical methods** | | | |
|  | Statistical methods that will be used to compare groups for primary and secondary outcomes |  |  |
|  | Methods for additional analyses, such as subgroup analyses and adjusted analyses. |  |  |
| 10. Ethical issues explained in detail with **level of risk as per ICMR 2017** | |  |  |
| 11. Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date | |  |  |
| 12. Confidentiality mentioned as per IHEC MGMCRI guidelines in consent form part 1 | |  |  |
| **13. Information to the participant/ parent/guardian** in layman (simple) language. | |  |  |
| 14. Informed Consent Document **in both English and Tamil** attached as per IHEC, MGMCRI SOP format | |  |  |
| * Separate assent form for subjects >12yrs< 18 yrs attached **(if applicable)** * Separate consent form for cases and controls attached **(if applicable)** * **No discrepancy** between Tamil and English consent form | |  |  |
|  |  |
|  |  |
| 15. Validated questionnaire both in Tamil and English attached | |  |  |
| 16. Adequate justification for exemption from obtaining informed consent given **(if applicable).** | |  |  |
| 17a | Permission from DCGI (**if applicable)**. |  |  |
| 17b | DCGI approval for the mentioned indication in the study (for drugs, devices, cosmetics etc) |  |  |
| 18a | Declaration form from principal investigators / Guide stating that all procedures used in the study are standard and professionally acceptable (for faculty projects / for all UG/PG/PhD/DM, MCh) |  |  |
| 18b | Declaration form from Guide (for all UG/PG/PhD/DM, MCh projects) regarding overall responsibility for the research |  |  |

Signature of the PG Signature of Guide

PART II – THE PROTOCOL

# 1 INTRODUCTION

* *Introduces the reader to the general area/to pic 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.*
* *Expected Outcome and application*
* *(Delete after entering the introduction)*

# 2 AIMS ANDOBJECTIVES

* + *“Aim” is a broad statement of what their search 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: ***(Primary & Secondary)***

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

# 4 RESEARCH QUESTION ORHYPOTHESIS

* *“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*
  + *Randomization details (for interventional studies)- intervention details with standardization techniques (drugs /devices/ invasive procedures/ noninvasive procedures/ others)*
  + *Describes the eligibility or inclusion and exclusion criteria*
  + *Withdraw criteria, if any (Trial-related therapy, follow-up and documentation are terminated prematurely as it is indicated to ensure safety of the participants)*
  + *Rescue criteria. If applicable*
  + *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 incase of adverse event*
  + *Describes clearly the study procedures*
  + *Describes clearly methods of data collection in details*
  + *Describes the study tools(questionnaire, proforma, tests, procedures) and parameters*
  + *Registration with CTRI in case of Clinical Trial, if applicable*

*(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 OFEVENTS**

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

Click to replace with Text

## 5.2 STUDYTERMINATION

Click to specify study termination

# 6 STUDYVARIABLES

* *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 dependent and independent variables*
* *Outcome variables*
* *Confounding and interacting 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 DONEALREADY

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*
* *Categories the level of Risk according to the ICMR 2017 Guidelines with justification*
* *Risk vs. Benefit assessment details*
* *If Vulnerability group of Participant are involved in the study then justifications need to be given. (Kindly refer to the ICMR 2017 guidelines: Section 6, for further details.)*
* *Describes the process of getting informed consent/ascent*

O *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 *(Available in SBV Protocol Proforma Version 2 updated folder)*

# 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

1. Sponsors for the study, if any (with address, contact number and email)
2. Outside funding, if any

**For student project, the guide should give a signed statement on a separate sheet with details of the project proposal that “I take full responsibility and accountability for planning, executing and adverse events occurring during the study. The data collected and records received will be retained for a period of three years”**

***(Reference: application folder form number 04 on website)***

# 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 2017 guidelines, ICP-GCP 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 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

Appendix1 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 studying 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. Ionizing 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 section8.

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 as per the new IHEC protocol template.