# Appendix -1A



# [FORMAT OF MAJOR/MINOR RESEARCH PROJECT]

A
SYNOPSIS OF
MAJOR/MINOR PROJECT
ON
TOPIC OF RESEARCH PROJECT

NAME OF PRINCIPAL INVESTIGATOR	NAME OF CO-INVESTIGATOR
DESINGNATION	DESIGNATION
SIGNATURE-	SIGNATURE
NAME OF INSTITUTION	NAME OF INSTITUTION

# **CONTENT OF SYNOPSIS**

CHAPTER	PARTICULAR	PAGE NUMBER

T	The title of the research project should be brief but informative; it should neither be too short nor
to	oo long. A good title will clue the reader into the topic but it cannot tell the whole story. Any name
0	of the institution, the number of cases to be studied should not be included. The hypothesis to be
S	tudied can be included.

#### **CHAPTER-1**

#### 1.1 INTRODUCTION /ORIGIN OF PROPOSAL

Follow the title with a strong introduction. The introduction provides a brief overview that tells a fairly well informed (but perhaps non-specialist) reader what the proposal is about. It might be as short as a single page, but it should be very clearly written. [It includes brief introductory information related to the study which develops conceptual frame work of the researcher]

This may include the highlight of the problem/issue to be resolve. This can be followed by socioeconomical status of the health problem, national /international health scenario or the severity to address the problem.

Setting the outline area is a start but researcher needs to get specific about what his/her research will address. What is his proposal about?

Why this work is important? What are the implications of doing it? How does it link to other knowledge? How does it stand to inform policy making? What will we learn from your work? This should show how this project is significant to our knowledge. Why is it important to our understanding of the world? It should establish why I would want to read on. It should also tell me why I would want to support, or fund, the project.

#### **CHAPTER-2**

#### 2.1 RATIONALE/HYPOTHESIS

Rationale includes the basis upon which project strategy stands. It correlates the existing literature with the proposed plan of study, on scientific ground.

[Hypothesis is mentioned as a tentative prediction or explanation of the relationship between two or more variables. Hypothesis should not be a haphazard guess but should reflect the knowledge, imagination, and experience of the investigator. Hypothesis can be formulated by understanding the problem, reviewing the literature on it, and considering other factors. A researcher can state the problem and the hypothesis in about 200 words covering all the aspects.]

#### **CHAPTER-3**

#### 3.1 AIMS AND OBJECTIVES

[MENTION ALL OBJECTIVES OF THE STUDY]

[All research projects should have objectives and aims and every effort should be made to achieve them. The objectives and aims should be only a few (2-3). They must pertain to the study problem. Usages of terms like "first study", "the only study", etc. should be avoided.]

#### Note:

- Aim is a broad term which precisely combine overall objective of the project within one sentence
- Objectives are the stepping stone through which researcher is going to achieve the aim; Objectives may be 3-4 in numbers and cover entire theme of the project

#### **CHAPTER -4**

#### **4.1 REVIEW OF LITERATURE**

[This chapter includes review of the work carried out by the other researchers in the similar area or related area]

- Minimum 15-20 relevant literature reviews should be given.
- Latest articles related to plan of study should be included as reference, as much as possible.

#### **CHAPTER -5**

#### **5.1 RESEARCH METHODOLOGY**

[Methodology in clinical research may varied from non-clinical proposals]

This chapter includes—

- a. STUDYDESIGN
- b. STUDYSETTINGS
- c. SAMPLING
- d. VARIABLES
- e. CONTROLS
- f. STUDY METHODS EXAMINATIONSORINVESTIGATIONS
- g. DATACOLLECTION
- h. DATAANALYSIS
- i. ETHICAL CLEARANCE

#### FOREXAMPLE-

#### a. STUDY DESIGN

The methodology starts with selection of study design. A single study design or a combination can be selected e.g.:

## > Descriptive designs

Cross-sectional study or survey

Epidemiological description of disease occurrence Community diagnosis Study of Natural history of a disease

#### Observational analytical designs

Prospective study

Retrospective study Follow-up study

### > Experimental designs

Animal studies

Therapeutic clinical trials - drugs Prophylactic clinical trials- vaccines Field trials Operational designs

#### **b.** STUDY SETTINGS

A mention about the research setting should be made. This includes information about the facilities available, time of study, and population of study.

#### c. SAMPLING

Sampling is selecting a sample of appropriate size for the study. The sample size depends on the study design. The study population can be population of cases, population of people, or population of recipients of certain treatment.

There are many methods for sampling like simple random, systemic and stratified sampling, cluster sampling, etc. Care should be taken to ensure that the sample size is adequate to produce meaningful results. The sample size should be adequate to apply all relevant tests of statistical significance. The samples should be representative of the population and should be reliable. This minimizes sampling errors.

#### d. VARIABLES

Variables are the factors that can change. These changes can affect the outcome of a research project. Thus, it is important to identify the variables at the planning stage.

They should be quantified with a measurable unit. Knowledge of the various

variables in a research project will assist in refining the objectives. Usually, objectives of a research will be to see the effect of independent variables on dependent variables. There are four types of variables.

#### Independent variables

These are the variables that can be manipulated by the researcher and the effects of that are observed on the other variables. For example; predisposing factors, risk factors and cause.

#### Dependent variables

The changes occur as a result of independent variables. For example; disease and outcome.

#### Intervening variables

These may influence the effect of independent variables on the dependent variables.

For example, while studying the response of HIV-AIDS to -highly active antiretroviral therapy or HAART, the outcome may be influenced by the presence of anti-tuberculardrugs.

### Background variables

These are changes that are relevant in the groups or population under study. These need to be included in the study. For example; age, sex, and ethnic origin.

#### e. CONTROLS

Control groups increase the validity of the research project. They usually consist of units of same population but differ in some respects. Controls are not necessary for all research projects.

As far as possible they should be used in all analytical studies, drug trials, and intervention programs.

### f. STUDY METHODS

Here the researcher will have to describe the method of data collection, which may be in the form of:

- 1. Questionnaire
- 2. Interviews
- 3. Medical examination
- 4. Laboratory investigations
- 5. Screening procedures

A sample of the pro-forma should be prepared and attached.

#### g. DATA ANALYSIS

Data analysis is an important part of a research project. A good analysis leads to good results. The plans for data analysis should be mentioned under the following heads Statistical methods, Computer Program used, and Data sorting method. A general statement "appropriate statistical methods will be used." Must be avoided.

#### h. ETHICAL CLEARANCE

Wherever necessary, ethical committee clearance from the institute should be obtained after the approval of the project. The certificate/letter should be submitted to the research cell before commencing the work. Ethical clearance is required in all human and animal studies.

#### **CHAPTER-6**

#### 6.1 PLAN OF WORK

It include phase wise distribution of work plan (methodology) and, description of each protocol /study/scheme/process, with standard references (Details of methods)

#### **CHAPTER-7**

#### 7.1 TIMELINE

[Divide the proposed time period of the project in smaller sections of 5-6 and place the tentative work plan as per progress of the project]

[Provide information about estimated timetable (if possible in table form), indicating the sequence of research phases and the time that researcher will probably need for each phase. Take into account that at this stage, it can only be estimated, but make clear that researcher have an idea about the time span that will be needed for each step.]

### Example: (A project of three year duration)

Months	Work Plan		
1-3	Procurement of equipment, chemicals and other consumables.		
4-10	Wet Lab Experiments: Synthesis and characterization of developed product		
11-18	In-vitro Experiments: Investigating tissue		
19-26	In vivo studies using Wistar rats animal model and investigations		

27-30	Feedback protocol development and reassessment
31-36	Check overall progress of work and revised strategies if necessary. Documentation
	and paper/patent filing.
Months	Work Plan
1-3	Procurement of equipment, chemicals and other consumables.
4-10	Wet Lab Experiments: Synthesis and characterization of
11-18	In-vitro Experiments: Investigating tissue

# **CHAPTER-8**

#### **8.1 EXPECTED OUTCOMES**

[THIS INCLUDES EXPECTD RESULT OF THE STUDY]

### **CHAPTER-9**

#### 9.1 PRELIMINARY WORK DONE BY THE INVESTIGATOR

(Provide details with available references of investigators)

# **CHAPTER-10**

### 10.1 BIBLIOGRAPHY (in Vancouver style)

# **Example of references in the Vancouver style**

Eg. Kwan I, Map stone J. Visibility aids for pedestrians and cyclists: a systematic review of randomized controlled trials. Acid Anal Prev.2004;36(3):305-12.

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### NAME OF PRINCIPAL INVESTIGATOR:

(Email id and phone no.)

# NAME OF CO-INVESTIGATOR:

(Email id and phone no.)

# PERIOD OF RESEARCH PORJECT:

#### **BUDGET:**

# A. Recurring Expenditure:

Sr.	Components	Year-wise /month-wise	Total
1	Salary for Personnel (Research assistant,		
	Research associate, staff, etc.)		
2	Chemicals		
3	Glass wares		
4	Travel		
5	Stationary		
6	Cost of		
	Diagnostic test		
7	Miscellaneous (postage, printing,		
	Photocopying etc)		
Total			

# **B.** Non-recurring expenditure:

Sr.	Components	Year-wise /month-wise	Total
1	Equipments		
2	Computer (in any)		
3	Any software		
4	Any other capital		
Total			

## C. **TOTAL BUDGET**: A +B=\_

 Along with the proposal a short CV of PI and co-PIs (Max. 2-page) is required to attach.