لجنة مراجعة اخلاقيات البحث العلمي
IRB

# SUGGESTED FORMAT FOR PROTOCOL FOR MASTER AND MD THESIS (2012)

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| **TITLE** | • A title must not be too short or too long. (about 15 -20 words)<br>• It must be specific, stating:<br>-What? -Where? -Who? -When?<br>• It must not contain abbreviation |
| **SUPERVISORS** | • The first is the one from the department and the rest by seniority.<br>• Title of the supervisors and the name of their departments must be stated. |
| **INTRODUCTION (BACKGROUND)** | • Build the case for why the study was needed and why it is important<br>• Briefly state the background for your study (keep it short)<br>• Citations for other major studies on same topic<br>• Construct reference list as you go |
| **RATIONAL** | • Why this study is important?<br>• Why it is needed? What areas need further exploration?<br>• Has this study been done before? If so, is there room for improvement<br>• What is the gap in the scientific knowledge that is going to fill?<br>• Why we cannot solve the problem without this study? |
| **RESEARCH QUESTION** | • Only one or two, usually not more<br>• Research questions have to be:<br>-Concise -Narrow<br>• Its types will determine the type of study:<br>1-What is or are: Descriptive studies<br>2-What is the relationship: Descriptive, correlation, observational |

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| | 3-Why: Analytical, Experimental?<br><br>We should ask ourselves:<br>• Do I know the field and its literature well?<br>• What are the important research questions in my field?<br>• Is the timing right for this question to be answered?<br>• Is it a hot topic, or is it becoming obsolete?<br>• If you are proposing a service program, is the target community interested?<br>• Most importantly, will my study have a significant impact on the field? |
| **HYPOTHESIS** | • A hypothesis is a statement about the expected relationship between two or more variables:<br>**Independent variables → Cause or determine → Dependant variables**<br>• It is not stated for all types of studies. Not for descriptive cross section or operational research<br>• We cannot use: may, might, can and could |
| **AIM** | • The aim describes what is *expected* to arise from the study,<br>• It is not necessary reached by the end of the study.<br>• It is a wishful thinking.<br>• It will be accomplished through the specific objectives.<br>• It is almost the title |
| **OBJECTIVES** | • The **objectives** describe what will *happen*, it indicates the **variables** that will be examined and what the researcher promises that will happen.<br>• In other words, it describes what we intend to do.<br>• It uses action verbs.<br>• It usually start by a verb<br>• The objectives are the elements which together achieve the goal.<br>• It should be **SMARTER**:<br>o **S:** specific<br>o **M**: measurable<br>o **A**: attainable<br>o **R**: relevant<br>o **T**: time bound |

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| | ○ **E**: ethical<br>○ **R:** recordable<br>• Preferably it should not be more than 4 |
| **SUBJECTS AND METHODS** | It covers:<br>1-*Technical design*: setting, , subjects, type of study, sampling, inclusion and exclusion criteria<br>2-*Operational design:* process, time line, obstacles and limitations of the study.<br>3-*Administrative design*: approval from concerned authority and Institutional Review Board at faculty. |
| *<u>1-TECHNICAL DESIGN</u>:*<br><br>1-Setting<br><br>2- Population or Subjects<br><br>3-Inclusion criteria/ exclusion criteria<br><br>4-Study Design<br><br>5-Sampling | • State where the study will take place.<br>• Why this site is the most suitable?<br><br>• Who is your population? From the community, special groups, patients etc.<br><br>• Inclusion Criteria, it has to state who we are going to include as regards for example: residence, age groups, sex, some special condition, duration of disease, presence of concomitant conditions etc.<br>• Exclusion criteria will state whom we should not include usually they are the opposite of the inclusion criteria.<br><br>• The study design usually describes how you are going to carry out your study.<br>• Therefore it is very important to state your type of study before proceeding into the details of your work.<br>• Broadly speaking, a study can be either **experimental** or **non-experimental** (observational).<br>• Also, we can add a third entity which is the **operational research.**<br>**(See the Appendix A)**<br><br>• The sample size has to be calculated with stating the parameters used.<br>• The method used to draw the sample must be |

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| | stated such as: a simple random, systematic random, stratified random, cluster sample or multistage sampling.<br>**(See Appendix B)** |
| *2-Operational Design:*<br>1-Process<br><br>2-Time line<br><br>3-Obstacles/limitations of study. | • It should cover what exactly we are going to do for subjects included in the study such as:<br>o Interview<br>o Clinical Examination<br>o Investigation<br>o Manipulation such as given some medical treatment (test new drug for example), surgical operation etc<br>o Details of the manipulation must be fully described<br>o Any side effects or complications expected have to be mentioned.<br>o **Withdrawal criteria** from the study have to be mentioned and reasons for the withdrawal must be explained.<br>• Time expected to accomplish each mentioned activity<br>• Difficulties that might arise and affect the study accomplishment and how to overcome it.<br>• Limitations that can restrict the value of results of the study. |
| *3-Administrative Design:*<br><br>1-Approval from authority<br><br>2-Approval from Institutional Review Board (IRB) | • From concerned authority as MOH if the study is outside the premise of the Faculty<br>• Filling of needed documentations and submit the proposal for approval. |
| **RESULTS/DISCUSSION** | • It covers:<br>o Pilot study.<br>o Expected findings<br>o Methods for its presentation<br>o Type of statistical analysis to be used<br>o Presence of comparative findings from other studies ( from Egypt and internationally)<br>o How the results will be interpreted. |
| **CONCLUSION** | • Items to be presented in the conclusion are |

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| | expectations of what we are going to find:<br>o It must be derived from the study results<br>o Summary of expected results.<br>o It must highlight the important finding |
| **RECOMMENDATIONS** | • What we expect to be able to do from the findings of the study.<br>• It must be drawn specifically from the study results.<br>• How we can use it to improve the health of the individuals/community.<br>• What do we need to be able to implement such recommendations<br>• Who else we need to involve to implement the recommendations. |
| **REFERENCES** | • Ordered as it appears in the text. |

# APPENDIX (A)
# Study Design

The study design usually describes how you are going to carry out your study. Therefore it is very important to state your type of study before proceeding into the details of your work.
Broadly speaking, a study can be either **experimental** or **non-experimental** (observational). Also, we can add a third entity which is the **operational research.**

## 1-Experimental:

- In experimental study, the researcher takes an active role and applies certain measure or exposure to the included subjects.
- It is a type of prospective study, where we follow the subjects till the outcome occurs
- The point of starts is the presence of two groups:
  - The first one is the experimental group where the manipulation will be applied e.g. clinical trial of a new drug or new line of treatment.
  - The second group is the control group.
- **True Experimental** studies has to have three elements:
  - Randomization
  - Control group
  - Manipulation
- If the randomization is not present; it is a **quasi-experimental** study.
- If also the control group is absent; it is **uncontrolled experimental study**.

- Randomized Control Trials (RCT) is the gold standard method for obtaining evidence about the effect of a treatment/ intervention

## 2-Non-experimental (Observational):

In non-experimental studies, the investigator does not assign the exposure. In other words, he only observes and record. Non-experimental studies are of two types: Descriptive and analytical. In the descriptive there is no comparative group, while in the analytical we compare between two groups.

**A-Descriptive studies** are concerned with describing disease general characteristics.
Its Types are:
1-Case reports,
2- Case series and
3-Cross-sectional survey.
They usually answer the question **what?** They cannot test hypothesis but they are important in generating one.

**B-Analytical:**

Analytical studies try to identify causal relationship. It is formed of two comparative groups. They can answer the question **why?**
Their types are:
1-Comparative cross-sectional
2-Case-control
3-Cohort: -Prospective
-Retrospective

- **Exposure ⟶ Outcome:**
  ***Cohort*** (follow-up)

- **Exposure ⟵ Outcome:**
  ***Case-control*** (retrospective)

- **Exposure and Outcome at same time:**
  ***Cross-sectional***

## 3-Operational Research

- **Operations research**, or **Operational Research**, deals with the application of advanced analytical methods to help make better decisions.
- It can be used to identify the best solution, technique etc to deal with a specific problem.



# APPENDIX B

### Sampling

We have two main types of sampling:

1- *Non Probability Sample:*

Which does not allow to get a true presentation of the population from which it was drawn. It has two types:

- Accessible or convenient
- Quota sample.

2- *Probability Sample:*

In which every individual has an equal chance of being selected in the sample. There four main types depending on the type of study, resources etc:

- Simple random sample
- Systematic random sample
- Stratified random sample
- Cluster sample.

Sample Size has to be calculated in order not to get a false result.

- If too small, you will fail to prove a significance that is present.
- If too large :
  -Costly as regards time and money
  -Prove a significant that is not present