# Topics in the Research Protocol

### Protocol Title .....

- 1. Background and Rationale
- 2. Research Questions
- 3. Research Objectives
- 4. Research Hypothesis
- 5. Literature Review
- 6. Conceptual Research Framework
- 7. Scope of Research
- 8. Operational Definition
- 9. Research Methodology
  - 9.1 Research Design
  - 9.2 Population and Sample
  - 9.3 Sampling Method
  - 9.4 Sample Size Calculation
  - 9.5 Inclusion and Exclusion Criteria
  - 9.6 Withdrawal/ Discontinuation Criteria
  - 9.7 Termination Criteria
  - 9.8 Participants Recruitment Process
  - 9.9 Research Methods/ Research Process
  - 9.10 Research Tools and Validity/reliability
  - 9.11 Outcome Measurement
- 10. Data Collection
- 11. Data Analysis/ Statistics

#### Ethical consideration

- 1. Ethical Principles/ Belmont Report
- 2. Human Subjects Protection

## **Expecting Benefit**

## bibliography

### **Example for writing "Research Ethical Considerations"**

The researcher will follow the ethical principles for human research or the Belmont Report, consisting of 3 principles:

### 1. Respect for person

This research study has a process for requesting consent from those who are the target population of the research to participate as research volunteers. All volunteers will be fully informed about the research and will be allowed to make their own decisions. Without threats, force, or rewards. Before signing consent to participate in the research, the researcher will maintain the confidentiality of the volunteers. There will be no identifier in the data record/questionnaire/interview form to identify the volunteers.

#### 2. Beneficence

The researcher has assessed the risks or dangers that may result from research and there is an evaluation of the benefits. Which this research study volunteers will receive benefits including .......(Please specify the benefits that the sample/volunteers received from this research.)

and this research study. There may be a risk to the volunteer...... (*Please specify the risk or inconvenience that the sample/volunteers received from this research.*)

Personal information and information obtained from the inquiries of all research participants/volunteers will be kept confidential. However, the results of the study and various relative factors may be disclosed to the public for academic benefit. The names of the research participants were not specified.

#### 3. Justice

This research study has a selection of subjects with clear inclusion and exclusion criteria, without bias, and with equal distribution of benefits and risks by random sampling method. And in organizing volunteers into study groups, they were randomly assigned to study groups without bias