Mahidol University Institutional Review Board (MU-IRB) Submission form

1. Title of Project _____

2. Title of Investigator _____

Status ❑ Staff from Faculty _____

❑ Student from Faculty _____

❑ Bachelor Program ❑ Master Program ❑ Doctoral Program

❑ other, please specify _____

Contact address_____

Telephone number_____

E-mail address: _____

3. Co-investigator (– name, affiliation, address, phone number, email address)

4. Funding Source ❑ No ❑ Ongoing process

❑ Funding Source_____

Budget_____

5. Background & Rational

6. Objective of the Study

7. Research Plan

7.1 Type of Research

❑ Biomedical / Clinical Research

❑ Drug trial phase _____ Study Drug_____

❑ registered drug ❑ investigational new drug

(Please attach document)

❑ Medical device _____

❑ registered ❑ investigational device

❑ Vaccine trial phase _____ Study vaccine _____

❑ Procedural / intervention _____

❑ Pilot study

❑ other, please specify _____

❑ Social / Behavioral Research; Descriptive study, Observational study, Quasi-Experimental study, Experimental study, Pilot study, Participatory action research, other, please specify _____

❑ Epidemiological Research; Retrospective review, Surveillance, Monitoring other, please specify _____

❑ Repository (using stored materials: cells, tissue, fluid)

7.2 Subject selection and allocation

7.2.1 Inclusion criteria

7.2.2 Exclusion criteria

7.2.3 Termination criteria

7.2.4 Subject allocation

7.3 Sample size calculation

7.4 Sample size _____

❑ vulnerable subjects ❑ children ❑ mentally disable

❑ chronic illness

❑ others (please specified) _____

❑ healthy volunteers

❑ not vulnerable subjects

7.5 Replacement procedure if subject withdraw from the study

8. Study procedures

9. Study site ❑ single center _____

❑ multicenter ❑ within Thailand, please specify _____

❑ specify other countries and sites) _____

10. Having **Specimen** sending out of Mahidol University ❑ No ❑ Yes (MTA will be needed, Contact Applied and Technological Service Center, Tel. 0-2201-5746)

11. Duration of study _____

12. Data collection process (Case Record form, Questionnaire, Interview, In-depth interview, other tools)

13. Outcome measurement/Data analysis

- Primary outcome and secondary outcome (if any)
- Assessment of efficacy
- Assessment of safety
- Statistical analysis or data Analysis

14. Recruitment process

15. Informed consent process

❑ 15.1 immediately after recruitment process

❑ 15.2 when _____by whom_____

❑ 15.3 Separate documents: Participant information sheet and Informed consent form

❑ 15.4 waiver document for Informed Consent

16. Ethical Consideration

16.1 Reason to be carried out in human, please specify the extent of problem that lead to research question, previous information and its controversy

16.2 Possible benefit for research subject personally and for all society

16.3 Foreseeable risk of research related injury

16.3.1 Explain information from previous study about severity and probability of adverse events

16.3.2 Management of adverse events

16.3.3 Responsibility for research related injury

16.3.4 Contact person in case of adverse events

16.3.5 In case of clinical research, How can Principal Investigator give the information about research participation to subject's family doctor?

16.4 Reference for safety

16.5 Privacy and confidentiality protection

❑ Coded data/specimen)

❑ recorded by ❑ photograph) ❑ VDO ❑ tape recorder

❑ not recorded by previous methods

17. Submitted documents

❑ 4 copies of MU-IRB Submission form

❑ 4 copies of Protocol / Proposal

❑ 10 copies of Participant information sheet (Please attach file)

❑ 10 copies of Informed consent form (Please attach file)

❑ 4 copies of Principal Investigator's curriculum vitae

❑ 4 copies of commitment for research conduct

❑ 4 copies of Protocol synopsis (if any)

❑ 4 copies of Case record form

❑ 4 copies of Questionnaire

❑ 4 copies of Permission from authorized to use medical records (In case of retrospective medical record review)

❑ 4 copies of Permission from authorized person to use stored specimen (In case of stored specimen)

❑ 4 copies of other documents: advertisement, recruitment materials

❑ 4 copies of Advisor's curriculum vitae

❑ 4 copies of approval document from post graduate program

18. Commitments

1. I, as the principal investigator, and my co-investigators as listed and signed in this documents will conduct this study according to the protocol approved by MU-IRB. I will conduct the informed consent process by providing adequate information as approved and sufficient opportunity to consider whether or not to participate to potential subjects, with respect for person, without coercion and undue influence.
2. I will obtain pre-approval of any changes in research activity and informed research subjects about the change for their considerations to continuing their participations in the study.
3. I will report MU-IRB all serious adverse events and unanticipated events and will do my best to help research subjects.
4. I will provide reports concerning the progress of the research annually or when requested.
5. I and my co-investigator have adequate knowledge and training in procedural intervention needed in conducting research and providing care for any research-related injury to research subjects.

Signature of principal investigator_____, date_____

Signature of co-investigator_____, date_____

18. Permission from Thesis Advisor/ Direct Superior Authorized to Approve Research Projects

Signature of Thesis Advisor/ Direct Superior Authorized to Approve Research Projects _____, date_____

Research Protocol

1. Back ground and Rational for research question
2. Objectives - main objective
   - secondary objective
3. Method of Study
4. Population of Study - inclusion and exclusion criteria
   - allocation of subject into study area
   - sample size calculation
5. Interventions
6. Discontinuation criteria
   - withdrawal criteria for participant
   - termination criteria for the study
7. Outcome Measurement
8. Statistical Analysis
9. Risk and benefit expected from the study
10. Payment for research subject
11. Responsibility for research related injury in terms of
    - contact person
    - plan
    - compensation

Protocol Synopsis

1. Method of Study ❑ Prospective ❑ Retrospective

2. Population of Study ❑ vulnerable specify _____
   ❑ not vulnerable, specify _____

3. Expected number of subject _____

4. Allocation of subject ❑ random
   ❑ not random, specify _____

5. Intervention (in brief)

6. Outcome measurement
   - primary outcome _____
   - secondary outcome _____

7. Statistical analysis, specify _____