**Research Protocol**

1. (Thai Title) (If you have)

(English Title)

1. Principal Investigator
2. Co-investigator
3. Contract person
4. Background or Introduction must be cited the references, all the references must be writen in the Another page
5. Objectives
6. Method of the Study
7. Protocol flow chart
8. Number of the subject (screening study), screening must include 20% for drop out of the Subjects

**- Inclusion Criteria** must increase the sentence “ I’m appreciate to participate in this study with sign”

**- Exclusion Criteria** must include the sentence “ I can refuse or withdrawn anytime during the

study ”

1. Time : Duration of the study after received the certificated of the protocol
2. Risks of the study
3. Benefit and Side effect of the study must be include
4. Ethic consideration
5. Grant agency

- budget

1. Investigator and advisor must sign in the last page of the protocol
2. Reference
3. **Patient Information Sheet** : Must be in Thai version if the subjects are Thai

- Two physicians to take care the volunteers and please contact the telephone number (mobile)

- In the Patient Information Sheet investigators must be writen in the common sentense and easy

to understand in Thai

- And Investigator must write step by step that the volunteer must understand cleary

1. **Informed Consent Form** : Must be in Thai version if the subjects are Thai
2. Cirriculum Vitae of the principle investigator
3. Certificate of Good Clinical Practice (GCP),  Collaborative Institutional Training Initiative (CITI Program)
4. Case record form
5. Questionnaires
6. Other

**Notification**

1. Enter the page number on every page of the document. (Bottom right corner)
2. If the researcher is not the personnel in Faculty of Medicine, Ramathibodi Hospital, there must be a physician from the faculty of Medicine, Ramathibodi Hospital to be advisor or co investigators and must be signed
3. In case of a private company research. The company must be paid 10,000 baht

by cheque to " Mahidol University, Faculty of Medicine, Ramathibodi Hospital,"

1. Please send full protocol 1 original,13 copies with 1 CD to the IRB office
2. If the project is finished. Investigator must be reported to the IRB office