**Research Proposal**

**Suggestion for Research Proposal Writing**

1. ***Italic Text*** is a suggestion text / characteristic that must be followed (If you understand the suggestion text, you can delete the text from the research proposal form.)

✓

1. The Item that is a multiple choice, please put in the space that corresponds to your information.

**Research Proposal**

**1.** **Project title**

 ………………………………….…………………………………………………………………..…….................................

………………………………………………………………………………………………………………………………………………

**2. Names, Institutions and Addresses of Principal Investigator and all Co-Investigators**

**2.1. Name of Principle Investigator** ……………………….………………………………………………………….……….…...

**Position**................................................................... **Department**.................................................................................

**Hospital**.......................................................... **E-mail** ............................................... **Tel**..........................................

**Educational Degree**....................................................................................................................................................

**2.2. Name of Co-Investigator** ……………………….………………………….…………………………………..………….…...

**Position**................................................................... **Department**.................................................................................

**Hospital**.......................................................... **E-mail** ............................................... **Tel**..........................................

**Educational Degree**....................................................................................................................................................

2.3. **Name of Co-Investigator** *(see item 2.2)*

**3. Research Site**

❏ Single center, please specify ......................................................................................................................................

❏ Multiple centers

❏ Only in Thailand ……………………………...………………………………………………………………………..….

 *(Please specify every institute that takes part in the research project, number of participants/volunteers and the result of IRB consideration in each institute)*

❏ collaboration with overseas ...............................................................................................................................

*(Please specify the country and every institute in Thailand that take part in the research project, with number of participants/volunteers and the result of IRB consideration in each institute in Thailand)*

**4. Duration of Research Project**

 *(Researcher can start collecting data only after obtaining the IRB approval)*

 For the whole project……………….……Years ......................Months

 Duration of data collection .......................Years.....................Months

**5. Background and Rationale**

 *(Please explain the important content approximately 450 words in one page )*

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**6. Literature Reviews**

*(Please explain the important content; the content should comply with the research proposal if you have attached it. approximately 1,200 words in three page)*

………….……………………………………………………………………………….……………………………………….

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**7. Objectives**

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………………………………………………………………………………………………………………………………………………

**8. Conceptual Framework**

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**9. Research Category** (can choose more than one items )

❏ Experimental biomedical / Clinical research

 ❏ Drug trial phase....................... please specify drug name..................................................................................

 ❏ Registered drug *(Please attach drug registration or drug leaflet)*

 ❏ Investigational (new) drug

 ❏ Medical device trial ระบุชื่อเครื่องมือ.....................................................................................................................

 ❏ Registered device

 *(Please attach device registration or device leaflet)*

 ❏ Investigational (new) device

 ❏ Vaccine trial phase....................... please specify name/code of vaccine

...............................................................................................................................................................................

❏ Registered vaccine

 *(Please attach vaccine registration or vaccine leaflet)*

 ❏ Investigational (new) vaccine

 ❏ Experimental procedure / intervention, please specify……................................................................................

 ❏ High-risk ❏ Minimal risk

 ❏ Bioequivalence

❏ In vitro / laboratory-based study

❏ Research using repository of biological products (cells, blood, tissues, fluids, etc.)

\*Specify kind/quantity/number of products use ....................................................................................................................................................................................

❏ Observation clinical research

❏ Prospective (cohort) study

❏ Case series

 ❏ Retrospective (chart) review

 *(Attach the letter of permission to use the medical records from Head of Department/Division with the submission form)*

 ❏ Epidemiology research

 ❏ Surveillance

 ❏ Monitoring

 ❏ Others, please specify............................................................................................................

❏ Social / Behavioral research

❏ Questionnaire-based research

 ❏ Others, please specify .............................................................................................................

**10. การออกแบบการวิจัย (Research Design)**

❏ Randomized-controlled trial

❏ Quasi-experimental study (manipulation and control only, without randomization)

❏ Pre-experimental study (manipulation only, without control and randomization)

❏ Prospective cohort study

❏ Descriptive study

❏ Cross-sectional study

❏ Pilot study

❏ Others, please specify ...........................................................................................................................................

**11. Research Methodology**

**11.1 Variable**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.2 Variable Definition**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.3 Population and Sample**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.4 Sample Size Calculation**

 *(Please specify the background of sample size in each group. If the fixed formula has been used, please show the formula for calculation and indicate the variables used in the formula with references)*

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.5 Inclusion Criteria**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.6 Exclusion Criteria**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.7 Withdrawal or Termination criteria**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.8 Methods**

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.9 Data Collection Process and Research Instrument**

*Please provide case record form, and/or questionnaire, and/or interview question, and/or telephone script to obtain consideration (if any).*

**Data collection must be started after obtaining the IRB approval**

*The case record form must not indicate name, Hospital Number (HN) or any identifications that link to individual subjects,(using the code instead*

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.10 Outcome measurement / Data analysis**

 *(including statistics used in the research)*

 ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**11.11 Evidence, Data or References**

 *(writing references should be complied with the international standard)*

……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**12. Ethical Consideration**

**12.1 Describe whether there are the physical, mental, social and economy impacts especially the risk, or not**

 *(Are there any research identical to the proposed proposal and any adverse events occurred? Please explain in details the opportunity that the adverse event may occur from the information and reviewer assessment including the inconvenience and wasting time)*

❏ No

❏ Yes please specify .............................................................................................................................................

………………………………………………………………………………………………………………………………………………

**12.2 Regulation for protection and correction as well as additional safeguards to protect the participants rights and welfare prepared by the researcher if the adverse event occurs**

…………………………………………………………………………………………………………………………………..……………………………………………………………………………………………………………………………………………...……………………………………………………………………………………………………………………………………………

**13. Outline of the Study**

|  |  |
| --- | --- |
| **Outline of the Study** | ***Months*** |
| ***1*** | ***2*** | ***3*** | ***4*** | ***5*** | ***6*** | ***7*** | ***8*** | ***9*** | ***10*** | ***11*** | ***12*** |
| *1……………………………* |  |  |  |  |  |  |  |  |  |  |  |  |
| *2……………………………* |  |  |  |  |  |  |  |  |  |  |  |  |
| *3……………………………* |  |  |  |  |  |  |  |  |  |  |  |  |
| *4……………………………* |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

**14. Informed Consent Form** *(Please attach Informed Consent Form)*

**15. Participant Information Sheet** *(Please attach Participant Information Sheet)*

**16. Implementation**

…………………………………………………………………………………………………………………………………..……………………………………………………………………………………………………………………………………………...……………………………………………………………………………………………………………………………………………

**17. Research Budget**

 *(Please specify details of research budget)*

|  |  |
| --- | --- |
| **Budget Items** | **Cost** |
| *1. Employment costs*  |  |
| *2. Equipment* |  |
| *3. Travel & Meeting costs* |  |
| *4. Other costs (e.g. sub-contracting). Please specify* |  |
| *5. Miscellaneous expenses* |  |
| *6………………………………………………..* |  |
| **Total** |  |

**18. Research funding**

 ❏ No ❏ Applying for funding...................................................................................

 ❏Research fund was granted\*

❏ Government (please specify) …………………...………….……..….…….……..….……..……..………...

❏ Private (please specify) ………………………………...……………………………..………….……….....

❏ NGO (please specify) ………………………………………..………...……………….………….……….…

❏ Other (please specify) ………………………………………......….………………….……………..………

 Signature...............................................Principle Investigator

 (...............................................)

Date………/…….……/………..

Signature...............................................Co-Investigator

 (...............................................)

Date………/……….…/………..

*(Principle Investigator and all Co-Investigator must be signed and specified date in this research proposal)*

**19. Consideration of Medical Academic and Research Development Specialist**

❏ Approved

❏ Improved

 Signature ………………………………………Medical Academic and Research Development Specialist

(......................................................)

 Date………………………………....

**20. Consideration of Research and Medical Innovation Development Director**

❏ Approved

❏ Improved

 Signature ……………………………..………... Research and Medical Innovation Development Director

 (......................................................)

 Date……………………………….....

**21. Consideration of Center of Private Research and Innovation Accelerator Executive Director**

❏ Approved

❏ Improved

 Signature ………………………………………...Center of Private Research and Innovation Accelerator Executive Director

 (......................................................)

 Date…………………………………...