**REC-MURA.07**

**Non-experimental Study Protocol Template for Ramathibodi EC submission**

(All information can be written in **Thai** or **English**. *Descriptions in red* must be deleted before submission)
***หมายเหตุ****: ห้ามตัดหัวข้อออก คงไว้ตามแบบฟอร์ม หากไม่มีข้อมูลที่เกี่ยวข้อง ให้ระบุว่า” ไม่มี” (ตัดเฉพาะคำอธิบายสีแดงออก) และสามารถระบุรายละเอียดเป็นภาษาไทยได้*

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| **Study Title (English):**  |
| **Study Title (Thai):**  |
| **Principal investigator:***<please include name, affiliation and contact data,* *signed and dated CV is required in separate documents>* |
| **Co-investigator(s):** *<please include name, affiliation and contact data, signed and dated CVs of all co-investigators are required in separate documents>**<Please remark who is the advisor for student/resident research project>* |
| **Sponsor or planned sponsor, grant, scholarship <if applicable>:*** *Detail all sources and types of financial, material, and other support.*
* *Name and contact information for the trial sponsor or intended funding sources.*
* *please note that Mahidol University do not allow using of healthcare insurance or beneficiary for research purpose. If the investigator believes that all study procedures in the study are within reimbursable standard of care, please enclose letter of confirmation from the head of the department. >*
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| **Conflict of Interest:****<** describe any potential issue that the outcome of the research may lead to a investigators’ personal advantage, and that might compromise the integrity of the research. * + Do investigator or their immediate family or someone with whom they are in a close personal relationship is working for pharmaceutical company that sponsor the clinical trial?
	+ Do investigators receive honorarium from pharmaceutical company that sponsor this clinical trial and how much?
	+ In case of receiving educational non-restrictive grant, letter of intent from sponsor is needed.>
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| **Study sites:** *<please include all study site(s) e.g., Phaya Thai, CNMI campus, Siriraj>* |
| **Background and Significance:** **<** *This section is based on your research question. How would you answer the questions and give explanations to your answer? What are the assumptions and relationships?Justification of your conducting this study based on existing knowledge and your research question.* *- Describe the disease including incidence**- Description of the Study factor/intervention- Provide summary of previous studies. Details should be enough to show that thorough literature reviews have been done and investigator has adequate expertise in that research question.- Each reference from the literature should be cited in the text using superscript or blanket/parentheses arabic numerals. A list of references should be put at the end of the protocol. - In the last paragraph, please state the main purpose/rational of the study summarizing all the information provided in your background section >* |
| **Objectives:** **Primary Objective:** **<** *The primary objective is the main question to be answered by the results of the study, which determines study design and sample size.* ***>*****Secondary Objectives (if any):**< *Secondary objectives are additional questions to be addressed, if possible, which can be two or three can be dependent or independent of the primary objective.>* |
| **Study design/methodology:***<* *Include the description of the study type, e.g., mixed methods, qualitative study, or quantitative study, specifying prospective, retrospective, observational, survey, or questionnaire. Preferable if investigators describe it as a cohort, case-control, or cross-sectional study.Type of study and design should be decided based on the proposed primary objectives.**Provide an overview of the design of the study, including the research methods you plan to employ to meet your study objective. Describe in general terms how you will accomplish you research objectives. Describe each specific assay/test that will be performed on the biospecimens if such assay/test is not routinely used in clinical setting.**Indicate if this study will involve the use of identifiable biospecimens, data, or* ***Including of study flow diagram*** ***will be useful for reviewing. >*** |
| **Study Population, Type and Source of** **Biospecimens/Data**<In this section, include the following information* Any specific inclusion criteria (age, disease status, gender etc.)
* For case-control study, provide definition of case and control group separately.
* The source of the specimens and/or data that will be analyzed (eg. medical records, radiology images, a public or privately Database or Biorepository, other completed studies)
* If collected under a different protocol, the COA # for each protocol from which data/biospecimen was or will be collected.
* If biospecimens/data were collected for non-research purposes, describe the source eg. routine clinical investigation.
* Declare how the research team has access to these materials, eg. served as investigators on the previous protocol or seeking access from another investigator, etc.
* Whether all data/biospecimens are existing at the time of protocol submission (retrospective only) or whether data/biospecimen collection will be prospective.
* Indicate the period of time (duration) during which the biospecimens/data were originally collected (dd/mm/yyyy to dd/mm/yyyy) or if there will be prospective collection (dd/mm/yyyy to dd/mm/yyyy).
* Please note that if biospecimens or data are being prospectively collected, they would need to being collected for routine clinical purposes or under another research protocol initially to be used as part of this protocol. Otherwise, informed consent must be obtained.
* Describe the types of biospecimens and data, and format of data and/or information (paper, digital, image (specify), audio or visual recordings) which will be used for the research.
* For studies in which you intend to review medical charts or data sets, include a copy of the data abstraction sheet/cased record form reflecting all the data elements you plan to abstract from each database as an appendix.
* The data you propose to collect must be relevant to the aims & objectives of the research and the minimum necessary to accomplish it. If applicable, explain when and how identifiers will be removed from the data collected.>
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| **Study Schedule** **(for prospective cohort or registry study):** *<Provide the total length of time participants will remain in the study or will be taking drug including the follow-up period.* *Include an approximate end date of the study.**It is convenient for the reviewer to see the events of the study schedule or duration in the form of a flow chart. Include screening, enrollment, active dosing phase, follow-up visits, and final study visits.>* |
| **Data Analysis Plan / Statistical Analysis Plan:** <*Describe* * *For descriptive statistics, describe how categorical and continuous data will be presented (e.g., percentages, means with standard deviations, median, range).*
* *For inferential tests, indicate the p-value and confidence intervals for statistical significance (Type I error) and whether one or two-tailed.*
* *State whether checks of assumptions (e.g., normality) underlying statistical procedures will be performed and whether any corrective procedures will be applied (e.g., transformation or nonparametric tests).*
* *How missing data will be handled.*
* *If the study is descriptive or hypothesis generating with no planned statistical analysis, state this here and mark the following sections as n/a.*
* *If the study is qualitative, data analysis plan for qualitative study needs to be stated in detail.*

*It is recommended to consult a biostatistician for details in this section. Deviation from the protocol may be considered as data falsification.>* |
| **Sample size determination:***<The number of subjects required for the study should be justified.* * *The number of subjects should always be large enough to provide a reliable answer to questions addressed. Also, the size of detectable differences should be of clinical relevance.*
* *The number of subjects is usually determined by the primary objective of the trial. If the sample size is determined on some other basis, then this should be made clear and justified.*
* *There are many formulas to calculate the size of the study population. It should be clear which method is used and the reasons why this method has been chosen.*
* *Also, the calculation itself should be given with a predefined p-value (usually 5%) and power. The power of the study is the probability that the study will have a significant (positive) result – provided a positive effect exists. Ask advice from a statistician to help you with this matter*.>
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| **Informed Consent Process (for interview, group discussion, observe, survey, prospective cohort, or registry study):**<*Please give a description of the recruitment and informed consent procedures. How and by whom (investigator, supervising doctor, other person) will subjects be informed about the study and asked for their consent? How much time will they be given to consider their decision?* *The patient advertisement document (e.g., letter, poster) and informed consent form must be attached as a separate document.*For study in children and adolescent age 7 to 18 years, assent with languages appropriate for ages must be included.Wavier of consent or consent by action may be allowed as case-by-case basis.> |
| ***Privacy and confidentiality:****<Accroding to Thai Personal Data Protection Act, this section is mandatory.** Who will be responsible for data management?
* How will new data be collected or generated?
* What data (for example the kind, formats, and volumes), will be collected or generated?
* How will the data be organised, documented, and described, to ensure for both quality control and reproducibility.
* How will data be stored and backed up during the research?
* How will data security and protection of sensitive data be taken care of during the research?
* If personal data are collected, stored, or processed, how will compliance with legislation on personal data and on security be ensured?
* Who, which investigators and research staff, will have access to biospecimens and data?
* How will access be controlled?
* Any plans for sharing or providing access of the data.
* Outline the plan for data preservation and give information on how long the data will be retained.
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| **Ethical consideration:*** ***Risks to participants and how to minimize the risks:***

*<Identify any risks and burdens involved while conducting the study and procedure to minimize such risk/burden eg. pain from blood sampling, time wasting from interview>** ***Direct Benefits to Participants***

*<Include potential benefit to health and wellbeing of participants. Please do not overclaim. Any examination or test that will not be used for treatment decision or diagnosis will consider as no direct benefit.>* * **Scientific or social value**

*<Include potential knowledge advancement or application to the society.>**Sample text: This study does not present the prospect of direct benefit to the participants. However, the study does provide an opportunity to gain a better understanding of…** **Justification if enrolling potentially vulnerable subjects.**

*<Please specify the justification for enrolment of children and/or incapacitated adults participating in research. This should also be specified in the informed consent.*>Travel compensation and compensation for participating the study (for interview, survey, prospective cohort or registry study): <*Please describe any special incentives, compensation, or treatment that subjects will receive through participation in the study*.> |
| **Study Timeline:**<Provide timetable of the study*Sample language:**Data collection, questionnaire distribution ----6 months from January 20xx to June 20xx**Data analysis -----2 months from ….>* |
| **Budget (if applicable):***<Describe planed budget for each category eg. laboratory testing, participant compensation.>* |
| **References:***<List all the references used in the background section at the end of the protocol. Vancouver style is preferred.>* |

Signature.....................................................Principal Investigator

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

 Date......................................................

 Signature.....................................................Major Advisor (if any)

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

 Date......................................................