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| **Participant Information Sheet** |
| □ Original □ Revise No. .................................... Revise Date ............/............/............ |
| ***In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. To help your decision making in participating in the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctors.*** |

**Instructions** 1) Please specify all the details related to the research project, along with other documents

 2) Please use the general words (easy and understandable)

 3) Please erase the explanation phrase *(italicize texts)*, to make this document easier to read

 4) Please revise the created date (the footer), as the current date

**Title of Research Project:** ...................................................................................................................................................................

**Name of Researcher:** *(Principal Investigator and all Co-Investigators)* ............................................................................................

**Office and private telephone number available for contact both during and outside of office hours**

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**Research Site** ........................................................................................................................................................................................

**Duration of the Study** *(time when the research project will be conducted)* ......................................................................................

**Funding Source:** …………................................................................................................................................................................

**Details about the research project**

Rationale of the research project *(please provide a brief description) ........................................*…………

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This research project aims to *(briefly describe the research objectives in lay language, which is easily understandable, not the medical nor technical terms) ...................................................................................................................................................*

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You are invited to participate in this research project because *(indicate the important characteristics that make him/her suitable to be the research subjects)* ..................................................................................................................................................

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You may not receive the direct benefit from this research project. However, there will be certain relative advantages over the research outcomes for…………. *(please specify the positive impact and/or beneficial effect)*

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There will be (number of) ........................ participants, and the duration of research participation will be ………….... *(days/months/years).*

If you decide to participate in the research project, you will go through the following procedures. *(Give a list to make the procedures easy to read. Instances are as follows.)*

1. *Take medicines or receive a surgery or something else;*
2. *Indicate details of diagnosis or treatment such as how often will blood draws be taken, how much blood at each blood draw (indicate a measurement in teaspoon or tablespoon), how long the suspension of food and water consumption before blood draws, etc.;*
3. *If normal treatment procedures are not excluded, clearly inform which procedures are part of the research and which are part of normal treatment;*
4. *If placebos are used, this implies that the subject does not receive a treatment. The subject therefore needs to be informed that he/she may be given the placebos. Indicate the proportion of the placebos to the real medicines used in the research.*
5. *In case that any interventions are used, to illustrate how the intervention works, these intervention procedures can be clarified as images.*
6. *In case a research project is in the field of social or behavioral sciences like conducting interviews, focus group discussions, or distributing questionnaires etc., details must be given including interview topics, number of interview questions, period and number of interview sessions. Will there be audio/video recording, house visit, observations?*
7. *If the subject’s information is kept, please specify the personal data i.e. voice recording, photograph, video clip etc.*

**Risks and benefits**

Risks that may occur during research participation.................................................................and indicate preventive and treatment or supportive protocol in case those risks occurred) ......................................................................................................

*(such as drug allergies or other side effects, chance of disablement or death. Indicate the proportion of risk such as one tenth, two-thirds, etc.)*

*(In case of the social and behavioral science such as interview or survey, the risks that can happen are the uncomfortable feelings, stresses, or wasting time with answering questions. Subjects have the right to refuse answering those questions.)*

**Right to participation**

You have the right to freely participate in the research project. You can withdraw from the project at any time without prior notice. And the refusal to participate or the withdrawal from the research project will not at all affect **the proper service or treatment** that the subject will receive. *(Please specify* ***the bold statements*** *according to the details of this research project, for example 1. This participation will not affect the academic performance, in case that participant is student 2. Will not affect the job performance, in case that participant is employee 3. Will not affect the healthcare services in case that participant is patient, which means patients will receive the standard diagnostic and treatment)*

If any discomforts, physical sufferings, or any interference with mental health condition occurs during the period of research project, you have the right to timely inform the researcher. And if you have any questions related to research project, or have any illness, or have any adverse events, you can contact………...........................................................................……… phone number……......................... (available 24/7).*(If the principal investigator is the student, the name and phone number of the thesis advisor need to be provided.)*

If adverse events/unanticipated events occur, what help will be given to the subject? .....................*(Indicate process to ask for help)*

**Remuneration (if any)** ........................ (*Indicate if remuneration is given for research participation such as travel expense, compensation for time spent, medication fees, lab fees, etc. (the research participants will not have to pay these fees) verify how many time such payments will be occurred.)*

**Expense (if any)** ........................... (*Indicate if the participant is to be responsible for any expense or not.*)

If relevant information arises about benefits and risks of the research project, the researcher will inform the subject immediately and without concealment.

**Confidentiality**

Your private information will be kept confidential for the period of…………. and when this period is due, the researcher will terminate information by…………………………. (*Indicate the retention period and process of data destruction. If data is digital records, the protection of personal data must be clarified.)*

This research project is approved by the Mahidol University Central Institutional Review Board (MU-CIRB), located at the office of MU-CIRB, Office of the President, Mahidol University, Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170
Thailand, Tel 66-2-8496224-5, Fax 66-2-8496224. On the condition that you are not treated as indicated in this information sheet, you can contact the Chair of MU-CIRB or the representative as above-mentioned contact.

I thoroughly read the details in this document.

Signature…………………………………………… Participant

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

Date……………/….................../..................