Participant Information Sheet

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 the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctor.

Title of Research Project.....

Name of Researcher.....

Research Site - Office and its telephone number available for contact both in and out of the office hours

.....

Source of Fund…….....…….....

This research project aims to (Describe the objectives with language accessible to people who are not medical personnel.), which expects the following benefits: .....

You are invited to participate in this research project because (Indicate characteristics relevant to the research study such as coronary constriction, and indicate that this research is conducted to support its diagnosis or to find out an alternative treatment and why this is better than the existing method.) .....

There will be (number of) ..... participants, and the research project will last for (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.)

- Take medicines or receive a surgery or something else;
- Indicate details of diagnosis or treatment such as how many times of blood sampling , how much of each blood sample (Indicate a measurement in teaspoon or tablespoon.), how long the consumption of water and food are to be suspended before a blood sample is drawn etc.;
- If normal treatment procedures are not excluded, clearly inform which procedures are part of the research and which are part of normal treatment;
- If placebos are used, this implies that the subject does not receive a treatment. The subject therefore needs to be informed that he/she will be given the placebos. Indicate the proportion of the placebos to the real medicines used in the research;

- In case that this is a research project in the field of social or behavioral sciences conducting interviews, focus groups or something else, details must be given such as interview topics, number of interview questions, period and number of interview sessions. Will there be tape recording or a house visit?;
- Risks that may occur in the research participation (such as drug allergy or other side effects, chance of disablement or death. Indicate the proportion of risk such as one tenth.);
- In case that this is a research project in the field of social or behavioral sciences conducting interviews or distributing questionnaires, the likely risks include uneasiness or discomfort due to some questions. In that case, the participant has the right not to reply.

If you do not participate in this research project, you will receive a standard diagnosis and treatment (such as a treatment by medicine instead of surgery or other details helpful to the decision making.) .....

If adverse events/unanticipated events occur, what help will be given to the participant? .....Indicate the name of the researcher whom he/she can contact when having questions, injury or illness resulting from the research. .....

Remuneration. (Indicate whether it is given and what it is such as money for travel fees on appointment days, for medicine fees, or lab fees.) .....

Expense. (Indicate whether 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 participant immediately and without concealment.

The participant's private information will be kept confidential, it will not be subject to an individual disclosure, but will be included in the research report as part of the overall results. Individual information may be examined by groups of persons e.g. from a funding organization, a government agent in charge, the ethics committee, etc.

The participant has the right to withdraw from the project at anytime 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 he/she will receive.

On the condition that you are not treated as indicated in this information sheet, you can contact the Chair of Mahidol University Institutional Review Board (MU-IRB) at the office of MU-IRB, Research Administration Division, Office of the President, Mahidol University, Tel 66-2-8496223-5, Fax 66-2-8496223.

I thoroughly read the details in this document.

Signature…… Participant

(.....)

Date…….....

Note: If the participant is a minor (under 18 years old) and this information sheet is read by the guardian/proxy, the pronoun "you" must be replaced with "the child under your guardianship" wherever appropriate.