Instructions for Researcher

Regarding the writing of the Participant information sheet and the Informed consent form:

1. This instruction page does not have to be included when submitting the Participant information sheet and the Informed consent form

2. Researchers can adjust the structure of the Participant information sheet and the Informed consent form to suit the context of their study. Unnrelated headings can be deleted. For example, if the study incorporates only questionnaires, the heading such as the risks that might occur from blood sampling can be deleted.

3. The first version of the Participant information sheet and the Informed consent form should be labelled as Version 1.0, together with the date. For the first amendment, it should be labelled as Version 2.0, together with the date. If there is further amendment, the version needs to be renewed, together with the date for each amendment.

4. The use of medical termilinogies and technical terms should be used as least as possible. If necessary as there is no Thai substitutuion for that term, use transliteration, followed by its English term in brackets.

5. If the research procedure concerning the subjects consists of many steps and is complicated, it should be summarized in a form of a table or a diagram to facilitate the understanding, both in the research project and in the Participant information sheet.

6. If the subject is less than 20 years old and the Participant information sheet and the Informed consent form are required, the following documents must be used according to the age of the subject (as shown in the table below).

Age of the Subject	Document for Subject	Document for Legal Guardian
Less than 7 years old	A Participant information sheet (Use the document for children and read it to the subject and his/her legal guardian.)	(Signed by the legal guardian)
7 – 12 years old	A Participant information sheet and an Informed consent form (Use the documents for children and read them to the subject and his/her legal guardian, and ask for consent.)	(Signed by the legal guardian)

Age of the Subject	Document for Subject	Document for Legal Guardian
13 years old or more, but less than 18 years old	A Participant information sheet and an Informed consent form (Use the documents for legal guardian. The signature of the subject is to be asked to show his/her consent before the signature of the legal guardian is asked to show the approval)	(Signed by the legal guardian and the subject)

7. In case the subject cannot read and/or write, the information and details in the Participant information sheet needs to be explained to the subject, and for the Informed consent form, a fingerprint of the subject can be used instead of his/her signature.

8. Verbal consent of the subject can be possible with the reasons and suitable condition indicated in the research project.

9. Waiver or changes of certain procedures to obtain the subject's consent, or a waiver of documentation of consent can be done (45 CFR 46.116 and 46.117), following the guideline indicated in 21CFR 50.23 and 50.24; 21 CFR 56.109 and the practices of CIOMS. The reasons for the waiver must be indicated both in the research project and the IRB Form-04. The process indicated in 9.1 and 9.2 shall be approved by KMUTT Institutional Review Board before starting the research.

9.1 Waiver of Informed consent procedure (45 CFR 46.116) can be done when

- The risks from the study does not exceed the risks that might occur from the subject's daily activities and the waiver of Informed Consent procedure does not affect the right and well-being of the subject. This waiver can only be applicable for the project going through an exemption review, or
- The study cannot be conducted if the Informed Consent procedure has to be done.

9.2 Waiver of documentation of consent for certain subjects or for all subjects (45 CFR 46.117) can be done when

- The risks from the study does not exceed the risks that might occur from the subject's daily activities

10. The documentation of consent in the Informed consent form is the only document that can identify the subject and this documentation of consent involves the risks of putting the subject in danger their participation in the study is disclosed.

Example: Content can be adjusted to suit the research project

Participant information sheets vary according to participants' age.

Please refer to No. 6 in the Instructions for Researcher

Participant Information Sheet

This document may contain some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanation. You will receive one copy of this document. Or you may bring this document back and consult your relatives, siblings, intimates, personal doctor, or others you wish to consult to help with your decision making in participating in the research.

Title of Research Project (in English) .....
Name of Researcher (Principal Investigator or Advisor or/and Student) .....
Name of Department/ Faculty/ Tel./ Email .....
Research site address (if any) .....
Funding source.....

This research project is conducted with the aims to (briefly describe the research objectives in simple language), ...
with the expected benefits as follows:
.....

You are invited to participate in this research project because (indicate the characteristics of the subject suitable for the study) .....
There will be a total of (number of) ..... **participants**
The total duration of the research project is (months/years) .....

If you decide to participate in the research project, you will go through the following procedures (please make a list to facilitate understanding):

<u>For the field of Social Science or Anthropology, the steps can be as follows:</u>

- For interviews, focus group discussions, or others, details must be given including the interview topics, number of interview questions, interview duration, number of interview sessions, and with or without audio recording or house visit

<u>For the field of Health Science, the steps can be as follows:</u>

- Receive medicines or a surgery (or others).

- Indicate the details of diagnosis or treatment, for example, how many times blood samples must be collected, how much blood is required for each blood draw, how long the suspension of food and water consumption before doing blood sample will be.
- If normal treatment procedures are involved, clearly inform which procedures are part of the research and which ones are part of the normal treatment
- If placebos are used, which implies that the subject does not receive a treatment, the subject needs to be informed of the possible proportion of the placebos to the real medicines used in the research

Risks that may occur when participating in the study

For the field of Social Science or Anthropology, the examples can be as follows:

- For an interview or questionnaires, potential risks may include the time spent, or uneasiness, discomfort, or stress caused by some questions. In these cases, subjects have the right not to reply to the questions.

For the field of Health Science, the examples can be as follows:

- Drug allergies or other side effects, chances of disability or death can possibly occur. Indicate the proportion of risk that might occur such as one in tenth

If you do not participate in this research project, it will not in any way affect (your study in case the subject is a student, or your work in case the subject is an employee in an organization) .....

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 alternative methods to help with your decision making) .....

If any unusual symptoms or conditions, physical sickness and/or mental effect occur during the study, you will inform the researcher as soon as possible. (explain what help will be given to the subject) .....

If you have questions regarding the research procedures or experience the adverse side effects caused by participating in this study, please contact (specify the name of researcher that can be contacted) .....

Remuneration (Indicate whether remuneration is given for research participation or not such as travel expenses, medication fees, and lab fees not to be responsible for by the subject) .....

Expenses to be responsible for by the subject (indicate whether there are or not)

.....

For further information regarding both benefits and risks of the research project, the researcher will inform the subject immediately and without concealment.

The private information of the subject will be kept confidential. It will not be individually disclosed, but will be disseminated as a part of the overall results.

Individual information of the subject, however, may be examined by certain groups of people such as funding organizations, institution, government organization responsible for the examination, KMUTT Institutional Review Board.

The subject has the right to withdraw from the project at any time without prior notice. And the refusal to participate in or the withdrawal from the research project will not at all affect the proper service or treatment that the subject will receive.

This research project is approved by KMUTT Institutional Review Board, the office of which is located at

Research, Innovation and Partnerships Office, 7th floor,
the Office of the President Building
King Mongkut's University of Technology Thonburi
126 Pracha Uthit Rd., Bang Mod, Thung Khru, Bangkok, 10140
Tel. 0-2470-9623 Fax. 0-2872-9083

If you are not treated as indicated in the participant information sheet, you can contact the Chair of KMUTT Institutional Review Board or his/her representative at the above address and phone number.

I thoroughly read the details in this document and fully understood. I hereby give my consent to participate in the research project (title of the research project in English)

.....

.....

Signature ..... Participant
(.....)
Date...../...../.....

Signature ..... Legal guardian/ Authorized
(.....) representative
Date...../...../.....

Remarks: If the subject is an underage (less than 18 years old) and this Participant information sheet is intended to be read by the legal guardian/ authorized representative, the pronoun “you” should be changed to “a child in your custody” when appropriate.