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)
Informed consent forms are varied according to participants' age.
Please refer to No. 6 in the instructions for researcher

Informed Consent Form

Date .....

My name is (participant's name) .....,
aged.....years old, lives at ..... road/street.....
sub-district/tambon..... district/amphur..... province.....
postal code..... tel. .....

My name is (legal guardian/ authorized representative) .....,
aged.....years old, lives at .....
road/street..... sub-district/tambon.....
district/amphur..... province..... postal code.....
tel. .....

I hereby express my consent to participate as a subject in the research project entitled (title of research project in English) .....

In this regard, I am informed of the research project's origin and purposes; its procedure to carry out or to be carried out; its expected benefits as well as the risks that might occur to the subjects, including the preventive methods and solutions to handle the harmful consequences that might occur; remuneration, and expenses that I have to be responsible for. I thoroughly read the detailed statements in the Participant information sheet given to research subjects. I was also given explanations and my questions were answered by the head of the research project.

I am informed of the right to obtain further information regarding both the benefits and the risks of being a subject in this research project; and the right to withdraw from the project at any time and this withdrawal will not at all affect the medical services and/or treatment I may receive in the future. I give my consent to the researcher to use my personal information obtained from the study, on condition that the information is kept confidential without being individually disclosed, but disseminated as a part of the overall results of the study.

If any unusual symptoms or conditions, physical sickness and/or mental effect occur during the study, I will inform the researcher as soon as possible.

If I have questions regarding the research procedures or the adverse side effects caused by participating in this study, I can contact (name) ..... Tel. (that can be reached 24 hours) .....

On condition that I am not treated as indicated in the Participant information sheet, I can contact the Chair of KMUTT Institutional Review Board or his/her representative, whose office 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

I thoroughly read the details in the Participant information sheet and this document.

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

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

Signature ..... A person giving information and asking for consent /Principal Investigator
(.....)
Date...../...../.....

In case the subject cannot read by him/herself, the person who read all the statements in the document to the subject is (name) .....

Signature ..... The person who read the document
(.....)
Date...../...../.....