Instructions for Researchers
in Preparing an Information Sheet for Questionnaire, a Participant Information Sheet and an Informed Consent Form

1. The example of Information Sheet for Questionnaire, Participant Information Sheet, and Informed Consent Form have been prepared to meet the international standards of ethical principles in human research and conform to the Personal Data Protection Act B.E. 2562 (PDPA 2019) in order to ensure that the research is conducted accurately and in compliance with the laws based on the principles of Freedom of the Data Owner, the "Participant", and the Personal Data Controller, the "Researcher"; i.e. the participant has freedom to provide information, deny to provide information, or withdraw his/her consent (Chapter 3 of PDPA), while the researcher has to request consent from the data owner (Part 1 of PDPA) and inform of the data collection (Part 2 of PDPA).
2. The researcher is requested to use all topics in the example of Information Sheet for Questionnaire, Participant Information Sheet, and Informed Consent Form but the content of each topic can be adjusted as appropriate for his/her own research project. Items in the document with an asterisk symbol (*) are additional topics which can be deleted, should the researcher considers that they are irrelevant.
3. Do not include this instructions when submitting the Information Sheet for Questionnaire, the Participant Information Sheet and the Informed Consent Form.
4. The Participant Information Sheet and/or the Informed Consent Form shall be applied for the research involving human subjects of Expedited Review and Full Board Review projects. However, for Exemption Review project, the Information Sheet for Questionnaire or the Participant Information Sheet can be used for explaining to the participant for more clarification.
5. The first-time arrangement of the Participant Information Sheet and the Informed Consent Form must be indicated as "Version 1.0" together with the date, month and year of such arrangement. For the first amendment, "Version 2.0" must be indicated together with the date, month and year of such amendment. And if there is still further amendment, the

version, date, month and year must be changed and indicated everytime of each amendment.

6. The medical and technical terminologies should be used as least as possible. If necessary as there is no Thai terminology to substitute for any terminology, the transliteration must be used with its English terminology in the brackets indicated next to such Thai transliteration.

   In case there is any specific terminology (e.g., medical term, educational technical terms) used in the research project, please specify the definition or the meaning in the Information Sheet for Questionnaire, the Participant Information Sheet, and the Informed Consent Form.

7. In case the research procedure concerning the participant consists of many steps and is complicated, it should be summarized in the table or diagram for easy understanding, in both the research project and the Participant Information Sheet.

8. In case the participants are minors under 20 years of age (at the time of giving consent), the Participant Information Sheet and the Informed Consent Form are required. The document shown in the table below is applicable based on age of participants. The table shown below shall also be applied to the incompetent and quasi-incompetent participants. (Table shown below – Section 20 of PDPA).

Age of Participant	**Document Applied for Minors**	**Document Applied for the Parents**
Under 10 years old	It is **optional to apply** the Participant Information Sheet and the Informed Consent Form. In case of applying said document, use images or language that are age appropriate for minors to mark or sign to be participant.	It is **necessary to have the** participant's parents, or the legal representative **signed** on the Participant Information Sheet and the Informed Consent Form **to consent such minor to be participant.**
	<u>Consent Process</u>	

<table>
<tr><th>Age of Participant</th><th>Document Applied for Minors</th><th>Document Applied for the Parents</th></tr>
<tr><td></td><td colspan="2">The researcher reads the document to the minor and the parents, asks for the minor’s willingness to participate, then, asks for consent from the parents or the legal guardian.</td></tr>
<tr><td rowspan="2">10 years old, but not yet reaching 20 years of age (including the incompetent and quasi-incompetent participants)</td><td>It is necessary to apply the Participant Information Sheet for minor using images or language that are age appropriate and The Inform Consent Form for the minor to mark or sign for consent to be participant.</td><td>It is necessary to have the parents, or the legal guardian signed on the Participant Information Sheet and the Informed Consent Form to consent such minor to be participant (or request consent from the curator of the incompetent participant, or from the guardian of the quasi-incompetent participant).</td></tr>
<tr><td colspan="2"><u>Consent Process</u>
1. The researcher reads the document to the participant or let the participant read by himself/herself, then, asks for the participant’s consent to participate in the research.
2. The participant signs for consent, then, have the parents or the legal guardian signed for consent afterward or the participant and the parents sign for consent at the same time (please adjust the process as appropriate for the incompetent and quasi-incompetent participants).</td></tr>
<tr><td>17 years old, but not yet reaching 20 years of age (minors have reached the age of</td><td>It is necessary for the minor having reached the age of majority upon marriage to sign on the Participant Information Sheet and the Informed Consent Form.</td><td>No consent required from the parents or the legal guardian.</td></tr>
</table>

Age of Participant	Document Applied for Minors	Document Applied for the Parents
majority upon marriage)		

9. In case the participant is incapable of reading and/or writing, it is necessary to have a process of explaining the details in the Participant Information Sheet to the participant, and a fingerprint of the participant stamped on the Informed Consent Form can be applied in replacing his/her signature.
10. The verbal consent of the participant may be applicable provided that appropriate reasons and suitability must be indicated in the research project.
11. The research project requiring a waiver or alteration of Informed Consent Procedure for obtaining the participant's consent, or a waiver of written sign for consent may be possible (45 CFR 46.116 and 46.117) according to the set guidelines indicated in 21CFR 50.23 and 50.24; 21 CFR 56.109 and the CIOMS practices provided that the reasons for requesting for such waiver and the process indicated in 11.1 and 11.2 must be approved by KMUTT's Institutional Review Board (KMUTT-IRB) before starting collecting data from the participants.

    11.1 Waiver of Alteration of Informed Consent Procedure (45 CFR 46.116) can be done when:

    - The risks from the research project does not exceed the risks that might occur from the participant's daily activities and the waiver of Informed Consent Procedure does not affect the right and well-being of the participant. This waiver can only be applicable for the research project of an Exemption Review, or
    - The research project cannot be conducted if the Informed Consent procedure must be done.

    11.2 Waiver of Documentation of Informed Consent (45 CFR 46.117) for some or all participants can be done when:

    - The risks from the research project do not exceed the risks that might occur from the participant's daily activities, or
    - The written sign in the Participant Information Sheet and the Informed Consent Form is the only information for identifying the participant that may put the

participant at risks of danger if such participation in the research project is disclosed.

Please adjust (letter(s) in red) to be in line with the details of your research project, and delete the statement (explanation)/ example.

Informed Consent Form

Date.....

I, (participant's name and surname) ....., age .....years old, home address ....., postcode....., telephone number....., email address.....,

I, (name and surname of the participant's parents/legal guardian/curator) ....., age .....years old, home address ....., postcode....., telephone number....., email address.....,

hereby, declare my intention that I consent to be a participant of the research project title ....

I have received the Participant Information Sheet, read through and understood all the details. Also, the principal investigator (or joint researcher or representative) has already given explanation and completely answered all my queries.

I have been informed of the details of the research objectives, details of the process steps that the participant must perform, duration of the participation, benefits and risks that will occur of the participation, preventive and corrective measures, compensation to be received, and expenses that I must be responsible for (if any).

I acknowledge that I have the right to receive additional information on both benefits and harms from participating this research and be able to withdraw or cease my participation any time without any impact on my study (or work performing, service, or medical treatment) in the future. I also consent the researcher to use my personal data for the research and present the research

results as an overview only. I also acknowledge that participant information will be accessed or audited by people involving in this research and certain groups of people, such as the research funders, or auditors from the related government offices and KMUTT's Institutional Review Board (KMUTT-IRB).

Should there be any unusual symptoms, sick feeling and/or impact on my mental occurred during participating in the research, I shall promptly inform the researcher.

Should I have any queries regarding the research procedure or there be any undesirable side effects incurred from participating in the research, I shall be able to contact ..... (Please specify name of the researcher, office address, and 24-hour contact telephone number)

If I am not treated as stated in the Participant Information Sheet, I shall be able to contact the chairman of KMUTT's Institutional Review Board (KMUTT-IRB) or the representative at the office 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 Road, Bangmod Subdistrict, ThungKhru District, Bangkok 10140
Tel (+66) 2470-9623 Fax (+66)-2872-9083
Email address: irb@kmutt.ac.th

I have thoroughly read and fully understood the contents. Therefore, I give my consent to participate in the research voluntarily and willingly. As evidence hereof, I have signed two copies of this Informed Consent Form.

Sign ..... Participant

(.....)

Date.....

Sign..... Parents/Legal Guardian/Curator

(.....)

Date.....

Sign..... Information Provider and Consent Requester/Principal Investigator

(.....)

Date.....

In case the participant is incapable of reading, the person who read the entire contents to the participant is (name).....

Sign..... Reader

(.....)

Date.....

(This Informed Consent Form is made in two copies with the exact same contents. Each copy is held by the researcher and participant.)