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).

<table>
<tr><th>Age of Participant</th><th>Document Applied for Minors</th><th>Document Applied for the Parents</th></tr>
<tr><td rowspan="2">Under 10 years old</td><td>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.</td><td>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.</td></tr>
<tr><td colspan="2"><u>Consent Process</u>
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>10 years old, but not yet reaching 20 years of age (including the incompetent and</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</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</td></tr>
</table>

<table>
<tr><th>Age of Participant</th><th>Document Applied for Minors</th><th>Document Applied for the Parents</th></tr>
<tr><td rowspan="2">quasi-incompetent participants)</td><td>Form for the minor to mark or sign for consent to be participant.</td><td>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 majority upon marriage)</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>

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.

Participant Information Sheet

Research Project Title: .....

Name of Researcher (Principal Investigator/ Advisor): .....
Department of....., **Faculty of** .....
King Mongkut's University of Technology Thonburi
Telephone Number..... **Email**.....

Name of Researcher (Researcher/ student): .....
Department of....., **Faculty of** .....
King Mongkut's University of Technology Thonburi
Telephone Number ..... **Email** .....
Name of Research Funding (if any): .....
Research Location (if any): .....

Research Project Objectives (Please state the objectives in a language that the general public can understand): .....
Expected Benefits (Please state the direct benefits for the participants or the community or others, etc.): .....
You are invited to participate in this research because (please state the qualification of participants qualified for this research project): .....
Total number of participants.....
Duration of the Research Project:
The project starting in ..... (month and year). The project ending in ..... (month and year).
Duration for collecting data from participants:
Data collection starting in ..... month and year). Data collection ending in ..... month and year).

Definition* (if any) in this questionnaire, "....." means ..... (to clarify specific statements or technical terms used in this questionnaire for the same understanding and accurate information can be obtained as per the purpose of the research project).

Should you decide to participate in the research project, the process steps of the research will be as follows: (please specify step-by-step to make it easy to understand)

Example A.

This questionnaire has total of .....parts with ..... questions:

Part ..... with total of ..... questions.

Part ..... with total of ..... questions.

The total time of conducting research shall not be more than .....minutes/hours

Example B.

1. Wearing the brain wave monitoring on your head (standard device) while watching VDO is harmless.
2. Watching VDO, title ..... for..... minutes
3. Answering the questionnaire ..... (parts/questions)

The total time the participant spends for this research shall not be more than .....minutes/hours

Example C.

1. Studying a subject of ..... with total of ..... topics for..... sessions and spending ..... minutes per session.
2. Taking pre-test/post-test/activity for.....sessions and spending ..... minutes per session

(The above process steps are example. Please adjust according to your research tools and process, such as numbers of group meeting, numbers of people attending the meeting, there are sound recording during the interview, recording video, taking photos, numbers of home visit for following up, numbers and period of fasting before blood testing, quantity of blood to be tested, etc. for the research purpose only.)

The risks that may occurred when participating in the research project:

Please specify the risks that may occurred when participating in the research project. For example, there is a need to spend some time watching the media, answering the

questionnaire, attending the study/teaching and there will be voice recording and photos taking, may waste participant's time, may cause uneasy or uncomfortable feeling or may be stressed with some questions. The participant has the right not to answer certain questions or to reject voice recording or photo taking.

(or the risks from drug allergy or other side effects, a chance of being disabled or dead to which the risk ratio must be informed. For example, the risk of occurrence is 1 in 10 and the corrective and preventive measures must be set in case of harms occurred).

Rights, Duties, and Responsibilities of the Participant:

1. You shall receive a copy of this Participant Information Sheet to keep for your information. If there is any statement that you still do not understand, please ask the Principal Investigator or the representative, so to help with your decision to participate in the research.
2. You have enough time to freely make your decision. You can ask your family, friends, or supervisor for suggestions to participate in this research project.
3. If you consent to be a participant in this research project, please sign on 2 copies of the Informed Consent Form. Please keep one copy to yourself and return the other copy to the researcher.
4. There is no compensation for participants in this research project. (or you will be paid compensation for travel cost or cost of laboratory tests responsible by the researcher at the rate of Baht .....per time, for total of .....times participation.)
5. Participants shall not be responsible for any expenses incurred. (If otherwise, please specify.)
6. You have the right not to answer question(s), not to allow sound recording and photo(s) taking or to deny participating in the research or withdraw your participation in the research any time without prior notice. Withdrawal from the research project shall not impact on your study, work, service, or medical treatment in any way.
   (or ask assistance from the participant to provide completed information in order to comply with the laws (specify name of the laws). Withdrawal of participation from the research shall impact on .....*)
7. Please inform the researcher as soon as possible should there be any unusual symptoms occurred to yourself during your participation in the research project. (Explain how the participant shall get help).

Should you have any queries regarding the research, please contact ..... (Please specify name of the researcher, office address and 24-hour contact telephone number).

Participant's personal information shall be kept confidential and not disclose to the public. The research results shall be reported as an overview.

People who have the right to access your information shall be limited to people involving in this research only with certain groups of people responsible for auditing such as the research funders or auditors from the related government offices and KMUTT's Institutional Review Board (KMUTT-IRB), etc.

The researcher shall delete or destroy the information provided by the participants within ..... days/months after the end of the research project.

Should there'll be any additional information or new information on both the benefits and harms in regarding this research, the researcher shall inform the participant promptly and openly.

This research project is approved by the KMUTT Institutional Review Board (KMUTT IRB) of which the 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 Road, Bangmod Subdistrict, Thung Khru District, Bangkok 10140
Tel (+66) 2470-9623 Fax (+66)-2872-9083
Email address: irb@kmutt.ac.th

If you are not treated as stated, please contact the chairman of KMUTT's Institutional Review Board (KMUTT-IRB) or the representative at the office and phone number indicated above.

Thank you for your kind cooperation.

Sign.....

(Principal Investigator)