IRB-approved Research Protocol Guideline

1. Conducting Research

The research must be conducted in compliance with the protocol guideline from IRB.

2. Obtaining Information from Participants

2.1 There must be no coercion or undue influence to obtain information from participants to ensure that participants voluntarily participate in the research.

2.2 Only the latest version of participant information sheet/informed consent form approved by KMUTT-IRB is used. The researcher must provide a copy of informed consent form to participants after signing the form.

3. Protocol Deviation Report

The researcher is required to report any departure from the IRB-approved Research Protocol to IRB and provide reasons for deviating from the approved process. He or she also shall make a plan to prevent the same thing happening again. If the deviation is deliberately repeated, IRB may terminate the approved research.

4. Protocol Amendment of Research

In case of a research proposal amendment/any changes to the research, the researcher shall identify the reasons for the amendment for IRB approval before conducting the research, except immediate problem solving, in order to prevent any harm which could occur to participants. Principal investigator (PI) is required to notify IRB of the harm too.

4.1 The research title can only be changed before research publishing. (IRB approval cannot be granted retroactively.)

4.2 When a modification is made to the current informed consent form, the revised consent form must be signed by the participant in order to ensure that the participant is informed of all the latest information.

5. Adverse Event Report

During the research, PI must report IRB any adverse events anytime whether serious or not if occur. (See No.14.2 of Guideline for KMUTT-IRB)

6. New information related to research project

If there is any new information related to the research project which affects safety and well-being of the participants, PI must inform IRB every time.

7. Site Visit

Site visits shall be conducted for the following events: a regular visit; recurring serious adverse events to many participants which may be related to the research project; and reported deviations in research which affect the participants' right and welfare, especially when recurring frequently.

8. Notification for Progress Report and Re-Approval

PI must submit a progress report to extend a certificate within 30 days before it expires. (The date of the renewed certificate will continue from the original.)

9. Close-out Report

When the research has been completed, PI must inform IRB by sending a hard copy of close-out report, together with a CD/DVD of PDF and WORD files.

***** IRB-approved Research Proposal *****

(1) For an Exemption Review obtaining a Certificate of Exemption (COE) which is valid until the end of research project, while neither progress report nor certificate extension is required, the researcher must send a close-out report.

In case the researcher is unable to complete the research project within a specified time frame, please submit a copy of the approved extension of the project to IRB and then send a closed-out report when completed.

(2) For an Expedited Review and Full-Board Review obtaining a Certificate of Approval (COA) which is valid for 1 year, the researcher must submit a progress report for a certificate extension, and send a close-out report when completed.

*** For further information, please contact
Research Ethics and Compliance Unit
Research Innovation and Partnerships Office (RIPO)
King Mongkut's University of Technology Thonburi
Tel. 0-2470-9623
Fax 0-2872-9083
E-mail: irb@kmutt.ac.th

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Please return this form to Research Innovation and Partnerships Office (RIPO), 7th Floor, Office of the President Building, Tel. 0-2470-9623, Fax 0-2872-9083, E-mail: irb@kmutt.ac.th

Research Proposal Number .....

- I have received an IRB Certification of KMUTT

Approval Certificate No.....

- I have read and acknowledged the IRB-approved Research Protocol Guideline and will conduct the research to my fullest capacity to complete it within the specified time frame. I understand that when non-compliance with the IRB-approved protocol occurs, IRB has the authority to suspend my research project.

Signature.....

(.....)

Date.....