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| **Report number ............................Date ........................................** |
| **➊ Research Project Information** |
| **Research Proposal Number**…………………………………………………………………………………………………………………………………………………… **Type of IRB Approval** 🞎 Exemption 🞎 Expedited 🞎 Full Board**Reference Number (COE/COA)** ..............................................................................................................................................................**Title of Research Project**(Thai)..............................................................................................................................................................................................................(English).........................................................................................................................................................................................................**Duration of the Study**: From ............................. to ...................................  |
| **➋ Information about the Principal Investigator/ Researcher and Research Subjects**  |
| **1. Principal Investigator/Advisor’s Name** ............................................................................................................................................Faculty...............................................................................Tel................................................................................**2. Researcher/Student’s Name**...............................................................................................................................................................Faculty.............................................................................. Tel.................................................................................**Or Research coordinator Name**..............................................................................................................................................................Faculty.............................................................................. Tel................................................................................. |
| **➌ Adverse Event Report** |
|  **3.1 Study site**..................................................................................................................................................................................... **3.2 Research subject ID number**................................................................................................................................................... **3.3 Date of event**................................................................................................................................................................................ **3.4 Event summary and corrections done (including the symptoms of the subject when reporting)** ................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................... **3.5 Researchers evaluate the relation between the adverse event and the research project as follows:** 🞎 Not related 🞎 Possible 🞎 Probable 🞎 Related |
| **➍ Management of the Subject after Adverse Event**  |
| 🞎 **Stop the research project** 🞎 Ask the subject to withdraw from the study 🞎 Others .................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................🞎 **Continue the research project** 🞎 Lack protocol amendment 🞎 Add more monitoring measures as follows (specify): ............................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................. 🞎 Others............................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................... |
| **➎ For Principal Investigator/ Researcher and Subject** |
| Signature ……………………………………………………………(Printed Name ......................................................................)Principal Investigator/ StudentDate .................................................... | Signature ……………………………………………………………(Printed Name .....................................................................)Department Head/ Program Chair/ Advisor Date .................................................... |
| **➏ ~~F~~or KMUTT Institutional Review Board Subcommittee of Faculty/ Institute ............................................** |
|   🞎 Informed of the adverse event  Signature………………………………………………Printed Name....................................................................Date........................................................... |
| **➐ For Coordinating Staff of KMUTT Institutional Review Board**  |
|   🞎 Complete document  🞎 Others....................................................................................................................................................................................................................................................................................................................................................................................................................... ........................................................................................................................................................................................................................... ........................................................................................................................................................................................................................... ...........................................................................................................................................................................................................................  Signature………………………………..................……(IRB Staff)Date………………............................................... |
| **➑ For KMUTT Institutional Review Board** |
| **For Secretary of KMUTT Institutional Review Board** 🞎 Informed of the adverse event 🞎 Presented in the meeting number .............../............... Agenda ............  🞎 Others....................................................................................................................................................................................................................................................................................................................................................................................................................... ........................................................................................................................................................................................................................... ...........................................................................................................................................................................................................................  Signature ……………………………….........…….…(IRB Committee Secretary)Date ............................................. |
| **Dear Chair of the KMUTT Institutional Review Board** 🞎 Acknowledged  🞎 Others .......................................................................................................................................................................................................................................................................................................................................................................................................................... ........................................................................................................................................................................................................................... ........................................................................................................................................................................................................................... Signature ………………….................................….............….…………… (Chair of the KMUTT Institutional Review Board) Date ........................................................................................  |