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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/ Student  Date .................................................... | 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 ........................................................................................ | |