**AF/02-17/01.0**

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| **โลโก้มทสขาวดำ Suranaree University of Technology**  **Institutional Ethics Committee** | **Adverse Event and Problem Report**  **(Investigator Initiated)** |

Instruction: Please fill in the form and attach documents if necessary

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| Protocol No. | REC No. | For the record only |
| Investigator No. |  |
| 1. Brief description of the adverse event or problem | |  |
| 2. Evaluation event of problem | |  |
| Seriousness: death \_\_\_\_  life threatening \_\_\_\_  disability \_\_\_\_  new/prolonged hospitalization \_\_\_\_  congenital anomalies \_\_\_\_  Others (specify:………………………………………………….) \_\_\_\_ | |  |
| Already mentioned in - investigator brochure yes \_\_\_\_  no \_\_\_\_  - patient information sheet yes \_\_\_\_  no \_\_\_\_  Relationship with the investigational drugs/procedure/devices: by  **sponsor investigator**  probably\_\_\_\_ probably\_\_\_\_  possibly\_\_\_\_ possibly\_\_\_\_  unknown\_\_\_\_ unknown\_\_\_\_  not related\_\_\_\_ not related\_\_\_\_  Outcomes: resolved/improved\_\_\_\_  unchanged\_\_\_\_  worsened\_\_\_\_  fatal\_\_\_\_  not available\_\_\_\_  Site involved: site responsible by Suranaree University of Technology / Affiliated sites\_\_\_\_  other sites\_\_\_\_ | |  |
| **Investigator considerations**:  1. Notification to human subjects using new or additional informed consent.  required immediately \_\_\_\_  required for the next appointment \_\_\_\_  not required \_\_\_\_  2. Change in or suspension of research.  suspension \_\_\_\_  change \_\_\_\_  no action required \_\_\_\_ | |  |

**Note**: Serious Adverse Events (SAE) and serious and unexpected adverse events from investigation site should be submitted to SUT-IEC within 7 days after the events or problems occur. Fatal case must be informed immediately within 24 hours after the event.

**Investigator signature** ……………………………………………................................................…dated…….……/……..……/….....…

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| **For Board use only**  **SAE subcommittee considerations**:  1. Notification to human subjects using new or additional informed consent.  required immediately \_\_\_\_  required for the next appointment \_\_\_\_  not required \_\_\_\_  2. Change in or suspension of research.  suspension \_\_\_\_  change \_\_\_\_  no action required \_\_\_\_  3. Acknowledgement \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Comment : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

Note: All actions have to be referred to full board.

**Chair of SAE subcommittee signature** …………..............................................................................………dated…..…..…/…..……/……