**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…..…..…/…..……/……