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| à¹à¸à¸ à¸²à¸à¸­à¸²à¸à¸à¸°à¸¡à¸µ à¸à¹à¸­à¸à¸§à¸²à¸¡**KamphaengphetRajabhat University****Research Ethics Committee** | **แบบรายงานเหตุการณ์ไม่พึงประสงค์****ชนิดร้ายแรง ในสถาบัน** **Adverse Events and Problem** **Report Form - Internal** |

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| **Protocol Title:**  |  |
| **COA No:** |  |
| **Principal Investigator:** |  |
| **Sponsor:** |  |
| **Medicine or cosmetic or device** |  |
| **Study site:** |  |
| **Adverse Event:** |  |
| **Onset of SAE: (dd/mm/yyyy)** |  |
| **Event reported:**  | 🞏 Initial report 🞏 Follow-up report  |
| **Severity of event:** | 🞏 Death 🞏 Life threatening 🞏 Hospitalization or prolongation of hospitalization 🞏 Persistent or significant disability or incapacity 🞏 Congenital anomaly or birth defect 🞏 Required intervention to prevent permanent impairment 🞏 Other ………………………………………………….. |
| **Causality of event:** | 🞏 Unrelated (clearly not related to the research)🞏 Unlikely (doubtfully related to the research)🞏 Possible (may be related to the research)🞏 Probable (likely related to the research)🞏 Definite (clearly related to the research) |
| **Is the reaction expected?**  | 🞏 Expected 🞏 Unexpected (not mentioned in the protocol or Investigator Brochure)  |
| **Is the event classified as a SUSAR**  | 🞏 No 🞏 Yes  |
| **Progression** | Is the event due to progression of an underlying illness? 🞏 No 🞏 Yes  |
| **Action take with study treatment:** | 🞏 Continued 🞏 Reduced 🞏 Increased 🞏 Temporary stop 🞏 Permanent stop  |
| **Outcome of SAE:** | 🞏 Resolved 🞏 Resolved with sequelae 🞏 Improved 🞏 Persistent 🞏 Worsened 🞏 Fatal 🞏 Unknown  |
| **Other actions taken:**  | 🞏 No action required🞏 Amend consent document🞏 Amend protocol🞏 Inform current subjects🞏 Terminate or suspend protocol🞏 Others ………………………………………………….. |
| **Have Similar Adverse Events Occurred on this protocol?** | 🞏 No 🞏 Yes How many? \_\_\_\_\_\_\_  |
| **Comment (Principle investigator or Site investigator):** ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| **□ Principle investigator □ Site investigator**  | **Name**: |
| **Date** | **Signature** |