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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** |