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| --- | --- | --- | --- |
| **Protocol title (ไทย)**  **(English)** | | | **IRB NO.**  \_\_\_\_\_\_ |
| **Study Code:** | | | |
| **Principal Investigator:** | | | |
| **Phone number:** | **E-mail address:** | | |
| **Sponsor’s Name:** | | | |
| **Address:** | | | |
| **Phone number :** | **E-mail address :** | | |
| **Study site(s) :** | | | |
| **Objectives(s) :** | | | |
| **Study materials :** | | | |
| **Study dose(s) :** | | | |
| **Treatment form :** | | | |
| **Duration of the study (since Med Chula IRB Approval):** | | | |
| **Proposed number of study participants :** | | **No. of Study Arms :** | |
| **Number of participants recruited in the study :** | | | |
| **In case the participants were enrolled more than the approved number, please indicates the reason(s) why this has occurred:** | | | |
| **Number of dropout participants in the study :** | | | |
| **Number of SAE/SUSARs occurred :** | | | |
| **Number of Non-Compliance / Protocol violation occurred:** | | | |
| **In case of clinical trial, describe how** **participants can access to study drug after finishing the trial:** | | | |
| **In case of the protocol is requested for termination by**  🞏 PI 🞏 Data Safety Monitoring Board 🞏 Sponsor  **Please describe reason(s) to terminate the study before the scheduled end date and how the participants are taken care of** | | | |
| **Brief summary of the result :** | | | |
| **Investigator’s signature** ………...........................…..................................... **Date**…….....…..…/…….....…..…/…….....…..…  ……………........................…...................................................................................... (Print Name-Surname) | | | |