|  |  |
| --- | --- |
| **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) |