**Inform Consent**

The subject (Subject No.) was fully explained the study information of \_\_\_\_\_\_\_\_\_ (Protocol No. /Brief Title), \_\_\_\_\_\_\_\_ (IRB No.) and the content of ICF \_\_\_\_\_\_\_\_\_\_\_( Version and Date ) by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(PI or COPI). The subject had enough time to consider and ask all questions regarding the study. The subject had signed ICF on \_\_\_/\_\_\_\_/\_\_\_\_\_(date) . A copy of each signed informed consent was given to the subject.

**Sub- study**

□Additional informed consent is required for those subjects who wish to participate in the optional pharmacogenetic(PG) sub- study

\* Subject will participate in phamacogenetic study ❑Yes ❑ No;

Genetic ICF version/date\_\_\_\_/\_\_\_\_\_\_\_\_was signed on \_\_\_/\_\_\_\_/\_\_\_\_\_(date) . A copy of each signed informed consent was given to the subject.

**Random (Not applicable for blinded study)**

The subject was assigned to \_\_\_\_\_\_\_\_ (group) and random No. is \_\_\_\_\_\_\_\_\_on \_\_\_/\_\_\_\_/\_\_\_\_\_(date)

**V1,V2,V3……**

\_\_\_\_\_\_\_ (Protocol No/ Brief Title) V1 \_\_\_\_/\_\_\_\_/\_\_\_\_\_(date)

\_\_\_\_\_\_\_ (Protocol No/ Brief Title) V2 \_\_\_\_/\_\_\_\_/\_\_\_\_\_(date)

\_\_\_\_\_\_\_ (Protocol No/ Brief Title) V3 \_\_\_\_/\_\_\_\_/\_\_\_\_\_(date)

**Screen Failure**

Reason for screening failure by \_\_\_\_\_\_\_\_\_\_\_ (Inclusion / Exclusion criteria/others) on \_\_\_/\_\_\_\_/\_\_\_\_\_(date)

**Discontinuation/Withdraw**

Reason for premature discontinuation/withdraw by \_\_\_\_\_\_\_\_\_\_ (AE/others) on \_\_\_/\_\_\_\_/\_\_\_\_\_(date)

**Reason for premature discontinuation** (check all that apply)**:**

□ 1. AE

□ 2. Subject withdrew consent, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

□ 3. Lost to Follow-up

□ 4. Other, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Primary reason for premature discontinuation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**AE/SAE Describe**

Grade\_\_\_\_ (CTC AE ) ( + ) Please describe.

Grade \_\_\_\_ (CTC AE) ( - )

**Study Completion**

**Study completion date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_