

	Central Committee for the Ethics of Human Research Central Research Ethics Committee; CREC Telephone: 082-258-9529 E-mail: official@crecthailand.org	AP 08-S04
		V. 5.1 date 5 Feb 2025
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List of Documents

Approval documents	Reference (e.g. version and date)
Research protocol	1. 2. Thai version of the protocol English Protocol Appendix of the protocol Memos reflecting changes to the research procedures specified in the protocol.
Informed consent Documents	Site XX 1) . 2) . Site XX 1) . 2) .
Case Report Form	1. 2.
Investigator's Brochure	1. 2 . Investigator's Brochure Toxicity guideline Package Insert
Research Tools	1. 2.

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Approval documents	Reference (e.g. version and date)
	Assessment (Research Team Use) Questionnaire (Participant Use) Participant Material (Participant Use)
Approval documents	Reference (e.g. version and date)
Acknowledgment Document	1. 2.

CREC approval includes:

Principal investigators	Investigator's CV and ICH-GCP Training Certificate and Declaration of conflict of interest Site XX 1) 2) Site XX 1) . 2)
Study sites	1. 2.

note :

1. Please provide the most recent version date of the document.
2. In the case of a research project renewal report, a list of documents that must be certified or acknowledged by CREC during the year in which certification has been completed.
3. In the case of documents requesting certification from the institution but not yet notifying CREC , they cannot be included in this COA .