



PROTOCOL AMENDMENT FORM

ERC Reference #: _____ Protocol No. _____
Principal Investigator: _____ Inst./Dept.: _____
Protocol Title: _____

Note: Kindly check below the document(s) for review. Submit 2 copies of the new version and supporting documents (if applicable) completed Protocol Amendment form and Summary of the revisions. One copy of the new version must indicate the track changes, new text is shown in bold type. The other copy of the new version must be the clean copy of the document amended.

- Protocol
 - Major (*e.g Study design, objective of study, procedures*) Does this have significant impact on:
 - The safety or physical or mental integrity of the subjects, or
 - The specific value of the trial or
 - The conduct or management of the trial, or
 - The quality or safety of any IND used in the trial.
 - Minor (*e.g Administrative changes, change of address, grammatical corrections*)

New version no. & date: _____

- Informed Consent Form
 - Major (*additional risks to the subjects (e.g Updates on side effects of study drug)*)
 - Minor (*administrative changes, change of address, grammatical corrections*)

New version no. & date: _____

- Change in investigator/member of study team (Pls complete information below)

a) Addition (*Kindly provide copy of individual's Curriculum Vitae. New members of the study team be ICH-GCP certificate*)

Name	Position
_____	_____
_____	_____

b) Deletion

Name	Position
_____	_____
_____	_____

- Other Study Related Materials: Please Specify (*Kindly indicate type of document with version date and no.*)

_____	_____
_____	_____
_____	_____

Submitted by:

(Name and signature of Principal Investigators)

Date

Received by: (ERC use only)

(Name and signature)

Date