Medical Research and Ethics Committee (MREC),
Minsitry of Health Malaysia
Amendment Application Form

Instructions to the Investigators:

- *Please complete and append this form together with the amendment submission to MREC. Amendment submission is to be done via NMRR system and could only be performed by the Corresponding Person of the study. Please refer to the manual available in the NMRR Homepage for Step by Step guide on submitting amendment.*

I. Project Information	
NMRR ID:	
Protocol ID:	
Research Title:	
Type of Study:	☐ Investigator Initiated Research (IIR) ☐ Industrial Sponsored Research (ISR)
Corresponding Principal Investigator:	
Corresponding Principal Investigator's Site:	
Contact information (H/P Number):	
Contact Information (E-mail Address):	
CC List (If Relevant): *Please list the names of other investigators you wish the MREC decision letter to be addressed to, other that the name of the Corresponding PI*	

II. Amendment Submission Package (Please tick checkbox to verify completeness)	
☐	All amended and new document/s (Please ensure the changes made have been highlighted/ indicated in the relevant document) ☐ Study Protocol/ Study Proposal ☐ Investigator Brochure ☐ Patient Information Sheet/ Informed Consent Form ☐ Questionnaire ☐ Study Clinical Report Form (CRF) / Data Collection Form ☐ Patient's Diary ☐ Advertisement for Subject Recruitment ☐ Trial Insurance Certificate ☐ IA-HOD-IA Forms *(For new study investigators/ study sites)* ☐ Curriculum Vitae *(For new study investigators/ study sites)* ☐ Good Clinical Practice (GCP) Certificate *(For new study investigators/ study sites- applicable for clinical trial studies)* ☐ Other Related Research Documents

No	List of Document(s) to be reviewed & approved (Complete with Version Number & Version Date) E.g.: Study Protocol Version 4, dated 08 April 2016

III. AMENDMENT DETAILS (Please tick checkbox)

Type of Amendment/s:	☐ Research Procedure/ Protocol (including Research Instruments) ☐ Participant Group ☐ Sponsorship/ Collaborators ☐ Patient Information Sheet/ Informed Consent Form ☐ Principle Investigator/ Study team/ Study sites ☐ Other/s _____
Summary of Changes: *Please describe in brief on the amendment requested*	

IV. SUBSTANTIAL AMENDMENT (Please tick checkbox)

Substantial Amendment

Definition: Change in the protocol that is likely to affect to a significant degree the :

- Safety or physical or mental integrity of the subjects of the study
- Scientific value of the study
- Conduct or management of the study or
- Quality or safety of any medicinal product used for clinical trials

☐	Changes to the design or methodology of the study, or to background information affecting its scientific value;
☐	Changes to the procedures undertaken by participants;
☐	Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
☐	Changes to the inclusion/ exclusion criteria;
☐	Significant changes to study documentation such as participant information sheets/ informed consent forms, questionnaires, advertisement, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or careers.
☐	A change of sponsor(s) or sponsor's legal representative
☐	Appointment of a new corresponding principle investigator;
☐	Addition of new trial site and/ or new PI (applicable for clinical trials only)
☐	A change to the insurance or indemnity arrangements for the study;

☐	A change to the payments, benefits or incentives to be received by participants or researchers in connections with taking part in the study, or any other change giving rise to a possible conflict of interest on the part of any investigator/ collaborator
☐	Temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt
☐	A change to the definition of the end of the study;
☐	Change in subject recruitment number
☐	Any other significant change to the protocol or the terms of the MREC application (Please Explain) _____

V. NON-SUBSTANTIAL AMENDMENT (Please tick checkbox)	
Non-Substantial Amendment	
☐	Minor changes to the protocol or other study documentation, (e.g. correcting errors, updating contact points, minor clarifications;
☐	Updates of the investigator's brochure / Summary of product report
☐	Changes to the research team (other than appointment of new principle investigator);
☐	Changes in funding arrangements
☐	Changes in the documentation used by the research team for recording study data;
☐	Changes in the logistical arrangements for storing or transporting samples
☐	Inclusion of new sites and investigators in study protocol
☐	Extension of the study beyond the period specified.
☐	Changes to the presentation of previously approved wording such as an approved advertisement being used in a different format.
☐	Routine closure of sites at the end of the study
☐	Changes to contact details for the sponsor(s) or sponsor's legal representative, principle investigator, study team or other project staff
☐	Any other non-substantial amendment (Please Explain) _____

VI. Principle Investigator Certification	
I certify that I have reviewed the details of this report and the information above and reflect my conclusions.	
Name of Investigator:	Role in the Study:
Signature of the Investigator:	Date Signed:

MREC OFFICE USE ONLY (Do not write below this line)- Please Tick (√) at the appropriate checkbox

Screening by MREC Secretariat

Submission complete?	☐ Yes ☐ No. Further information is required; Specify: _____ _____
Screened by:	Date screened:

Review by MREC Chairperson/Deputy Chairperson / Member/ Member Secretary or Member Secretariat Delegated by Chairperson

Any significant amendment(s) which affects the risk/ benefit ratio?	☐ No. (No further action required)	
	☐ Yes. Delegated review required:	☐ By Chairperson/ Deputy Chairperson ☐ By Delegated Reviewer: _____
Additional actions or information needed?	☐ Yes. ☐ No. Specify: _____ _____	
Date reviewed:	Reviewed by:	

To be endorsed in the next full-board meeting:	☐ Red Panel Meeting Date: …… ☐ Blue Panel Meeting Date: ……