

CONTINUING REVIEW FORM
MEDICAL RESEARCH & ETHICS COMMITTEE,
MINISTRY OF HEALTH MALAYSIA

NMRR NO.:			
STUDY TITLE:			
PROTOCOL NO. (Applicable for ISR Studies Only):			
NAME OF CORRESPONDING PRINCIPAL INVESTIGATOR:			
LIST OF ALL MREC APPROVED SITE(S):			
DATE OF MREC INITIAL APPROVAL:		DATE OF LAST MREC ETHICAL RENEWAL:	
EXPECTED STUDY DURATION (Including Recruitment Period) FROM DATE OF MREC INITIAL APPROVAL:			
<p>CURRENT STUDY STATUS IN MREC APPROVED SITE(S). CHECK ALL THAT APPLY:</p> <p><input type="checkbox"/> Study has not been initiated/ is put on hold. EXPLAIN why:</p> <p><input type="checkbox"/> Data Collection (Applicable for non – Clinical Research only)</p> <p><input type="checkbox"/> Data Analysis (Applicable for non – Clinical Research only)</p> <p><input type="checkbox"/> Active Enrollment (Applicable for Clinical Research only)</p> <p><input type="checkbox"/> Closed Enrollment. Follow up of enrolled subjects (Applicable for Clinical Research only)</p>			
PLEASE SELECT EITHER ONE:			
(A) SUMMARY OF STUDY SUBJECTS IN MREC APPROVED SITES (APPLICABLE IN STUDIES WITH INFORMED CONSENT):		(B) SUMMARY OF STUDY DATA (IF WHERE APPLICABLE):	
	Targeted number of subjects/ participants approved by MREC		Targeted number of records/ biological specimens/ data approved by MREC
	Number of new subjects enrolled since initial approval / last annual renewal		Number of records/ biological specimens/ data accessed
	Total number subjects enrolled since study was initiated.	<input type="checkbox"/> No Data Collection/ Assessment till Date. Reason:	
<input type="checkbox"/> No Enrollment to Date. Reason:			

HAS ANY SUBJECT WITHDRAWN/ TERMINATED FROM THIS STUDY (MREC APPROVED SITE ONLY) SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NA (Applicable for non – Clinical Research only)
☐ NO (Applicable for Clinical Research only)
☐ YES (Narrate in the table below) (Applicable for Clinical Research only)

Subject Study ID	Study Site Name	Withdrawn / Terminated (W/T)	Date Withdrawn / Terminated	Reason/ Description of withdrawal/ Termination	Actions taken to ensure subject's safety

HAS THERE BEEN ANY CHANGE IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NO
☐ YES. EXPLAIN:

HAS THERE BEEN NEW/ ADDITIONAL INVESTIGATIONAL NEW DRUG/ DEVICE REGISTRATION ASSOCIATED WITH THIS STUDY SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL? (Applicable for Clinical Trials Only)

- ☐ NO
☐ Investigation New Drug (IND)
☐ Investigational Device exemption
- FDA Number:
Name:
Sponsor:
Holder:

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT MREC'S EVALUATION OF THE RISKS / BENEFITS ON HUMAN SUBJECTS INVOLVED IN THIS STUDY SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL? (Eg: Investigator Brochure, Data Safety Monitoring Board Report, etc)

- ☐ NA (Applicable for non – Clinical Research Only)
☐ NO
☐ YES. EXPLAIN:

SUMMARY	STUDY DOCUMENTS UPDATED? (YES/ NO)	DOCUMENT(S) UPDATED (with Version Number/ Date)	Date Approved/ Acknowledged by MREC	Additional Remarks

HAS ANY UNEXPECTED COMPLICATION OR SIDE EFFECT BEEN NOTED SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NA (Applicable for non – Clinical Research)
☐ NO
☐ YES. (Explain in the table below)

SUSAR / INVESTIGATOR BROCHURE (with Version Number/ Date if applicable)	Site Name (if SUSAR occurred at a local site)	Summary of Complications/ Side Effects	Date Approved/ Acknowledged by MREC

HAS THERE BEEN ANY CHANGE IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NA (Applicable for studies that has waiver of informed consent)
☐ NO
☐ YES (Explain changes in the table below)

Informed Consent Form with Version Number/ Date	Summary of Changes	Date Approved by MREC

HAS ANY CO- / SITE INVESTIGATORS BEEN ADDED OR REMOVED SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NO
☐ YES (Identify all changes in the table below)

Investigator's Name	Study Site	Role (Principal Investigator/ Sub-Investigator) – PI/ SI	Added/ Removed	Date Approved by MREC

HAS ANY NEW COLLABORATING SITE (INSTITUTION) BEEN ADDED OR REMOVED SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NO
☐ YES (Identify all changes in the table below)

Study Site	Added/ Removed	Date Approved by MREC

HAS THERE BEEN ANY OTHER AMENDMENT (OTHER THAN THE ONES LISTED ABOVE) SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NO
☐ YES (Explain changes in table below)

Summary of Amendments	Date Approved by MREC

HAS ANY INVESTIGATOR DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS STUDY WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NO
☐ YES (Append a statement of disclosure)

AS THERE BEEN ANY PROTOCOL DEVIATION (PD)/ PROTOCOL VIOLATION (PV) REPORTED TO MREC INVOLVING THE MREC APPROVED SITES SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NA (Applicable for non – Clinical Research)
☐ NO
☐ YES. (Summarise in the table below)

Subject Study ID	Study Site Name	Brief Description of Protocol Deviation	Date Reported to MREC

HAS THERE BEEN ANY SERIOUS ADVERSE EVENT (SAE) REPORTED TO MREC INVOLVING THE MREC APPROVED SITES SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NA (Applicable for non – Clinical Research)
☐ NO
☐ YES. (Summarise in the table below)

Subject Study ID	Study Site Name	Brief Description of SAE	Date Reported to MREC

HAS THE STUDY TRIAL INSURANCE BEEN UPDATED SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?

- ☐ NA
☐ NO
☐ YES

Trial Insurance Policy No	Date of Expiry	Date Approved by MREC

Is this Continuing Review Form (CRF) being submitted past the expiration date of MREC ethical approval?

- ☐ NO
☐ YES.
 If you are submitting this CRF after the expiration date of MREC ethical approval, were research-related activities conducted during the time MREC approval of this research was expired?
☐ No
☐ Yes, EXPLAIN what activities were conducted:

I DECLARE THAT THE INFORMATION PROVIDED ABOVE IS TRUE & CORRECT TO THE BEST OF MY UNDERSTANDING
 COMPLETED BY:

.....
 NAME:
 (CORRESPONDING PRINCIPAL INVESTIGATOR)
 DATE:

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

SUBMISSION DATE:

Additional actions or information needed?

☐ NO

☐ YES

Specify:

APPROVED VIA

☐ EXEMPT REVIEW BY CHAIRPERSON/ DEPUTY CHAIRPERSON

☐ FULL-BOARD REVIEW – Date of Panel Meeting: _____

DATE:

SCREENED BY:

EXEMPT REVIEW BY CHAIRPERSON/ DEPUTY CHAIRPERSON

DATE:

SCREENED BY: