**CONTINUING REVIEW FORM**

**MEDICAL RESEARCH & ETHICS COMMIITTEE,**

**MINISTRY OF HEALTH MALAYSIA**

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| 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:  |
| CURRENT STUDY STATUS IN MREC APPROVED SITE(S). CHECK ALL THAT APPLY:[ ]  Study has not been initiated/ is put on hold. EXPLAIN why:[ ]  Data Collection (Applicable for non – Clinical Research only)[ ]  Data Analysis (Applicable for non – Clinical Research only)[ ]  Active Enrollment (Applicable for Clinical Research only)[ ]  Closed Enrollment. Follow up of enrolled subjects (Applicable for Clinical Research only) |
| **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. | [ ]  No Data Collection/ Assessment till Date. Reason: |
| [ ]  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| HAS ANY SUBJECT WITHDRAWN/ TERMINATED FROM THIS STUDY (MREC APPROVED SITE ONLY) SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?[ ]  NA (Applicable for non – Clinical Research only)[ ] 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)

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| **Subject Study ID** | **Study Site Name** | **Withdrawn / Terminated (W/T)** | **Date Withdrawn / Terminated** | **Reason/ Description of withdrawal/ Termination** | **Actions taken to ensure subject’s safety** |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

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

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| **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** |
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| 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)

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

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

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| **Study Site** | **Added/ Removed** | **Date Approved by MREC** |
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| 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)

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| **Summary of Amendments** | **Date Approved by MREC** |
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| 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)

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

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| **Subject Study ID** | **Study Site Name** | **Brief Description of SAE** | **Date Reported to MREC** |
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| HAS THE STUDY TRIAL INSURANCE BEEN UPDATED SINCE THE LAST MREC INITIAL APPROVAL/ RENEWAL?[ ]  NA [ ]  NO[ ]  YES

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| **Trial Insurance Policy No** | **Date of Expiry** | **Date Approved by MREC** |
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| 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 (√) 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:** |