

Sunway Medical Centre Independent Research Ethics Committee (SREC)

RESEARCH AMENDMENT APPLICATION FORM

(Please complete all sections of this form. Incomplete forms will be rendered invalid)

Following SREC written approval to conduct a research project, all proposed amendments to be made to the study documents (i.e. study protocol, subject information sheet, informed consent form, advertisements, questionnaires, product summary, investigator's brochure etc.) must be submitted to SREC for review. No changes should be implemented to these documents without prior written approval from SREC, *except* where necessary to eliminate immediate hazard to subjects or when only logistical or administrative aspects are changed. In such exceptional circumstances, SREC should be informed in writing.

Title of Research Project	
Protocol No.	
Name of Principal Investigator	
Name of Sponsor	
SREC Approval No.	
Name of SREC-Approved Document(s) to be Amended, Version(s) and Date(s)	
New Version(s) and Date(s) of above Document after the Proposed Amendment	

For the amendments to be made, please provide:

Page & Section to be Amended	Before Proposed Amendment	After Proposed Amendment	Reasons for Proposed Amendment

**For a list of amendments to be made, please attach list in a different sheet.*

Will the proposed amendment(s) adversely affect the safety, rights or welfare of subjects?

Yes

No

If yes, please describe the risk(s) and justify if necessary.

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Does the proposed amendment(s) affect the scientific value of this research project?

Yes

No

If yes, please explain and justify if necessary.

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**Please note: If the proposed amendments MAY negatively affect the safety, rights or welfare of subjects as well as scientific value of this research project, please submit 3 copies (1 original and 2 photocopies) of this form with supporting documents to SREC. If the proposed amendments DO NOT negatively affect the safety, rights and welfare of subjects as well as scientific values of this research project, please submit to SREC only one copy of this application form with supporting documents. If in doubt, please contact the Secretariat.*

Signature of Principal Investigator	
Full Name	
Date	

Please return the completed form with supporting documents to:

SREC Secretariat, c/o SunMed Clinical Research Centre,

Sunway Medical Centre,

No. 5 Jalan Lagoon Selatan,

Bandar Sunway 46150 Petaling Jaya, Selangor

Tel: 03-7491 1256 Fax: 7491 1255