

**Sunway Medical Centre Independent Research Ethics Committee (SREC)**

**RESEARCH APPROVAL APPLICATION FORM**

*(Only forms using legible handwriting or typewritten will be processed. Please complete all sections and attach all supporting documents before submitting application)*

**1. Title of Project & Protocol No.**

<b>Title :</b>
<b>Protocol No. :</b>

**2. Details of Research Personnel**

**2.1. Principal Investigator Details**

<b>Full Name:</b>	<b>Passport / IC No:</b>	
<b>Professional Mailing Address :</b>	<b>Title: Mr / Mrs / Prof / Dr</b>	
<b>Tel:</b>	<b>Fax:</b>	<b>Email:</b>
<b>Academic Qualification:</b>		

**2.2. Co-investigator 1 or Supervisor 1 Details (whichever applicable)**

<b>Full Name:</b>	<b>Passport / IC No:</b>	
<b>Professional Mailing Address :</b>	<b>Title: Mr / Mrs / Prof / Dr</b>	
<b>Tel:</b>	<b>Fax:</b>	<b>Email:</b>
<b>Academic Qualification:</b>		

**2.3. Co-investigator 2 or Supervisor 2 Details (whichever applicable)**

<b>Full Name:</b>	<b>Passport / IC No:</b>	
<b>Professional Mailing Address :</b>	<b>Title: Mr / Mrs / Prof / Dr</b>	
<b>Tel:</b>	<b>Fax:</b>	<b>Email:</b>
<b>Academic Qualification:</b>		

**2.4. Person submitting this application (if different from above)**

<b>Full Name:</b>	<b>Passport / IC No:</b>	
<b>Professional Mailing Address :</b>	<b>Title: Mr / Mrs / Prof / Dr</b>	
<b>Tel:</b>	<b>Fax:</b>	<b>Email:</b>
<b>Academic Qualification:</b>		

**3. Project Description (please tick where appropriate & fill accordingly)**

<b>Protocol ID / Short title:</b>
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<b>Proposed Date of Commencement:</b>	
<b>Proposed Date of Completion:</b>	
<b>Duration (months) :</b>	

<b>Research Type</b>	<input type="checkbox"/> Pharmaceuticals, including vaccine (Please provide NMRR ID No) : _____
	<input type="checkbox"/> Medical devices
	<input type="checkbox"/> Medical radiation / Medical imaging
	<input type="checkbox"/> Surgical procedures
	<input type="checkbox"/> Medical records
	<input type="checkbox"/> Biological samples <input type="checkbox"/> Epidemiological investigation <input type="checkbox"/> Social & psychological investigation <input type="checkbox"/> Others, specify:

Is this a multi-centre research?  Yes  No

If yes, please provide details of research status in other centres. (e.g. *not started, recruiting, on-going, completed etc*)

Name of Centre(s)	Status

Please attach with this application, a research proposal / project description / protocol including the information mentioned below:

<ul style="list-style-type: none"> <li>▪ Objectives of research</li> <li>▪ For Clinical Trials, state the Phase of Study</li> <li>▪ Rationale or background of research</li> <li>▪ Expected outcome/value/benefit</li> <li>▪ Study Population</li> <li>▪ Sample size</li> <li>▪ Inclusion criteria of subjects</li> <li>▪ Exclusion criteria of subjects</li> </ul>	<ul style="list-style-type: none"> <li>▪ Potential risks or side effects to subjects</li> <li>▪ Method(s) of recruitment (<i>please attach advertising materials, if any</i>)</li> <li>▪ Method(s) of data collection (<i>please attach, data collection instruments, i.e. surveys, questionnaires, interview schedules etc., if any</i>)</li> <li>▪ Method(s) of data analysis</li> <li>▪ Summary of study</li> </ul>
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*\* For research involving genetic tests, please refer to 'Genetic Research Checklist' (Checklist 3), for additional criteria to be included.*

#### 4. Subject(s) Interest

Will subject(s) receive financial remuneration or other benefits for participating in your research?

Yes  No

If yes, please provide details of benefit and/or origin of fund. (*Please attach, budget allocation sheet, if any*)

Will you seek subject(s) written consent before they are recruited into your research?

Yes       No

If yes, please attach Subject Information Sheet and Informed Consent Form. *(please refer to 'Informed Consent Form & Written Subject Information Checklist' (Checklist 2) for guidance)*

If no, please justify why not.

Is there any potential risk or conflict of interest to the subject(s)? (i.e. physically, culturally, socially, financially etc.)

Yes       No

If yes, please provide details and justify if necessary.

### **5. Sponsor Information**

<b>Sponsor Type</b>	<input type="checkbox"/> Investigator-initiated study	<input type="checkbox"/> Industry-sponsored study
	<input type="checkbox"/> Student Project	<input type="checkbox"/> Others, specify:

<b>Funding Source</b>	<input type="checkbox"/> International Grant	<input type="checkbox"/> MOH Grant
	<input type="checkbox"/> University Research Grant	<input type="checkbox"/> Government (Non-MOH) Grant
	<input type="checkbox"/> Self-funding	<input type="checkbox"/> MOSTI Research Grant (Any type)
	<input type="checkbox"/> Industry	<input type="checkbox"/> Others, specify:

<b>Grant Details</b> <i>(if available)</i>	<b>Grant Sum:</b>
	<b>Validity:</b> <i>(year)</i> to <i>(year)</i>

*\*For investigator-initiated study and student project, please attach letter of support or institutional approval from the organization(s) or institution(s) represented.*

*\*For industry-sponsored studies or studies conducted in collaborations with local companies, please provide: 1. the details below; 2. letter or statement indemnifying the institution where the research is to be conducted, the investigator and SREC and; 3. certificate of insurance for coverage of subjects in research (i.e. clinical trial).*

<b>Sponsor Name:</b>		
<b>Contact Person:</b>		
<b>Mailing Address:</b>		
<b>Tel:</b>	<b>Fax:</b>	<b>Email:</b>

*\*Please attach company profile for studies in collaboration with local companies.*

### **6. Handling of Confidential Information**

What form of data capturing method(s) used in your research? (e.g. typewritten records, audiotapes, videotapes, machine generated reports etc.). Please provide details as below:

<b>Method(s) used</b>	<b>Mode of data storage</b>	<b>Who will have access to it</b>	<b>How do you secure subject(s) confidentiality for this method</b>

Please provide information on the dissemination of research results to subject(s) and parties involved. How will your publication(s), if any, secure subject(s) confidentiality?

### **7. Ethics Approval**

Have you applied for Ethics Approval for this research before?

Yes

No

If yes, please provide status of application (*please attach a copy of ethics approval(s) obtained, if any*)

Name of Institution/Human Ethics Committee	Status (e.g. approved, disapproved, pending etc.)

**8. Declaration of Investigator(s)**

I certify that to the best of my knowledge, the information given in this application is correct and all information pertaining to my research is disclosed. I agree to inform Clinical Research Centre, Sunway Medical Centre of any variations to the research during the application period or during the conduct of my research. If approval is granted, the research will be undertaken in accordance to the terms and conditions established by Sunway Medical Centre.

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**Name of Principal Investigator:**

\_\_\_\_\_  
**Person Submitting the Form:**  
*(if other than the principal investigator)*

**Date:**

**Date:**

*\* Please send 3 copies (1 original and 2 photocopies) of the completed application 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.*

FOR OFFICE USE ONLY	
<b>Date Received</b>	
<b>Reviewed By</b>	