Sunway Medical Centre Independent Research Ethics Committee (SREC)

RESEARCH APPROVAL APPLICATION CHECKLIST

(Please send 3 copies (1 original and 2 photocopies) of the completed application forms with supporting documents and this checklist 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)

Title of research project	
Protocol number	
Principal Investigator	
Research site	
Sponsor	

Documentation	***Remark***		***√ if attached and specify***		
			√	***Version***	***Date***
Proposal / Project Description / Protocol	*Compulsory (Protocol is compulsory for clinical trials)*		☐		
Investigator's Brochure / Product Information Sheet	*Compulsory for clinical trials or research involving medical devices*		☐		
Investigator's Curriculum Vitae	*Compulsory (signed & date)*		☐		
Co-investigator(s)' or Supervisor(s)' Curriculum Vitae	*Compulsory if co-investigator(s) or supervisor(s) exist (signed & date)*		☐		
Investigator(s)' GCP Certificate	*If any*		☐		
Company Profile	*Compulsory for research in collaboration with private companies*		☐		
Advertising Material(s)	*If any*		☐		
Data Collection Instrument(s)	*Surveys / Questionnaires /linterview schedules (if any)*		☐		
Subject Information Sheet (SIS) **please refer 'Informed Consent Form & Written Subject Information Checklist' (Checklist 2) as guidance*	*Compulsory for clinical trials (please attach available translations)*	*English*	☐		
		Bahasa Malaysia	☐		
		Chinese	☐		
		Other Languages	☐		
Informed Consent Sheet (ICF) **please refer 'Informed Consent Form & Written Subject Information Checklist' (Checklist 2) as guidance*	*Compulsory for clinical trials (please attach available translations)*	*English*	☐		
		Bahasa Malaysia	☐		
		Chinese	☐		
		Other Languages	☐		

Case Report Forms	*If any*	☐		
Translation Certificate	*Compulsory for PIS and ICF attached in other languages (clinical trials)*	☐		
Budget Allocation Sheet	*If any*	☐		
Other Ethics Approval Letter	*If any*	☐		
Institutional Approval / Letter of Support	*Compulsory for investigator-initiated study or student project*	☐		
Letter of Indemnification	*Compulsory for industry-sponsored study*	☐		
Insurance Statement	*Compulsory for industry-sponsored study*	☐		
Others, specify:		☐		