Research Ethics Committee
Research Management Centre
Universiti Teknologi MARA
40450 SHAH ALAM
Tel: 03 – 5544-8069, Fax: 03 – 5544-2096/2767

Monitoring of Ongoing Studies Form

Borang Pemantauan Kajian Berterusan

This application is for the purpose of acceptance/approval of amendments to Research Ethics Committee.
Please attach a copy of the cover letter and relevant documents.
Permohonan ini dikemukakan untuk tujuan penerimaan/kelulusan pindaan Jawatankuasa Etika Penyelidikan.
Sila lampirkan surat iringan dan dokumen berkaitan.

Part A : Details of Researcher

Bahagian A: Maklumat Penyelidik

Title of Research :
Tajuk Penyelidikan :

Name of Researcher* :
Nama Penyelidik :*

Name of Supervisor :
Nama Penyelia :

Address of Department/
Hospital/ Institute :
Alamat Jabatan/ Hospital/ Institut :

No.Telefon/ E-mel :
Contact No/ E-mail :

Registration Number :
Nombor Pendaftaran :

Date registered/ Approval :
Tarikh daftar/ Kelulusan :

Research Duration :
Jangkamasa Kajian :

Name of Study coordinator** :
*Nama Koordinator Kajian** :*

Contact No/ Email** :
*No.Telefon/ Emel** :*

☐ * Undergraduate / *Sarjana Muda*

☐ * Postgraduate / *Pasca Siswazah*

☐ * Staff/Lecturers / *Staf/Pensyarah*

☐ * External / *Pihak Luar*

** For Clinical Studies Only / *Untuk Kajian Klinikal Sahaja*

Part B: Protocol Summary and Timeline
Bahagian B: Ringkasan Protokol dan Jangkamasa

☐ Intervention, specify type (tick more than one if applicable):
Intervensi, nyatakan jenis (tanda lebih daripada satu jika berkaitan):

- ☐ Drug
  Ubatan
- ☐ Biologic sample
  Bahan biologi
- ☐ Behavioral/Lifestyle
  Tingkahlaku/ Gaya hidup
- ☐ Surgical
  Pembedahan

	Site 1 ***Lokasi 1***	**Site 2** ***Lokasi 2***
Study commencement date *Tarikh kajian bermula*		
Site *Lokasi*		
Target of first enrolment date *Sasaran tarikh enrolmen pertama*		
First enrolment date *Tarikh enrolmen pertama*		
Target enrolment number *Sasaran bilangan enrolmen*		
Current enrolment number (%) *Bilangan enrolmen semasa*		
Target completion date *Sasaran tarikh selesai*		
Actual completion date *Tarikh sebenar selesai*		
Number screened *Bilangan yang disaring*		
Number of screen failure *Bilangan gagal saringan* Reason 1 (state) *Sebab 1 (nyatakan)* Reason 2 (state) *Sebab 2 (nyatakan)*		
Number of completed participants *Bilangan peserta selesai*		
Number of missing participants *Bilangan peserta hilang*		
Number of participants discontinued/ withdrawn *Bilangan peserta diberhentikan/ menarik diri*		
Number of active participants *Bilangan peserta aktif*		

Part C: Submission for monitoring
Bahagian C: Serahan untuk pemantauan

☐ Protocol Amendment *Pindaan Protokol* ☐ Protocol Deviation *Pelanggaran Protokol* ☐ Change in informed consent *Perubahan persetujuan termaklum* ☐ Change in investigator brochure *Perubahan brosur penyelidik* ☐ Annual Report *Laporan Tahunan* ☐ SUSAR	☐ Investigator addition/change *Penambahan/ perubahan penyelidik* ☐ Site addition *Penambahan lokasi* ☐ Adverse Event Reporting *Pelaporan Kejadian Buruk* ☐ Suspension *Penggantungan* ☐ Early termination *Penamatan Awal* ☐ CIOMS Form *Borang CIOMS* ☐ Others (please state) *Lain-lain (Sila nyatakan)* _____ _____

Tick more than one if applicable
Tandakan lebih daripada satu jika berkaitan

Protocol Amendments ***Pindaan Protokol***	**No** ***Tidak***	**Yes (explain)** ***Ya (jelaskan)***
Intervention *Intervensi*		
Study population *Populasi kajian*		
Sample size *Saiz sampel*		
Duration *Jangkamasa*		
Others *Lain-lain*		

Protocol Deviation ***Pindaan Protokol***	**No** ***Tidak***	**Yes (explain)** ***Ya (jelaskan)***
Administration of Investigational Product (IP) *Penyampaian produk kajian*		
Follow up visit *Lawatan susulan*		
Handling of IP *Pengendalian produk kajian*		
Others *Lain-lain*		

Change in informed consent: ***Perubahan persetujuan termaklum:***	**No** ***Tidak***	**Yes (explain)** ***Ya (jelaskan)***
Intervention *Intervensi*		
Duration *Jangkamasa*		
Updated indication *Indikasi terkini*		
Updated adverse events *Kesan buruk terkini*		
Others *Lain-lain*		

Change in investigator brochure: ***Perubahan brosur penyelidik:***	**No** ***Tidak***	**Yes (explain)** ***Ya (jelaskan)***
Intervention *Intervensi*		
Duration *Jangkamasa*		
Updated indication *Indikasi terkini*		
Updated adverse events *Kesan buruk terkini*		
Others *Lain-lain*		

Investigator addition/ change: ***Penambahan/ penukaran penyelidik:***	**No** ***Tidak***	**Yes (explain)** ***Ya (jelaskan)*** ***Please provide justification for the addition / change of investigator(s)** ****Sila sertakan justifikasi terhadap penambahan / penukaran penyelidik***
Addition *Penambahan*		
Change *Perubahan*		
Good Clinical Practice (GCP) trained *Terlatih dalam Amalan Klinikal yang Baik*		
Others *Lain-lain*		

Site addition/ change ***Penambahan/ penukaran lokasi***	**No** ***Tidak***	**Yes (explain)** ***Ya (jelaskan)***
Addition *Penambahan*		
Change *Perubahan*		
Others *Lain-lain*		

Adverse Events ***Kejadian Kesan Buruk***	**No** ***Tidak***	***Yes (explain)*** ***Ya (jelaskan)***
Data and Safety Monitoring Board (DSMB) report *Laporan Lembaga Pemantauan Data dan Keselamatan*		
Total number of reports *Jumlah bilangan laporan*		
Total number of Serious Adverse Event (SAE) *Jumlah bilangan kejadian kesan buruk yang serius*		
Total number of deaths *Jumlah bilangan kematian*		
Total number of Events of Clinical Interest (ECI) *Jumlah kejadian klinikal yang berkepentingan*		
Total number of Suspected Unexpected Serious Adverse Reaction (SUSAR) *Jumlah kejadian klinikal serius diluar jangkaan yang disyaki*		
Adverse Event at UiTM Site *Kejadian buruk di lokasi UiTM*		
Total number of reports *Jumlah bilangan laporan*		
Total number of Serious Adverse Event (SAE) *Jumlah bilangan kejadian kesan buruk yang serius*		
Total number of Events of Clinical Interest (ECI) *Jumlah kejadian klinikal yang berkepentingan*		
Total number of Suspected Unexpected Serious Adverse Reaction (SUSAR) *Jumlah kejadian klinikal serius diluar jangkaan yang disyaki*		
Total number of deaths *Jumlah kematian*		
Others (please state) *Lain-lain (sila nyatakan)*		

Suspension ***Penggantungan***
Briefly explain *Nyatakan secara ringkas*

Early termination ***Penamatan awal***
Briefly explain *Nyatakan secara ringkas*

Research Leader Verification ***Pengesahan Ketua Penyelidikan***	
Signature & Stamp : *Tandatangan & Cop :*	Date : *Tarikh :*