UITM RESEARCH ETHICS COMMITTEE (REC) GUIDE FOR APPLICANTS

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INTRODUCTION

Requirement for research ethics approval

UiTM REC approval is mandatory for all research involving human subjects*, conducted by:

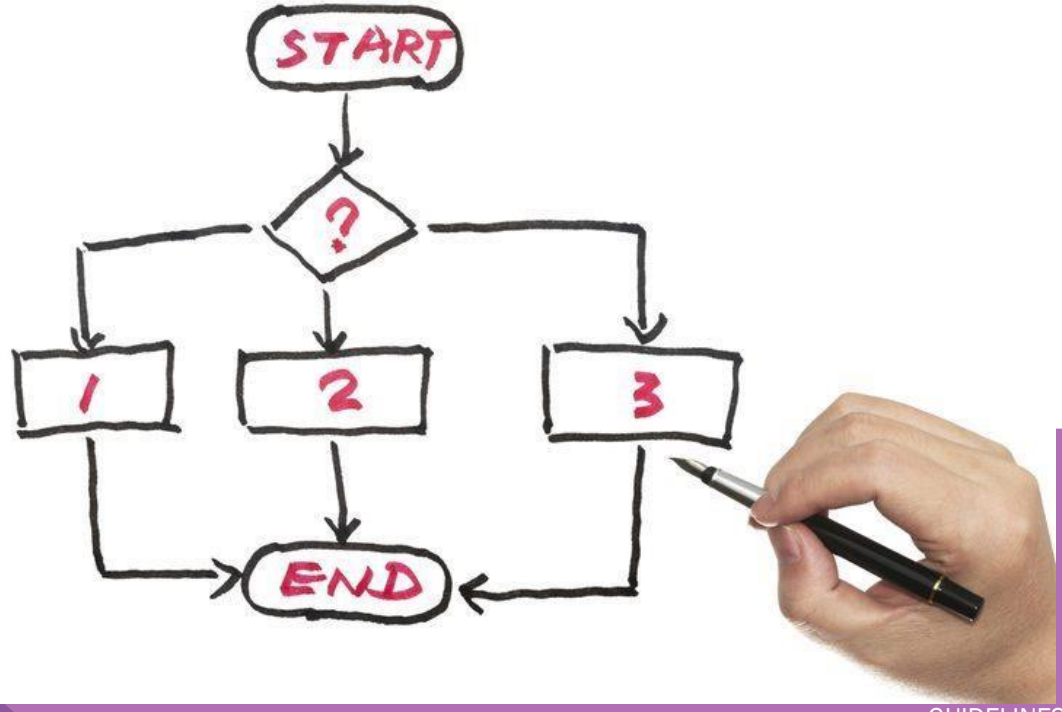
i. UiTM staff
ii. UiTM students
iii. external parties conducting research on UiTM staff and students, and/or in UiTM premises

**UiTM Policy for Research Ethics Involving Human Subjects (2019)*

REC 1 FORM

Flowchart of Research Ethics Approval

Carta Alir Kelulusan Etika



Categories of reviews

Full board

- More than minimal risk - presentation at REC meeting

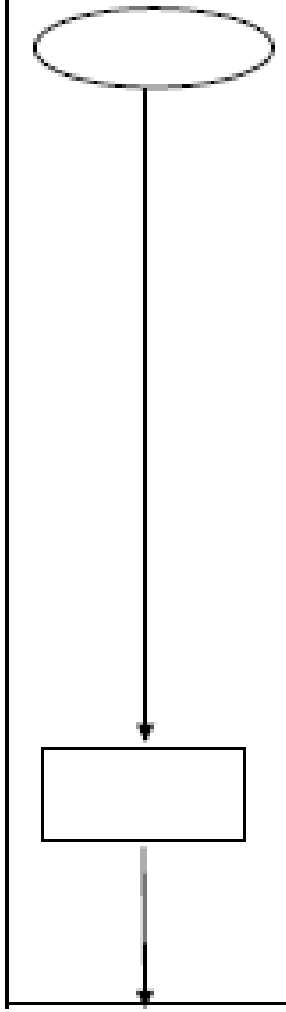
Minimal risk

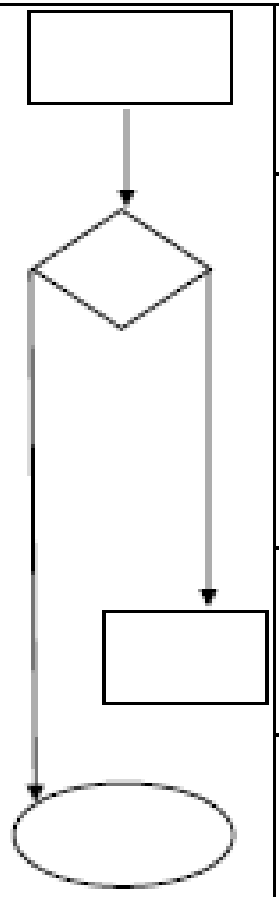
- Expedited review

Flowchart I: Research Ethics Approval Application for Minimal Risk (MR) Research

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

Flowchart I: Research Ethics Approval Application for Minimal Risk (MR) Research

Flow	Process/ Activity	Record/reference	Personnal	Timeline
	Complete and submit the relevant ethics approval application forms to the JPF/JPN secretariat: 1. Application Form for Ethics Approval (REC 2). 2. Research Risk Classification Form (REC 3). 3. Subject Information Sheet (REC 4) and Assent form (REC12) (if applicable). 4. Checklist for Applicants (REC 5). OR Application of Exemption from Ethical Review (REC 11) (if applicable).	Forms: REC 2,3,5 and 4/and 12 Form: REC 11 (if applicable)	Applicants	
	Screening of REC 2,3,5 and 4/and 12 or REC 11 forms JPF/JPN secretariat to submit completed forms (softcopy) and related documents to REC secretariat by uploading at the following link: https://forms.gle/KdyINMNsLT2UR6fL7 or email recultmsubmit@gmail.com	Cover letter from JPF/JPN Forms REC 2,3,5 and 4/and 12 or REC 11 (softcopy). Other relevant documents.	JPF/JPN secretariat	Within 14 working days upon submission*

	Screening of REC 2,3,5 and 4 /and 12 or REC 11 forms	Forms REC 2,3,5 and 4 /and 12 or REC 11. Other relevant documents.	REC Secretariat	7 working days*
	Reviewing process and decision by the reviewer: I. Approved II. Conditional Approvals: • Minor corrections: Amendments within one (1) month. • Major corrections: Amendments within three (3) months.	Forms REC 2,3,5 and 4 /and 12 or REC 11. Other relevant documents.	REC Members/ Associate Members	7 working days*
	If decision by reviewer is MMR refer to Flowchart II.			
	Notification to the applicants	Notification of decision via email	REC Secretariat	7 working days

*Considering no amendments required

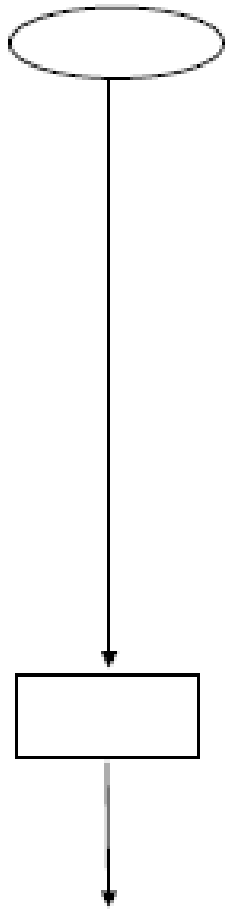
Terms of Submission of Ethics Approval Application

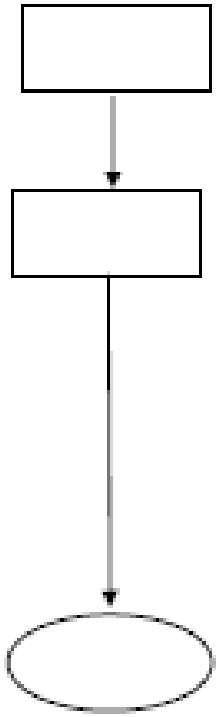
1. All incomplete forms will be returned.
2. Only approved applications by JPF/JPN will be submitted to REC.
3. Any data collection instruments requiring respondent/subject/participant input must be prepared in both Malay and English languages, and other language(s) understood by the respondent/subject/participant (if necessary)
4. Submission of Research Completion Report Form (REC 8 form) within 2 months upon completion of research.

Flowchart II: Research Ethics Approval Application for More than Minimal Risk (MMR) Research

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

Flowchart II: Research Ethics Approval Application for More than Minimal Risk (MMR) Research

Flow	Process/ Activity	Record/reference	Personnel	Timeline
	Complete and submit the relevant ethics approval application forms to the JPF/JPN secretariat: 1. Application Form for Ethics Approval (REC 2). 2. Research Risk Classification Form (REC 3). 3. Subject Information Sheet (REC 4) and Assent form (REC12) (if applicable). 4. Checklist for Applicants (REC 5). OR Application of Exemption from Ethical Review (REC 11) (if applicable).	Forms: REC 2,3,5 and 4/and 12 Form: REC 11 (if applicable)	Applicants	
	Screening of REC 2,3,5 and 4/and 12 or REC 11 forms JPF/JPN secretariat to submit completed forms (softcopy) and related documents to REC secretariat by uploading at the following link: https://forms.gle/KdyINMNsLT2UR6fL7 or email recultmsubmit@gmail.com Submission to REC at least two (2) weeks before the subsequent meeting (3rd Tuesday of each month).	Cover letter from JPF/JPN Forms REC 2,3,5 and 4/and 12 or REC 11 (softcopy). Other relevant documents.	JPF/JPN secretariat	Within 14 working days upon submission*

	Screening of REC 2,3,5 and 4 /and 12 or REC 11 forms	Forms REC 2,3,5 and 4 /and 12 or REC 11. Other relevant documents.	REC Secretariat	7 working days*
	Full board presentation by applicants to REC committee I. Approve II. Conditional Approval: • Minor corrections: Amendments within one (1) month. • Major corrections: Amendments within three (3) months. III. Reject	Forms REC 2,3,5 and 4/12 or REC 11. Other relevant documents.	Applicants, REC Committee	3rd Tuesday of each month
	Notification to the applicants	Notification of decision via email	REC Secretariat	14 working days

*Considering no amendments required

Terms of Submission of Ethics Approval Application

1. All incomplete forms will be returned.
2. Only approved applications by JPF/JPN will be submitted to REC.
3. Any data collection instruments requiring respondent/subject/participant input must be prepared in both Malay and English languages, and other language(s) understood by the respondent/subject/participant (if necessary)
4. Submission of Research Completion Report Form (REC 8 form) within 2 months upon completion of research.

Terms of condition for Clinical Trials

1. Submission of Monitoring of Ongoing Studies Form (REC 6 Form) every 6 or 12 months upon approval.

REC 2 FORM

Application Form for Ethics Approval

Borang Permohonan Kelulusan Etika

REC 2 FORM

REC 2 consists of the following 5 sections:

I. Part A: Researcher Details
II. Part B: Research Details
III. Part C: Funding
IV. Part D: Agreement to conduct the research project.
V. Part E: Verification of Faculty/State Research Committee

Applicants are required to complete **ALL** sections.

BAHAGIAN A: Maklumat Penyelidik
Part A : Details of Researcher

Tajuk Penyelidikan :
Title of Research Project :

Nama Penyelidik*:
Name of Researcher :

Nama Penyelia:
Name of Supervisor :

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

No.Telefon/ Emel :
Contact No/ Email :

Nama Koordinator Kajian**:
Name of Study coordinator:

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

☐ *Sarjana Muda / *Undergraduate*
☐ *Pasca Siswazah / *Postgraduate*
☐ *Staf/Pensyarah / *Staff/Lecturers*
☐ *Pihak Luar / *External*

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

Title should contain the independent variable, dependent variable and population. Do not exceed 15 words

Researcher can be undergraduate student/ postgraduate student/ staff or external applicant

Supervisor (for undergraduate or postgraduate students)

Department, Faculty, Campus or External Institution

Contact details of the researcher (not the supervisor)

This section is for **Clinical Trials** only.
If the study is not a Clinical Trial, please write "not applicable". **Do not** leave blank.

Please select (tick) the appropriate option

Adakah penyelidikan ini memerlukan kelulusan Jawatankuasa Etika Penyelidikan Luaran? (contoh MREC) *Does the research require an external Research Ethics Committee approval? (e.g. MREC)*	
☐ Ya / Yes ☐ Tidak / No	External Committee Name:

Select (tick) “Yes” if the study involves premises governed by external bodies (eg. Studies conducted at the Ministry of Health hospitals require approval of the Medical Research Ethics Committee (MREC).
Provide the name of the external Research Ethics Committee.

Dana Penyelidikan: Ada/ Tiada
Research funding: Yes/ No

Jika ada, sila lengkapkan bahagian C.
If obtained, please complete section C.

Select (tick) “Yes” if the study is funded
Select (tick) “No” if the study is not funded

BAHAGIAN B: Maklumat Penyelidikan *Part B : Research Details*

Bahagian B1 ***Part B1***	
☐ Temubual *Interviews*	☐ Kajian kes *Case study*
☐ Kumpulan focus *Focus groups*	☐ Kajian klinikal *Clinical trial study*
☐ Soal selidik *Questionnaires*	☐ Kajian intervensi *Intervention study*
☐ Kajian tindakan *Action research*	☐ Rekod peribadi *Personal records*
☐ Pemerhatian *Observation*	☐ Analisis data sekunder *Secondary data analysis*
	☐ Lain-lain, (nyatakan) *Others (provide details):*

Select (tick) the appropriate research details (you may select more than one)

Bahagian B2 *Part B2*	
1.	**Latar belakang:** *Background:* (Keterangan ringkas tentang masalah yang dikaji dan penyemakan literatur untuk menyokong keterangan tentang masalah yang dikaji. Sila lampirkan sekiranya ruang tidak mencukupi) *(A brief explanation of the problem to be studied and literature review to support. Please append if more space is required)* **Penyataan masalah:** *Problem statement:* **Rujukan**: *References:*

Briefly describe the study.
The description should include the independent variable, dependent variable and the population

Include only **references cited** in the Background Section

2.	**Objektif penyelidikan:** *Research objectives:*
3.	**Faedah yang dijangka:** *Expected benefits:*

Should be numbered.
Use measurable verbs (eg. to compare, to measure etc.)

Briefly describe social benefits to the study subjects/researchers/stakeholders, and expansion of the existing knowledge

4.	**Tarikh penyelidikan bermula-berakhir:** *Date of research commencement-end:*
5.	**Jangkaan tarikh pengumpulan data bermula:** *Expected date of initial data collection:*

For undergraduates studies, at least two semesters or until the study is completed. (eg: March 2020 – February 2021)

Date should be **after REC approval.**
Allow at least two months interval from the date of complete document submission (eg. if completed documents are submitted in March 2020, expected date of initial data collection should be in May 2020)

6.	**Lokasi penyelidikan dijalankan:** *Location of research:* 	Location should be specific (eg: Faculty of Sports Science, UiTM Shah Alam, Dataran Kemerdekaan etc.)
7.	**Rekabentuk penyelidikan dan metodologi:** *Research design dan methodology:*	Specify the study design (eg. cross sectional/ experimental) Describe the methodology i.e. data collection procedure, tools etc. (eg. in a questionnaire-based study describe the number of domains, number of items and scoring of the questionnaire)
8.	**Kriteria kemasukan dan pengecualian:** *Inclusion and exclusion criteria:* **Kriteria kemasukan:** *Inclusion criteria:* • **Kriteria pengecualian:** *Exclusion criteria:* •	Characteristics of the samples/ respondents to be included and excluded from the study
9.	**Saiz sampel:** *Sample size:* **Calculation:** *Pengiraan:*	Indicate the sample size (taking into consideration dropout/attrition rates. Provide the calculation for sample size. If the calculation is based on a previous study, please cite and attach the reference.

10.	**Carta alir penyelidikan:** *Research flowchart:*	A summary of Part B2 (Item 7)
11.	**Analisa statistik:** *Statistical analysis:*	Should appropriately address the Objectives in Part B2 (2). Explain whether descriptive or inferential statistics will be used. If inferential, explain the type of statistical test to be used (eg T-test, ANOVAetc.)

Bahagian C: Maklumat Dana
Part C: Funding details

1.	**Geran / Sumber:** *Grant / Source:*	
2.	**Jumlah peruntukan:** *Total allocation:*	
3.	**Jangkamasa peruntukan:** *Duration of grant:*	
4.	**Yuran perkhidmatan penyelidik / professional :** *Investigator services / professional fees:*	
5.	**Yuran kepada UiTM :** *UiTM fees :*	
6.	**Lain-lain kemudahan / sumber disediakan organisasi penaja / syarikat kepada penyelidik:** *Other facilities/resource provided by sponsoring organisation / company to investigator:*	
7.	**Nama dan alamat penyelidik tempatan / Organisasi Penyelidikan Klinikal (OPK) yang ditaja:** *Name and address of local sponsor / Clinical Research Organisation (CRO):*	

If the study is funded, please provide details.
If the study is not funded, please state "Not Applicable"

Please complete this section if the study is a sponsored clinical trial.
If the study is not a clinical trial, please state "Not Applicable"

Bahagian C: Maklumat Dana
Part C: Funding details

1.	**Geran / Sumber:** *Grant / Source:*	N/A
2.	**Jumlah peruntukan:** *Total allocation:*	N/A
3.	**Jangkamasa peruntukan:** *Duration of grant:*	N/A
4.	**Yuran perkhidmatan penyelidik / professional :** *Investigator services / professional fees:*	N/A
5.	**Yuran kepada UiTM :** *UiTM fees :*	N/A
6.	**Lain-lain kemudahan / sumber disediakan organisasi penaja / syarikat kepada penyelidik:** *Other facilities/resource provided by sponsoring organisation / company to investigator:*	N/A
7.	**Nama dan alamat penyelidik tempatan / Organisasi Penyelidikan Klinikal (OPK) yang ditaja:** *Name and address of local sponsor / Clinical Research Organisation (CRO):*	N/A

If the study is funded, please provide details.
If the study is not funded, please state "Not Applicable"

Please complete this section if the study is a sponsored clinical trial.
If the study is not a clinical trial, please state "Not Applicable"

Bahagian D: Pengesahan persetujuan menjalankan penyelidikan.
Part D: Agreement to conduct the research project.

Mesti dilengkapkan dan ditandatangani oleh semua ahli kumpulan penyelidikan.
Must be completed and signed by all members of the research group.

1. Penyelidik utama (untuk dilengkapkan oleh Staf Akademik/Pelajar Pasca-siswazah sahaja)
   Principal Researcher (to be filled by Academic Staf/Post-graduate Student only)

Nama: *Name:*		
No.Staf/No. Pelajar: *Staff ID/Student ID:*		
Jawatan/ Kepakaran: *Position/ Specialisation:*		
Jabatan: *Affiliation:*		
Telefon pejabat: *Office:*		
Telefon bimbit: *Mobile phone:*		
Emel: *Email:*		
Tandatangan: *Signature:*		**Tarikh:** *Date:*

This section is to be completed and signed by **staff/ postgraduate students** only

2. Penyelia (sekiranya ada)
Supervisor (If any)

Nama: *Name:*		
No.Staf: *Staff ID:*		
Jawatan/ Kepakaran: *Position/ Specialisation:*		
Jabatan: *Affiliation:*		
Telefon pejabat: *Office:*		
Telefon bimbit: *Mobile phone :*		
Emel: *Email:*		
Tandatangan: *Signature:*		**Tarikh :** *Date:*

This section is to be completed and signed by **supervisors** only (if any)
If there are no supervisors involved, please state “Not Applicable”

3. Penyelidik Bersama
Co-Researcher

Nama: *Name:*		
No.Staf/No. Pelajar: *Staff ID/Student ID:*		
Jawatan/ Kepakaran: *Position/ Specialisation:*		
Jabatan: *Affiliation:*		
Telefon pejabat: *Office:*		
Telefon bimbit: *Mobile phone :*		
Emel: *Email:*		
Tandatangan: *Signature:*		**Tarikh:** *Date:*

(Tambah sekiranya perlu. *Add if necessary*)

This section is to be completed and signed by **undergraduate students/ co-researchers** (may be more than one)
Please duplicate the tables for addition of more than one undergraduate student/ co-researcher.

Bahagian E: Pengesahan Jawatankuasa Penyelidikan Fakulti/Negeri
Part E: Verification from Faculty/State Research Committee

Kami telah meneliti permohonan ini dan mencadangkan seperti di bawah:
We have deliberated on the application and propose as below:

☐ Penyelidikan melibatkan risiko minima. Dicadangkan untuk mendapat kelulusan tanpa pembentangan.
Minimal risk research. Recommend for approval without presentation.

☐ Penyelidikan melibatkan risiko melebihi minima. Dicadangkan untuk mendapat kelulusan dengan pembentangan.
More than minimal risk research. Recommend for approval with presentation.

Ulasan jika ada:
Comment if any:

Signed		
Tandatangan *Signature:* **Pengerusi/Pengerusi Ganti JK Penyelidikan Fakulti/Negeri** *Chairman/Co-chairman of Faculty/State Research Committee*	**Cop rasmi:** *Official stamp:*	**Tarikh:** *Date:*

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

To be **signed, stamped and dated by the Chair or Co-Chair of Faculty/State Research** Committee after forms have been checked for completion, and amendments made according to suggestions by the Research Committee

REC 3 FORM

Research Risk Classification Form

Borang Klasifikasi Risiko Kajian

REC 3 FORM

Contains 4 sections:

i. Subject profile
ii. Privacy and confidentiality
iii. Risk of harm
iv. Other ethical issues

Please answer each item in the REC 3 form by selecting (ticking) the option that applies.
If “Yes” is selected, please describe details of risk and how the risk is minimized

Do not leave any items blank.
If any of the items in the REC 3 form does not apply to your research, please state “**Not Applicable**”

SILA JAWAB KESEMUA SOALAN DI BAWAH.
Sekiranya jawapan anda **'Ya'** kepada mana-mana soalan di bawah, sertakan maklumat ringkas di ruang yang disediakan.

PLEASE ANSWER ALL QUESTIONS BELOW.
*If your answer is **'Yes'** to any of the following questions, please include a brief information in the space provided.*

	SUBJECTS' PROFILE	No	Yes	Brief description
1.	Adakah subjek kanak-kanak (Umur di bawah 18 tahun)? *Are the subjects children (under 18 years old)?*			
2.	Adakah subjek daripada golongan rentan? (cth: kecelaruan mental, kelainan keupayaan intelektual, berkeperluan khas, minoriti dan sebagainya.) *Are the subjects from a particular vulnerable group? (e.g. mental disorder, mentally challenged, disabled, minority, disadvantaged group etc.)*			
3.	Adakah subjek/pesakit ini memerlukan rawatan terminal? *Are any of these subjects/patients in terminal care?*			

4.	Adakah subjek tidak boleh atau tidak berupaya memberi izin? (spt: izin akan diambil secara tidak langsung daripada penjaga sah dan sebagainya.) *Are any of these subjects unable or are incapable of giving consent?* *(i.e. consent will be obtained indirectly from a legal guardian etc.)*			
5.	Adakah subjek diberi sebarang emolumen untuk menyertai kajian? *Are the subjects given any form of emolument to participate?*			

	PRIVACY AND CONFIDENTIALITY	No	Yes	Brief description
6.	Adakah data yang dikumpul berpotensi untuk menyebabkan ketidak selesaan, keaiban atau gangguan psikologi kepada subjek? (cth: orientasi seksual dan sebagainya.) *Does any of the data collected have the potential to cause discomfort, embarrassment, or psychological harm to the subjects?* *(e.g. sexual orientation etc.)*			
7.	Adakah penyelidikan anda melibatkan langkah-langkah yang tidak dimaklumkan kepada subjek? (cth: pemerhatian rahsia dan sebagainya.) *Does your research involve measures undeclared to the subjects?* *(e.g. covert observations etc.)*			
8.	Adakah data yang dikumpulkan akan didedahkan kepada pihak lain yang tidak terlibat dalam penyelidikan? (cth. agensi kerajaan) *Will the collected data be made available to other parties not involved in the research? (e.g. government agencies)*			

	RISK OF HARM	No	Yes	Brief description
9.	Adakah anda akan mengumpul sampel biologi contohnya. cecair badan? *Will you be collecting biological samples e.g. body fluids?*			
10.	Adakah anda mempunyai akses kepada apa-apa maklumat yang akan membolehkan pengenalpastian subjek secara individu? *Do you have access to any information that will allow the identification of individual human subjects?*			
11.	Adakah kaedah pengumpulan invasif dan berpotensi menyebabkan kemudaratan, kesakitan atau ketidakselesaan? (kecuali tusukan jari, tumit, telinga.) *Is the collection method invasive and has the potential to cause harm, pain or discomfort? (except finger, heel, ear prick.)*			
12.	Adakah subjek akan melalui ujian fizikal atau senaman berintensiti tinggi? (jika 'Tidak', teruskan ke Soalan 15.) *Will the subjects be subjected to vigorous physical tests or exercise regime? (if 'No', go to Question 15.)*			
13.	Adakah subjek bukan atlet atau pesakit dengan penyakit kronik? *Are the subjects non-athletes or patients with chronic illness?*			
14.	Adakah mereka akan melalui senaman berintensiti maksimum? *Will they be subjected to maximal exercise intensity?*			

15.	Adakah terdapat sebarang prosedur/ ubat yang terlibat? *Is there any form of procedure/ medication involved?*			
16.	Adakah terdapat ubat atau peranti yang digunakan dengan tanpa indikasi yang diluluskan? *Is there any drug or device used with an unapproved indication?*			
17.	Adakah keizinan kajian telah didapati daripada sesiapa selain pesakit/subjek? *Can the informed consent be obtained from anyone other than the patient/subject?*			
18.	Adakah terdapat sebarang kemudaratan kepada subjek jika dia memilih untuk menarik diri? *Is there any kind of risk to the subject if he/she chose to withdraw?*			

19.	Adakah sampel yang dikumpul akan disimpan untuk penyelidikan di masa hadapan? *Will the samples obtained be stored for future research?*			
20.	Adakah anda bercadang untuk menganalisa sampel selain tujuan asal ia dikumpulkan? *Do you propose to analyse the sample outside of the original purpose for which it was collected?*			
21.	Jika 'Ya' pada No. 20, adakah anda mendapat persetujuan daripada peserta untuk tujuan ini? *If 'Yes' to No. 20, have you obtained consent from participants for this purpose?*			
22.	Apakah jenis sampel biologi yang dikumpul? (Sila nyatakan jumlah dan kekerapan.) *What type of biological samples collected?* *(Please indicate amount and frequency.)*			

	OTHER ETHICAL ISSUES	No	Yes	Brief description
23.	Adakah terdapat sebarang isu etika lain yang tidak dinyatakan dalam senarai semak ini? *Are there any other ethical issues not stated in this checklist?*			

REC 4 FORM

Subject Information Sheet

Borang Maklumat Subjek

REC 4 FORM

Contains 2 sections:

i. Borang Maklumat Subjek

Subject Information Sheet

ii. Borang Izin

Consent Form

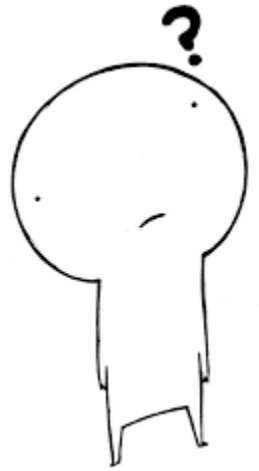
REC 4 – SUBJECT INFORMATION SHEET

i. Include both Malay and English versions. If the study population does not understand either Malay or English, include a version in the spoken language of the population.

ii. Ensure that versions in all languages carry the same meaning.

iii. Please use non-expert language (Do not include technical jargon).

REC 4 – SUBJECT INFORMATION SHEET



iv. Do not include citations

v. The **Introduction** Section should be brief.
Cover information that is important and relevant to the subject.

iv. Remove all the **instructions** (in the brackets) when the form has been completed.

v. Should be worded as an explanation to the subject/ legal guardian (LAR)
(eg. You/your child will be requested to answer questions)

Subject Information Sheet

Research Title
(State)

Introduction of Research
(Maximum of 300 words using non-expert language/terms)

Purpose of Research
(Maximum of 150 words using non-expert language/terms)

Research Procedure
(Using non-expert language/terms)

Participation in Research
Your participation in this research is entirely voluntary. You may refuse to take part in the study or you may withdraw yourself from participation in the research at any time without penalty.

Benefit of Research
(State the benefit to subjects)

Information obtained from this research will benefit the individuals, researchers, institution and community for the advancement of knowledge and future practice.

Research Risk
(State the risks involved)

Confidentiality
(Include the confidentiality clause provided below)

Your information will be kept confidential by the investigators and will not be made public unless disclosure is required by law.

By signing this consent form, you will authorize the review of records, analysis and use of the data arising from this research.

If you have any question about this research or your rights, please contact *(state the name of the investigator)* at *(state the direct telephone number of the said investigator)*

State the title of the study

Briefly introduce the study

Briefly explain in simple terms the purpose of the study

Briefly explain procedures/protocol involving the subject

The statement provided as example in the form may be retained if relevant

Briefly explain how the study will benefit the subject

Briefly explain risks (if any) to the subjects (eg minimal discomfort during procedure, time consuming protocols, fatigue due to the protocol)
Explain how the risks will be minimized and what safety precautions will be taken

The statement provided on confidentiality as example in the form may be retained if relevant

Subject Information Sheet

Research Title
(State)

Introduction of Research
(Maximum of 300 words using non-expert language/terms)

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Your information will be kept confidential by the investigators and will not be made public unless disclosure is required by law.

By signing this consent form, you will authorize the review of records, analysis and use of the data arising from this research.

If you have any question about this research or your rights, please contact *(state the name of the investigator)* at *(state the direct telephone number of the said investigator)*

If the Subject Information Sheet is used to explain to the legal guardian (LAR) of a minor, phrase sentences using "your child" instead of "you".

Provide the name and direct telephone numbers of contact person for the study.

REC 4: CONSENT FORM

Consent Form[1]

To become a subject in the research, you or your legal guardian are required to sign this Consent Form.
I herewith confirm that I have met the requirement of age and am capable of acting on behalf of myself / as[2] a legal guardian as follows:

1. I understand the nature and scope of the research being undertaken.
2. I have read and understood all the terms and conditions of my participation in the research.
3. All my questions relating to this research and my participation therein have been answered to my satisfaction.
4. I voluntarily agree to take part in this research, to follow the study procedures and to provide all necessary information to the investigators as requested.
5. I may at any time choose to withdraw from this research without giving any reason.
6. I have received a copy of the Subjects Information Sheet and Consent Form.
7. Except for damages resulting from negligent or malicious conduct of the researcher(s), I hereby release and discharge UiTM and all participating researchers from all liability associated with, arising out of, or related to my participation. I agree to hold them harmless from any harm or loss that may be incurred by me due to my participation in the research.

Name of Subject/Legally authorized representative (LAR)	Signature
I.C No	Date
Name of Witness[3]	Signature
I.C No	Date
Name of Consent Taker	Signature
I.C No	Date

Ensure that the consent form is completed.
The original consent form is to be retained by the researcher.
A duplicate copy is provided to the subject/ legal guardian (LAR)

REC 5 FORM

Checklist for Applicants

Senarai Semak Pemohon

REC 5 FORM

Contains 3 sections:

i. Part A: For all applicants
ii. Part B: For clinical trial applicants only
iii. Part C: For all applicants

Signature of the researcher on **Page 4** is **required**

	ITEM *PERKARA*	YES *YA*	NO *TIDAK*
Part A – For All Applicants *Bahagian A – Untuk Semua Pemohon*			
1	Have you completed the REC 2 form? *Adakah anda telah melengkapkan Borang REC 2?*		
2	Have you completed the REC 3 form? *Adakah anda telah melengkapkan Borang REC 3?*		
3	Have you completed the REC 4 form? *Adakah anda telah melengkapkan Borang REC 4?*		
4	Has the form been signed by all researchers? *Adakah borang ditandatangani oleh semua penyelidik?*		
5	Has your application been approved and endorsement by your Faculty/State Research Committee? *Sudahkah permohonan anda mendapat kelulusan dan pengesahan Jawatankuasa Penyelidikan Fakulti/Negeri?*		
6	Has your supervisor checked for grammatical errors in REC 2 and REC 4 forms? *Adakah penyelia anda telah menyemak untuk kesalahan tatabahasa dalam Borang REC 2 dan Borang REC 4?*		

* For **Clinical Trials**, please complete Part B. For **Non-Clinical Trial** application please proceed to Part C, and sign on page 5.

*Bagi permohonan **Penyelidikan Klinikal**, sila lengkapkan Bahagian B. Bagi permohonan penyelidikan **Bukan Klinikal** sila isi Bahagian C dan tandatangan di Halaman 5.*

Part B – For Clinical Trial Applications* ***Bahagian B – Untuk Permohonan Penyelidikan Klinikal****			
6	Have you submitted a cover letter for application? *Adakah anda telah menghantar surat iringan bagi untuk permohonan?*		
7	Have you submitted: - Study Protocol - Study amendments (if applicable) - Case Report Forms (CRF) *Adakah anda telah menghantar:* - *Protokol Penyelidikan* - *Pindaan Protokol (jika berkaitan)* - *Borang Laporan Kes*		
8	Have you submitted documents given to trial subjects such as: - Information of study - Advertisement of subject recruitment *Adakah anda telah menghantar dokumen-dokumen yang diberikan kepada subjek penyelidikan seperti:* - *Maklumat Penyelidikan* - *Iklan bagi pengambilan subjek*		
9	Have you submitted signed agreement between involved parties: - Investigator and sponsor - Investigator and Contract Research Organization(CRO) *Adakah anda telah menghantar dokumen perjanjian yang telah ditandatangani antara pihak-pihak yang terlibat:* - *Penyelidik dan penaja* - *Penyelidik dan Contract Research Organization(CRO)*		

10	Have you submitted the Investigator's Brochure? *Adakah anda telah menghantar risalah penyelidikan?*		
11	Have you submitted the Financial Agreement with sponsor? *Adakah anda telah menghantar dokumen perjanjian kewangan bersama penaja?*		
12	Have you submitted the Insurance Statement and related documents? *Adakah anda telah menghantar penyata insurance dan dokumen-dokumen berkaitan?*		
13	Have you submitted the clinical trial agreement (CTA)? The completed CTA with signature must be submitted within three (3) months of REC approval.		

	Adakah anda telah menghantar dokumen perjanjian penyelidikan klinikal? Dokumen perjanjian penyelidikan klinikal yang lengkap dengan tandatangan perlu dihantar tiga (3) bulan selepas kelulusan Jawatankuasa Etika Penyelidikan (REC).		
14	Have you submitted Curriculum Vitae of all investigators involve in study? The CVs submitted must be dated, signed and stamped. *Adakah anda telah menghantar Curriculum Vitae (CV) bagi semua penyelidik terlibat? Curriculum Vitae penyelidik perlu ditandatangan berserta cop dan tarikh.*		
15	Have you submitted Good Clinical Practice certificates of all Investigators? *Adakah anda telah menghantar sijil Good Clinical Practice bagi semua penyelidik?*		
16	Have you submitted the Annual Practicing Certificate (APC)? The APCs submitted must be signed, stamped and dated. *Adakah anda telah menghantar Annual Practicing Certificate (APC)? Annual Practicing Certificate penyelidik perlu ditandatangan berserta cop dan tarikh.*		

Part C – For All Applicants ***Bahagian C – Untuk Semua Pemohon***			
	1. Please upload the scanned forms to the following link: *Sila muat naik salinan borang asal permohonan (REC 2, REC 3, REC 4 / REC12, REC 5) yang lengkap ditandatangan beserta cop dan tarikh ke pautan berikut:* *https://forms.gle/KdyiNMNsLT2UR6fL7* You are advised to submit your application at least TWO (2) working weeks before the meeting (please check the meeting schedule at the website: http://uitmethics.uitm.edu.my) *Anda dinasihatkan untuk menyerahkan borang permohonan sekurang-kurangnya DUA (2) minggu hari bekerja sebelum tarikh mesyuarat (Sila semak tarikh mesyuarat di laman sesawang: http://uitmethics.uitm.edu.my)*		
	You may be invited to present your applications. *Anda mungkin dijemput untuk membentangkan permohonan anda.*		

Decisions for the applications will be informed within TWO (2) working weeks after the meeting.
Decisions:
Keputusan permohonan akan dimaklumkan DUA (2) minggu hari bekerja selepas mesyuarat. Keputusan:

(a) Approved
Lulus

(b) Conditional approval (subject to corrections)
Lulus bersyarat (tertakluk kepada pembetulan)

Applicant is required to:
Pemohon dikehendaki:

- include cover letter indicating the correction/s.
  menyertakan surat iringan memaklumkan pembetulan.
- include supporting documents if necessary.
  menyertakan dokumen sokongan sekiranya perlu.
- highlight the correction/s in the relevant forms.
  tandakan pembetulan dalam borang berkaitan.
- Please upload the scanned amended forms to the following link:
  Sila muat naik salinan imbasan borang pembetulan tersebut ke pautan berikut:

  https://forms.gle/LJ4i6NDepi2Kf93g8 LINK

(c) Re-present
Pembentangan semula
Applicant is required to:
Pemohon dikehendaki:

- include cover letter indicatig the correction/s.
  menyertakan surat iringan memaklumkan pembetulan.
- include supporting documents if necessary
  menyertakan dokumen sokongan sekiranya perlu.
- highlight the correction/s in the relevant forms.
  tandakan pembetulan dalam borang berkitan.
- Please upload the scanned amended forms to the following link:
  Sila muat naik salinan imbasan borang pembetulan tersebut ke pautan berikut:

  https://forms.gle/LJ4i6NDepi2Kf93g8 LINK

- to present again in subsequent REC meeting
  membentang semula pada mesyuarat REC berikutnya

	(d) Not approved due to ethical issues that cannot be satisfactorily resolved. Recommend to resubmit. *Tidak lulus disebabkan penyelesaian isu etika yang tidak memuaskan. Dicadangkan untuk memohon semula.*

Additional comments (if any):
Komen Tambahan (Jika Ada):

Applicant's Signature	Date
Supervisor's Signature	Date

REC 12 FORM

Assent Form

Borang Persetujuan

REC 12 FORM

i. If research subjects are below 18 (7 – 17) years of age (minors), an **Assent Form** is required.

ii. Assent is defined as a minor's "affirmative agreement" to participate in research.

iii. It is similar to a subject information sheet, but uses simpler, age-appropriate language which can be understood before an decision for participation is made by the minor.

iv. Consent from parents or legally acceptable representative (LAR) overrides dissent of the minor when it involves the safety and wellbeing of the minor

ASSENT FORM

Your parent/legally authorized representative (LAR) has given permission for you to be in a project called *(state name of project here*). We would like to explain it to you, so that you can decide if you want to be in it. If you don't understand, please ask questions. You can choose to be in the study, or not to be in the study, or to take more time to decide.

What is the project about? (*Briefly describe the project)*

Why do I need to be in this project? (*Briefly describe the purpose of the project)*

What should I do in this project? (*Briefly explain the minor's role in the project)*

What will happen to me in the project? (*Briefly explain the risk)*

Do I have to be in the project?

You don't have to be in the project if you don't want to. If you are in the project, you can stop at any time without making anyone upset. If you want to be in the project, please write your name below. Please make sure that you understand what has been explained to you.

Who can I talk to about this project?

If you want to ask anything, you can call me anytime.

Name of Researcher:

Contact number:

Will anyone know about what I say or do in the project? (*Briefly explain the anonymity and confidentiality of research participation)*

Assent Questions:
Instructions to minor: Please circle your answer below.

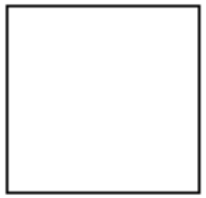
1.	Has somebody explained this project to you?	Yes/No
2.	Do you understand what this project is about?	Yes/No
3.	Do you have any questions about the project?	Yes/No
4.	If you have asked a question, do you understand the answer?	Yes/No
5.	Do you understand it's ok to stop taking part at any time?	Yes/No
6.	Are you ok to take part?	Yes/No
7.	Are you ok for your voice to be recorded?	Yes/No
8.	Are you ok to be on video?	Yes/No
9.	Are you ok to have photographs taken?	Yes/No

If you want to take part, please write your name and sign, or place your thumb print in the box.

Name of participant _____

Signature _____

Date _____



Name of consent taker _____

Signature _____

Date _____

(*In instances where the minor is unable to read, or where the research covers sensitive issues, a witness should attest in the section below)*

Name of witness _____

Signature _____

Date _____

A. **To apply for research ethics approval: fill up**
   i. **REC 2 (APPLICATION FORM)**
   ii. **REC 3 (RISK CLASSIFICATION)**
   iii. **REC 4 or REC 12 (if subjects are minors) (CONSENT FORM)**
   iv. **REC 5 (CHECKLIST)**

Research ethics application guidelines

i. Ethics application forms can be accessed online at the following URL: *https://uitmethics.uitm.edu.my/v1/index.php*

ii. Use **the latest version** of application forms (revision 2019/2020)

iii. Ensure that the application forms are **complete** and **signed** by members of the research team before submission

iv. Submission of all forms prescribed by the REC must be in English, with the exception of research conducted in other languages (with Senate approval)

Research ethics approval application

viii. Before submission to the REC, applications for ethics approval or exemption from ethical review must be approved and endorsed by the **Faculty/State Research Committee**

viii. Only **completed forms** will be forwarded for REC review**. Incomplete applications** and applications with **major grammatical errors** will be returned to applicants for amendments

ix. All required documents must be submitted to the REC within two (2) working weeks before the REC meeting for the month (schedule of REC meeting is available on the REC website)

ENQUIRIES

- Contact : Secretariat

  UiTM Research Ethics Committee

- Email: recsecretariat@uitm.edu.my

- Contact number:
  - 03 - 5544 8069 (Pn. Nur Adilah Ruslee)
  - 03 - 5544 2794 (Pn. Raiminazihah Osman)

ENQUIRIES

- Contact :

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Thank you