UiTM RESEARCH ETHICS COMMITTEE (REC)

GUIDE FOR APPLICANTS

UiTM Research Ethics Committee

10 April 2020

TABLE OF CONTENTS

SUMMARY OF REC FORMS

NO	PROCESS DESCRIPTION	RELEVANT REC FORMS
1	DESCRIPTION OF APPLICATION PROCESS	REC 1 FORM : FLOWCHART OF APPLICATION PROCESS
2	APPLICATION FOR ETHICS APPROVAL	REC 2 FORM : APPLICATION FORM FOR ETHICS APPROVAL REC 3 FORM : RESEARCH RISK CLASSIFICATION FORM REC 4 FORM : SUBJECT INFORMATION SHEET REC 5 FORM : CHECKLIST FOR APPLICANTS REC 10 FORM : COVER LETTER FOR AMENDMENT (FOR CONDITIONAL APPROVALS) REC 12 FORM : ASSENT FORM (FOR STUDIES ON MINORS)
3	APPLICATION FOR THE EXEMPTION OF ETHICS REVIEW	REC 11 FORM : EXEMPTION FROM ETHICS REVIEW APPLICATION FORM
4	PROGRESS REPORT	REC 6 FORM : MONITORING OF STUDIES FORM
5	PROJECT MEMBER AMENDMENT	REC 7 FORM : RESEARCH PROJECT MEMBERSHIP AMENDMENT FORM
6	PROJECT COMPLETION REPORT	REC 8 FORM : PROJECT COMPLETION REPORT FORM
7	REC REVIEW FORM	REC 9 FORM : RESEARCH ETHICS APPLICATION REVIEW FORM (FOR REC REVIEWERS)

INTRODUCTION (1)

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)*

INTRODUCTION (2)

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. REC1: *Flowchart of Research Ethics Approval* summarizes the approval process
iv. To apply for **research ethics approval**, fill up forms REC2, REC 3, REC4, REC5 and REC 12 (if subjects are minors)
v. To apply for **exemption from ethical review**, fill up form REC11
vi. Ensure that the application forms are **complete** and **signed** by members of the research team before submission
vii. Submission of all forms prescribed by the REC must be in English, with the exception of research conducted in other languages (with Senate approval)

INTRODUCTION (3)

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**

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

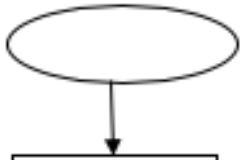
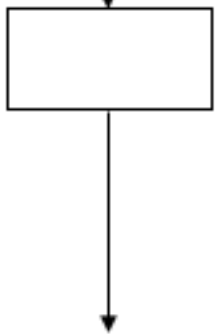
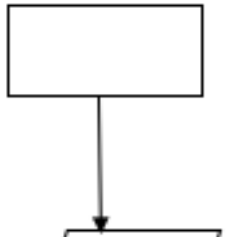
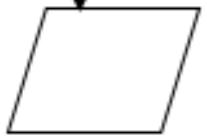
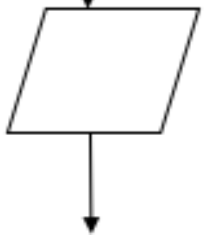
x. Any data collection instruments requiring respondent/subject/participant input must be prepared in both Malay and English languages, and other language/s understood by the respondent/subject/participant (if necessary)

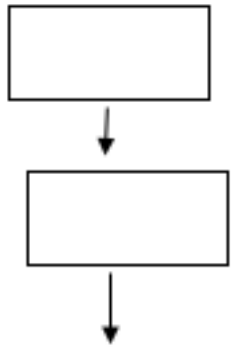
xi. All required documents must be submitted to the REC within two (2) working weeks before the REC meeting for the month (schedule of REC meeting is available on the REC website)

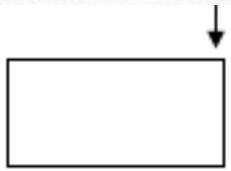
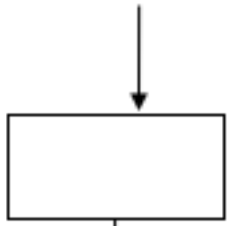
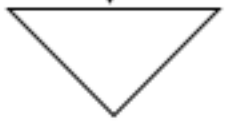
REC 1 FORM

Flowchart of Research Ethics Approval
Carta Alir Kelulusan Etika

Flowchart of Research Ethics Approval Application

Personnel	Flow	Process/ Activity	Record/reference
Researchers & Faculty		Research proposal presentation at the Faculty/State.	Proposal
Researchers		Complete the relevant ethics approval application forms: 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 1. Application of Exemption from Ethical Review (REC 11) (if applicable).	Forms: REC 2,3,5 and 4/12 Form: REC 11 (if applicable)
Researchers		Submit Forms (REC 2,3,5 and 4 and12 (if applicable) or REC 11 (if applicable), and other relevant documents (e.g. questionnaires, survey form, interview protocol) to the Secretariat of the Faculty/ State Research Committee.	Forms REC 2,3,5 and 4/12, or REC 11. Other relevant documents.
Secretariat of the Faculty / State Research Committee		Check for completion of Forms REC 2,3,5 and 4/12 or REC 11 are completed.	Forms REC 2,3,5 and 4/12 or REC 11 Other relevant documents.
Secretariat of the Faculty / State Research Committee		Submit completed forms (*softcopy) and related documents to Secretariat of the REC, at least two (2) weeks before the subsequent meeting. * Please upload the softcopy (scanned forms) at the following link: https://forms.gle/KdyiNMNsLT2UR6fL7 or email recuitmsubmit@gmail.com	Cover letter from Faculty/ State Research Committee Forms REC 2,3,5 and 4/12 or REC 11 (softcopy). Other relevant documents.

REC Secretariat		Check for completion of Forms REC 2,3,5 and 4/12 or REC 11.	Forms REC 2,3,5 and 4/12 or REC 11. Other relevant documents.
REC Secretariat		Sends applications to reviewers	Forms REC 2. Other relevant documents.
REC Secretariat		Confirm that quorum is met for REC meetings scheduled on the 3rd Tuesday of every month	Notice of Meeting
REC Secretariat		Send invitations to researchers (of 'More than Minimal Risk' study protocols) for fullboard presentation to the REC	Letter of Invitation
REC		Report on expedited review applications*. Deliberation and decision on research ethics approval applications	Minutes of Meeting
REC		Approvals without Amendment: Decision will be minuted	Minutes of meeting
REC		Conditional Approvals: Minor corrections: Amendments within one (1) month. Major corrections: Amendments within three (3) months.	Forms REC 2-5. Other relevant documents.

REC Secretariat		Inform researchers of the decision: 1. Within two weeks of the meeting for fullboard presentations. 2. Within a week of review decision for expedited review	Letter of Approval/ Conditional Approval/ Represent/ Resubmit
Researchers		Update the committee of progress and changes in protocol. Submit progress report to the REC every 6 or 12 months after receiving ethics approval.	Form REC 6
Researchers		Submit Research Completion Report Form to the REC upon within 2 months of study completion	Form REC 8

*Decision on expedited review will be given within one week of completed review

REC 2

Application Form for Ethics Approval

Borang Permohonan Kelulusan Etika

REC 2

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:

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 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.

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 Backround 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:*	For undergraduates studies, at least two semesters or until the study is completed. (eg: March 2020 – February 2021)
5.	**Jangkaan tarikh pengumpulan data bermula:** *Expected date of initial data collection:*	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:*
7.	**Rekabentuk penyelidikan dan metodologi:** *Research design dan methodology:*
8.	**Kriteria kemasukan dan pengecualian:** *Inclusion and exclusion criteria:* **Kriteria kemasukan:** *Inclusion criteria:* • **Kriteria pengecualian:** *Exclusion criteria:* •
9.	**Saiz sampel:** *Sample size:* **Calculation:** *Pengiraan:*

Location should be specific (eg: Faculty of Sports Science, UiTM Shah Alam, Dataran Kemerdekaan etc.)

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)

Characteristics of the samples/ respondents to be included and excluded from the study

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, ANOVA etc.)

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 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:

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

Research Risk Classification Form

Borang Klasifikasi Risiko Kajian

REC 3

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

Subject Information Sheet
Borang Maklumat Subjek

REC 4

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.

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

ii. 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)

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)*

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

Checklist for Applicants

Senarai Semak Pemohon

REC 5

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 6

Monitoring of Ongoing Studies Form
Borang Pemantauan Kajian Berterusan

Form REC6 is to be submitted annually until completion of the study.

Borang Pemantauan Kajian Berterusan
Monitoring of Ongoing Studies Form

Permohonan ini dikemukakan untuk tujuan penerimaan/kelulusan pindaan Jawatankuasa Etika Penyelidikan.
Sila lampirkan surat iringan dan dokumen berkaitan.
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.

Bahagian A: Maklumat Penyelidik
Part A : Details of Researcher

Tajuk Penyelidikan :
Title of Research :

Nama Penyelidik*:
Name of Researcher :

Nama Penyelia:
Name of Supervisor :

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

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

Nombor Pendaftaran:
Registration Number:

Tarikh daftar/ Kelulusan:
Date registered/ Approval:

Jangkamasa Kajian:
Research Duration:

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*

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

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

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

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

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

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

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

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

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

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

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

Penambahan/ penukaran penyelidik: ***Investigator addition/ change:***	**Tidak** ***No***	**Ya (jelaskan)** ***Yes (explain)***
Penambahan *Addition*		
Perubahan *Change*		
Terlatih dalam Amalan Klinikal yang Baik *Good Clinical Practice (GCP) trained*		
Lain-lain *Others*		

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

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

Penggantungan *Suspension*
Nyatakan secara ringkas *Briefly explain*

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

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

Bahagian D : Pengesahan Jawatankuasa Penyelidikan Etika
Part D : Endorsement from Research Ethics Committee

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

☐ Dicadangkan untuk diterima/ diluluskan tanpa pembentangan.
Recommend for acceptance without presentation.

☐ Dicadangkan untuk pembentangan.
Recommend for presentation.

Ulasan jika ada:
Comment if any:

Tandatangan *Signature* Ahli JK Etika Penyelidikan *Member of Research Ethics Committee*	Cop rasmi *Official stamp*	Tarikh *Date*

REC 7

Research Project Membership Amendment Form
Borang Perubahan Keahlian Projek Penyelidikan

BORANG PERUBAHAN/PENAMBAHAN KEAHLIAN BAGI PROJEK PENYELIDIKAN

Research Project Membership Amendment Form

Tajuk Projek
Project Title :

Kod Projek
Project Code :

Bidang Penyelidikan
Area of Specialisation :

Tempoh Projek
Project Duration :

Jumlah Peruntukan
Total budget :

Ketua Projek
Project Leader :

Tandakan (/) pada ruangan yang disediakan/*Tick (/) at the related field*:

☐ **Penambahan Ahli Projek**
Project Membership Addition

☐ **Pertukaran Ahli Projek**
Project Membership Amendment

Nama/*Name* :	
No. Staf :	Email :
Tel. Pejabat (*Office*):	No. Tel. Bimbit (*Handphone*):
Fakulti/Pusat/Bahagian/Jabatan/*Affiliation* :	Tandatangan/*Signature* :

Nama/*Name* :	
No. Staf :	Email :
Tel. Pejabat (*Office*):	No. Tel. Bimbit (*Handphone*):
Fakulti/Pusat/Bahagian/Jabatan/*Affiliation* :	Tandatangan/*Signature* :

(Tambah sekiranya perlu. *Add if necessary*)

Dokumen Sokongan / Perakuan (*Supporting Documents/Declaration*)

Bagi perubahan keahlian, penyelidik diminta melampirkan dokumen seperti di bawah.
For Research Project Membership Amendment/Addition, researcher is required to provide documents as follows:

Tandakan (/) pada ruangan yang disediakan/*Tick (/) at the related field*:

☐ *MYRA CV'* calon yang ingin dilantik/*MYRA CV of the candidate*

Justifikasi / Sebab Memohon Perubahan Keahlian Projek (WAJIB dinyatakan):
Justification/Reason for the Research Project Membership Amendment/Addition (Compulsory):

.....

.....

.....

Pengesahan Ketua Penyelidikan (*Research Leader Verification*)

Tandatangan & Cop :
Signature & Stamp

Tarikh :
Date

Perakuan Pengerusi Jawatankuasa Penyelidikan Fakulti/Negeri (*Faculty/State Research Committee Verification*)

Ulasan/*Comment* :

.....

.....

.....

Keputusan : *Decision*

☐ **Diluluskan (Disokong)** Approved

☐ **Tidak Diluluskan** Rejected

Tandatangan & Cop : *Signature & Stamp*

Tarikh : *Date*

REC 8

Research Completion/Termination

Report Form

Borang Laporan Akhir/Penamatan Penyelidikan

REC 8

i. For postgraduate or staff research, the REC 8 form is to be submitted to the REC Secretariat within 6 months of completion of the research.

ii. For undergraduates, submission of REC 8 to the REC Secretariat is to be made when the Final Year Project (FYP) report is submitted.

Bahagian A: Maklumat Penyelidik
Part A : Details of Researcher

Tajuk Penyelidikan :
Title of Research :

Nama Penyelidik*:
Name of Researcher :

Nama Penyelia:
Name of Supervisor :

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

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

Nombor Pendaftaran:
Registration Number:

Tarikh daftar/ Kelulusan:
Date registered/ Approval:

Jangkamasa Kajian:
Research Duration:

Tarikh Tamat:
Date of completion:

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

Bahagian B1
Part B1

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

Bahagian B2 (Penyelidikan klinikal sahaja) *Part B2 (Clinical Research only)*	**Lokasi 1** ***Site 1***	**Lokasi 2** ***Site 2***
Tarikh penyelidikan bermula *Study commencement date*		
Lokasi *Site*		
Sasaran tarikh enrolmen pertama *Target of first enrolment date*		
Tarikh enrolmen pertama *First enrolment date*		
Sasaran bilangan enrolmen *Target enrolment number*		
Sasaran tarikh selesai *Target completion date*		
Tarikh sebenar selesai *Actual completion date*		
Bilangan yang disaring *Number screened*		

Bahagian C: Laporan Penamatan Kajian
Part C: Study End Report

Ringkasan dapatan kajian.
Summary of research findings.

Sebarang permasalahan sekiranya ada:
Concerns if any:

Pengesahan Ketua Penyelidikan (*Research Leader Verification*)

Tandatangan & Cop :
Signature & Stamp

Tarikh :
Date

Bahagian D : Pengesahan Jawatankuasa Penyelidikan Etika
Part D : Endorsement from Research Ethics Committee

Saya telah meneliti makluman ini dan mencadangkan ia diterima dan direkodkan.
I have deliberated on this notification and propose its acceptance and to be recorded.

Ulasan jika ada:
Comment if any:

Tandatangan *Signature* Ahli JK Etika Penyelidikan *Member of Research Ethics Committee*	Cop rasmi *Official stamp*	Tarikh *Date*

Bahagian E : Hasil Kajian
Part E : Research Output

Senarai penerbitan *List of Publications*	Kepentingan dan sumbangan kepada masyarakat dan negara (cth: polisi) *Significance and contribution to society and nation (eg. policy)*
Kertas Pembentangan Persidangan *List of Conference Presentations*	Lain-lain *Others*
Senarai pelajar Sarjana Muda/Pascasiswazah yang dilatih *List of undergraduate/postgraduates trained*	

REC 9

Research Ethics Application Review Form
Borang Penilaian Pemohonan Etika

(For REC reviewers)

REC 10

Cover Letter for Amendment
Surat Iringan Pembetulan

Chairman
Research Ethic Committee (REC)
Institute of Research Management and Innovation (IRMI)
Universiti Teknologi MARA
Shah Alam, Selangor

(Date of submission)

Attn: UiTM REC Secretariat

Dear REC Chairman

AMENDMENT ETHICS APPROVAL BY UiTM RESEARCH ETHICS COMMITTEE

With reference to your letter dated (date of conditional approval letter) [Our reference: REC/1/16], this is to inform you that we have made the amendments to the proposal entitled "(title of proposal)".

The amendments done are listed below:

No.	Amendment	Action Taken
1	(what is been written in the Conditional Approval letter)	(Please highlight the page and form.) Eg: We already include the muslim participants in Inclusion Criteria. (Part B, pg. 5, inclusion criteria)

We wish to express our gratitude for your good cooperation.

Thank you.

Sincerely,

(Supervisor Name)
(Position)
(Address)

REC 11

Exemption from Ethics Review Application Form
Borang Permohonan Pengecualian Semakan Etika

Requires approval and endorsement of Faculty/State Research Committee before submission to the REC

Application for Exemption from Ethical Review
Permohonan Pengecualian daripada Semakan Etika

Please attach a copy of Research Proposal.
Sila lampirkan salinan kertas cadangan penyelidikan.

Part A : Details of Researcher
Bahagian A: Maklumat Penyelidik

Title of Research Project :
Tajuk Penyelidikan _____

Name of Researcher :
Nama Penyelidik _____

Name of Supervisor :
Nama Penyelia _____

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

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

☐ *Sarjana Muda / *Undergraduate*

☐ *Pasca Siswazah / *Postgraduate*

☐ *Staf/Pensyarah / *Staff/Lecturer*

☐ *Pihak Luar / *External*

Part B : Details of Research
Bahagian B: Maklumat Penyelidikan

Executive summary
(Not more than 300 words. Please include brief methodology, objectives of research, justification of research, benefits and possible risks)

Ringkasan eksekutif
(Tidak melebihi 300 patah perkataan. Sila masukkan metodologi ringkas, objektif penyelidikan, justifikasi penyelidikan, faedah dan risiko yang mungkin berlaku)

Part C : Justification for Exemption from Ethical Review (tick where applicable, can be more than one)

Bahagian C: Justifikasi Pengecualian daripada Semakan Etika (tandakan yang berkenaan, boleh melebihi daripada satu)

☐ This research does not involve human participants, human tissues and/or biological samples.
Kajian ini tidak melibatkan peserta manusia, tisu manusia dan/atau sampel biologi.

☐ This research does not collect sensitive and/or identifiable data of an individual.
Kajian ini tidak mengumpul data sensitif dan/atau data yang boleh mengenal pasti individu.

☐ This research is for institutional quality assurance purposes (eg. clinical audit) related to evaluation of public service programs, public health surveillance, educational evaluation activities, consumer satisfaction, and consumer acceptability tests.
Kajian ini adalah untuk tujuan jaminan kualiti institusi (contoh audit klinikal) yang berkait dengan penilaian program perkhidmatan awam, pengawasan kesihatan awam, aktiviti penilaian pendidikan, kepuasan pengguna dan ujian penerimaan pengguna.

☐ Others (provide details):
Lain-lain (nyatakan butiran):

Part D: Verification from Faculty/State Research Committee

Bahagian D: Pengesahan Jawatankuasa Penyelidikan Fakulti/Negeri

The Faculty/State Research Committee has reviewed the study protocol and recommends for exemption from ethical review.
Jawatankuasa Penyelidikan Fakulti/Negeri telah mengkaji protokol kajian dan mengesyorkan untuk pengecualian daripada semakan etika.

Signature *Tandatangan:* **Chairman/Alternate Chair of Faculty/State Research Committee** *Pengerusi/Pengerusi Ganti JK Penyelidikan Fakulti/Negeri*	**Official stamp**: *Cop rasmi*:	**Date**: *Tarikh*:

REC 12

Assent Form

Borang Persetujuan

REC 12 – Assent 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

Guidelines to ethics application 2020

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 _____

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)

THANK YOU