APPLICATION FOR EXEMPTION (REC 11) FROM ETHICAL REVIEW

Permohonan Pengecualian Daripada Semakan Etika

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Faculty of Medicine UiTM/ Hospital Al Sultan Abdullah UiTM

Research Ethics Committee

Research Management Centre Universiti Teknologi MARA 40450 Shah Alam





Introduction

The National Statement on Ethical Conduct in Human Research (paragraphs 5.1.22 and 5.1.23) defines research that can be exempted from ethics review as:

Negligible risk research that involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

Source: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018





Standard Practices

Most university practices does not normally require formal ethical review for these activities provided the following criteria are met:

- 1. The data is completely anonymous with no personal information being collected
- The data is not considered to be sensitive or confidential in nature
- 3. The issues being researched are not likely to upset or disturb participants
- 4. Vulnerable or dependent groups are not included
- 5. There is no risk of possible disclosures or reporting obligations





Full board Ethical Review application basis

- 1. Collection or use of person-identifiable or special category data
- Collection or use of data which is classed as sensitive or confidential
- 3. Involving vulnerable groups, including children or adults with special needs
- 4. Ingestion (by whatever means of delivery) of any substance by participants
- 5. Invasive/semi-invasive procedure or the administration of drugs
- 6. Physical testing of participants
- 7. Psychological tests or interventions
- May cause physical risk, distress, embarrassment, anxiety, stress, fatigue or inconvenience to the participant
- 9. May cause adverse effect on the personal, social or economic well-being of the participant
- 10. Socially sensitive topics
- 11. Research likely to uncover illegal or potentially harmful activities





When can I apply for EXEMPTION?





My research does not involve human participants, human tissues and/or biological samples.





My research does not collect sensitive* and identifiable secondary data of an individual.





My research involves content analysis / textual analysis / metaanalysis.

(E.g.: non-identifiable data lawfully collected, public/private records, published/unpublished reports, and documents available in libraries, repositories, archives, websites)





Case study / doctrinal study / policy study that utilizes a qualitative approach that does not involve human participants / sensitive* / identifiable data of an individual.





Concept paper which synthesizes knowledge from the previous study on a particular topic and presents it in a new context with the aims to fill knowledge gaps.

This research does not involve human participants and does not collect sensitive* and identifiable data of an individual.





Market survey, opinion poll / online vote, and consumer acceptability tests that do not collect sensitive* and identifiable data of an individual.





Observational studies based on video recording obtained from public domains that do not collect sensitive* and identifiable data of an individual.





Filming of documentary / documentation of cultural / traditional practices that have obtained prior approval from the relevant parties / authorities and does not collect sensitive* and identifiable data of an individual.





Activities for quality assurance purposes (e.g., clinical audit, communication audit, compliance audit) related to the evaluation of public service programs, public health surveillance, educational evaluation.





Sensitive issues











REC 11: EXEMPTION FORM



THE EXEMPTION FORM

Exemption (REC 11) form is a manual form, available from https://www.recuitm.org/other-rec-forms.

The form has four parts:

- Part A: Details of researchers
- Part B: Research details
- Part C: Justifications from ethical review
- Part D: Agreement to conduct research
- Part E: Verification from department / Postgraduate Committee





Research Ethics Committee Research Management Centre Universiti Teknologi MARA 40450 SHAH ALAM



Tel: 03 - 5544-8069, Faks: 03 - 5544-2096/2767

Application for Exemption from Ethical Review Permohonan Pengecualian daripada Semakan Etika

Please attach a copy of the Research Proposal.

Please attach a copy of the 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:
Te. No/ Email : No.Telefon/ Emel:
*Sarjana Muda / Undergraduate *Pasca Siswazah / Postgraduate *Staf/Pensyarah / Staff/Lecturer *Pihak Luar / External

Part B: Research Details

Bahagian B: Maklumat Penyelidikan

Executive summary

(Please include research justification, objectives, research methodology, significance, risks)

Ringkasan eksekutif

(Sila masukkan justifikasi, objektif, metodologi, kepentingan dan risiko penyelidikan)

- 1. Research Justification
 - Justifikasi Penyelidikan
- 2. Research Objectives

Objektif Penyelidikan

 Research Methodology (including sample size, if applicable) Metodologi Penyelidikan (termasuk saiz sampel, sekiranya ada)

Research Significance
 Kepentingan Penyelidikan

5. Research Risks Risiko Penyelidikan.





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.
Renyelidikan ini tidak melibatkan peserta manusia, tisu manusia dan/atau sampel biologi.

This research does not collect sensitive* and identifiable secondary data of an individual.
Ennyelidikan ini tidak mengumpul data sekunder yang sensitif * dan yang dapat dikenal pasti identiti individu.

This research involves content analysis / textual analysis / meta-analysis. (E.g.: non-identifiable data lawfully collected, public/private records, published/unpublished reports, and documents available in libraries, repositories, archives, websites.

Penyelidikan ini melibatkan analisa kandungan / teks / meta-analisis. (Contoh: pengumpulan data yang tidak akan dapat dikenal pasti identiti diperplehi, secara sah daripada rekod awam / swasta, lappran yang diterbitkan / tidak diterbitkan, dan dokumen yang terdapat di perpustakaan, repositori, arkib, laman web.

Case study / doctrinal study / policy study that utilizes a qualitative approach that does not involve human participants / sensitive* / identifiable data of an individual.

Kajian kes / kajian, doktrin, / kajian, dasar yang menggunakan pendekatan kualitatif serta tidak melibatkan peserta manusia./ data sensitif */ data yang dapat dikenal pasti identiti individu.

Concept paper which synthesizes knowledge from the previous study on a particular topic and presents it in a new context with the aims to fill knowledge gaps. This research does not involve human participants and does not collect sensitive* and / identifiable data of an individual.

Kertas konsep yang mensintesis pengetahuan dari basil kajian lampau mengenai topik tertentu dan membentangkannya dalam konteks baru dengan tujuan merapatkan jurang pengetahuan. Benyelidikan ini tidak melibatkan peserta manusia dan tidak mengumpulkan data sensitit * dan / data yang dapat dikenal pasti identiti individu.

Market survey, opinion poll / online vote, and consumer acceptability tests that do not collect sensitive* and / identifiable data of an individual.

Jinjauan pasaran, persepsi / undian dalam talian, dan ujian penerimaan pengguna yang tidak mengumpulkan data sensitif * dan / data yang dapat dikenal pasti identiti individu.

Observational studies based on video recording obtained from public domains that do not collect sensitive* and / identifiable data of an individual.

Kajian pemerhatian berdasarkan rakaman video yang diperolehi daripada domain awam yang tidak mengumpulkan data sensitif * dan / data yang dapat dikenal pasti identiti individu.

Filming of documentary / documentation of cultural / traditional practices that have obtained prior approval from the relevant parties / authorities and does not collect sensitive* and / identifiable data of an individual. (*random video/photo)

Penggambaran dokumentari / dokumentasi amalan budaya / tradisi yang telah mendapat persetujuan daripada pihak berkenaan / berkuasa dan tidak mengumpulkan data sensitif * dan / data yang dapat dikenal pasti identiti individu.

Activities for quality assurance purposes (e.g. clinical audit, communication audit, compliance audit) related to the evaluation of public service programs, public health surveillance, educational evaluation. Aktiviti untuk tujuan jaminan kualiti (contoh: audit klinikal, komunikasi, pematuhan) yang berkaitan dengan penilaian program perkhidmatan awam, surveilan kesihatan awam, penilaian pendidikan.

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

- * Sensitive refers to the following (but not limited to):
- * Sensitif merujuk kepada yang berikut (tidak terhad kepada):
- Corruption Rasuah
- Fraud or cyber fraud Penipuan atau penipuan siber
- Specific-entity review Ulasan entiti khusus
- v. Vulnerable group Kumpulan rentan





Part D: Agreement to Conduct the Research Project

Bahagian C: Pengesahan Persetujuan Menjalankan Penyelidikan

Must be completed and signed by all members of the research group.

Mesti dilengkapkan dan ditandatangani oleh semua ahli kumpulan penyelidikan.

Penyelidik utama (untuk dilengkapkan oleh Staf Akademik/Pelajar 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:	Tarikh:
Signature:	Date:

Penyelia (sekiranya ada)
 Supervisor (If anv)

Supervisor (If any)	
Nama:	
Name:	
No.Staf:	
Staff ID:	
Jawatan/Kepakaran:	
Position/Specialisation:	
Jabatan:	
Affiliation:	
Telefon pejabat:	
Office:	
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Telefon bimbit:	
Telefon bimbit: Mobile phone :	
Telefon bimbit: Mobile phone : Emel:	
Telefon bimbit: Mobile phone : Emel: Email:	
Telefon bimbit: Mobile phone : Emel: Email: Tandatangan:	Tarikh :
Telefon bimbit: Mobile phone : Emel: Email:	Tarikh : Date:

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:	Tarikh:
Signature:	Date:

(Tambah sekiranya perlu, Add if necessary)

Part E: 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:



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Exemption (F.BERC 4) form is a manual form, available from https://www.recuitm.org/other-rec-forms.

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- Part A: Details of researchers
- Part B: Research details
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- Part D: Agreement to conduct research
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PART A: DETAILS OF RESEARCHERS PART B: RESEARCH DETAILS

FERC/BERC 4

Faculty/Branch Ethics Review Committee Universiti Teknologi MARA



Application for Exemption from Ethical Review

Permohonan Pengecualian daripada Penilaina Etika

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

Part A	Details	οf	Researcher
ranca	Details	vı	Researcher

Bahagian A: Maklumat Penyelidik		
Title of Research Project : Tajuk Penyelidikan		
Name of Student : Nama Pelajar		
Name of Supervisor : Nama Penyelia		
Address of Department/ Institute : Alamat Jabatan/ Institut :		
Te. No/ Email : No.Telefon/ Emel:		
☐ Undergraduate / Sarjana Muda ☐ Masters by Coursework/ Sarjana Ke	erja Kursus	

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Рап	в:	Researd	n L	etalis

Bahagian B: Maklumat Penyelidikan

Executive summary

(Please include research justification, objectives, research methodology, significance, risks)

Ringkasan eksekutif

(Sila masukkan justifikasi, objektif, metodologi, kepentingan dan risiko penyelidikan)

1. Research Justification

Justifikasi Penyelidikan

2. Research Objectives

Objektif Penyelidikan

3. Research Methodology (including sample size, if applicable)

Metodologi Penyelidikan (termasuk saiz sampel, sekiranya ada)

4. Research Significance

Kepentingan Penyelidikan

5. Research Risks

Risiko Penvelidikan



PART C: JUSTIFIACTION OF EXEMPTION

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)

C1	This research involve: Penyelidikan ini melibatkan:	YES Ya	NO Tidak
1.	Human participants, human tissues and/or biological samples. Peserta manusia, tisu manusia dan/atau sampel biologi.		
2.	Collecting sensitive* and identifiable secondary data of an individual. Mengumpul data sekunder yang sensitif * dan yang dapat dikenal pasti identiti individu.		
3.	Collecting sensitive* data of an individual or organization that reflects these attributes: • Corruption - Rasuah • Fraud or cyber fraud - Penipuan atau penipuan siber • Specific-entity review - Ulasan entiti khusus • Vulnerable group - Kumpulan rentan		

C2	This research involves: <u>Penyelidikan ini melibatkan:</u>	Tick where applies Tandakan yang berkenaan
1.	Content analysis / textual analysis / meta-analysis. (E.g.: non-identifiable data lawfully collected, public/private records, published/unpublished reports, and documents available in libraries, repositories, archives, websites. Penyelidikan ini melibatkan analisa kandungan / teks / meta-analisis. (Contoh: pengumpulan data yang tidak akan dapat dikenal pasti identiti diperolehi secara sah daripada rekod awam / swasta. Japoran yang diterbitkan / tidak diterbitkan, dan dokumen yang terdapat di perpustakaan, repositori, arkib, Jaman web.	

2.	Case study / doctrinal study / policy study that utilizes a qualitative	
	approach that does not involve human participants / sensitive* /	
	identifiable data of an individual.	
	Kajian kes / kajian doktrin / kajian dasar yang menggunakan pendekatan	
	kualitatif serta tidak melibatkan peserta manusia / data sensitif * / data	
	yang dapat dikenal pasti identiti individu.	
3.	Concept Paper which synthesizes knowledge from a previous study on a	
٥.	particular topic and presents it in a new context with the aim of fulfilling	
	knowledge gaps. This research does not involve human participants and	
	does not collect sensitive* and / identifiable data of an individual.	
	Kertas konsep yang mensintesis pengetahuan dari hasil kajian lampau	
	mengenaj topik tertentu dan membentangkannya dalam konteks baru	
	dengan tujuan merapatkan jurang pengetahuan. Penyelidikan ini tidak	
	melibatkan peserta manusia dan tidak mengumpulkan data sensitif.* dan	
	/ data yang dapat dikenal pasti identiti individu	
4.	Market survey, opinion poll / online vote, and consumer	
٠.	acceptability tests that do not collect sensitive* and / identifiable data of	
	an individual.	
	Tinjauan pasaran, persepsi / undian dalam talian, dan ujian penerimaan	
	pengguna yang tidak mengumpulkan data sensitif * dan / data yang	
	dapat dikenal pasti identiti individu.	
5.	Observational studies based on video recording obtained from public	
	domains that do not collect sensitive* and / identifiable data of an	
	individual.	
	Kajian pemerhatian berdasarkan rakaman video yang diperolehi daripada	
	domain awam yang tidak mengumpulkan data sensitif * dan / data yang	
	dapat dikenal pasti identiti individu.	
6.	Filming of documentary / documentation of cultural / traditional	
	practices that have obtained prior approval from the relevant parties /	
	authorities and does not collect sensitive* and / identifiable data of an	
	individual. (*random video/photo)	
	Penggambaran dokumentari / dokumentasi amalan budaya / tradisi yang	
	telah mendapat persetujuan daripada pihak berkenaan / berkuasa dan	
	tidak mengumpulkan data sensitif * dan / data yang dapat dikenal pasti	
	identiti individu.	
7.	Quality assurance purposes (e.g., clinical audit, communication audit,	
	compliance audit) related to the evaluation of public service programs,	
	public health surveillance, educational evaluation.	
	Aktiviti untuk tujuan jaminan kualiti (contoh: audit klinikal, komunikasi,	
	pematuhan) yang berkaitan dengan penilaian program perkhidmatan	
	awam, surveilan kesihatan awam, penilaian pendidikan.	
8.	Others (provide details):	

Lain-lain (nvatakan butiran):

PARD D: AGREEMENT TO CONDUCT RESEARCH PART E: VERIFICATION FROM DEPARTMENT/ PG COMMITTEE

F/BREC 4 (2021)

Part D: Agreement to Conduct the Research Project

Bahagian C: Pengesahan Persetujuan Menjalankan Penyelidikan

Must be completed and signed by all members of the research group.

Mesti dilengkapkan dan ditandatangani oleh semua ahli kumpulan penyelidikan.

 Student (to be filled by Undergraduate/Masters by Coursework Student only) Pemohon (untuk dilengkapkan oleh Pelajar Siswazah / Sarjana Kerja Kursus sahaja)

Staff ID/Student ID: No.Staf/No. Pelajar:	
Mobile phone: Telefon bimbit:	
Email: Emel:	
Signature: Tandatangan:	Date: Tarikh:

Supervisor Penyelia

Staff ID/Student ID: No.Staf/No. Pelajar:	
Mobile phone: Telefon bimbit:	
Email: Emel:	
Signature: Tandatangan:	Date: Tarikh:

Part E: Verification from Department or Postgraduate Research Committee

Bahagian D: Pengesahan Jawatankuasa Penyelidikan Jabatan atau Pascasiswazah

The Department or Postgraduate Research Committee has reviewed the study protocol and recommends for exemption from ethical review.

Jawatankuasa Penyelidikan Jabatan atau Pascasiswazah telah mengkaji protokol kajian dan mengesyorkan untuk pengecualian daripada semakan etika.

Signature Tandatangan:	Official stamp:	Date:
Undergraduate / Postgraduate / Research	Cop rasmi:	Tarikh:
Coordinator Koordinator Peringkat Pra- siswazah/Pasca-siswazah/Penyelidikan		





Thank you

