

Human Research Ethics Workshop



Outline





Research

A **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.



What is Research Ethic?

About norms, values, right and wrong, good and bad, and what ought and ought not to be done in the context of research.



<https://www.scu.edu/mobi/resources--tools/blog-posts/ethics-in-life-and-business/ethics-in-life-and-business.html>



Significant events in research involving human subject

Historical cases	Ethical concerns	Results
Nuremberg Doctors Trial Nazi	Significant violations of personal autonomy, malevolence, unjustifiable harm	Nuremberg Code Declaration of Helsinki
Stanford Prison Experiment, 1971	Deception, emotional and psychological harms, violations of privacy and confidentiality	Research Principles, 1973
Tuskegee Syphilis Study	Uninformed consent, injustice, risk to participants and family members	National Research Act, 1974 The Belmont Report



<https://orise.orau.gov/health-surveillance/human-subjects-research.html>

Does your research involve human subjects?



Human subject

A living individual about whom a researcher obtains:
(1) data through intervention or interaction with the individual or
(2) identifiable private information.



<https://www.denverpost.com/2015/01/09/the-future-of-the-job-what-humans-do-better-than-robots/>

Human subject

***Interaction* includes communication or interpersonal contact between investigator and subject.**



Human subject

Intervention includes both physical procedures, in which, data is gathered and manipulation of the subject or the subject's environment is executed for research purposes.



Human subject



Private information includes information about behavior that can be expected from an individual without observation or recording taking place.



Why you need ethical approval?

Protection for participants, and also helps to protect the researcher.

Adhered to the accepted ethical standards of a genuine research study.

Funder & publication



What are the key principles in research ethics?

**Respect for
persons
(and their
autonomy)**

Beneficence

Non-maleficence

Justice



When do I need to apply for Human Research Ethics Approval at UPSI?

Adakah saya perlu memohon Kelulusan Etika Penyelidikan Manusia UPSI?

- 
- ✓ Penyelidikan melibatkan manusia sebagai sampel
 - ✓ Penyelidikan melibatkan sebarang interaksi dan/ atau intervensi terhadap manusia
 - ✓ Penyelidikan merangkumi kerahsiaan dan identiti manusia sebagai contoh maklumat kesihatan pesakit di pusat kesihatan
 - ✓ Terdapat keperluan Kelulusan Etika Penyelidikan Manusia (Human Ethics Clearance) untuk penerbitan jurnal
 - ✓ Terdapat pemantauan daripada Kementerian Pendidikan Malaysia/ agensi luar mengenai Kelulusan Etika Penyelidikan Manusia
 - ✓ Dinyatakan dalam cadangan penyelidikan berkenaan keperluan untuk mendapatkan kelulusan **Etika Penyelidikan Manusia**

You must apply for Human Ethics Approval if your research involves:

- ✓ Humans as research participants – for example, surveys, interviews, experiments, or case studies.
- ✓ Any form of interaction or intervention with humans – such as giving treatments, training, or collecting responses.
- ✓ Confidential or personal information – like patient health records, student data, or anything that identifies individuals.
- ✓ Requirement for journal publication – most journals now require an official Human Ethics Clearance before accepting your manuscript.
- ✓ Oversight by the Ministry of Education Malaysia or external agencies – they may request proof of ethical approval for monitoring purposes.
- ✓ Research proposals that explicitly state ethics approval is needed – for example, when applying for grants or institutional support.



Important Note

- Ethics clearance is to be **obtained before the research project starts**. Researchers **should not** approach or recruit participants or collect data for any purpose (including pilot study) prior to receiving ethical approval.
- Applications for research where data collection has already started or been completed will **not be accepted**.
- Submit their ethics clearance application as **EARLY as possible** prior to their data collection.
- **We DO NOT provide urgent reviews**. Therefore, please plan your research accordingly as any request for an expedited review will not be entertained.
- Please make sure that your submission is complete prior to the checklist. The secretariat will strictly **reject** and will not entertain any **incomplete submissions**.



Human Subject Research

involving potentially vulnerable groups

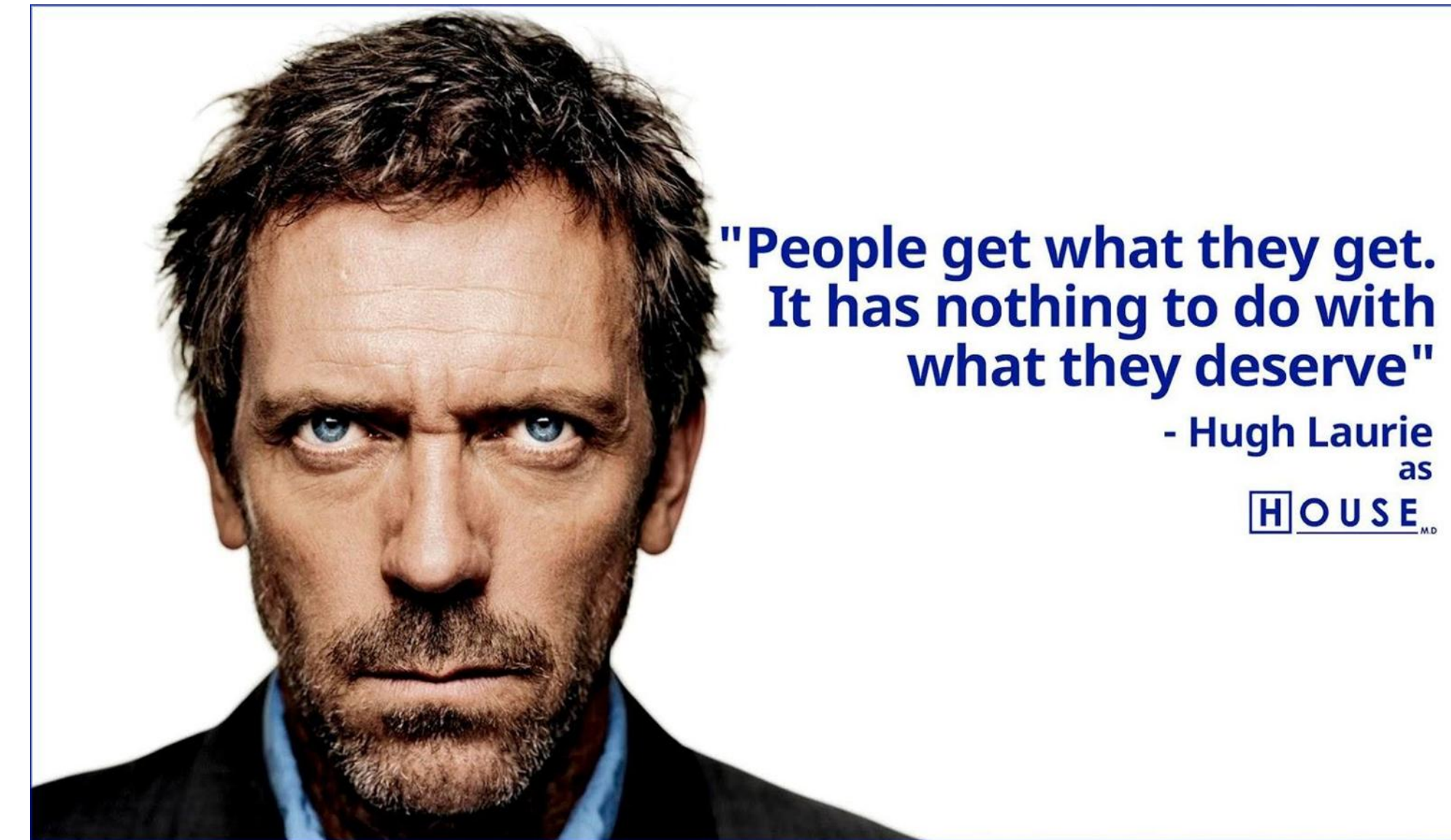
involving groups where permission of a gatekeeper is normally required for initial access to members.

access to records of personal or confidential information, including genetic or other biological information concerning identifiable individuals.

induce psychological stress, anxiety or humiliation or cause more than minimal pain.

undertaken outside of Malaysia where there may be issues of local practice and political sensitivities

involving planned prospective collection of human biological samples including those for the purpose of bio-banking



Human Subject Research

respondents through the internet, in particular where visual images are used, and where sensitive issues are discussed

secondary use of data includes a dataset intended for secondary use contains identifiers or can be linked back to identifiers

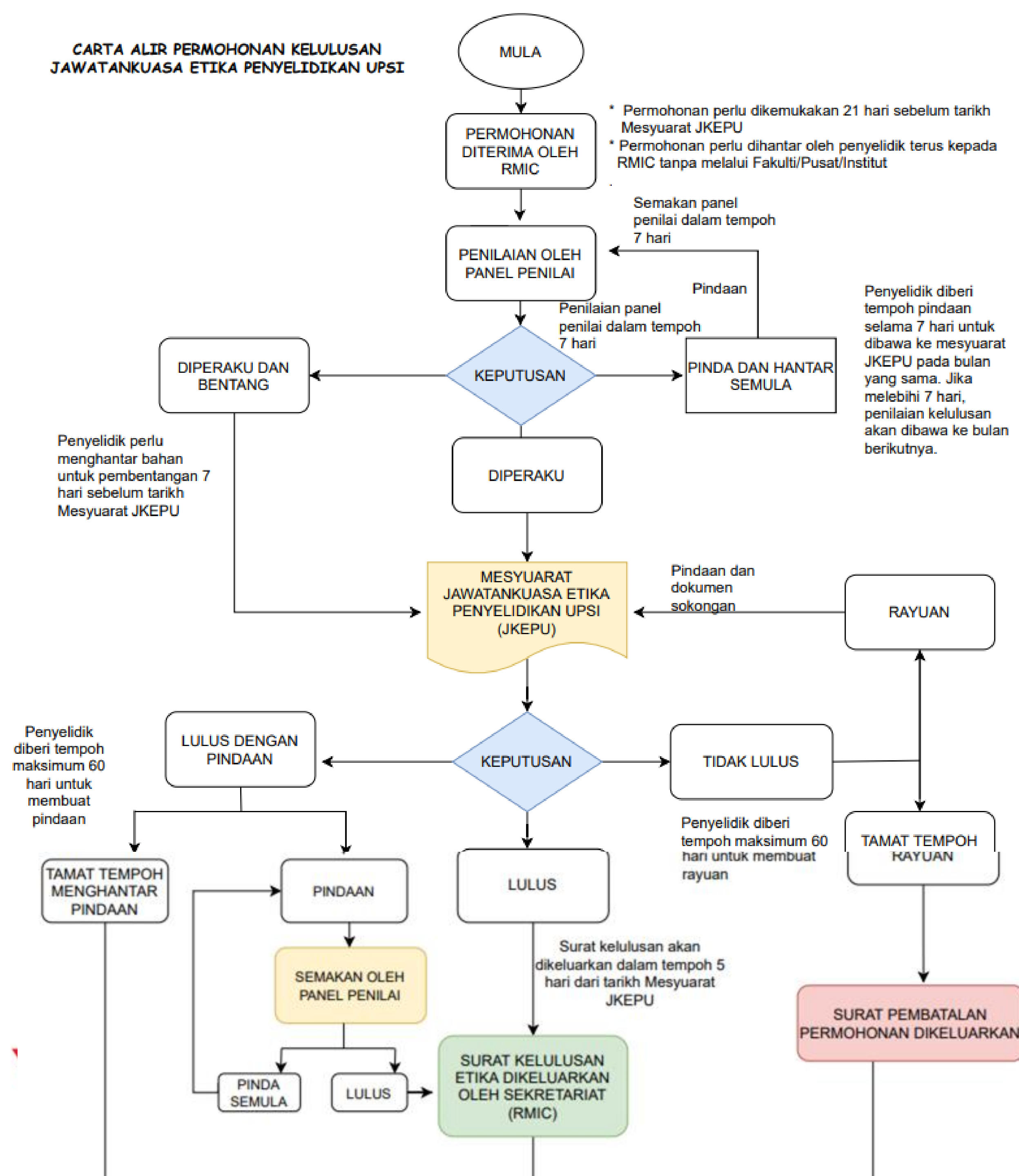
research which may involve data sharing of confidential information beyond the initial consent given

using administrative data or secure data

involving in case study or case report. Researchers should seek written and signed consent information from the patient(s) or their guardian(s)/participants prior to conducting the research activities and publication.

involving planned prospective collection of human biological samples including those for the purpose of bio-banking





Human Ethical Approval flow chart

- The process involves **application** → **panel review** → **committee meeting** → **decision (approve, amend, or reject)** → **final approval or cancellation**.
- Researchers must **follow timelines strictly** (7 days for minor amendments, 60 days for major amendments or appeals).
- Otherwise, the application will be delayed or cancelled.

Application Timeline and Review Cycle

HUMAN RESEARCH ETHICS COMMITTEE MEETING

Search:

NO.	HUMAN RESEARCH ETHICS COMMITTEE MEETING 2025	DATE	APPLICATION DEADLINE
1	62nd Meeting (January)	27 January 2025	30 December 2024
2	63rd Meeting (February)	27 February 2025	28 January 2025
3	64th Meeting (March)	28 March 2025	27 February 2025
4	65th Meeting (April)	25 April 2025	24 March 2025
5	66th Meeting (May)	26 May 2025	25 April 2025
6	67th Meeting (June)	26 June 2025	23 May 2025
7	68th Meeting (July)	28 July 2025	26 June 2025
8	69th Meeting (August)	28 August 2025	25 July 2025
9	70th Meeting (September)	29 September 2025	28 August 2025
10	71st Meeting (October)	27 October 2025	26 September 2025
11	72nd Meeting (November)	27 November 2025	24 October 2025
12	73rd Meeting (December)	29 December 2025	28 November 2025

- **Reviews are conducted on a monthly basis, in accordance with the submission deadlines.**
- **Applicants are strongly encouraged to submit their applications at least 3 months before the intended start of data collection.**



Plan your submission properly

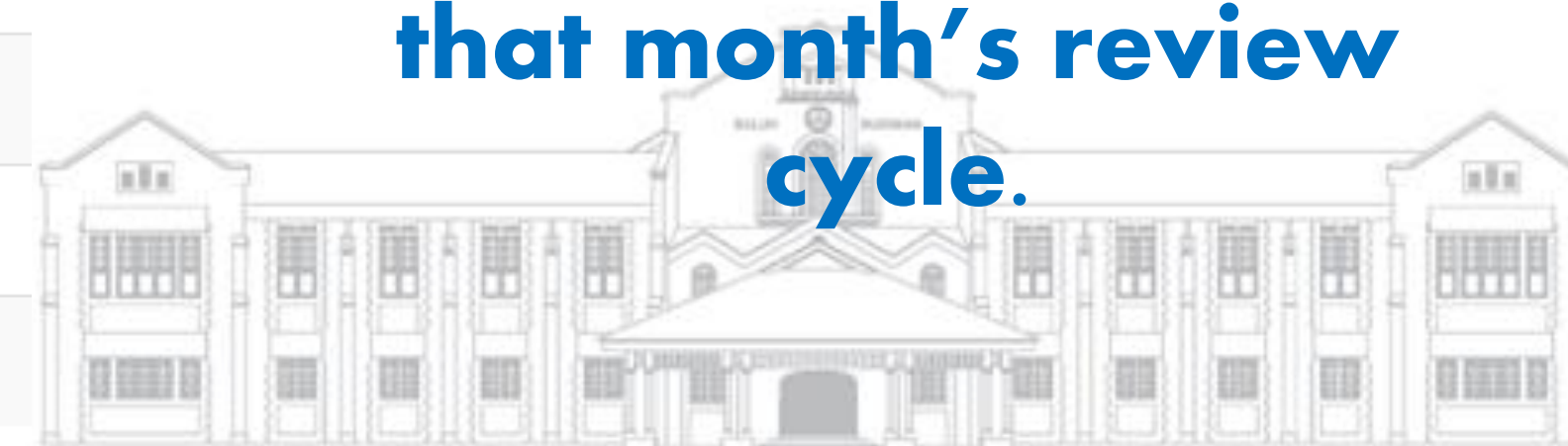
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12	73rd Meeting (December)	29 December 2025	28 November 2025

Submissions received after the application dateline will be carried forward to the following month's review cycle.

Applications must be submitted before the dateline of each month to be considered for that month's review cycle.



Saya mahu memohon. Apa harus saya lakukan?



Pelajar pasca:

1. Berjumpa dan berbincang dengan penyelia
2. Layari laman web RMIC atau terus ke <http://rmic.upsi.edu.my/research-ethics-management/> untuk mulakan permohonan Etika Penyelidikan Manusia anda.

Pensyarah: Layari laman web RMIC atau terus ke <http://rmic.upsi.edu.my/research-ethics-management/> untuk mulakan permohonan Etika Penyelidikan Manusia anda.



If You Are a Postgraduate Student

1. Meet and discuss with your supervisor first.
This ensures your research proposal is ethically sound and ready for submission.

2. Visit the RMIC website or go directly to:

👉 <http://rmic.upsi.edu.my/research-ethics-management/>

to start your **Human Research Ethics application.**

If You Are a Lecturer/Researcher

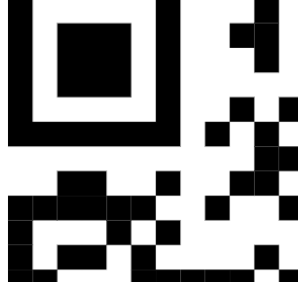
1. You may directly visit the RMIC website or go straight to the same link:

👉 <http://rmic.upsi.edu.my/research-ethics-management/>

to begin your **Human Research Ethics application.**



UNIVERSITI
PENDIDIKAN
SULTAN IDRIS
اوپن اديتي قاديديان سلطان ايدريس
SULTAN IDRIS EDUCATION UNIVERSITY



 **TQRCG**

hard copy module



Should I use AI to prepare my Human Research Ethics application?



Use AI for:

- Clarifying wording, grammar, and readability (e.g., lay summaries, PIS/consent plain-language edits).
- Formatting, checklists, timelines, and consistency checks.
- Translating between English/Malay (then you verify technical terms).



How to start? Download Human Research Ethic form

1.

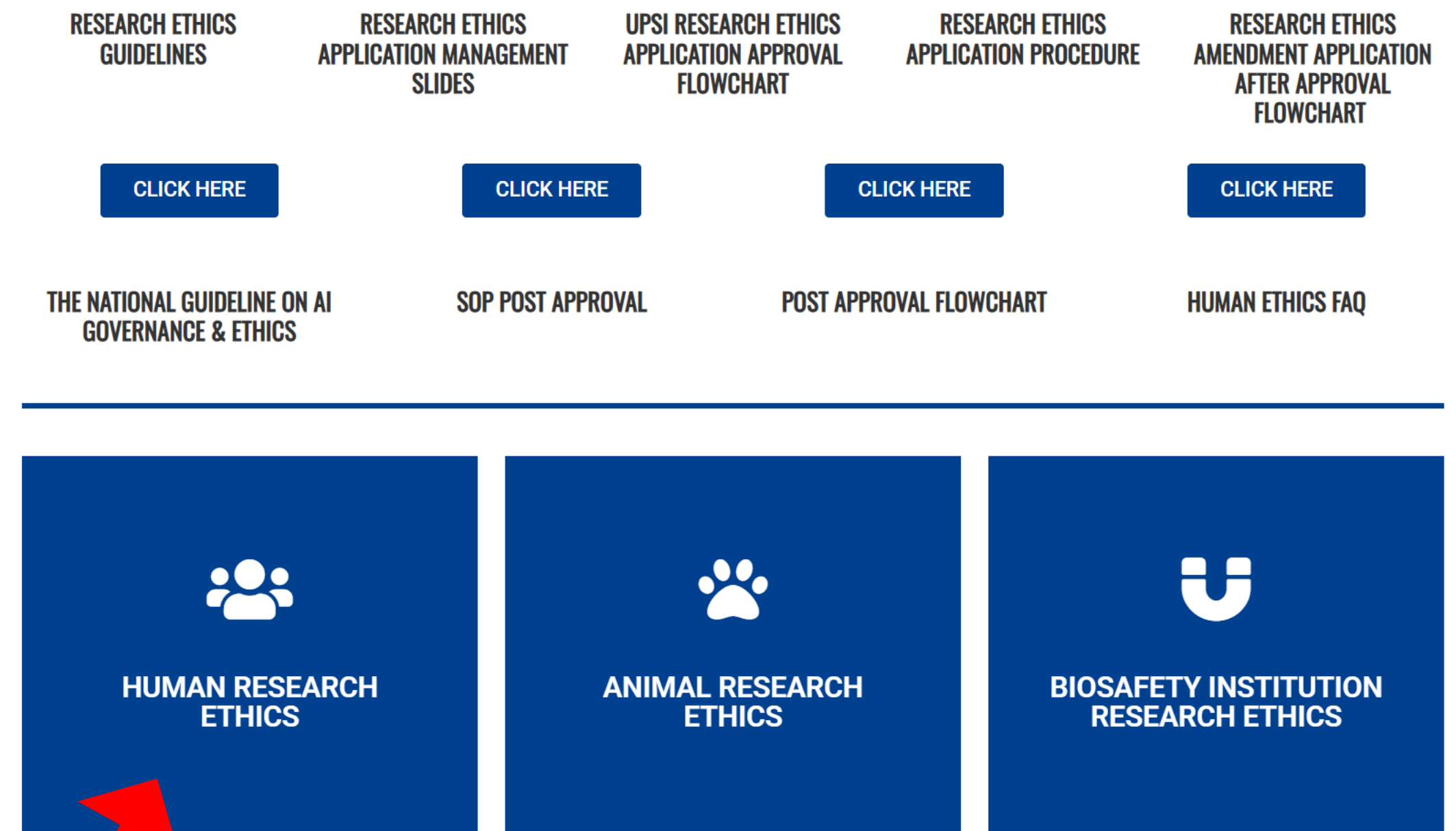


Browse - <https://rmic.upsi.edu.my/>
&
Click “RESEARCH ETHICS”



SCAN ME

2.



<http://rmic.upsi.edu.my/human-research-ethics/>
&
Click “ETIKA PENYELIDIKAN MANUSIA”

How to start? Download Human Research Ethic form

3.

HUMAN RESEARCH ETHICS

HUMAN RESEARCH ETHICS
COMMUNITY SLIDES

CLICK HERE

GUIDELINE

CLICK HERE

HUMAN RESEARCH SUBJECT
RENEWAL FORM

CLICK HERE

GUIDELINES FOR APPLICATIONS
TO USE HUMAN RESEARCH
SUBJECTS

CLICK HERE

RESPONDENT SAMPLE &
CONSENT

CLICK HERE

HUMAN RESEARCH SUBJECT
AMENDMENT FORM

CLICK HERE

HUMAN RESEARCH ETHICS
APPLICATION FORM

CLICK HERE

HUMAN ETHICS MODULE
(EBOOK)

CLICK HERE

HUMAN RESEARCH SUBJECT
ADVERSE EVENT REPORT

CLICK HERE

HUMAN RESEARCH ETHICS
WORKSHOP APPLICATION
FORM

CLICK HERE

HUMAN ETHICS MODULE
(HARDCOPY)

CLICK HERE

HUMAN RESEARCH SUBJECT
SITE VISIT REPORT

CLICK HERE

4.

DOCUMENT CHECKLIST FOR APPLICATION TO USE HUMAN RESEARCH SUBJECTS SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)

Document Checked		
	Applicant	RMIC
1. Completed Application Form	☐	☐
2. Research Proposal (not more than 10 pages)	☐	☐
i. Objectives	☐	☐
i. Background and rationale	☐	☐
ii. Research design	☐	☐
iii. Sample	☐	☐
iv. Measurement/Instrument	☐	☐
v. Research procedures	☐	☐
vi. Data analysis	☐	☐
vii. References	☐	☐
3. Informed consent	☐	☐
4. Guardian's/Parent's consent (if applicable)	☐	☐
5. Any letters, flyers, etc. distributed to the research subjects (if applicable)	☐	☐
6. Certificate of Human Research Ethic Workshop	☐	☐
*At least one of the members has attended the workshop		
Document Checked by RMIC		

Application received by RMIC on:

Human Research Ethic Application Form

- 1) Application Detail
- 2) Responsible Research Principal Investigator (PI)
- 3) Investigator(s)
- 4) Type of Research
- 5) Research Period
- 6) Location(s) of the Research
- 7) Human Subject Review
- 8) Subjects
- 9) Recruitment
- 10) Devices (if applicable)
- 11) Biological/ Chemical Materials (if applicable)
- 12) Risks/ Benefit Analysis
- 13) Confidentiality/ Anonymity
- 14) Consent
- 15) Supporting Documents



Human Research Ethic Application Form

APPLICATION TO USE HUMAN RESEARCH SUBJECTS SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)

Section 1. Application Detail

Title of Research	:	
Research Code (if applicable)	:	
Funding Institution (if applicable)	:	
Research design (e.g.: survey or experimental)	:	

Provide information about the research title, research code and research design

Provide details concerning yourself include name, telephone number, email, office address, department, and faculty.

Section 2. Responsible Research Principal Investigator (PI)

Name	:				
Telephone	:		E-mail	:	
Office Address	:				
Faculty (if applicable)	:		Department	:	



Human Research Ethic Application Form

Section 3. Investigator(s)				
If more investigators exist than lines provided, please attach a separate list.				
Name	Position	Faculty	Role	Signature
Include all co-researchers (internal and/or external) in this section of the application form and ensure each of them signs the declaration				

Provide details about investigators involves in this research.

For postgraduate students, you are strongly advised to discuss and review your application with your supervisor before submission.

Please state what type of your research

Section 4. Type of Research	
This research is being conducted as part of (please tick all that apply):	
☐ University Research	☐ Master's Research
☐ External Research	☐ Bachelor's Research (e.g.: Final Year Project)
☐ Ministry of Education Research (e.g. FRGS)	☐ Other (specify)_____
☐ Doctoral Research/ Postdoctoral Research	

Human Research Ethic Application Form

Section 5. Data Collection Period (The start and end dates of research activities for e.g.: collecting data through interviews)	
Start date (DD/MM/YY)	____/____/____
End date (DD/MM/YY)	____/____/____
Duration :	_____

Provide details about the start and end date of the research and the duration of the research.

The ethics approval is only valid until the project's end date as stated in your approval letter.

Section 6. Location(s) of the Research
This research will be conducted at the following location(s): (Please indicate city & state)
Locations:
☐ UPSI Campus: _____
☐ School/ Academic Institution(s) (Specify): _____
☐ Government/ Non-Government Organization(s) (Specify): _____
☐ Community setting (Specify): _____
☐ Other (Specify): _____

Provide details about location you will conduct the research



Human Research Ethic Application Form

Bila saya perlu memohon Kelulusan Etika Penyelidikan
Manusia UPSI?

✓ **Sebelum kutipan data dilakukan.**



Peringatan, Permohonan kelulusan **Etika Penyelidikan Manusia** bagi kutipan data yang telah berjalan tidak akan diterima.



Human Research Ethic Application Form

Section 7. Human Subject Review

Has this research been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?

☐ Yes (please attach the relevant document)

☐ No

Has you or any of the co-researcher (s) completed any Human Research Ethics Workshop (HREW)?

☐ Yes (please attach the relevant document)
Date (DD/MM/YY) ____/____/____

☒ No (please download the HREW form from RMIC website and attach to this application.)

<http://rmic.upsi.edu.my/human-research-ethics/>

This section
asks detail
about other
reviewer for
your
research.

Human Research Ethics

SLIDE HUMAN RESEARCH ETHICS
COMMUNITY

Klik disini

GUIDELINES FOR APPLICATIONS
TO USE HUMAN RESEARCH
SUBJECTS

Klik disini

BORANG PERMOHONAN HUMAN
RESEARCH ETHICS

Klik disini

HUMAN RESEARCH ETHICS
WORKSHOP APPLICATION FORM

Klik disini



Human Research Ethic Application Form

Section 8. Subjects

Indicate the anticipated maximum number of subjects to be enrolled in this protocol as justified by the hypothesis and research procedures: _____

Vulnerable Subjects*:

If this research will involve potentially vulnerable subject population(s), please tick all that apply.

- | | |
|---|--|
| ☐ Children (under age 18) | ☐ Economically/ Educationally Disadvantaged Persons (e.g. to investigate the lower income of SES) |
| ☐ Pregnant Women | ☐ Developmentally Disabled Persons (e.g. for Special Education purposes) |
| ☐ Indigenous People | ☐ Poor and Unemployed |
| ☐ Disabled Person | ☐ Victims/ Survivors |
| ☐ People diagnosed with Sickness | ☐ Interventions (s) that include medical or psychological treatment |
| ☐ Patients in Emergency Care | ☐ Single parent |
| ☐ Patients with Mental Health Problems | ☐ Others (specify): _____ |
| ☐ People on Welfare/Social Assistance | |
| ☐ Homeless People | |
| ☐ Elderly People (age: 65 and above) | |

**A group is generally considered vulnerable because there is good reason to suspect that the individuals in the group may have special difficulty giving free and informed consent to being the subjects of research.*

Provide the **maximum numbers** of subjects involved in this research.

If your research **involves** children or vulnerable people, you are required to tick any subjects in the section. If the subjects are not in the list, please specify the subject(s) involved in your research.

Human subjects who are comparatively or entirely inept of defending their own well-being. These subjects require additional care to protect their rights.

Type of
vulnerability

Cognitive and communicative vulnerability

Juridical or institutional vulnerability

Deferential vulnerability

Medical vulnerability

Economic vulnerability

Infrastructure vulnerability

Social vulnerability

Human Research Ethic Application Form

Section 9. Recruitment

How will the subjects be recruited? (In a step-by-step manner, describe the recruitment process. Please provide any protocol or procedure, and/ or a copy of the sign-up sheet, newspaper advertisement which will be used to recruit subjects).

Provide details regarding the recruitment process in step by step manner.
You have to provide details information about inclusion and exclusion criteria for you subject.

Please provide inclusion criteria for your subjects

The inclusion criteria for the subject populations comprise of gender, age ranges, ethnic background, health status, and any other applicable information.

Inclusion criteria are characteristics that the prospective subjects must have if they are to be included in the study.

Please provide exclusion criteria for your subjects

The exclusion criteria for the subject populations comprise of gender, age ranges, ethnic background, health status, and any other applicable information.

Exclusion criteria are those characteristics that disqualify prospective subjects from inclusion in the study.



Human Research Ethic Application Form

Section 10. Devices (if applicable)

Name of the Device(s): _____

Please state the reasons: _____

Is there any specific protocol that needs to be followed: (Please provide the relevant document)

Section 11. Biological/ Chemical Materials (if applicable)

Will any biological/ chemical materials will be used with the subjects?

☐ Yes (please state: _____)

☐ No (please proceed to Section 12)

How are these materials being used in the research? Please describe

Is the research need to collect biological material?

☐ Yes (please state who: _____)

☐ No (please proceed to Section 12)

i.e. blood, urine, semen,
vaginal secretion, human
tissue

State the name of the devices and the reason to use the devices in your research. Please provide any specific protocol that need to be followed and relevant document when using the devices.

Describe the biological materials that will be collected.

What is the intended use of the biological material that will be collected?

Who will have access to biological material? (Tick all that apply)

☐ Biological material will be used by members of the research team

☐ Biological material will be shared with outside researchers

☐ Others (please specify)

Will the biological material be destroyed after completion of the study?

☐ Yes

☐ No

This section ask about biological/ chemical material used/consumed by the subjects?

Human Research Ethic Application Form

Section 12. Risks Subjects / Benefit Analysis

a. State the risk (s) to participants. Tick the level of risk and explain the possible risks in details.

Low risk ☐

Moderate risk ☐

High risk ☐

Explanation of the potential risk:

Potential harms for research participants: physical harm, physiological harm, disrespect or harm to dignity, social or cultural harm, privacy harm, economic harm, legal harm, data harm, autonomy harm

b. State the reasons why the research needs to be conducted despite the above risk(s).

c. Describe the steps taken to reduce the risks to participants without jeopardizing the research objectives. Please provide the relevant document.

This section is concerned with the details of risks and benefit in the research specifically to subjects.

Provide the risks to the subject that will be involved and reasons need to be conducted despite its risk. You will also describe the steps to be taken in reducing the risk by providing the relevant document(s) if applicable.

The benefits for the subjects also need to be explained.



Human Research Ethic Application Form

d. What are the benefits of the research for the subjects?

The benefits for the subjects also need to be explained.

Benefits could include:

- Gaining new knowledge or skills
- Receiving health information or feedback
- Contributing to scientific knowledge that may help their community in the future

e. Are research subjects will be given a compensation or reimbursement? If yes, what cost for the gift?

Compensation*	OR	Reimbursement**
☐ Yes, please specify:		☐ Yes, please specify:
☐ No		☐ No

* **Compensation** refers to anything given to subjects as remuneration for the time and inconvenience of participation in research. Compensation can be monetary or non-monetary, and can be offered in a range of forms, including but not limited to cash, gift cards, vouchers, trinkets, course credit, and the opportunity to enter a drawing for a prize.

** **Reimbursement** refer to researchers pay some or all of the subjects' costs for participation - e.g. transportation, parking, lodging, etc.

e. Will research subjects be given compensation or reimbursement?

There are two options:

1. Compensation

- Something given to participants as a token of appreciation for their time and effort.
- Can be monetary or non-monetary (e.g., cash, vouchers, gift cards, small gifts, course credits, entry to a lucky draw).
- Researchers must tick "Yes" and specify what, or tick "No".

2. Reimbursement

- Covers **expenses incurred by participants** when joining the research.
- Examples: transportation, parking fees, meals, or lodging.
- Again, researchers must tick "Yes" and specify, or tick "No".

Human Research Ethic Application Form

Provide details regarding the confidentiality arrangements you are intending to implement.

You will describe the procedures for protection the anonymity in your research. You will also have to explain procedures you will use to protect the confidentiality of your data.

The more pieces of information that are presented together, the easier it is to identify someone.

Section 13. Confidentiality/ Anonymity

Describe the procedures for protecting the anonymity.

Anonymity means that there is no way for anyone (including the researcher) to personally identify participants in the **study**. This means that no personally-identifying information can be collected in an anonymous study.

Explain the procedures you will use to protect the confidentiality of your data.

Confidentiality refers to a condition in which the researcher knows the identity of a research subject, but takes steps to protect that identity from being discovered by others.



Human Research Ethic Application Form

Section 14. Consent

Describe the process to obtain informed consent from subjects.

Describe the information about the process of obtaining informed consent from the subjects.

Describe the approach in ensuring that the subjects are voluntary.

Also, describe your approach in ensuring that the subjects are voluntary participate in your research.

GARIS PANDUAN ETIKA
PENYELIDIKAN

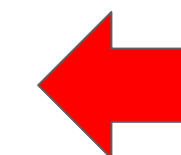
SLIDE PENGURUSAN
PERMOHONAN ETIKA
PENYELIDIKAN

CARTA ALIR
PERMOHONAN
KELULUSAN ETIKA
PENYELIDIKAN UPSI

PROSEDUR
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CARTA ALIR
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PINDAAN SELEPAS
KELULUSAN ETIKA

CONTOH-CONTOH
BORANG ETIKA



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Universiti Pendidikan Sultan Idris

No.1 Education University

www.upsi.edu.my

Human Research Ethic Application Form



Section 15: Declaration

I hereby declare that the information given is accurate and complete in all respects. Upon request, I agree to provide with any information or documents required in relation to the application and ensure to inform any changes of information if applicable soon as possible.

(_____)

Research Principal Investigator

Date:

Attach a description of the following documents such as research proposal, informed consent, Guardian's/ Parent's consent (if applicable) and any related documents which will distributed to the subjects (etc. letter, questionnaires or flyers).



PUSAT PENGURUSAN PENELITIAN DAN INOVASI
Research Management & Innovation Centre (PPIC)
Kompleks Pendidikan & Inovasi, Kampus Sultan Abdul Shah
Universiti Pendidikan Sultan Idris, 35900 Tanjung Malim,
Perak Darul Ridzuan
Tel: 051 - 46275 7120/ 7860/ 7867
E-mail: ppic@upsi.edu.my
Laman web: <http://rmi.upsi.edu.my/>



Application Ref. No.:

DOCUMENT CHECKLIST FOR APPLICATION TO USE HUMAN RESEARCH SUBJECTS SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)

Document Checked			
		Applicant	Faculty
1)	Complete Application Form	☐	☐
2)	Research Proposal		
	i. Objectives	☐	☐
	ii. Background and Rationale	☐	☐
	iii. Research Design	☐	☐
	iv. Sample	☐	☐
	v. Measurement/ Instrumentation	☐	☐
	vi. Research Procedures	☐	☐
	vii. Data Collection	☐	☐
	viii. References	☐	☐
3)	Informed Consent	☐	☐
4)	Guardian's/ Parent's Consent/ Assent Form (if applicable)	☐	☐
5)	Any letters, flyers, etc. distributed to the research subjects	☐	☐
6)	Certificate of Human Research Ethic Workshop (HREW)	☐	☐

Human Research Ethic Application Form

Human Ethics Review Committee Endorsement

Comments:

|
Endorsed (without presentation) ☐
Presentation ☐
Amend and resubmit for review ☐
Amend and resubmit for approval ☐

(_____)
Chairman of Human Ethics Review Committee

Date:

Human Ethics Review Committee Endorsement (Second Review, if Applicable)

Comments:

|
Endorsed (without presentation) ☐
Presentation ☐
Amend and resubmit for review ☐
Amend and resubmit for approval ☐

(_____)
Chairman of Human Ethics Review Committee

Date:

Human Research Ethic Application Form

Human Ethics Committee Approval

Comments:

|

Approved

☐

Approved with condition

☐

Not approved

☐

(

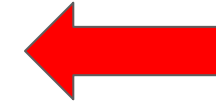
Chairman of Human Ethics Committee

)

Date:



GOOGLE FORMS LINK



ANIMAL RESEARCH ETHICS

GOOGLE FORMS LINK

BIOSAFETY INSTITUTION RESEARCH ETHICS

GOOGLE FORMS LINK

Any enquiries please contact the Ethics Coordinator, Dr. Syazwan Saidin at 054507243 or the Secretariat Ms. Farahathirah Mustaffa at 054507254.

Type of Application: ★

- ☐ New Application
- ☐ Amendment (eg;change of title, method, time, etc)
- ☐ Revision Application (List of correction)

Completed Application Form: ★

 Add file

Supporting Document (Certificate of Human Research Ethic Workshop, Informed Consent, Research Proposal, Any Letters, Flyers, etc)

[Add file](#)

A copy of your responses will be emailed to the address you provided.

Submit

[Clear form](#)

ONLINE SUBMISSION OF HUMAN RESEARCH ETHICS APPLICATION FORM

IMPORTANT NOTICE

We are currently experiencing technical difficulties with the Google Form for Submission of Human Research Ethics Application Forms.

Until further notice, all applications must be submitted via email to:

 etika.manusia@upsi.edu.my

We sincerely apologize for the inconvenience caused and appreciate your understanding.
Thank you.

Bil.	Kategori Pemohon	Kadar Bayaran yang dikenakan (RM)
1.	Institusi luar	1000.00
2.	Institusi luar melalui penyelidik bersama di UPSI	500.00
3.	Pensyarah	Tiada caj
4.	Pelajar pasca siswazah	Tiada caj
5.	Pelajar pra siswazah	Tiada caj

Application Fee by Category

- External Institutions
 - Fee: RM 1000.00
- External Institutions with a UPSI collaborator
 - Fee: RM 500.00
- UPSI Lecturers
 - No charge
- UPSI Postgraduate Students
 - No charge
- UPSI Undergraduate Students
 - No charge



Human Research Ethic Application Form

**Saya telah menghantar permohonan.
Kenapa masih tiada kelulusan, dan pindaan masih perlu
dilakukan selepas 2 bulan?**



A. Borang permohonan tidak diisi dengan lengkap?

Contoh: Bahagian "Risks" dan "Recruitment" dibiarkan kosong atau tidak dinyatakan dengan lengkap.

B. Dokumen sokongan tiada?

Contoh: Surat maklumat penyelidikan dan surat keizinan subjek tidak disertakan

C. Ayat tidak jelas?

Contoh: Surat keizinan penyelidikan hanya diberikan kepada pelajar Sekolah Rendah tetapi tidak kepada ibu bapa/penjaga.

D. Terdapat keperluan pembentangan permohonan disebabkan keraguan kaedah pengutipan data dan sampel yang digunakan.



Why is my application still not approved after 2 months?

1. Application form is incomplete

- Example: The sections on *Risks* or *Recruitment* are left blank or not filled in properly.

2. Missing supporting documents

- Example: You did not attach the *participant information sheet* or the *consent letter*.

3. Wording is unclear

- Example: The consent letter is only given to primary school students but not to their parents or guardians.

4. Presentation is required

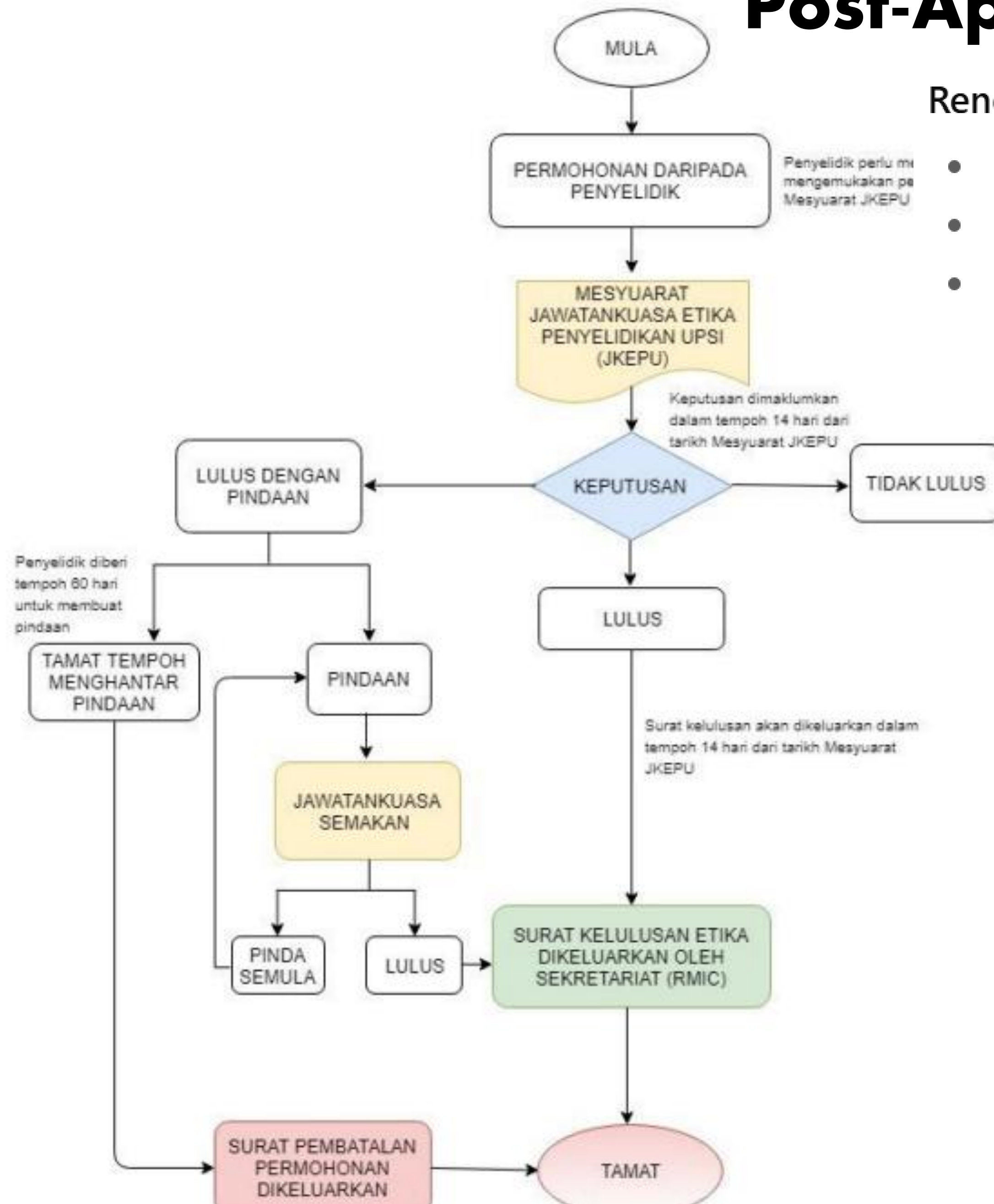
- Sometimes the committee may ask you to present your application because there are doubts about your data collection methods or the instruments used.

The review and approval process typically takes between 30 to 90 days from the submission deadline. The exact duration may vary depending on factors such as the complexity of the application, the nature of reviewer feedback, and the timeliness of the applicant's response to any requested revisions or additional information.

Post-Approval for **Renewal** Requests

Renewal of Human Research Ethics Approval

- Renewal must be done 3 months before the approval expiry date.
- If the researcher fails to renew on time, the approval will automatically lapse.
- In that case, the researcher will need to **submit a brand-new ethics application**, and the review process will start all over again.



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FORM

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(HARDCOPY)

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Post-Approval for **Amendment** Requests

All amendments must be submitted to the RMIC Secretariat for approval *before* implementation.

This includes any change that could affect participants, data, or study conduct.

What counts as an amendment?

- Study design or procedures (methods, instruments, timing, sample size)
- Recruitment, inclusion/exclusion criteria, or study sites
- Consent/assent forms, information sheets, or compensation
- Data handling/privacy, storage, or sharing plans
- Research team members, roles, or supervisor/PI changes
- Schedule changes (extensions), adverse event management plans

Major amendments are defined as changes to the protocol which substantially changes the study design or analysis plan and potentially alter the risk-benefit profile of the study. For example:

- **Change in the primary hypothesis**
- **Change to the design of the study**
- **Additional outcomes or exposures**
- **Use of additional linkages to other databases.**

- **Submit your amendment request at least 60 days before your ethics approval expires.**
- Requests submitted after the approval expiry date will not be accepted. A new ethics application will be required.**
- Failure to comply may result in the withdrawal of your ethical approval.**

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Human Research Ethics Auditing Program



- **All ongoing projects which have human research ethics approval from UPSI may be audited in accordance with the Guideline.**
- **Projects are audited to ensure research is conducted ethically, legally, safely and in compliance with the protocol and conditions approved by the Human Research Ethics Committee.**
- **Projects are selected to be audited based on:**
 - Request by the Human Research Ethics Committee
 - Risk
 - Random selection
 - A complaint

If your project has been selected to be audited you will be contacted by the Secretariat who will provide you with more details.

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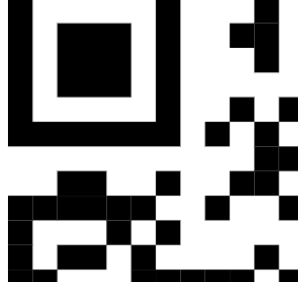
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HUMAN ETHICS FAQ



Download me!!!



Human Research Ethics Secretariat
etika.manusia@upsi.edu.my

Dr. Syazwan Saidin
+60132661405

Ms. Farahathirah Mustaffa
+605-48797743

**You will be notified you by
email once a final decision has
been made on your application.**

Thank You



Requirement for Ethical Research

Scientific value

Each study must have social or scientific significance. The treatment or hypotheses being tested should improve health and well being or increase knowledge about the research area.



Requirement for Ethical Research

Scientific validity

Research or clinical research should be well designed not only to ensure its scientific quality but also its ethical propriety



Requirement for Ethical Research

Fair subject selection

Fair subject selection means that vulnerable individuals or “convenient” sample are not unfairly targeted for risky research; and the rich and socially powerful are not favored for potentially beneficial research.



Requirement for Ethical Research

**Favorable risk
benefit ratio**

**There is always an element of
risk in research or clinical
research.**



Requirement for Ethical Research

**Respect for
research subjects**

**Individuals must continue to
be treated with respect from
the time they are enrolled,
throughout their participation
and even after their
participation ends.**



Requirement for Ethical Research

Informed Consent

Informed consent is a procedure through which a competent subject, after having received and understood all the research-related information, can voluntarily provide his or her willingness to participate in a research.



Requirement for Ethical Research

Independent Review

**important for social
accountability; assures the
public that human subjects
who enroll in trials will be
treated ethically.**

