Research Ethics Committee

How To Determine the Categories of Review?

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Prof Rohana Abdul Ghani
Prof Madya. Dr Daleleer Kaur Randawar

Research Ethics Committee
UiTM

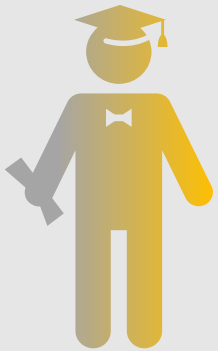
"LET'S GET ETHICAL"

Acknowledgement

Professor Dr Nor Ashikin Mohamed Noor Khan

Associate Professor Datin Dr Hjh Sarina Md Yusof

Dr Amirah Abdul Rahman



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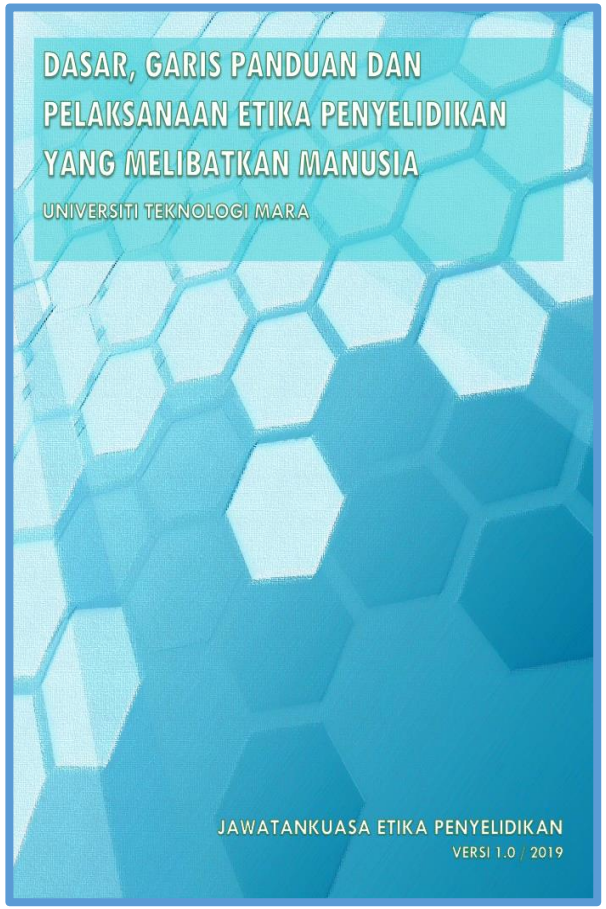
1) Haswira Nor Mohamad Hashim. Internal Member (Law)

2) Dr Aimi Nadia Mohd Yusof. Internal Member (Medical Ethics)

Our Discourse

- Research Ethics Review
  - Policy
  - Purpose
  - Approach
  - Guiding Principles
- Preliminary Determination
  - Research Requiring Ethics Review
  - Classification of Risks
  - Categories of Risks
- Determination of Type of Review
  - Exempted Review (Minimal Risk)
  - Full Board Review (More than Minimal Risk)
  - Exemption

RESEARCH ETHICS REVIEW



Policy

1.0 PENDAHULUAN

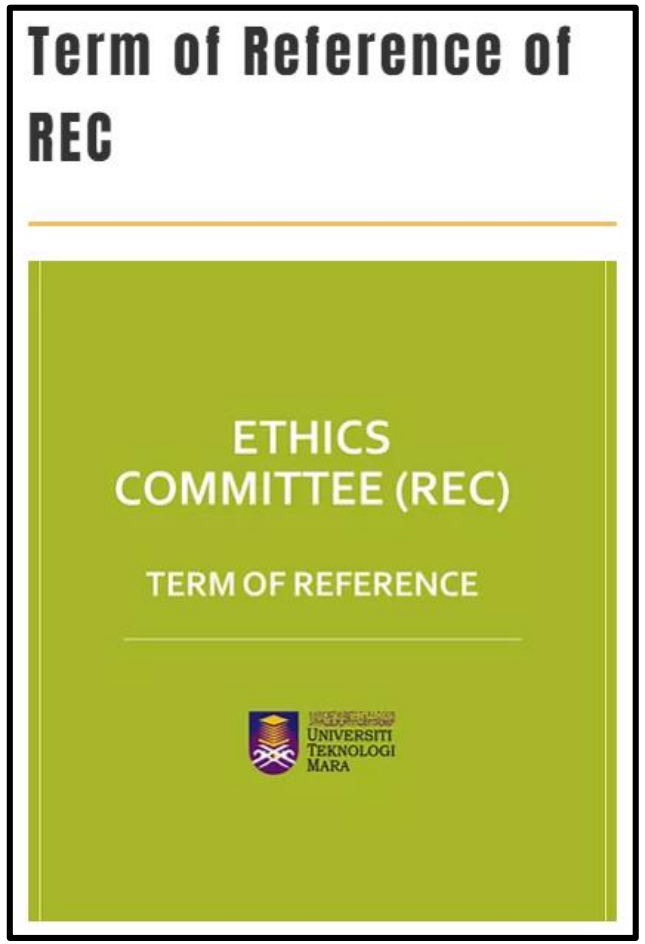
Dasar dan Garis Panduan ini telah dibentangkan oleh Institut Pengurusan Penyelidikan dan Inovasi (IRMI) kepada Mesyuarat Senat Ke-242 Universiti Teknolgi MARA (UiTM) pada 12 Februari 2019 dan mendapat kelulusan serta Pelaksanaannya pada Perkara Berbangkit pada 9 Mei 2019.

Jawatankuasa Etika Penyelidikan (*Research Ethics Committee* – REC) UiTM telah diluluskan oleh Naib Canselor dan ditubuhkan pada tahun 2004. Jawatankuasa ini dipengerusikan oleh Penolong Naib Canselor (Penyelidikan & Inovasi). Jawatankuasa ditempatkan di Tier 2: Eksekutif dalam governan penyelidikan dan inovasi UiTM, di mana ia melapor kepada Jawatankuasa Induk Penyelidikan Universiti (JKIPU) dan seterusnya kepada Senat UiTM.

Polisi Etika Penyeldikan UiTM yang dicadangkan dalam kertas kerja ini ialah sejajar dengan Deklarasi Helsinki 1964 pada Perhimpunan Agung ke-18 Persatuan Perubatan Dunia (World Medical Association - WMA) pada Jun 1964. Deklarasi ini mengisytiharkan **prinsip etika melindungi hak, maruah dan kepentingan semua subjek manusia yang terlibat dalam projek penyelidikan**. Pindaan terakhir Deklarasi Helsinki ialah Pindaan 2013 yang dilaksanakan di Fortaleza, Brazil pada Perhimpunan Agung WMA yang ke-64.

Selaras dengan piawaian global, polisi ini bertujuan untuk memperkasakan agenda penyelidikan UiTM dan memastikan bahawa semua penyelidikan yang melibatkan manusia yang dijalankan oleh ahli akademik dan pelajar UiTM adalah mendapatkan kelulusan etika penyelidikan sebelum ianya dijalankan. Ia juga dilaksanakan untuk memastikan proses kelulusan etika penyelidikan dijalankan mengikut garis panduan dan prosedur yang ditetapkan. Dijangkakan masih terdapat banyak penyelidikan yang melibatkan manusia di UiTM masih tidak mendapatkan kelulusan etika penyelidikan.

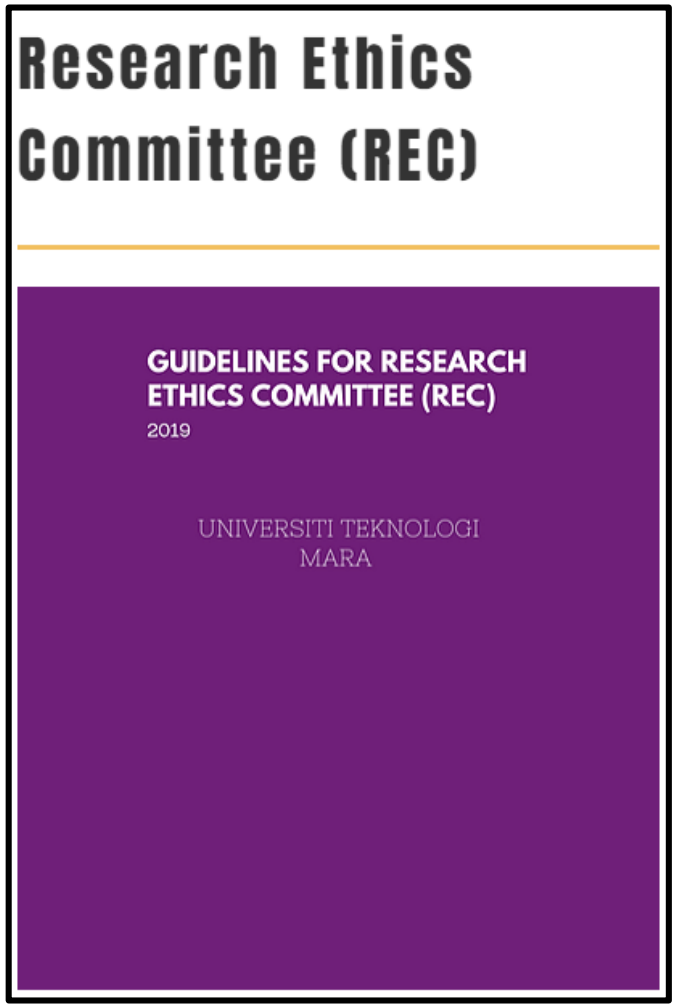
RESEARCH ETHICS REVIEW



Purpose

- Promote ethically sound research;
- Protect the rights, interests and wellbeing of research participants;
- Safeguard the researchers and their research institutions.

RESEARCH ETHICS REVIEW



Approach

- A proportionate approach in reviewing application for ethics approval from the researchers by striking a balance between:
  - The foreseeable risks
    - Risk based approach –understand, measure, mitigate
  - The potential benefits to the research participants
    - Fair and Equitable Benefit Sharing approach
  - The ethical implications of the research
    - Precautionary approach

RESEARCH ETHICS REVIEW

Guiding Principles

- Informed consent to be obtained from potential research participants
  - REC4 - Consent Form; and REC12 – Assent Form
- The risk of harm to participants is to be minimized (beneficence and non-maleficence);
  - REC 4 – Research Risk
- Anonymity and confidentiality of research participant is to be protected
  - REC4 - Confidentiality
- No deceptive practice in data collection
  - REC 4 - Research Procedure
- Participants have the right to withdraw from the research
  - (REC4 -Participation in Research)

PRELIMINARY DETERMINATION

Research Requiring Ethics Review - REC 2 / 2019 Rev 3 (2020)

Human Participants

- Interviews
- Focus group
- Survey
- Action research
- Observation
- Case study
- Clinical trial
- Intervention study

Use of Human Body

- Human cells
- Human genome
- Human tissues
- Human organs
- Body fluids

Research with Potential Risks on Human

- Physical
- Psychological
- Socio-Economic
- Privacy
- Confidentiality
- Legal

PRELIMINARY DETERMINATION

Classification of Risks [REC 3 / 2019 Rev 2 (2020

Risks Arising From Participant Profile

- Participants under 18 years old
- Participants from a particular vulnerable group
- Participants/patients in terminal care
- Participants unable or are incapable of giving consent
- Participants are given emolument to participate

Risks Arising From Privacy And Confidentiality

- Data collected have the potential to cause discomfort, embarrassment, or psychological harm to the participants
- Research involve undeclared methods of data collection to the participants.
- Data be made available to other parties not involved in the research.

Risks Arising From Physical Activity

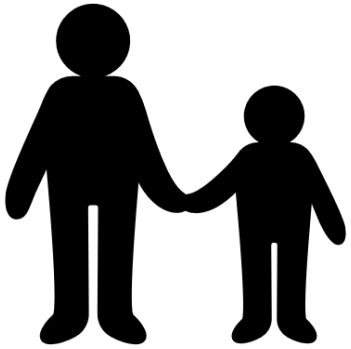
- Research collects biological samples e.g body fluids
- Collection method is invasive and has the potential to cause harm, pain or discomfort (except finger, heel, ear prick.)
- Non-athlete participants subjected to vigorous physical tests or exercise regime
- Participant is patient with chronic illness
- Participants subjected to maximal exercise intensity
- Data collection involves clinical procedure/ medication involved
- Unapproved drug or device used/tested on the participants

VULNERABLE PEOPLE

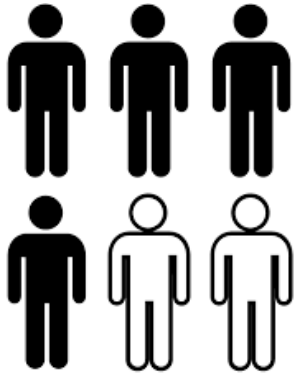
People who are less able to protect their own interests

1. A person with poor health or with mental and cognitive impairment

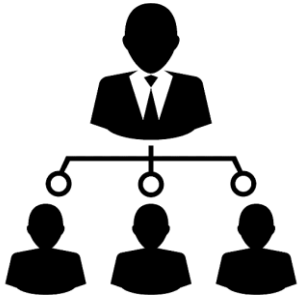
2. A person is too young to legally consent to participate / too old to fully understand the consequences of participation



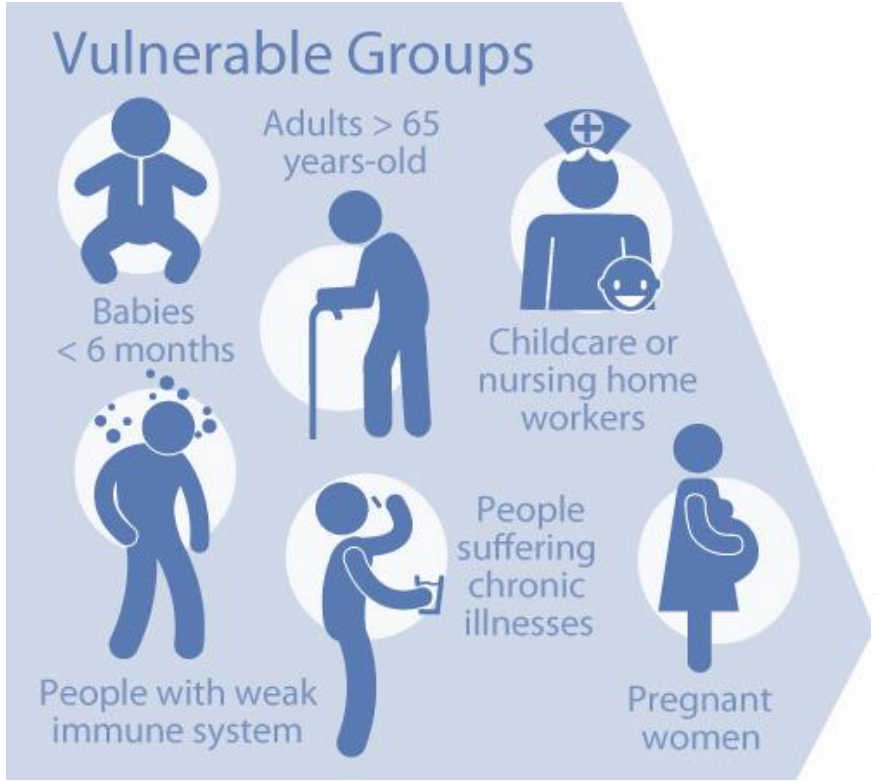
3. A person of minority status (e.g a foreign worker or a refugee)



4. A person in a dependent relationship with the researcher or hierarchical structure who feels obliged to do something they may not normally want to do.



VULNERABLE GROUP OF PEOPLE



- Groups/ individuals who may have an increased likelihood of being wronged or where additional harm may incur
  - Indigenous/Aborigines
  - Refugees
  - Irregular /Illegal migrants
  - Sex workers
  - Dissidents
  - Disabled
- All vulnerable groups and individuals should receive specifically considered protection.
- Research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group.
- The vulnerable group must also stand to benefit from the knowledge, practices or interventions that result from the research.

PRELIMINARY DETERMINATION

Categories of Risks - REC 3 / 2019 Rev 2 (2020)

Minimal Risk

- The probability and magnitude of possible harms anticipated by participation in the research is no greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and where confidentiality is adequately protected.
- Reviewed by a delegated reviewer amongst REC member
- Reviewer proposed as Minimal Risk research
- Expedited review

More Than Minimal Risk

- The probability and magnitude of possible harms anticipated by participation in the research is greater than those encountered in everyday life
- Reviewed by a delegated reviewer amongst REC member
- Reviewer proposed as more than minimal risk research for presentation before the full board.
- Full board review

Exempted Risk

- Less than normal risk (risk free/nominal risk) of harms anticipated arising from the research/data collection
- Research activity that fits one of the exempt review criteria under REC11 form
- Includes risk of data collection not related to research activities
- Reviewed by delegated reviewer amongst REC member
- Reviewer proposed for exemption.
- Exempted from further ethical review

DETERMINATION OF TYPE OF REVIEW

Exempted Review (Minimal Risk) -REC 9 / 2019 Rev 3 (2020)

Risks Arising From Participant Profile

- Research does not involve vulnerable populations.
- Non-interventional research
- Research survey/questionnaire of a non-sensitive nature

Risks Arising From Privacy And Confidentiality

- Research involves anonymous/unidentifiable data
- Research does not involve the collection of stigmatizing information/sensitive questions

Risks Arising From Physical Activity

- Research poses no more risk than expected in daily life (blood draw, physical exam, routine psychological testing).

DETERMINATION OF TYPE OF REVIEW

Full Board Review (More Than Minimal Risk)

Risks Arising From Participant Profile

- Research which involves clinical trial of new drug/treatment/procedure
- Research which involves randomized control trial and intervention
- Research which involves questionnaires or survey to vulnerable groups

Risks Arising From Privacy And Confidentiality

- Genetic and/or genomic studies
- Online survey that requires participant's e-mail address to be disclosed

Risks Arising From Physical Activity

- Research is to be carried out in an unstable or volatile setting
- Research requires travelling or taking place in high-risk locations / place with travel warning issued by the authority
- Research presents risk to the personal safety of the researcher or research participant beyond what is normal in the setting
- Research involves non-standard methodologies or approaches
- Research possibly causes distress the researcher or research participant in one or more ways

Economic and Social Research Council

ESRC Framework for Research Ethics

Examples of More Than Minimal Risk Research

- Research involving potentially vulnerable groups and people unable to consent
- Research involving sensitive topics and those which might cause psychological stress, anxiety or humiliation
- Research involving potentially sensitive topics, such as participants' sexual/illegal behavior
- Intrusive interventions or data collection methods, such as the administration of substances
- Research where the safety of the researcher may be in question
- Research involving respondents through the internet, where visual images are used, and where sensitive issues are discussed
- Any research where biological samples are collected and/or medical imaging technologies are used

Ethics in Social Science and Humanities Research

Checklist for Higher-Risk SSH Research

Participants	Children, vulnerable groups (e.g persons unable to consent, minorities, marginalized people, migrants, refugees, victims of abuse and violence)
Sites of research	Conflict regions, sites of historical value to indigenous people, troubled neighborhoods, non-EU countries or regions within them where the economic, political, environmental and health conditions may pose risks.
Sensitive areas of research	Risk of exposure to harm to participants, researchers; potentially sensitive topics, such as participants' sexual behavior; illegal or political activities; experience of violence, abuse or exploitation; mental health; participants' personal or family lives; or their gender or ethnic status. Research into criminal activity.
Methodology	Deception, covert research, invasive methods as part of interdisciplinary research, profiling and web-crawling
Data processing, sensitive data	Data collection and processing to be implemented – risk of traceability and re-identification through small groups of participants, linking of large amounts of data from different sources; uncertainty whether children are participating; sensitive data
Consequences of research	Potential for misuse of findings

DETERMINATION OF TYPE OF REVIEW

Exemption (Exempted Risk) - REC 11 / 2020 Rev. 2

Research Does Not Involve Human

- Research does not involve human participants, human tissues and/or biological samples.
- .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.
- Case study / doctrinal study / policy study that utilizes a qualitative approach that does not involve human participants / sensitive* / identified / identifiable personal data
- Observational studies based on video recording obtained from public domains that do not collect sensitive and / identifiable data of an individual.

Research Does Not Collect Identified/Identifiable Personal Data

- Secondary data does not contain sensitive and identified/identifiable personal data of an individual
- "*Personal data*" means any information that relates directly or indirectly to a data subject, who is identified or identifiable from that information or from that and other information.
- "*Sensitive personal data*" means any personal data consisting of information as to the physical or mental health or condition of a data subject, his political opinions, his religious beliefs or other beliefs of a similar nature, the commission or alleged commission by him of any offence or any other personal data as the Minister may determine by order published in the Gazette (sec 4, PDPA 2010)

Non-Research Activities Involving Human

- Market survey, opinion poll, online vote, consumer awareness and acceptability
- Data collection for quality assurance purposes (MQA audit, INQKA audit, compliance audit)
- Documentary (photographing / recording / filming of real events, cultural, traditional practices.

THANK YOU

Q&A