Guideline for Non-Clinical Research Ethics Universiti Teknologi Malaysia

Name of Guideline	:
Ref. no of Guideline	:
Endorsed by	:
Effective Date	:
Official Document Link	:

SECTION 1 : INTRODUCTION

1.1 PURPOSE

The Guideline for Non-Clinical Research Ethics provides the framework within which human participant may be used at Universiti Teknologi Malaysia (UTM) for research in a manner that conforms with all government laws and regulations, provides for approved research activities and safeguards the health and welfare of staff and students involved in scholarly activities using human being as subject.

1.2 SCOPE

This guideline is applicable to all researchers in UTM who are conducting their research involving humans as samples / test materials (e.g. questionnaires, data related to human anatomy and physiology).

This guideline is also applicable to all researchers in UTM who are conducting their research involving humans as samples in the field of social sciences.

This guideline does not apply to researchers conducting clinical research or animal research.

This guideline also does not apply to researchers conducting research involving premises and / or staff of the Ministry of Health Malaysia (MoH).

1.3 RELATED POLICIES

No.	Name of Policies	Location
1	*Dasar Universiti Teknologi Malaysia*	*Jabatan Canselori*
2	*Polisi Tadbir Urus Dokumen Polisi*	*Jabatan Pendaftar*
3	*Polisi Penyelidikan dan Inovasi*	*Jabatan Timbalan Naib Canselor (Penyelidikan dan Inovasi)*
4	*Prosedur Penyelidikan dan Inovasi*	*Jabatan Timbalan Naib Canselor (Penyelidikan dan Inovasi)*
5	*Polisi Pengurusan Makmal Universiti*	*Pusat Pengurusan Makmal Universiti (PPMU)*
6	*Polisi Penerbitan Universiti*	*Penerbit UTMPress*
7	*Polisi Libatsama Komuniti dan Industri (2021)*	*Pusat Jaringan Komuniti dan Industri (CCIN)*
8	*Polisi Pelestarian Kampus (2020)*	*Pejabat Pelestarian Kampus*
9	*Polisi Kelestarian Kewangan*	*Jabatan Bendahari*
10	*Polisi Pengurusan Kewangan Universiti Teknologi Malaysia 2021*	*Jabatan Bendahari*
11	*Polisi Pengumpulan Dana (2019)*	*Jabatan Timbalan Naib Canselor (Pembangunan)*
12	*Polisi Kod Amalan dan Pembelajaran Prasiswazah (2018)*	*Jabatan Timbalan Naib Canselor (Akademik dan Antarabangsa)*
13	*Peraturan Akademik Pengajian Siswazah (2020)*	*Jabatan Timbalan Naib Canselor (Akademik dan Antarabangsa)*

1.4 DEFINITION

No.	Terms/Abbreviation	Definition
1	UTM / University	Universiti Teknologi Malaysia
2	JPU	Jawatankuasa Pengurusan Universiti
3	REC UTM / Committee	Research Ethics Committee of UTM
5	Non-Clinical Research	Any research and studies involving social sciences
8	NCRE	Non-Clinical Research Ethics Committee
10	GCP	Good Clinical Practice
11	Secretariat	Secretariat of Research Ethics Committee of UTM
12	Researchers	Staff and Student of UTM
13	SOP	Standard of Procedures
14	Chair	Chair of Research Ethics Committee of UTM
15	Deputy Chair	Deputy Chair of Research Ethics Committee of UTM
16	PTJ	*Pusat Tanggung Jawab*
17	DVCRI	Department of Deputy Vice-Chancellor (Research & Innovation)
18	PI	Principal Investigator

1.5 LEGAL CONTEXT

No.	Documents
1	*Akta Badan Berkanun (Tatatertib dan Surcaj) 2000 (Akta 605)*
2	*Akta Perlembagaan UTM*
3	*Polisi Penyelidikan dan Inovasi UTM*
4	*Perlembagaan UTM 2010*
5	*Statut UTM*
6	*Akta Badan Berkanun (Tatatertib dan Surcaj) 2000 (Akta 605)*

SECTION 2 : DESCRIPTION OF CLINICAL RESEARCH ETHICS GUIDELINE

2.1 INTRODUCTION

2.1.1 This guideline is used to explain to researchers about their roles and responsibilities to ensure that research activities are conducted in an integrity and ethical manner and to outline the process involved in obtaining non-clinical ethical approval.

2.1.2 All research conducted by staff and students of the university involving human participants must be referred to the appropriate ethics committee. These include all research, qualitative or quantitative, regardless of whether the research is funded by internal/external grants or even unfunded.

2.1.3 Accountability for the proper conduct of research involving human participants is the collective responsibility of the NCRE and the Principal Investigator (PI). NCRE only deals with research that excludes patients, MOH staff, does not involve attachment of any kind of medical devices to the human body or other research that relates to any kind of medical condition of participants. For this type of research, PI is advised to seek ethical approval from the appropriate Clinical Research Ethic Committee.

2.1.4 Special attention should be given to projects involving:

i. Research with children, prisoners, and adults not competent to give consent
ii. Research involving the use of genetic material
iii. Research that may impose an undue disadvantage upon participants.

2.1.5 The proposed study must be conducted within the compound of UTM and related to the proposed study outside UTM. In the case of the study to be conducted outside of UTM compound, project study Principal Investigator and related personnel (student, Research Officer, etc.) must be present, and the researchers from UTM must be aware of the procedure.

2.1.6 However, if the research compound is at a hospital/clinic (government, private), the researchers are strongly urged to also seek ethics approval from the respective institution (e.g., National Medical Research Registry (NMRR) for public hospital and clinic) before conducting the studies.

2.2 NON-CLINICAL RESEARCH ETHICS (NCRE)

2.2.1 UTM has established a Non-Clinical Ethic Committee (NCRE) that undertakes ethics review of all research involving human participants including funded and unfunded research which is non-medical.

2.2.2 The NCRE conducts an ethics review prior to the beginning of any research involving human participants. The NCRE examines the ethics components of the research such as, sound methodology, possible risks to the subjects, recruitment of subjects, consent from the subjects, confidentiality or anonymity for the subjects, the way in which the data is handled, and how feedback can be provided for the subjects.

2.3 GUIDELINE FOR NON-CLINICAL RESEARCH ETHICS (NCRE)

2.3.1 ELEMENTS IN REVIEWING THE NRE APPLICATION

2.3.1.1 In the consideration of a study, the NCRE requires that it be conducted in accordance to The Malaysia Code of Responsible Conduct in Research.

2.3.1.2 In principle, there should be respect for the dignity of the person (the right to information, informed consent, and the right to refuse or withdraw from the study), and the research should not override the health, well-being, and care of the subject.

2.3.1.3 Also, if there is any token to be given to participants, the amount will not in any way sway the participants' consent. In this regard, the

information given to subjects in the obtaining of informed consent should be in simple layman language. The committee may request for translations if they think the study population would require that specific language for better understanding before giving their consent.

2.3.1.4 The elements of the NCRE review would also encompass:

i. The scientific worth of the study as it would be unethical to inconvenience subjects for a futile study,
ii. Scientific merit regarding the appropriateness of the study design in relation to the objectives and the statistical methodology,
iii. The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities,
iv. The justification for the use of control arms
v. Criteria for withdrawal of research participants, suspending or terminating the research as a whole,
vi. Facilities including the availability of supporting staff and emergency equipment at site.
vii. The capability and suitability of the investigators to undertake the study,
viii. Investigators as a team must have adequate knowledge and capability to conduct the study.
ix. The criteria for recruitment of study subjects
x. The means of contact and recruitment, to ensure no undue coercion, use of any force or inducement,
xi. The characteristics of the research participants including gender, age, literacy, economic status, and ethnicity,
xii. Mode of initial contact, disseminate information and recruitment of potential research participants or their representatives,
xiii. Inclusion and exclusion criteria for research participants
xiv. Care and protection of subjects;
xv. The risks to subjects are minimized and that risks are reasonable in relation to anticipated benefits,

xvi. Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action,

xvii. The medical care to be provided to research participants during and after the course of the research,

xviii. The adequacy of medical supervision and psychosocial support for the research participants,

2.3.1.5 Steps to be taken if research participants voluntarily withdraw during the course of the research,

i. Information on insurance and indemnity arrangements.

ii. Special safeguards to protect vulnerable subjects, such as children, pregnant women, the mentally disabled and prisoners,

iii. Provisions for privacy and confidentiality of data obtained,

iv. Description of the persons who will have access to personal data of the research participants,

v. Measures taken to ensure the confidentiality and security of personal information concerning research participants.

vi. Cost considerations including coverage of inconvenience, adverse reactions and injuries to subjects, and special sensitivities of the community.

vii. The impact and relevance of the research on the communities from which the research participants are drawn,

viii. The influence of the community on the consent of participants

ix. The extent to which the research contributes to capacity building, such as the enhancement of local well-being, re-search, and the ability to respond to public needs; The manner in which the results of the research will be made available to the research participants and the general public.

2.3.1.6 The review process in principle will be conducted on-paper only, but in certain conditions may involve an interview of the Principal Investigator for further clarification on the proposed study.

2.3.1.7 Principal Investigator and researchers are advised to follow these principles:

i. Researchers must conduct non-clinical research in accordance with the policy of the institution and follow proper practices for safety and security.

ii. Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence.

iii. Researchers must follow codes of ethical guidelines for research involving human participants as stipulated in item 3.2.

iv. Written approval from NCRE, safety and other regulatory bodies must be obtained when required.

v. Researchers should conduct their research so as to minimize adverse effects on the wider community and the environment.

vi. A researcher who considers that research misconduct may have occurred must act in a timely manner, having regard to the UTM policies

vii. Maintain high standards of responsible research fostering a research environment of intellectual honesty and integrity, and scholarly and scientific rigor. Researchers must:

viii. Respect the truth and the rights of those affected by their research.

ix. Manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly considerations.

x. Adopt methods appropriate for achieving the aims of each research proposal.

xi. Follow proper practices for safety and security.

xii. Cite awards, degrees conferred and research publications accurately, including the status of any publication, such as under review or in press.

xiii. Promote adoption of this manual and avoid departures from the responsible conduct of research.

xiv. Conform to the policies adopted by UTM and bodies funding the research.

2.3.2 RESEARCH INVOLVING HUMAN PARTICIPANTS

2.3.2.1 All non-clinical research conducted by staff and students must follow codes of ethical guidelines for research involving human participants which include:

i. Sources of Data – The participant is subject to ethical clearance, meaning the researcher must define whether the data involves new data collection or existing data and how the data will be collected.

ii. Risk Assessment – The researcher is required to undertake “Risk Assessment” to ensure that participants’ interests and rights are protected.

iii. Informed Consent – The participant is given the opportunity to choose what shall or shall not happen to them, meaning the researcher should provide the participants with sufficient information using words that are easy to understand and the language/s that the participants speak.

iv. Recorded consent other than written consent - online/email recorded response can also serve as a means of obtaining informed consent as long as it is in response to a proper information sheet.

v. Waiver of the Requirement of Recorded Informed Consent - participants must normally give recorded informed consent to any use of their personal data unless existing personal data is being used for the purposes for which they were collected or a directly related purpose.

vi. Pilot Studies – It is a must to seek consent before obtaining data in pilot studies.

vii. Parental consent - For research involving children under 18 years old, researchers should seek written consent from parents by providing a full justification for the data collection and an information sheet.

viii. Privacy and confidentiality of data - researchers must maintain the confidentiality of data related to individual research participants. Except by public observation, researchers should clearly indicate the purpose of the collection of data and the method to ensure the

confidentiality of collected data. Researchers must also avoid the use of any personal identifiers such as individuals' names and addresses in their research reports which could lead to the human participants being identified.

ix. Security - Information collected will not be publicly disclosed for security reasons. As for private sensitive data, researchers are advised to use indirect identifiers and to keep the direct identifiers separate from the data.

x. Benefits - All reimbursement of expenses, such as traveling expenses, should be commensurate with standard practice and be reasonable.

xi. Sensitive issues – The researcher should be aware of sensitive issues that are highlighted in 3.3

2.3.3 RESEARCH INVOLVING HUMAN PARTICIPANTS

2.3.3.1 In the context of national security, sensitive issues mean any issue that can cause prejudice, hatred, enmity or contempt between or towards any ethnic or religious group and can affect public safety, national security and/or the integrity of the Government and is generally connected with the following acts or behaviour:

2.3.3.2 Questioning the implementation of certain government policies pertaining to economic development, education and social matters.

2.3.3.3 Questioning the implementation of particular provisions in the Federal and State Constitutions pertaining to Federal Laws, the freedom of religion, the special position of the indigenous community (Bumiputera), citizenship and rights of the other communities.

2.3.3.4 Regarding a racial or religious group as neglected or given preference in the implementation of a particular policy without providing the background or reasons that necessitate it.

2.3.3.5 Promoting the success of one racial or religious group on the basis of the preference and facilities provided by the government to individuals or the ethnic group concerned.

2.3.3.6 Questioning the authority, wisdom and abilities of a group

2.3.3.7 Associating and blaming a racial or religious group as the cause of an incident.

2.3.3.8 Publicising the name or the ethnic group involved.

2.3.3.9 Publicising the details of an incident or violent happening that can arouse anger amongst those who read and/or hear about it.

2.3.3.10 Publicising and displaying photographs or sketches that show the racial origin or religion of the parties involved in causing the incident.

2.3.3.11 Conveying the impression that the authorities have failed or are unable to control the situation and are rude and unjust in the discharge of their duties.

SECTION 3 : GOVERNANCE

3.1 GUIDELINES OWNER AND DOCUMENT MANAGER

Owner of Guideline	Research Ethics Committee UTM
Manager of the Guideline Document of the Department	Chair, Research Ethics Committee UTM
Manager of the Guideline Document (UTM)	Head of Section of Governance, Department of Registrar

3.2 RESPONSILITIES

Owner of Guideline	i. The owner of the Guidelines is responsible for the amendment of the Guidelines as well as obtaining a certificate from JKTDEU followed by approval from the JPU / Senate. ii. The owner of the Guidelines is responsible for ensuring that the relevant Guidelines are registered in the UTM Policy Register. iii. The owner of the Guidelines is responsible for ensuring that the relevant Guidelines are communicated to the University staff. iv. The owner of the Guidelines is responsible for reviewing the Guidelines from time to time.
Manager of the Policies Document of the Department (PTJ)	i. The manager is responsible for all storage, recording, and updating Guidelines at the PTJ level. ii. The manager is responsible for monitoring and ensuring the implementation of guidelines at the PTJ level.

Manager of the Policies Document (UTM)	i. The manager is responsible for all storage, recording, and updating guidelines. ii. The manager is responsible for ensuring that all guidelines approved by the University are gazetted by the Registrar or any relevant department. iii. The manager is responsible as the Secretary to JKDEU.

3.3 MONITORING AND ANNOUNCEMENT METHODS

Monitoring and Improvement	i. All University Guidelines must be reviewed annually to ensure that the Guidelines are still relevant. ii. Any party may propose amendments to the Guideline by informing the Guideline Owner. Any amendment should refer to the matter of Policy Document Governance Guideline. iii. The Guideline Owner shall notify the Policy Document Manager in the event of any amendment to the Guideline.
Broadcast / Guideline Announcement	i. Policies that have been approved by the Senate / JPU will be registered in the UTM Policy Register by the Policy Document Manager and gazetted by the Registrar through the University Circular. ii. The Guideline Owners shall make announcements of guidelines that have been approved and gazetted for the effective implementation of the policy. iii. Guidelines must be kept regularly according to the cluster in the UTM Policy

	Register. iv. Guidelines can be accessed by University residents.

3.4 VERSION CONTROL AND AMENDMENT CHRONOLOGY

Version No.	Endorsement Date	Endorsed by	Amendment

SECTION 4 : SUPPORTING DOCUMENTS

4.1 STAGE OF WORK PROCESS

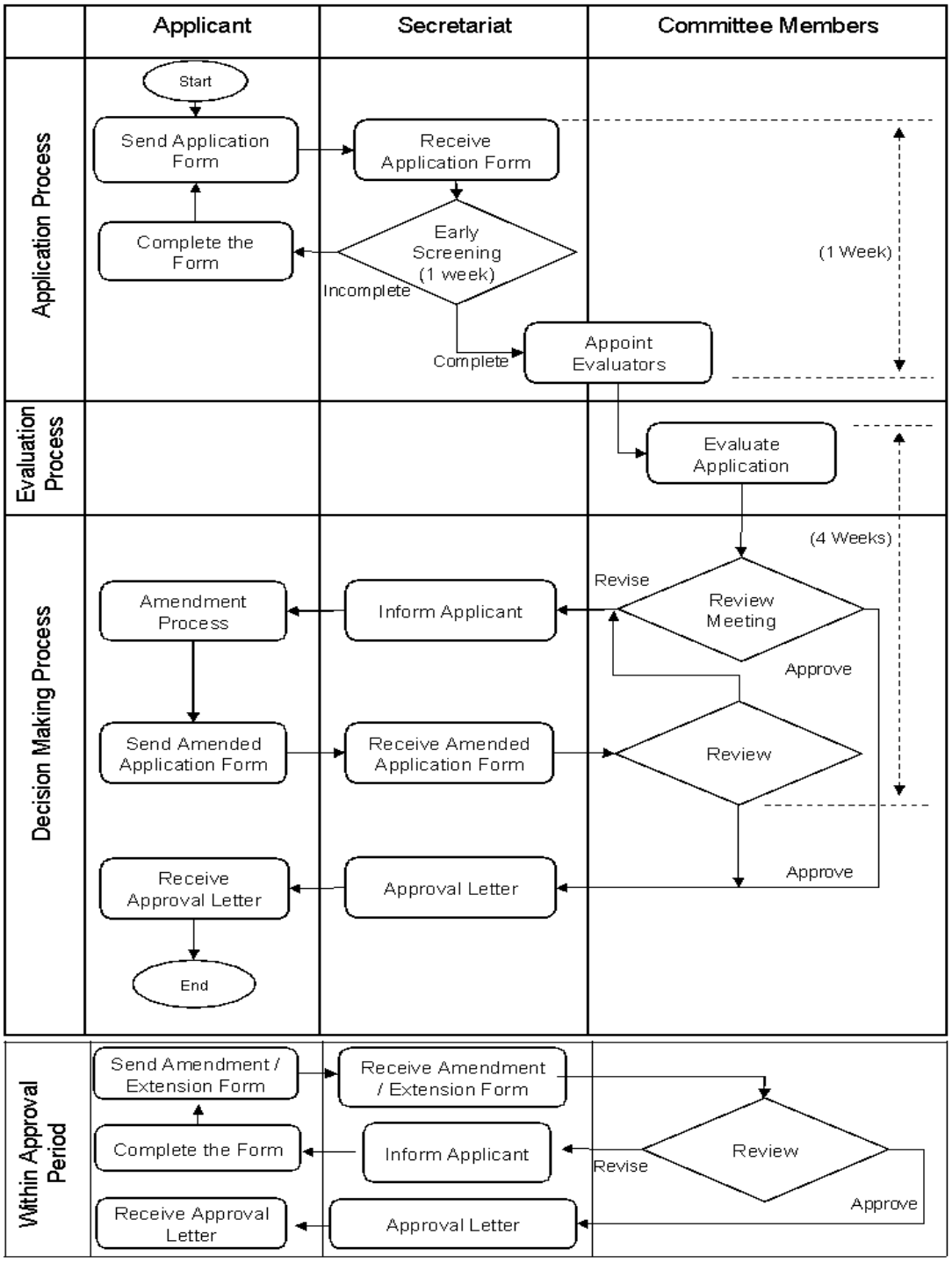
No.	Stage of Work Process	Items	Person in Charge
1	Application Process	Made an announcement with regards to the submission period and the due date.	Secretariat
2		The applicant fills in the forms and submit the required documents to the secretariat	Applicant
3		Receive research ethics application form from the applicant.	Secretariat
2	Evaluation Process	Early screening of application form.	Secretariat
		Assign evaluators for each application received.	Secretariat
		Conduct evaluation.	Evaluator (the head of sub-committees)
		Prepare documentation for the review meeting based on the evaluation.	Secretariat
3	Decision-Making Process	Attend a review meeting for decision-making.	Committee Members
4	Approval Process	Inform the applicant of the meeting outcome(s).	Secretariat
5	Revision Process (if required)	Revise application based on recommendation/decision by the review meeting and resubmit (if applicable).	Applicant

		Evaluate the revised application.	Chair
		Inform the applicant of the meeting outcome(s).	Secretariat
6	Amendment Process (if required)	Inform committee if amendments were made to any information provided earlier in the application form. This is applicable to the case where approval has been obtained previously and still valid within the approval period.	Applicant
		Evaluate the amended application.	Chair
		Inform the applicant of the meeting outcome(s).	Secretariat

4.2 RELATED FORMS

4.2.1 Non-Clinical Research Ethics (NCRE) Application Form

4.3 FLOW CHARTS



SECTION 5 : REFERENCE DOCUMENTS

No.	Documents
1	*Polisi Persekitaran, Keselamatan dan Kesihatan Pekerjaan (2021)*
2	The Malaysian Code of Responsible Conduct in Research 2nd Edition 2020
3	Children Act 2001 (Act 1511); Amendment 2016 (Act A1511)
4	Personal Data Protection Act 2010 (Act 7097)
5	Atomic Energy Licensing Act 1984
6	Biosafety Act 2007
7	Customs Act 1967
8	Environmental Quality Act 1974
9	Factories and Machinery Act 1967
10	*Kod Etika Profesional UTM 2017*
11	Blueprint Research & Innovation 2025
12	Envision UTM 2025