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**ETHICAL CONDUCT IN HUMAN RESEARCH**

**APPLICATION FORM**

|  |  |
| --- | --- |
| **Type of Ethic’s Application. Please tick (/)** | |
|  | **Social Sciences** |
|  | **Health Sciences** |

**PART A: Brief Details of Project**

|  |  |  |
| --- | --- | --- |
| Title of Proposal | **:** |  |
| Project Start | **:** |  |
| Project End (Maximum 3 years) | **:** |  |
| Research Grant | **:** |  |
| Amount of Research Grant | **:** |  |

**PART B: Applicant Details**

1. Principal Investigator

Name :Click here to enter text.

Title : Click here to enter text.

Position :Click here to enter text.

Telephone : Click here to enter text.

Email : Click here to enter text.

Department :Click here to enter text.

Faculty/Institute/Centre : Click here to enter text.

(Please provide CV as attachment)

1. Co-Investigator/s (if any)

Name :Click here to enter text.

Title : Click here to enter text.

Position :Click here to enter text.

Telephone : Click here to enter text.

Email : Click here to enter text.

Department :Click here to enter text.

Faculty/Institute/Centre : Click here to enter text.

(if more than one, please provide a list of co-investigators and their CV as an attachment)

1. Student Investigator/s (if any)

Name :Click here to enter text.

Title : Click here to enter text.

Position :Click here to enter text.

Telephone : Click here to enter text.

Email : Click here to enter text.

Department :Click here to enter text.

Degree/Programme :Click here to enter text.

Faculty/Institute/Centre : Click here to enter text.

(if more than one, please provide a list of co-investigators and their CV as an attachment)

**PART C: Purpose of Research**

🞎 Academic requirement (Thesis, Dissertation, Training Requirement)

🞎 Independent research work

🞎 Multi-institutional or multi-country collaboration

🞎 Others (indicate):

**PART D: Type of Research**

🞎 Interventional Study (e.g. Sensory Evaluation)

🞎 Observational Study

🞎 Health Sciences Survey

🞎 Social Sciences

🞎 Public Health/Epidemiology

🞎 Clinical Study

🞎 Others, please indicate:

**PART E: Data Collection**

1. New data to be collected from human participants. Please tick any that apply.

|  |  |
| --- | --- |
|  | Focus group |
|  | Experimental procedures/treatment/intervention |
|  | Internet survey |
|  | Observation |
|  | Personal interviews |
|  | Telephone survey |
|  | Participant Journals / Diary |
|  | Questionnaire |
|  | Others (please state):Click here to enter text. |

1. Existing records with personal data. (For example, records from organisations that contain the medical status of participants)

|  |  |
| --- | --- |
|  | Yes |
|  | No |

1. Brief description of the study.
2. Background of study (less than 300 words).
3. Rationale of study/problem statement (less than 300 words)
4. Objective(s) of study.
5. Data collection procedures
6. Study sample including sample size calculations. Please specify.
7. How will participants be recruited? Please specify.

1. Who will perform the data collection?
2. Participant inclusion criteria (e.g. residents aged 18 years and above).

Click here to enter text.

1. Participant exclusion criteria.
2. Are the participants given any form of payment/incentive to participate?

Please provide details:

**PART F: Risk and Benefits**

1. Possible benefits to participants:
2. Risk of harm (new data to be collected from human participants).

|  |  |  |
| --- | --- | --- |
| **RISK** | **YES** | **NO** |
| Will the study involve intervention, such as treatment of any type? If YES, please give details:  Click here to enter text. |  |  |
| Is it possible that the duration of the procedures will cause minimal stress, in particular, for children, given their age and capacity? |  |  |
| Is it possible that the study will involve greater than minimal privacy risks, which could induce stress to research participants, such as political behaviour, illegal and sexual conduct, drug or alcohol use? |  |  |
| Will the study cause psychological stress/pain/discomfort?  If YES, please state the precautions taken to minimize such stress/pain/discomfort/risk: |  |  |
| Are any of these participants from a minority/culturally identifiable/disadvantaged group? (e.g. *Orang Asli*)  Please specify: Click here to enter text. |  |  |

If any of the responses above is yes, describe the potential risk/conflict of interest of the study and **provide a plan to mitigate the risk/conflict of interest**.

|  |  |
| --- | --- |
| Potential Risk/Conflict of Interest | Mitigation Plan |
|  |  |
|  |  |
|  |  |
|  |  |

**PART G: Privacy and Confidentiality**

1. Describe how you will preserve participant’s confidentiality as you collect and analyse the data and when you report the result. (e.g. anonymity of participants or company / organisation involved).
2. Existing data (if you are using existing records containing personal data).
3. Please state the source of the data.

1. Are the data sensitive? (e.g. sexual preference, health status, criminal activity)

|  |  |
| --- | --- |
|  | YES |
|  | NO |

1. Please provide full details of the types of personal data to be used:

1. Data record.
2. Do you intend to use any of the following recording devices as a means of collecting data? *(tick all that apply)*

* Audio/Sound recorder (tape/CDs /telephone)
* Photography (including digital cameras/phones)
* Film/Video/DVD recorder
* Computer/USB
* Other
* *If ‘Other’, please give details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

1. Describe what you will do with the recorded data once it has been analysed.
2. Specify who apart from yourself will have access to the research data.
3. Details who will own the data and the results of your research.

**PART H: Human Sample Disposal (if any)**

1. Please describe how the human samples will be disposed.

**PART I: Conflict of Interest**

1. Do any of the researchers have any potential conflicts of interest? If YES, please provide details.

**PART J: Ethical Approval from Other Body**

1. Has this proposal received Ethical Approval from another body?

|  |
| --- |
| *(e.g. Hospital or any organisations)*  Yes  No |

If Yes, give details below:

Name of the organisation that has approved the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Please attach a copy of the approval in your supporting documentation*

**PART K: ATTACHMENTS**

1. Please tick the boxes - which of the following documents are enclosed.

|  |  |
| --- | --- |
|  | Questionnaire/ interview protocol |
|  | Participant Information Sheet |
|  | Informed Consent Form (should at least include the following):   * A statement that the study involves research, an explanation of the purposes of the research, the expected duration of a subject's participation, a description of the procedures to be followed, and if applicable identification of any experimental procedures. * A description of any foreseeable risks or discomforts to the subject * A description of any benefits to the subject, or society, that may reasonably be expected from the research. * If appropriate, a disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to the subject. * A statement describing the extent to which confidentiality of records identifying the subject will be maintained. * Explanation of whom to contact for answers to pertinent questions about the research and subjects' rights, and whom to contact in the event of a research-related injury. * A statement that taking part in the study is voluntary, refusal to participate will involve no penalty or loss of benefits the subject is otherwise entitled to and the subject may discontinue participation at any time with no penalty or loss of benefits |
|  | Ethical Approval from Other Body |
|  | Brief CV for all Investigators (not more than 2 pages of each CV) |
|  | Others: Please state \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**PART L: Declaration**

“In making this application, I certify that I have read and understand the Guidelines for Human Ethics Universiti Malaysia Terengganu and I will comply with the ethical principles of the documents. I will submit, as appropriate, a report for amendment of an approved project, if there are significant changes to my research or if there is an adverse incident”.

Signature of Applicant : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Stamp (if any) :

Signature of Supervisor : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Stamp :

I hereby endorse that this applicant is appropriately qualified in the research area involved to conduct the proposed research project and is capable of undertaking this research study in a safe and ethical manner.

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Dean of Faculty/Director of Institute)

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Update 29092014

Stamp :

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**Jawatankuasa Etika Penyelidikan (JKEP UMT Research Ethics Committee)**

**CHECKLIST FORM**

Submit all the documents:

1. **ONE (1)** hard copy of all related documents to the JKEP Secretariat.
2. **Email the softcopy** of the application to **sekretariat.jkep@umt.edu.my**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Research Title** | |  | | |
| **Principal Investigator** | |  | | |
| **Date of Submission** | |  | | |
|  | |  | | |
| **No** | **Document** | | **Applicant** | **Secretariat** |
| **Compulsory Documents. Please (√)** | | | | |
|  | Checklist Form | |  |  |
|  | Application Form | |  |  |
|  | Subject Information Sheet (English or Malay or Relevant Language) | |  |  |
|  | Consent Form (English or Malay or Relevant Language) | |  |  |
|  | Questionnaire if applicable (English or Malay or Relevant Language) | |  |  |
|  | Curriculum Vitae (CV) of researchers (including post/ undergraduate student) | |  |  |
|  | Research Tools (*e.g. Data Collection Forms, Questionnaires*) | |  |  |
|  | Ethical Form sign by Dean of Faculty/Director of Institute | |  |  |
|  | **Additional Documents (*if applicable*)** | | | |
| 1. | Other Institutional Ethics Approval (*e.g. NMRR*) | |  |  |
| 2. | Approval Letter from related agencies/ institution | |  |  |
| 3. | Grant Approval Letter from related agencies/ institutions | |  |  |
| 4. | Good Clinical Practice Certificate (GCP) | |  |  |
| 5. | List of Drugs, content, and safety profile sheet | |  |  |
| 6.. | Statement Insurance and/or Indemnity Coverage | |  |  |
| 7. | An appointment letter as the contract researcher from companies/ industries with related multi-centered and multi-national trial document | |  |  |
| 8. | Other Related Documents | |  |  |

|  |  |
| --- | --- |
| **For JKEP UMT Secretariat Purposes Only** | |
| Is the submission complete? | Yes  No |
| Completeness Verified by JKEP UMT Secretariat |  |
| Date Receive |  |
| Reviewer (At least 2 person) |  |
| Dateline: |  |