**ETHICAL CONDUCT IN HUMAN RESEARCH**

**APPLICATION FORM**

**PART A: Brief Details of Project**

|  |  |  |
| --- | --- | --- |
| Title of Proposal | **:** |  |
| Project Start  | **:** |  |
| Project End | **:** |  |
| Research funding/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.

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

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.

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

 (if more than one, please provide a list of co-investigators 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.

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

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

**PART C: Data Collection**

1. New data to be collected from human participant. 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 medical status of participants)

|  |
| --- |
|[ ]  Yes |
|[ ]  No |

1. Brief description of 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. Study participants (new data to be collected from human participants).
6. Study sample. 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).
3. Participant exclusion criteria.
4. Are the participants given any form of payment/incentive to participate?

**PART D: 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. |[ ] [ ]

1. If any of the responses above is yes, describe 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 E: 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.
4. Are the data sensitive? (e.g. sexual preference, health status, criminal activity)

|  |
| --- |
|[ ]  YES |
|[ ]  NO |

1. Please provide full details of 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)*
3. Audio/Sound recorder (tape/cds / telephone) [ ]
* Photography (including digital cameras/phones) [ ]
* Film/Video/DVD recorder [ ]
* Computer [ ]
* 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 F: Conflict of Interest**

1. Do any of the researchers have any potential conflicts of interest?

**PART G: Ethical Approval from other Body**

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

|  |
| --- |
| *(e.g. Hospital or any organisations)* [ ]  Yes, all sections [ ]  Yes, some sections [ ]  No   |

1. If Yes, give details below:

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

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

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

 If not all sections have been approved by this body, please provide a brief account of aspects not covered:

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

**PART H: 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 includes the followings):* 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.
* For research involving more than minimal risk, an explanation of the compensation and medical treatments available if injury occurs, and where further information may be obtained.
* 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
* One of the following statements about any research that involves the collection of identifiable information.
 |
|[ ]  Ethical Approval from other Body  |
|[ ]  Brief CV for all Investigators (not more than 2 pages of each CV) |
|[ ]  Others: Please state \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**PART I: Declaration**

“In making this application, I certify that I have read and understand the Guidelines for Research Ethics University 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 /Head of Department)

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

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

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Stamp :