**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) |  |  |  |  |
|  | 1. Objectives
 |  |  |  |  |
|  | 1. Background and rationale
 |  |  |  |  |
|  | 1. Research design
 |  |  |  |  |
|  | 1. Sample
 |  |  |  |  |
|  | 1. Measurement/Instrument
 |  |  |  |  |
|  | 1. Research procedures
 |  |  |  |  |
|  | 1. Data analysis
 |  |  |  |  |
|  | 1. 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: |
|  |  |
|  | Application checked by: |
|  | Staff ID: |
|  | Date |
|  |  |

 **`**

**APPLICATION TO USE HUMAN RESEARCH SUBJECTS FORM (UPSI/PPPI/UPP/BE01)**

**APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

|  |
| --- |
| Section 1. Application Detail |
| **a.Title of Research** | : |  |
| **b.Research Code** **(if applicable)**  | : |  |
| **c.Funding Institution/s****(if applicable)** | : |  |
| **d.Research design** **(e.g.: survey or experimental)** | : |  |
| Section 2. Responsible Research Principal Investigator (PI) |
| **a. Name**  | : |  |
| **b.Telephone No.** | : |  | **c. E-mail** | : |  |
| **d. Office Address**  | : |  |
| **e. Faculty (if applicable)** | : |  | **f. Department** | : |  |
| Section 3. Investigator(s)If more investigators exist than lines provided, please attach a separate list. |
|

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Position** | **Faculty** | **Role** | **Signature** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

 |

|  |
| --- |
| 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  |
| Section 5. Data Collection Period (The start and end dates of research activities for e.g.: collecting data through interviews) |
| 1. Start date (DD/MM/YY) \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_
2. End date (DD/MM/YY) \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_
3. Duration : \_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| **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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Section 7. Human Subject Review** |
| 1. **Has this research been reviewed by any other Human Ethic Committee (university, governmental, private sector) for the protection of human research subjects?**

 Yes (please attach the relevant document) No 1. **Have 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.)  |
| **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.

|  |
| --- |
| Economically/ Educationally Disadvantaged Persons (e.g. to investigate the lower income of SES) |
| Developmentally Disabled Persons (e.g. for Special Education purposes) |
| Poor and Unemployed |
| Victims/ Survivors |
| Interventions (s) that include medical or psychological treatment |
| Single parent |
| Others (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
|  Children (under age 18) |
|  Pregnant Women  |
|  Indigenous People  |
|  Disabled Person  |
|  People diagnosed with Sickness |
|  Patients in Emergency Care |
|  Patients with Mental Health Problems |
|  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. |
| **Section 9. Recruitment** |
| 1. **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).**

1. **Please provide inclusion criteria for your subjects**

*Inclusion criteria comprise the characteristics or attributes that prospective research participants must have in order to be included in the study. Common inclusion criteria can be demographic, clinical, or geographic in nature.* 1. **Please provide exclusion criteria for your subjects**

*Exclusion criteria comprise characteristics used to identify potential research participants who should****not****be included in a study.*  |
| **Section 10. Devices (if applicable)** |
| 1. **Name of the Device(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. **Please state the reasons:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. **Is there any specific protocol that needs to be followed: (Please provide the relevant document)**
 |
| **Section 11. Biological/ Chemical Materials (if applicable)** |
| 1. **Will any biological/ chemical materials will be used with/on the subjects?**

 Yes (please state: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) No (please proceed to Section 12)1. **How are these materials being used in the research? Please describe.**

|  |
| --- |
|  |

1. **Does the research need to collect biological material (s)?**

 Yes (please state who: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) No (please proceed to Section 12)1. **Describe the biological materials that will be collected.**

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. **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) 1. **Will the biological material be destroyed after completion of the study?**

 Yes No   |
| **Section 12. Risks Subjects / Benefit Analysis** |
| 1. **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:** 1. **State the reasons why the research needs to be conducted despite the above risk(s).**
2. **Describe the steps taken to reduce the risks to participants without jeopardizing the research objectives. Please provide the relevant document.**
3. **What are the benefits of the research for the subjects?**

 1. **Are research subject 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. |

|  |
| --- |
| **Section 13. Confidentiality/ Anonymity** |
| 1. **Describe the procedures for protecting the anonymity.**
2. **Explain the procedures you will use to protect the confidentiality of your data.**
 |
| **Section 14. Consent** |
| 1. **Describe the process to obtain informed consent from subjects.**
2. **Describe the approach in ensuring that the subjects are voluntary.**
 |

|  |
| --- |
| **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.**( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Research Principal Investigator**    |

|  |
| --- |
| **Endorsement** **by** **Human Ethics Review Committee** |
| **Comments:**1. **Panel decision**

Endorsed (without presentation)PresentationAmend and resubmit for reviewAmend and resubmit for approval 1. **Do you think this project require monitoring?**

Yes No 1. **Level of research’s risk**

Low ModerateHigh **Justification for monitoring:** **( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Human Ethics Review Committee**   |

|  |
| --- |
| **Endorsement by** **Human Ethics Review Committee****(Second Review, if Applicable)** |
| **Comments:****Endorsed (without presentation)****Presentation****Amend and resubmit for review****Amend and resubmit for approval****( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Human Ethics Review Committee**   |

|  |
| --- |
| **Approval by Human Ethics Committee** |
| **Comments:****Approved****Approved with condition****Not approved****( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Human Ethics Review Committee**  |