**DOCUMENT CHECKLIST FOR**

**APPLICATION TO USE HUMAN RESEARCH SUBJECTS**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

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| **Document Checked** |
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|  | 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
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|  |  |  |  |  |  |
| 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** |
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|  | Application received by RMIC on: |
|  |  |
|  | Application checked by: |
|  | Staff ID: |
|  | Date |
|  |  |

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

**APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

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| Section 1. Application Detail |
| **Title of Research** | : |  |
| **Research Code** **(if applicable)**  | : |  |
| **Funding Institution/s****(if applicable)** | : |  |
| **Research design** **(e.g.: survey or experimental)** | : |  |
| Section 2. Responsible Research Principal Investigator (PI) |
| **Name**  | : |  |
| **Telephone** | : |  | **E-mail** | : |  |
| **Office Address**  | : |  |
| **Faculty (if applicable)** | : |  | **Department** | : |  |
| Section 3. Investigator(s)If more investigators exist than lines provided, please attach a separate list. |
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| **Name** | **Position** | **Faculty** | **Role** | **Signature** |
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| 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) |
| Start date (DD/MM/YY) \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_End date (DD/MM/YY) \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_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** |
| **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 **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.

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| 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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|  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) |

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| **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).**

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

*The inclusion criteria for the subject populations comprise of gender, age ranges, ethnic background, health status, and any other applicable information.*

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

*The exclusion criteria for the subject populations comprise of gender, age ranges, ethnic background, health status, and any other applicable information.*  |
| **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)**
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| **Section 11. Biological/ Chemical Materials (if applicable)** |
| 1. **Will any biological/ chemical materials will be used with the subjects?**

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

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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.**

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

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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**

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1. **State the reasons why the research needs to be conducted despite the above risk(s)**

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1. **Describe the steps taken to reduce the risks to participants without jeopardizing the research objectives. Please provide the relevant document**

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1. **What are the benefits of the research for the subjects?**

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| **Section 13. Confidentiality/ Anonymity** |
| 1. **Describe the procedures for protecting the anonymity.**

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1. **Explain the procedures you will use to protect the confidentiality of your data.**

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| **Section 14. Consent** |
| 1. **Describe the process to obtain informed consent from subjects.**

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1. **Describe the approach in ensuring that the subjects are voluntary.**

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| **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**    |

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

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| **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**   |

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