**DOCUMENT CHECKLIST FOR**

**APPLICATION TO USE HUMAN RESEARCH SUBJECTS**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

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

**APPLICATION TO USE HUMAN RESEARCH SUBJECTS**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

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| Section 1. Application Detail |
| **Title of Research** | : |  |
| **Research Code** **(if applicable)**  | : |  |
| **Funding Institution** **(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) Doctoral Research/ Postdoctoral Research Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| Section 5. Research Period |
| 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 committee (university, governmental, private sector) for the protection of human research subjects?** Yes (please attach the relevant document) No **Has 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.)  |

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| **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 |
| Indigenous People |
| Others (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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|  Children (under age 18) |
|  Pregnant Women  |
|  Indigenous People  |
|  Disabled athletes  |
|  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** |
| **How will the subjects be recruited? (Please provide a copy of the sign-up sheet, newspaper advertisement, or any other protocol or procedure, which will be used to recruit subjects).***In a step-by-step manner, describe the recruitment process*

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**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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 **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.*

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| **Section 10. Devices (if applicable)** |
| **Name of the Device(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Please state the reasons:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Is there any specific protocol that needs to be followed: (Please provide the relevant document)** |
| **Section 11. Biological/ Chemical Materials (if applicable)** |
| **Will any biological/ chemical materials will be used with the subjects?** Yes (please state: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) No (please proceed to Section 12)**How are these materials being used in the research? Please describe**

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**Is the research need to collect biological material?** Yes (please state who: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) No (please proceed to Section 12)**Describe the biological materials that will be collected.**

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

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**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) **Will the biological material be destroyed after completion of the study?** Yes No   |
| **Section 12. Risks/ Benefit Analysis** |
| **State the risk if any**

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

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

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**What are the benefits of the research for the subjects? (e.g. course credits)**

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

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

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

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**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**  |
| **Head of Department Endorsement** |
| **Comments:****( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Head of Department**  |
| **Deputy Dean (Research and Innovation) Endorsement** |
|  **Comments:****( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Deputy Dean (Research and Innovation)**  |

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| **Human Ethics Review Committee Endorsement** |
| **Comments:****Endorsed (without presentation)****Endorsed, and present****Amend and resubmit** **( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Human Ethics Review Committee**   |
| **Human Ethics Committee Approval** |
| **Comments:****Approved****Approved, with amendment****Not approved****( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Human Ethics Committee**  |