**DOCUMENT CHECKLIST FOR**

**APPLICATION TO USE HUMAN RESEARCH SUBJECTS**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

**`**

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

**APPLICATION TO USE HUMAN RESEARCH SUBJECTS**

**SULTAN IDRIS EDUCATION UNIVERSITY (UPSI)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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. | | | | | | | | | | | | | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **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)  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.) |

|  |
| --- |
| **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 | | Indigenous People | | Others (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  | | --- | | 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) | |
| **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*   |  | | --- | |  |     **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.*   |  | | --- | |  |   **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)** |
| **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**   |  | | --- | |  |   **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.**   |  | | --- | |  |   **What is the intended use of the biological material that will be collected?**     |  | | --- | |  |   **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**   |  | | --- | |  |   **State the reasons why the research needs to be conducted despite the above risk(s)**   |  | | --- | |  |   **Describe the steps taken to reduce the risks without jeopardizing the research objectives. Please provide the relevant document**   |  | | --- | |  |   **What are the benefits of the research for the subjects? (e.g. course credits)**   |  | | --- | |  | |

|  |
| --- |
| **Section 13. Confidentiality/ Anonymity** |
| **Describe the procedures for protecting the anonymity.**   |  | | --- | |  |   **Explain the procedures you will use to protect the confidentiality of your data.**   |  | | --- | |  | |
| **Section 14. Consent** |
| **Describe the process to obtain informed consent from subjects.**   |  | | --- | |  |   **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** |
| **Head of Department Endorsement** |
| **Comments:**  **( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Head of Department** |
| **Deputy Dean (Research and Innovation) Endorsement** |
| **Comments:**  **( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Deputy Dean (Research and Innovation)** |

|  |
| --- |
| **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** |