**Request for IRB Review of Research Involving Human Subjects
(PSUT-IRBRESEARCH-A)
To be completed by the Researcher.**

**THE RESEARCHER IS REQUIRED TO SUBMIT BOTH:
1) A SCAN OF THE SIGNED ORIGINAL COMPLETED FORM WITH ALL NECESSARY ATTACHMENTS AND 2) AN ELECTRONIC VERSION TO ????@????.**

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| **Researcher Information** |
| *Name:* | *Phone:* | *Email:* | *Affiliation: (Research center, university, independent, etc…)* |
|  |  |  |  |
| **Project Information** |
| *Title:* | *Start Date:* | *Data Collection Start Date:* | *Date of IRB Request:* |
|  |  |  |  |
| **Will this project be funded externally?** *Yes* ☐ *No* ☐*If yes, name the funding agency and proposal number.* |
|  |
| **Status of Project** |
| Submitted on: | Funding pending: Yes ☐ No ☐ | Funding confirmed:Yes ☐ No ☐ |

**UNDERSTANDING AND CONSENT FORM**

By my signature below, I understand and agree to follow all applicable national legislation and any other regulatory instructions related to conducting research with human subjects. If significant changes in research procedures are needed during the course of this project, I agree to seek approval from the IRB prior to their implementation. I further agree to immediately report to the IRB any adverse incidents with respect to human subjects that occur in connection with this project.

|  |  |
| --- | --- |
| Signature of Researcher | Date |

**THE RESEARCHER IS REQUIRED TO COMPLETE THE
ATTACHED RESEARCH PROTOCOL OUTLINE AND
ATTACH TO THIS COVER FORM WITH OTHER REQUIRED ATTACHMENTS.**

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| **RESEARCH PROTOCOL OUTLINE CHECKLIST** |
| **Attachments required for all projects:** |
| **[ ]** Project Abstract |
| **Attachments required for all projects where applicable:** |
| [ ]  Informed Consent Materials [ ]  Cover letter to subjects and/or parents or guardians[ ]  Questionnaire or survey [ ]  Relevant Grant Application(s) [ ]  Other      [ ]  Letter of Support from concerned entity (university, funding agency, …) |

**FOR ALL PROJECTS, PLEASE COMPLETE ALL SECTIONS BELOW.**

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| 1. **Describe the research problem(s) your project addresses.**
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|  |
| 1. **Describe expected benefits to subjects and/or knowledge to be gained from your project.**
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|  |
| 1. **Describe the population sample for your project.**
 |
| * 1. *How many subjects will participate in this project?*
 |
| * 1. *How will these subjects be identified and selected for participation?*
 |
| * 1. *Describe the rationale for inclusion or exclusion of any subpopulation.*
 |
| * 1. *How will you recruit subjects?*
 |
| * 1. *Describe any incentives for participation you plan to use.*
 |
| 1. **Will you include any of the following vulnerable populations in your research?**

*Check all that apply; if any of these populations are to be included, please address 4a through 4d.* |
| [ ]  Children [ ]  Mentally Ill [ ]  Prisoners [ ]  Mentally Handicapped/Disabled [ ]  Pregnant Women [ ]  Refugees |
| 1. *Any rationale for selecting or excluding a specific population:*
 |
| 1. *Description of the expertise of project personnel for dealing with vulnerable populations:*
 |
| 1. *Description of the suitability of the facilities for the special needs of subjects:*
 |
| 1. *Inclusion of sufficient numbers of subjects to generate meaningful data:*
 |
| 1. **Describe the data collection process.**
 |
| 1. *Will the data collected from human subjects be anonymous?*

*[ ]  Yes [ ]  No* |
| 1. *Will the data collected from human subjects be kept confidential?*

*[ ]  Yes [ ]  No* |
| 1. *Describe your procedures for ensuring anonymity and/or confidentiality:*
 |
| 1. *Describe the time commitment required of each subject:*
 |
| 1. *If the subjects are students, will their participation overlap with their class time?*
 |
| 1. *What methods, instruments, techniques, and/or other sources of material will you use to gather data from human subjects?*
 |
| 1. **Describe potential risks (beyond minimal risks) to subjects:**
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| 1. *Are the risks physical, psychological, social, legal or other?*
 |
| 1. *Assess the likelihood and seriousness of risks to subjects:*
 |
| 1. *Discuss the potential benefits of the research to the population from which your subjects are drawn:*
 |
| 1. *Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others, or in relation to the importance of the knowledge to be gained from the proposed research:*
 |
| * 1. *Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness:*
 |
| 1. *Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects:*
 |
| 1. **Will you be seeking informed consent?** [ ]  Yes [ ]  No

*If yes, please address 7a through 7e.* |
| 1. *What information will be provided to prospective subjects?*
 |
| 1. *What (if any) information will be concealed prior to participation, and why?*
 |
| 1. *How will you ensure consent is obtained without real or implied coercion?*
 |
| 1. *How will you obtain and document consent?*
 |
| 1. *Who will be obtaining consent? Provide names of specific individuals, where available, and detail the nature of their preparation and instructions for obtaining consent.*
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**ATTACH COPIES OF ALL ADDITIONAL MATERIALS THAT A SUBJECT WILL SEE TO THIS APPLICATION.***(Examples: consent forms, protocol sheets, scripts, instruments, tasks, etc.)*