# Request for IRB Review of Research Involving Human Subjects

**To be completed by the Researcher** and submitted both an electronic version to **irb@psut.edu.jo** and the signed original of the completed form and all needed attachments.

<table>
<tr><td colspan="4">Project Title:</td></tr>
<tr><td colspan="2">Researcher's Name:</td><td>Researcher's Phone:</td><td>Researcher's Email:</td></tr>
<tr><td colspan="4">Researcher's Affiliation: (Research Center, University, Independent, …)</td></tr>
<tr><td colspan="2">Project Start Date:</td><td>Date of IRB Request:</td><td>Data Collection Start Date:</td></tr>
<tr><td colspan="2">Will this project be funded externally? ☐ Yes ☐ No</td><td colspan="2">If yes, name of funding agency and proposal #:</td></tr>
<tr><td>Status of project:</td><td>☐ Submitted on</td><td>☐ Funding pending</td><td>☐ Funding confirmed</td></tr>
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By my signature below, I attest to an understanding 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 Investigator Date

**Complete the attached Research Protocol Outline and attach to this cover form with other required attachments.**

**Attachments required for all projects:**

☐ Project Abstract

**Attachments required 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.**

1) **Describe the research problem(s) your project addresses.**

2) **Describe expected benefits to subjects and/or knowledge to be gained from your project.**

3) **Describe the population sample for your project.**

   a) **How many subjects will participate in this project?**

   b) **How will these subjects be identified and selected for participation?**

   c) **Describe the rationale for inclusion or exclusion of any subpopulation.**

   d) **How will you recruit subjects?**

   e) **Describe any incentives for participation you plan to use.**

4) **Will you include any of the following vulnerable populations in your research?** (Check any that apply)

   ☐ Children ☐ Mentally Ill
   ☐ Prisoners ☐ Mentally Handicapped/Retarded
   ☐ Pregnant Women ☐ Refugees

   If any of these populations are to be included, please addresses the following:

   a) **Rationale for selecting or excluding a specific population:**

   b) **Description of the expertise of project personnel for dealing with vulnerable populations:**

c) **Description of the suitability of the facilities for the special needs of subjects:**

d) **Inclusion of sufficient numbers of subjects to generate meaningful data:**

5) **Describe the data collection process.**

a) **Will the data collected from human subjects be anonymous?** ☐ Yes ☐ No

b) **Will the data collected from human subjects be kept confidential?** ☐ Yes ☐ No

c) **Describe your procedures for ensuring anonymity and/or confidentiality:**

d) **How much time is required of each subject?**

e) **If subjects are students, will their participation involve class time?**

f) **What methods, instruments, techniques, and/or other sources of material will you use to gather data from human subjects?**

6) **Describe potential risks (beyond minimal risk) to subjects:**

a) **Are the risks physical, psychological, social, legal or other?**

b) **Assess their likelihood and seriousness to subjects:**

c) **Discuss the potential benefits of the research to the population from which your subjects are drawn:**

d) **Discuss why the risks to 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 as a result of the proposed research:**

e) **Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness:**

f) **Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects:**

7) **Will you be seeking <u>informed consent</u>?** ☐ Yes ☐ No
If yes, describe:

a) **What information will be provided to prospective subjects?**

b) **What (if any) information will be concealed prior to participation, and why?**

c) **How will you ensure consent is obtained without real or implied coercion?**

d) **How will you obtain and document consent?**

e) **Who will be obtaining consent? Provide names of specific individuals, where available, and detail the nature of their preparation and instructions for obtaining consent.**

8) **Attach a copy of all additional materials (Consents, protocol, scripts, instruments, tasks, etc.- everything a subject does or sees) to this application.**