

The Hashemite University  
Institutional Review Board  
(IRB)



الجامعة الهاشمية  
مجلس المراجعة المؤسسي

**SECTION 1 A - PROJECT IDENTIFICATION AND SUPPORT**

<b>Proposal Title:</b>	
<b>Purpose of the Proposal:</b>	
<b>Date of receipt of complete application form (s) and Protocol by the IRB:</b>	

	Name	Academic Degree	Institution	Position	Telephone Number	Email address	Signature *
Principal Investigator							
Co-Investigator							
Co-Investigator							
Co-Investigator							

\* Signature is required on the printed copy of this application document: By signing, the PI assures that he/she will protect the privacy and the rights and welfare of human research subjects to the best of his/her ability. Signature of all Co-investigators acknowledge that they are thoroughly familiar with the contents of this research and pledge to assist the PI in protecting the privacy and the rights and welfare of human research subjects.

<b>Is this research for your thesis/dissertation?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Does this research include a questionnaire? (if yes, please attach it)</b>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<b>List name of the Questionnaire</b>		

<b>Funding for the project (if any): Please detail funding:</b>
<input type="checkbox"/> <b>Commercial Support</b> please attach supporting documents

- Does this project involve the use of biohazardous materials, recombinant DNA and/or gene therapy?  
 Yes  No
- Does this project include the use of radioisotopes and/or radiation-producing devices regardless of whether the use is incidental to the project?  
 Yes  No
- Does this project involve the use of fetal tissue?  
 Yes  No
- Do any investigators or co-investigators have a conflict of interest?  
 Yes  No

A copy of the current Conflicts of Interest Disclosure Form for each Investigator and Co-Investigator involved with this study must be attached to this application.

**SECTION 1 B – OTHER INFORMATION**

<b>Sites where the research will be performed</b>
<b>Estimated duration of total project:</b>
<b>Estimated total number of subjects (including control subjects):</b>
<b>Timeline</b> Length of time study will be open to accrual                      month(s)

## **SECTION 2 - INFORMATION ON THE RESEARCH PROJECT**

2-1	<b>Introduction Rationale/ background</b> <i>(for example, historical background, investigator's personal experience, pertinent medical literature)</i>  <b>Background:</b>
2-2	<b>Significance of the current study:</b>
2-3	<b>Research question or Hypothesis:</b> <b>There is limited adoption of the palliative care curriculum for students in medical faculties internationally and in Jordan. This could affect the competency of medical students when they graduate and practice their professions in routine clinical practices specifically if they have opportunities to work in medical settings that deliver care to patients with advanced disease stages. The overall aim of this study is the development of a national standardized palliative care curriculum addressing medical students.</b>
2-4	<b>Primary objective:</b>
2-5	<b>Secondary objectives:</b>
2-6	<b>Study Design</b> <i>(include standard and experimental procedures, special or unusual equipment or procedures):</i>
2-7	<b>Sample:</b>
2-8	<b>Setting:</b>
2-9	<b>Data Collection:</b> <i>This section describes the instrument used for data collection, the procedure used for data collection, and ethical considerations regarding human subjects.</i>  <b><u>1. Instrument:</u></b>  <b><u>2. Study Procedure:</u></b>
2-10	<b>Human Protection:</b>
2-11	<b>Potential risks to benefit ratio:</b>
2-12	<b>Statistical Considerations</b> <i>(justification for sample size, power and analysis methods)</i>

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**References:**

1. Literature review references:

2. Study design references:

**SECTION 3 - CHARACTERISTICS OF HUMAN SUBJECT:**

3-1	<b>Health/disease categories of the subject:</b>
3-2	<b>Total duration of subject involvement (per person)? (ex: days, hours)</b>
3-3	<b>If the study is likely to provide direct benefits to the subjects, and more subjects want to participate than the protocol can accommodate, how will the selection proceed?</b>
3-4	<b>Is the research limited to any specific age, gender group or subpopulation group?</b>
3-4	<b>Does the research involve a health problem, which may have specific relevance to certain population groups?</b>
3-5	<b>Are "vulnerable populations" among the research subjects?</b> <input type="checkbox"/> None <input type="checkbox"/> Children (age < 18 years) <input type="checkbox"/> Mentally disabled (decisionally-impaired) persons <input type="checkbox"/> Women with child-bearing (reproductive) potential <input type="checkbox"/> Pregnant or lactating women <input type="checkbox"/> Fetus (ex utero) <input type="checkbox"/> Fetus (in utero) <input type="checkbox"/> in vitro fertilization
3-6	<b>Justification for inclusion of vulnerable or susceptible to coercion subjects, if applicable</b>
3-7	<b>Are populations who are susceptible to coercion among the research subjects?</b> <input type="checkbox"/> None <input type="checkbox"/> Economically or educationally deprived <input type="checkbox"/> Patients of the investigator <input type="checkbox"/> Students of the investigator <input type="checkbox"/> Employees of the investigator
3-8	<b>Criteria for inclusion and exclusion of the research subjects?</b>
3-9	<b>At what locations will the candidates be solicited for recruitment?</b>
3-10	<b>Will subjects receive any compensation for participating in cash or in any kind?</b> Yes <input type="checkbox"/> No <input type="checkbox"/> <b>if yes please describe amount or kind of compensation</b>
3-11	<b>If the research involves a health problem, which may have specific relevance to certain ethnic or minority group, or special population subgroup (e.g. Men/Women), what special measures will be taken to optimize recruitment of subjects from these groups?</b> (explain the rational for excluding these populations)

**SECTION 4- CONSENT FORM**

<b>4-1</b>	<b>Types of subject consent used with this study</b> (check all that apply) <input type="checkbox"/> None (request for waiver of consent must be explained in the protocol) <input type="checkbox"/> Written consent <input type="checkbox"/> Written consent in a foreign language <input type="checkbox"/> Written consent from a surrogate for the subject (does not include parents or other legal guardians) <input type="checkbox"/> Assent of children
<b>4-2</b>	<b>List names of study investigators who will obtain consent from subjects.</b>
<b>4-3</b>	<b>List anyone else who will obtain consent.</b> <i>(Explain how they will be informed about the study)</i>

**SECTION 5 - RISKS AND BENEFITS OF THE RESEARCH**

5-1	<b>To what kind of direct risks of harm could the human subjects be exposed by participating in this research, and what measures will be taken to minimize each risk?</b> (Describe the data monitoring procedures that will be employed to ensure the safety of subjects.)
5-2	<b>Does this study include a Placebo?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If yes, justify the need for a placebo control group if one is included in this study.</b>
5-4	<b>If “vulnerable populations” or populations susceptible to coercion are among the research subjects, what additional measures will be taken to minimize risks that may uniquely affect them?</b>
5-6	<b>Are there any indirect risks to the public or community, which could result from this research?</b>
5-7	<b>What are the potential <u>direct</u> benefits of this research to the <u>subjects</u>?</b>
5-8	<b>What are the potential <u>indirect</u> benefits of this research to the <u>public or others</u>?</b>

**SECTION 6- RESEARCH RECORDS**

<b>6-1</b>	<b>If information contained in the research records were to be revealed, would it place the subjects at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputation?</b>  <input type="checkbox"/> Yes <input type="checkbox"/> No  <b>If yes, please describe the plans to exclude this possibility.</b>
<b>6-2</b>	<b>What measures will be taken to preserve the confidentiality of research information collected, and the privacy of the subjects?</b>
<b>6-3</b>	<b>Will the sponsor cover the entire cost of this research?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No  <i>If no, please explain how the research will be carried out without a sponsorship.</i>
<b>6-4</b>	<b>Is their medical care provided for the participants?</b>

<p>_____</p> <p>Printed/Typed Name of Investigator</p> <p>_____</p> <p>Signature of Investigator</p>	<p>_____</p> <p>Telephone number</p> <p>_____</p> <p>Date</p>
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