|  |  |
| --- | --- |
| **) رسالة دراسات عليا) Postgraduate Thesis** ☐**) بحث علمي ينشر في مجلة)** **☐ Scientific Research Published in a Journal** **أخرى (اذكرها) : Other** ☐ | Research Type:  |

***Part 1: Investigators***

|  |  |
| --- | --- |
|  | Principal Investigator (PI): (English) |
|  | الباحث الرئيس (اللغة العربية) |
|  |  |
|  | Department : |
|  | Faculty: |
|  |  Email address: |
|  | Telephone number: |

***Additional Research Staff:***

|  |  |
| --- | --- |
|  | Co-Investigators:  |
| Is the co-investigator a graduate student: 🞎 Yes 🞎 No | Co-Investigator 1 |
|  | Name |
|  | Institute  |
|  | Email AddressesPhone number |
| Is the co-investigator a graduate student: 🞎 Yes 🞎 No | Co-Investigator 2 |
|  | Name |
|  | Institute  |
|  | Email AddressesPhone number |

Part 2: Study Information

|  |  |
| --- | --- |
| English tite |  |
| Arabic title |  |

|  |
| --- |
| **Abstract:**  |
| **Introduction:**  |
| **Objectives:**  |
| **Research Methodology and Data Analysis:**  |
| **Work Plan:**  |
| **Outcomes:**  |
| **References:**  |

***Part 3****:* ***Study Elements***

|  |  |  |
| --- | --- | --- |
|[ ]  Bio-specimen |[ ]  Biometrics |[ ]  Registry or repository |
|[ ]  Focus Group |[ ]  Genetic Analysis |[ ]  Genomic Data Sharing |
|[ ]  X-Ray |[ ]  Interview/ Survey |[ ]  MRI |
|[ ]  Video/Audio Recording |[ ]  Observation |[ ]  Record Review (Prospective) |
|[ ]  Record Review (Retrospective) |[ ]  Screening Procedures |[ ]  Sensors (Externally Placed) |
|[ ]  Sensors (Inserted) |[ ]  Other: |
| Interventions: [ ]  Drug/Biologic [ ]  Device [ ]  BehavioralAdditional Oversight: [ ]  Biohazards, Recombinant DNA, or Gene Transfer [ ]  Radiation exposure without direct clinical benefit [ ]  Human embryonic, human totipotent stem cells; or human gametes |

***Part 4: Study Location***

|  |  |  |
| --- | --- | --- |
|[ ]  Universities: YU, JUST, …. |[ ]  Community |[ ]  Medical centerse e.g. IVF centers, .. |
|[ ]  Hospitals |[ ]  Schools |[ ]  Daycare centers |
|[ ]  Refugees Camps |[ ]  Others:  |

***Part 5: Subject population***

|  |  |  |
| --- | --- | --- |
|[ ]  Human fetuses  |[ ]  Minors/children |[ ]  Individuals with mental disabilities |
|[ ]  Individuals with physical disabilities |[ ]  Refugees |[ ]  Individuals with limited Arabic proficiency |
|[ ]  Neonates  |[ ]  Pregnant  |[ ]  Prisoners |
|[ ]  Students | [ ]  Others:  |

***Part 6: Research Participants Information***

|  |  |
| --- | --- |
| Age range:  | From: To:  |
| Gender: | Any |
| Inclusion criteria: |  |
| Exclusion criteria: |  |
| Total Sample Size: |  |

***Part 7: Recruitment***

|  |  |  |
| --- | --- | --- |
|[ ]  Email  |[ ]  Flyer |[ ]  In-Person |
|[ ]  Letter  |[ ]  Social Media |[ ]  Research Pool |
|[ ]  Telephone/Text |[ ]  Other: |[ ]  Web-posting |
|[ ]  Word of Mouth |  |

***Part 8: Risks and Benefits***

|  |
| --- |
| Benefits: |
| Direct Benefits |[ ]  Yes, Explain:  |
|  |[ ]  No |

|  |
| --- |
| Risks: |
| [ ]  | No  | ☐ Yes, Explain:  |
| Describe the risk mitigation plan: |

|  |
| --- |
| Early Withdrawal: |
| List the criteria for withdrawing individual participants from the study (*e.g.*, safety or toxicity concerns, emotional distress, inability to comply with the protocol, or study sponsor).  |
|  |

***Part 9: Confidentiality***

|  |
| --- |
| Confidentiality  |
|[ ]  Identifiers will be coded to protect confidentiality. |
|[ ]  Identifiable data will be destroyed to protect confidentiality |
| [ ]  | Identifiable data will not be destroyed; Explain:  |

|  |
| --- |
| Data Access |
|[ ]  Study team members |[ ]  Collaborators |[ ]  Data coordinating center |
|[ ]  Sponsor |[ ]  Future sharing with other researchers |[ ]  Other:  |

|  |
| --- |
| Certificate of Confidentiality: |
|  |
|[ ]  The study does not require a Certificate of Confidentiality. |
|[ ]  The study requires a Certificate of Confidentiality (only for external researchers); Explain: |

***Part 10: Compensation and Cost***

|  |
| --- |
| Subjects receive compensation: [ ]  No [ ]  Yes |
| Costs associated with this study: ☐ No ☐ Yes, Choose from the list below: |
|[ ]  Transportation and parking  |[ ]  Study drugs or devices |
|[ ]  Administration of drugs/devices |[ ]  Other :  |

Signature of the principal investigator (PI) (REQUIRED):

Date:

**Please, submit this form and all the required documents to the following e-mail:** **irb@yu.edu.jo**