|  |  |
| --- | --- |
| **) 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 Addresses  Phone number |
| Is the co-investigator a graduate student: 🞎 Yes 🞎 No | Co-Investigator 2 |
|  | Name |
|  | Institute |
|  | Email Addresses  Phone 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  Behavioral  Additional 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**](mailto:irb@yu.edu.jo)