****

**IRB Application Form**

**2020-2021**

Bethlehem University Research Ethics Guidelines require that all research, including but not limited to research involving human subjects, animal participants, personal data, or human tissue, be reviewed and approved by the University Institutional Review Board (IRB) prior to conducting the research. This procedure aims at protecting the rights of human subjects recruited in any research activity at BU, following the BU research ethics policy and all applicable international instruments, agreements and protocols.

**If your research does not involve interactions with human subjects, animal participants, personal data, or human tissue, please fill out sections Ai-Av, B and H only. For research involving animals, please include section G as well.**

Researchers may be asked to provide documentation of mandatory online training prior to the IRB review. For further information on human subjects research policies, training requirements, and forms, please contact Dr. Jamil Khader at <jamilk@bethlehem.edu>.

**Instructions:**

* The application must be typed, proofread, signed and submitted to [jamilk@bethlehem.edu](mailto:jamilk@bethlehem.edu).
* If the proposed research has previously considered for BU IRB review, please provide the:

IRB number: Date approved:

* Please put your signature on page 4 of this form, section H.
* Please attach you consent form to this application.

**Section A: General information**

A.i. Project title:

A.ii. Anticipated start date: Anticipated end date:

A.iii. Principal investigator (PI):

Name:

Title:

Department:

Phone: Email:

A.iv. Please list below the name, title and email addresses of co-investigators, if any:

1.

2.

3.

A.v. **Funding Source**: If the proposed research is supported fully or partially by a grant please provide us with the following:

Sponsor name:

PI on grant:

Grant title or proposal number:

5.a. Will funding source create a conflict of interest? Yes \_\_\_\_\_\_ No \_\_\_\_\_\_\_\_\_\_

If yes, please explain \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A.vi. ***Please check any of the following categories that apply to the above mentioned research:***

|  |  |
| --- | --- |
|  | Participants of this study will include minors/ pregnant women/ prisoners. |
|  | This study will involve deception of participants |
|  | Participants will be paid |
|  | Participants might be exposed to hazardous materials in this study |
|  | This is not a drug study. |
|  | This study includes Human Tissues as the subjects of research. |

**Section B: Purpose of the research**

B. i. List the main objectives of the proposed research in a clear language accessible to scientists who are unfamiliar to your area:

1.

2.

3.

B. ii. State your main research hypothesis/question:

B.iii. Research outcomes: Describe the way in which the results of the study will shared and disseminated (publication, share at a conference, medically or commercially applied):

**Section C: Participant population:**

C.i. **Describe the research sample/ participants** (Check all that apply)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Number of participants |  | Prisoners |
|  | Adults |  | Pregnant women |
|  | Minors/less than 18 |  | Uneducated persons |
|  | Medical patients |  | Public officials |
|  | Mentally or developmentally disabled |  | Students |

C. ii. Will there be any **exclusion criteria** for participants? If yes, provide them.

**Section D: Type of data:** (Check all that apply)

D. i. Indicate the data collection procedures to be used in this study.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Questionnaire/surveys |  | Photographs |
|  | interviews |  | Audiotaping |
|  | observations |  | Videotaping |
|  | Data bases or archives |  | Educational test |
|  | Physiological measurements |  | Blood samples |
|  | MRI/X-rays |  | Other\* |

\*If you checked ‘other’, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D. ii. Indicate the setting or site of research other than BU facilities (schools, classrooms, hospitals, clinics, etc.):

D. iii. Describe the methods used to protect the anonymity, privacy and confidentiality of the participants.

Provide the names of people who will have access to these data.

D.iv. Describe possible risks and benefits to the participants. Risks may include emotional stress, loss of confidentiality, physical injury, etc.

**Section E: Participant recruitment**

E. i. Describe the methods to be used to recruit the participants. Such methods may include advertisement, flyers, email communication, face to face, etc.

E. ii. Who will contact and recruit the potential participants? Have they been trained in methods of recruitment?

**Section F: Consent Letters/ Forms**

Please attach a copy of all informed consent letters/forms that you will use to obtain the participants’ consent. If any research materials, including consents or explanation of the study written for participants in a language other than Arabic, please include these materials along with original and translated materials in this proposal.

**Section G: animal participant**

1. Common name of animal \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Scientific name (Genus, species) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Number of animals to be used \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Housing and husbandry to be provided to the animals:
5. Cage/pen size \_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Number of animals per cage \_\_\_\_\_\_\_\_\_\_\_\_\_\_
7. Place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
8. type of food \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
9. frequency of food and water \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
10. how often animal is observed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
11. What will happen to the animals after experimentation?

**Section H: Signatures**

I certify that the information given in this application is complete and correct and agree to conduct and lead the research involving human participants following the approved IRB and according to the ethical guidelines of BU. In case of any modification to this protocol, no work will be conducted before the approval of the IRB of BU on the proposed modifications. I also declare that neither I nor any of the co-investigators has any financial conflict of interest stemming from the proposed grant. I also certify that the conduct of this research will be carried out only by qualified researchers.

Principal investigator signature date:

Co-investigator signature date:

(If affiliated with BU)