REC OFFICE USE		
HUMAN RESEARCH ETHICS COMMITTEE No		
Date Received		
Institute/Centre/Faculty		
Campus		
	Master's project	
	Grants Awarded	
	Small Grants Awarded	
	General	
	Clinical Trials	

Al-Quds University

Research Ethics committee (REC)

Application Form

1. Project Title (in full)

RESEARCH PERSONNEL

Principal Investigator

Name	
Title	
Qualifications	
University Position Held: employee, affiliate (indicate type; eg. honorary associate, clinical academic), visiting	
Full mailing address	
Telephone	
Fax	
E-mail	

Associate Investigator(s)

Associate Investigator 1	
Name	
Title	
Qualifications	
University Position Held: employee, affiliate (indicate type; eg. honorary associate, clinical academic), visiting	
Full mailing address	
Telephone	
Fax	
E-mail	

Associate Investigator 2	
Name	
Title	
Qualifications	
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	
Full mailing address	
Telephone	

Fax	
E-mail	

Associate Investigator 3	
Name	
Title	
Qualifications	
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	
Full mailing address	
Telephone	
Fax	
E-mail	

Associate Investigator 4	
Name	
Title	
Qualifications	
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	
Full mailing address	
Telephone	
Fax	
E-mail	

Associate Investigator 5	
Name	
Title	
Qualifications	
University Position Held: employee, affiliate (indicate type eg honorary associate, clinical academic), visiting	
Full mailing address	
Telephone	
Fax	
E-mail	

PROJECT AND SITE DETAILS

2. Please provide details of the research setting (Research laboratory, Hospital, ..etc)

3. Provide information to demonstrate that the researchers involved in the project have the necessary training, expertise and experience to carry out their role in the research.

4. Please outline (or attach) the proposed procedure for dealing with any health emergencies that may arise during the conduct of the research. If the Principal Investigator at the proposed University site is not a health practitioner, please provide details of the medical practitioner who will be responsible for dealing with medical emergencies.

5. Risk assessment (please indicate that the following are accurate):

☐ The site has adequate data protection and security systems to ensure protection of participant's privacy

☐ The site has adequate, secure systems for storage of investigational products

☐ Participants are able to report adverse events and study outcomes reliably

6. Is this research at the University site commercially sponsored?

☐ NO

☐ YES – please provide a copy of the certificates

DECLARATION BY INVESTIGATORS

I confirm that I have read and understand the attached Code of Good Practise and Helsinki declaration in Research Conduct in Human Research.

I confirm that I have read and understand the Code of Good Practise and Helsinki declaration in Research Conduct in Human (Provided and declared by the Ethics Research Committee, Al-Quds University)

I confirm that the above information is accurate, and that the project will continue in accordance with the Human Research Ethics Committee approved protocol.

Principal Investigator

Name	*Signature*	*Date*

Associate Investigator(s)

Name	*Signature*	*Date*
Name	*Signature*	*Date*
Name	*Signature*	*Date*
Name	*Signature*	*Date*
Name	*Signature*	*Date*

SECTION 1: ADMINISTRATION

1.1

(a) Provide a brief summary of the project in non technical language (approximately 100 words)

(b) Outline the academic/scientific merits of this study (including potential contributions to the body of knowledge and methodological rigor) (approximately 100 words)

1.2 (a) Has this project already been submitted to any other HREC(s)? ☐ **N** ☐ **Y**

(b) Will this project be submitted to any other HREC(s)? ☐ **N** ☐ **Y**

If you answered YES to (a) or (b), give the name of the HREC(s)

1.3 (a) Indicate the proposed date of commencement of the project.

Projects should not commence without the prior written approval of the REC.

Date

(b) Indicate the proposed completion date of the project.

Date

1.4 (a) Has this protocol received research funding/contracting or is this submission being made as part of an application for research funding/contracting? ☐ **N** ☐ **Y**

If you answered YES, list the funding/contracting bodies to which you have submitted, or intend to submit, this project. Attach a copy of the grant application(s), contract(s) or similar agreement(s).

Funding/Contracting body 1:
Funding/Contracting body 2:
Funding/Contracting body 3:

SECTION 2: NATURE OF RESEARCH

2.1 The nature of this project is most appropriately described as research involving:- (more than one may apply):

- **behavioural observation** ☐ **Y**
- **self-report questionnaire(s)** ☐ **Y**
- **interview(s)** ☐ **Y**
- **qualitative methodologies (e.g. focus groups)** ☐ **Y**
- **psychological experiments** ☐ **Y**
- **epidemiological studies** ☐ **Y**
- **data linkage studies** ☐ **Y**
- **psychiatric or clinical psychology studies** ☐ **Y**
- **human physiological investigation(s)** ☐ **Y**
- **biomechanical device(s)** ☐ **Y**
- **human tissue** ☐ **Y**
- **human genetic analysis** ☐ **Y**
- **a clinical trial of drug(s) or device(s)** ☐ **Y**
- **Other (please specify in the box below)** ☐ **Y**

Proceed to Section 3.

SECTION 3: PARTICIPANTS AND RECRUITMENT

3.1 (a) What is the age range of all participants involved in this study?

(b) Are the participants include children (defined by statute for this purpose as anyone under 18) ☐ Y ☐ N

If you answered NO, give reasons why not.

3.2 Are the participants:- (more than one may apply)

- **in a teacher–student relationship with the researchers or their associates?** ☐ Y
- **in an employer–employee relationship with the researchers or their associates?** ☐ Y
- **in any other dependent relationship with the researchers or their associates?** ☐ Y
- **prisoners?** ☐ Y
- **refugees?** ☐ Y
- **members of the security services?** ☐ Y
- **mentally ill?** ☐ Y
- **intellectually impaired?** ☐ Y
- **unconscious or critically ill patients?** ☐ Y
- **in a doctor–patient relationship or a health giver–receiver relationship with the researchers or their associates?** ☐ Y

If you answered YES to any of the above, provide details.

3.3 (a) What is the sample size for the study? Comment on how this sample size will allow the aims of the study to be achieved.

3.4 Will participants receive any reimbursement ☐ N ☐ Y

If you answered YES, what is the amount or nature of the reward and the justification for this?

Proceed to section 4

SECTION 4: PRIVACY

4.1 Is there a requirement for the researchers to identify, collect, use, or disclose information of a personal nature *(either identifiable or potentially identifiable)* about individuals without their consent?

☐ N ☐ Y

If you answered YES, state what information will be sought and how many records will be accessed.

IF YOU ANSWERED NO, YOU DO NOT NEED TO COMPLETE ANY MORE OF SECTION 4. GO TO SECTION 5

Please provide details

Proceed to Section 5.

SECTION 5: COLLECTION OF DATA

5.1 Will any part of the study involve <u>recordings</u> using audio tape, film/video, or other electronic medium ? ☐ N ☐ Y

If you answered YES, what is the medium and how it will be used?

5.2 Does your research involve the <u>secretive</u> use of photographs, tape-recordings, ☐ ☐

or any other form of record-taking? **N** **Y**

If you answered YES, provide details and a justification for the secrecy.

5.3 (a) How will the results of the study be disseminated (e.g. via publication in journals and presentations in scientific meetings)?

5.4 How will the confidentiality of the data, including the identity of participants, be ensured during collection and dissemination?

5.5 (a) What is the proposed storage location of, and access to, materials collected during the study (including files, audiotapes, questionnaires, videotapes, photographs)?

Please cross (X) the appropriate box:

	Principal investigator's Office	**Room No.**		**Building**	
	Faculty / Departmental Office	**Room No.**		**Building**	
	Other (Please provide details below)				

(b) On completion of the study, where will the materials that were collected during the study (including files, audiotapes, questionnaires, videotapes, photographs) be stored?

Please cross (X) the appropriate box:

	Principal Investigator's Office	**Room No.**		**Building**	
	Faculty / Departmental Office	**Room No.**		**Building**	
	Other (Please provide details below)				

SECTION 6: ASSESSMENT OF RISKS

6.1 Indicate if the participants might experience any of the following:

Risk of physical harm (e.g., falling, muscle pain)

Y ☐

Physical discomfort (e.g., tiredness, weakness, nausea)

Y ☐

Risk of psychological or emotional harm (e.g., trauma)

Y ☐

Psychological or emotional discomfort (e.g., anxiety, stress, loss of confidence, regret for disclosing personal information)

Y ☐

Legal repercussions for participating in the study (e.g., possibility of being sued, charged with criminal activity)

Y ☐

6.2 POTENTIAL RISK TO PARTICIPANTS AND RISK MANAGEMENT PROCEDURES

Identify, as far as possible, all potential risks to participants (e.g. physical, psychological, social, legal or economic), associated with the proposed research. Please explain what risk management procedures will be put in place.

6.3 ARE THERE ANY SPECIFIC RISKS TO RESEARCHERS THAT ARE GREATER THAN THOSE ENCOUNTERED IN NORMAL DAY TO DAY LIFE?

☐ YES ☐ NO *(If YES, please describe.)*

End of the application