Print

MINISTRY OF DEFENSE
MEDICAL SERVICES DIVISION
PRINCE SULTAN MILITARY
COLLEGE OF HEALTH SCIENCES
INSTITUTIONAL REVIEW BOARD

وزارة الدفاع والطيران
الإدارة العامة للخدمات الصحية
كلية الأمير سلطان العسكرية للعلوم الصحية
لجنة أخلاقيات البحث العلمي

Institutional Review Board (IRB) Application Form

Official Use Only

Application #:

Submission Date:

This form should be completed by the Principal Investigator (PI)

PI Name:	
Institution:	
Department:	
Submission Date:	

1. Select one research category from the list below:

__ Clinical investigations or other studies of medical devices

Research administering questionnairs/interviews for quantitative analysing using mixed quantitative/qualitative methodology

__ Research involving qualitative and quantiative methods

Research limited to working with human tissue samples and/or dta

__ Research tissue bank

If your work does not fit any of these categories, select the option below:

Other research (specify): _____

Part A: Introduction

1. Title of Research	
Full Title:	
Key words:	

2. Principal Investigator	
Title:	
First name:	
Surname:	
Position:	
Qualifications:	
Work Address:	
Postal Code:	
E-mail:	
Telephone:	
Mobile:	
A copy of a short CV (maximum 2 pages of A4) for the Principal Investigator must be submitted with the application.	

3. Proposed study dates and duration		
Start date:		
End date:		
Duration:	**Years:**	**Months:**

4. Primary purpose of the research: (Tick as appropriate)

__ Scientific investigation

Educational qualification *(for students)*

__ Other research (specify):

A-1. What is the principal research questions/objective? *(Must be in language comprehensible to a lay person.)*

A-2. What are the secondary research questions/objectives? (If applicable, must be in language comprehensible to a lay person.)

A-3. What is the scientific justification for the research? What is the background? Why is this an area of importance? (Must be in language comprehensible to a lay person.)

A-4. Give a full summary of the purpose, design and methodology of the planned research, includng a brief explanation of the theoretical framework. It should be clear exactly what will happen to the research participant, how many times and in what order?

A-5. Give dertails of any clinical intervention(s) or procedure(s) to be received by research participans. (These include uses of medicinal products or devices, other medical treatments or assessments, mental health intervention,s imaging invetigations and taking samples of human biological material.)

A-6. Give details of any non-clinical research-related intervention(s) or procedure(s). (These include interviews, non-clinical observations and use of questionnaires.)

A-7. Will individual or group interviews/questionnaires discuss any topics or issue that might be sensitive, embarassing or upsetting. (e.g., during interviews/group discussions, or use of screening tests for smoking?**)**

◉ **Yes** ○ **No**

A-8. What is the expected total duration of particpation in the study for each participant?

A-9. What are the potential adverse effects, risks or hazards for each research participants from interventions (including non-clinical)?

A-10. What is the potential pain, discomfort, distress, inconvenience or changes to lifestyle for research participants?

A-11. What is the potential for benefit to research partcipants?

A-12. How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited? Give details for cases and controls separately if appropriate.

A-13. What are the principal inclusion criteria? (Please justify)

A-14. What are the principal exclusion criteria? (Please justify)

A-15. Will the participants be from any of the following groups? (Tick as appropriate)

__ Children under 16
Adults with learning disabilities
Adults who are unconscious or very severely ill
__ Adults who have terminal illness
__ Adults in emergency situations
General public
Healthy volunteers
__ Homes, medical students
Other vulnerable groups (pls specify)

A-16. Will informed consent be obtained from the research participants? (Copies of the written information and all other explanatory materials should accompany this application.)

◯ **Yes** ◯ **No**

A-17. How is it intended the results of the study wiill be reported and disseminated? (Tick as appropriate)

Peer reviewed scientific journals
__ Conference presentation
__ Other publications (please specify) _____

A-18. What measures have been put in place to ensure confidentiality of personal data?

A-19. Where will the analysis of the data from the study take place and by whom will it be undetaken?

A-20. Who will have control of and act as the custodian for the data generated by the study?

A-21. What is the primary outcome measure for the study?

A-22. Whare the secondary outcome measures? (if any)

A-23. How many participants will be recruited? If there is more than one group, state how many participants will be recruited in each group.

A-24. How was the number of participants decided upon? If a fomral sample size calculation was used.

A-25. Give details of all other members of the research team at this site, including academic supervisors and all people who will interact with rsearch partiicpants, their organs, tissue or data in a way that has a direct bearing on the quality of care.

PART B: Section 2 – Use ONLY of newly obtained human biological materials

B-1. What types of human tissue or other biological materials will be included in the study?

B-2. Who will collect the samples?

B-3. What types of test or analysis will be carried out on the samples?

B-4. Give details of where the samples will be stored, who will have accessed and the the custodial arrangements.

B-5. What will happen to the samples at the end of the research?

B-6. Specify all locations, departmens, or units at which or thorugh which research procedures will be conducted at this site and describe the activity that wil take place.

PART C: Section 3 – Declarations

Declaration by Principal Investigator

The information in this form is accurate to the best of knowledge and belief and I take full responsibility for it.

I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good clinical practice guidelines on the proper conduct of reesearch.

Print name:

Signature: _____

Date Signed: