جامعة طرابلس
لجنة أخلاقيات البحث العلمي
Scientific Research Ethics Committee
University of Tripoli / Tripoli- Libya

APPLICATION FORM FOR ETHICAL APPROVAL / HUMAN

OFFICE USE ONLY: ☐ Accepted as is ☐ Clearance Pending Revision ☐ Clarification Required ☐ Full Review ☐ Resubmission ☐ Withhold Clearance	Ref. No.: Received date:

Scientific Research Ethics Committee-Tripoli/Libya will review your application for approval; however, the applicant must provide all necessary information for developing the research. The accepted application is valid for one research project.

The applicant must follow the bioethics guidelines in case that his/her research project involves human participants or human materials.

! NOTE!
- **Submitted forms have to get approval before potential participants approached to take part in any research.**
- **The form should be completed in a clear language.**
- **Star tagged questions are mandatory to fill.**
- **The application form will be reviewed within four weeks from date of submission.**

SECTION A – Applicant details

***A 1. Principal Investigator (PI)**					
Title:		**Surname:**		**First name:**	
Department:					
Position / Staff			**Address**		
Contact Tel:			**Email:**		

***A2. Names and affiliations of all other researchers who will be working on the project:**				
First name	Last name	Position	Affiliation	Role on project

***A3. Research Proposal**	
Study or project title:	
Estimated period for data Collection: **Project Start date / End Date:**	

***A4. Funding**		
Funding source	**Please check all that apply, and then specify the funding scheme below:**	
UOT internal research grants		
LARST grant		
Other external grant		
Contract Research		
No funding		

N.B:
LARST (Libyan Authority for Research, Science and Technology**).**
UOT (University of Tripoli**).**

SECTION B – PROPASAL/ PROJECT DETAILS

***B1. Please provide a brief summary of the project outlining the intended value of the project, giving necessary scientific background (max 300 words).**

***B2. Aims and objectives of the study**

***B3. What is the academic/scientific justification for the research?**

Please put this in language comprehensible to a lay person

***B4. Please outline any ethical issues that might arise from the proposed study and how will be addressed.**

*** B5. Location where the research will be conducted**

- ☐ UOT Labs
- ☐ research institutes - (specify site[s])
- ☐ International - (specify site[s])
- ☐ Other - (specify site[s])

B6. Other research ethics committee clearance(s)(optional)

(a) Does the research involve another institution or site? ☐No ☐Yes

If yes clarify

(b) Has any other ethics committee cleared this project? ☐No ☐ Yes

*If Yes, please provide a copy of the clearance letter upon submission of this application.

If No, will any other ethics committee be asked for clearance?

☐No ☐ Yes

If Yes, from which institution?

B7:Recruitment Procedures

	If you answer 'yes' to any of the following questions please explain **1. Ethical issues may rise.** **2. How you plan to address these concerns.**	**Yes**	**No**	**N/A**
1	Does your project include children under 16 years of age?	☐	☐	☐
2	Does your project include people with learning or communication difficulties?	☐	☐	☐
3	Does your project include people in custody?	☐	☐	☐
4	Is your project likely to include people involved in illegal activities?	☐	☐	☐
5	Does your project involve people belonging to a vulnerable group?	☐	☐	☐
6	Does your project include people who are, or are likely to become your clients or clients of the department in which you work?	☐	☐	☐
7	Will any non-anonymised and/or personalised data be generated and/or stored?	☐	☐	☐
8	Will you have access to documents containing sensitive* data about living individuals? If "Yes" will you gain the consent of the individuals concerned?	☐	☐	☐

N.B* Sensitive data are *inter alia* data that relates to racial or ethnic origin, political opinions, religious beliefs, trade union membership, physical or mental health, sexual life, actual and alleged offences.

SECTION C – DESIGN AND METHODOLOGY

C1: Research procedures to be used: *please tick all that apply*.		
1.	Questionnaires (*please attach copies of all questionnaires to be used*)	☐
2.	Interviews (*please attach summary of topics or interview schedule to be explored*)	☐
3.	Focus groups (*please attach summary of topics or interview schedule to be explored / copies of materials to be used*)	☐
4.	Experimental / Laboratory techniques (*please include full details on section D5)*	☐
5.	Use of biomedical procedures to obtain human tissues (or other biological materials) (*please include full details under question D5.*	☐
6.	Other technique / procedure (*please include full details under question D5*)	☐

SECTION D –DETAILS OF PARTICIPANTS

***D1. How many research participants are to be recruited?**

Estimated number of volunteers:

Upper age limit: **Lower age limit:**

Please justify the age range, gender and sample size

***D2. What are the main inclusion criteria for research participants? (please justify)**

***D3. What are the main exclusion criteria for research participants? (please justify)**

***D4. Does the project involve recombinant DNA technology or infectious, toxic, radioactive or carcinogenic agents that may be harmful to other animals or persons? ☐ No ☐ Yes**
If Yes, **(a) Will adequate precautions be taken in accordance with statutory requirements and have relevant personnel been informed? ☐ No ☐ Yes** **(b) Has the appropriate authority or license been obtained? ☐ No ☐ Yes**

***D5 Please summarise your design and methodology**. *It should be clear exactly what will happen to the research participant for research involving human participants. Please complete this section in language comprehensible to the lay person.*

***D6** *Please include subject area risk assessment forms, where appropriate*

SECTION E – THE INFORMED CONSENT PROCESS

***E1. How will you record informed consent? (Please check all boxes that apply)**
(i) Written consent ☐ (ii) Audio-recorded consent ☐ (iii) Online/Email recorded consent ☐

***E2. Do you know the identity of participants? ☐ No ☐ Yes**
If "<u>Yes</u>", please explain why the study is not practicable with recorded informed consent.

***E3. Is the Title of the Project that is to be communicated to participants (e.g. on Consent Form/ Letter of Information) different from the Title of the Project indicated in this application? ☐ No ☐ Yes**

If "<u>Yes</u>", please provide the alternate project title and the reason for difference in Title:

***E4. Ongoing Consent is required if the research occur over multiple occasions or over an extended period of time. Does the research occur over multiple occasions and/or over an extended period of time? ☐ Yes ☐ No**

Please describe the process of how you intend to obtain ongoing consent?

SECTION F – SAFEGUARDS FOR PROTECTING PARTICIPANTS AND DATA

! NOTE !

Confidentiality: An ethical and/or legal responsibility to safeguard information entrusted to them.
Anonymity: Refers to the state of lacking identification, individuality, distinction, or recognisability to the research team.

Please review the companion document for information on distinguishing anonymity and confidentiality.

***F1 Confidentiality/ Anonymity**

(a) Will the data be treated as confidential? ☐ No ☐ Yes

(b) Will the participant be anonymous to the researcher or anyone associated with the research?

(c) ☐ No ☐ Yes

F2. Is there any possibility of participants being inappropriately identified or confidential data being divulged during or after the research has taken place? ☐ No ☐ Yes

If "<u>Yes</u>", please describe the measures you will take to ensure privacy, confidentiality and anonymity are preserved.

***F3. Would you <u>class</u> the data collected in this study as: ☐ anonymous, ☐ irrevocably anonymised,**

☐pseudonymised, ☐coded or ☐ identifiable data?
If 'coded', please confirm who will retain the 'key' to re-identify the data?

***F4. Where will the collected data be stored? Please comment on security measures which have been put in place to ensure the security of collected data.**

F5. Where will the data analysis take place and who will perform data analysis (if known)? (*optional*)

F6. After data analysis has taken place, will data be destroyed or retained? (*optional*) ☐ **If destroyed, how, when and by whom will it be destroyed?** ☐ **If retained, for how long, for what purpose, and where will it be retained?**

SECTION G– ATTACHMENTS/ CHECKLIST

Please check the boxes as appropriate to indicate which of the following documents are enclosed to this application. *(optional)*	
1. Questionnaire and/or interview script	
2. Informed Consent Form	
3. Consent script, for oral consent or email reply for consent	
4. Participant/s information sheet	
5. Deception: post debriefing consent form	
6. Recruiting advertisement/poster	

*SECTION H – DECLRATION & SIGNATURES

I certify that I have read and understand the *Policy of the UOT Ethics Committee for Animal Research*, and I will comply with the ethical principles of these documents. I will submit, as appropriate, a Report for Research Progress or Amendment of an Approved Project, if there are significant changes to my research, or an adverse incident, or when the report for annual progress is due.

Name of Principal Investigator	Signature	Date