Application for Ethical Clearance
Faculty of Applied Medical Sciences
Research Ethical Committee

Section I: Applicants Details

1.Principal Researcher

○ Last Name		First Name	
○ Title of position			
○ Institution		Department	
○ Qualification			
○ Contacts:			
✓ Phone		✓Mobile	
✓ Email			

2.Co-researcher/ faculty advisor

○ Last Name		First Name	
○ Title of position			
○ Institution		Department	
○ Qualification			
○ Contacts:			
✓ Phone		✓Mobile	
✓ Email			

Please state names of any other co-investigators

1	
2	
3	
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6	

Section II: Project details:

1. Title of the project							
2. This project is:							
	◯	Undergraduate	◯	Master	◯ PhD	◯	Faculty
3. Expected Duration of the project							
Project starting date			Project end date				
4. Background and Brief Review of Literature:							
4.1. Aims & objectives: (Maximum 250 words)							
4.2 (Rationale)Why this research is important and how it will add to existing knowledge:							
5. Design							
Specify							

6. Subjects:

6.1. Your subject / participants are:

◯	Human; Specify		◯	Animal; Specify	
◯	Records or data	◯	Others; specify		

6.2. Describe the inclusion& exclusion criteria for sample selection:

Inclusion Criteria

Exclusion Criteria

7. Anticipated risk and benefits:

7.1. Is there any risk?:

◯	No risk	◯	Minimal risk
◯	Great risk		

Describe the potential risk

7.2. Are there any precautions or measures to minimize the risk on the participant?

◯	No
◯	Yes. please Specify

8. Settings:

Indicate the sittings you plan to collect data or implement your research procedure

9. Data collection plan and subject's safety

The instrument that you will use to collect data is:

☐	Interviews	☐	Experimental test/ clinical procedure	☐	Focus group
☐	Record review	☐	Observation	☐	Survey / Questionnaire
☐	Others; specify				

10. Statistical Plan

10.1 Sample size determination (Include power calculations or provide justification for their absence, e.g., pilot/feasibility study)

11. Data Handling and Recording

11.1 Confidentiality (how and where is data stored, and who will have access):

11.2 Record retention (where and for how long)

12. Funding Source

Section III: Consent process safety and confidentiality

1- Informed Consent:

1. Is there a consent form?	◯	Yes			◯	No	
2. The language of consent is	◯	Arabic	◯	English	◯	Other. specify	

3. Will an interpreter be available if required or translation provided

◯ Yes ◯ No

4. Does the consent include the following items?

☐	Type of study	☐	Interventions	☐	Time of the study	☐	Subject role
☐	Risks	☐	Benefit	☐	Compensation	☐	Cost and reimbursement
☐	Right to refuse	☐	Confidentially and privacy guarantees			☐	Researchers contacts

5. To whom will consent be sought if a participant is unable to consent

☐	Participant's Parental permission	☐	Legally authorized representative
☐	Others specify:		

2-Data safety Monitoring:

a) How will data (including video tapes) be handled & stored to ensure confidentiality during collection, analysis after study?

b) What will be done with the raw data after completion of the study?

c) How long will the data be kept & who will be responsible for it safekeeping?

d) Who have right to access the raw data or study records during & after the study?

3- Privacy and confidentiality:

a) Do you plan to share the data with any one other than member of your research group?

- ○ No
- ○ Yes, describe who this will be and under what circumstances this will occurs

- ○ Explain how subject will be informant that this data will be shared

b) Will participant be identifiable

- ○ No
- ○ Yes, describe how their privacy and confidentiality will be protected

4- Disclosure of conflict of interest

a) Is this research being conducted in collaboration with other organization(contract research)

- ○ No
- ○ Yes, specify

b) Do you or any of this research investigators have significant financial or other conflict of interest that are related to this study?

- ○ No, go to the next section
- ○ Yes, briefly explain the conflict of interest

c) Has this conflict of interest been reviewed by any review committee in KAU or other s and managed the potential conflicts of interest?

- ○ No
- ○ Yes, explain who reviewed and attach copy of the approved plan for resolving the conflict of interest

Section IV: Declaration

Principle Investigator's Statement of Assurance

I certify that I have read and filled this application, which describes my proposed investigation involving human/ animal subject, and will conduct this study in accordance with the term of the Belmont Report, Helsink ethical Declaration and Islamic shariah law for the protection of subjects participating in research .

I understand research ethics involving human subject and I agree to:

a) Obtain the voluntary informed consent of subjects in a language that is understandable to them.

b) Report to the Ethical committee at the college of any serious or unexpected adverse event or unanticipated problems within the appropriate reporting period (24 Hours) of identification and will submit an Adverse Events Report.

c) Cooperate with the Ethical committee at the college for continuing the review of this project (submit research progress report)

d) Obtain prior approval from the Ethical committee at the college before implementing changes in the approved research protocol or approved informed consent document (submit a Modification Report).

e) Maintain informed consent document and the progress reports as required by the college and submit a final report at the end of the project informing the committee research completion.

f) Accept the responsibility for the conduct and supervision of this research and the protection of human/animal subjects

g) Agree to maintain adequate accurate records and to make them available for audit/ inspection any time needed.

h) Ensure that research staff and students have been trained and are qualified to conduct This research and protect human/ animal subjects. I agree to provide supervision to research staff and student that will ensure the protection of human / animal subjects. I will Keep records that prove that these requirements have been met.

i) Allow site visits for evaluation and monitoring by the college Ethical committee when ever requested

Signature of Principal Investigator (or Student Investigator		Date
Signature of co- Principal Investigator (if applicable) (or Faculty Advisor)		Date
Signature of co- Principal Investigator (if applicable) (or Faculty Advisor)		Date

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Faculty of Applied Medical Sciences
Research Ethical Committee

Approval of The Ethical Review Committee:	
I certify that this study titled:	
Proposed by the primary investigator:	
Co-investigators:	
1.	
2.	
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The Research ethical clearance application form was reviewed and the protocol for scientific or scholarly merit was examined, as well as the protection of human / animal subjects was ensured, and therefore, investigators are granted the ethical clearance to conduct the research.

Signature of chairman of Research ethical committee		Date

Print / type Name:	

Academic year	
Serial number of the research	