كليات الفارابي
ALFARABI COLLEGES

وحدة البحث العلمي

Research Ethical Committee

For Official Use Only	
Date Received :	/ /
Date Approved :	/ /
End Date :	/ /
File No. :	

APPLICATION FORM

(Academic staff Member only)

Please note that handwritten and/or incomplete forms will be returned to you.

Research Title

1) CORRESPONDING INVESTIGATOR

(Undergraduate and Graduate students cannot serve as corresponding Investigator, but may be listed as a Co- Investigator.)

Name :	
Highest Degree Completed :	
Current Position and Status :	
E-mail Address :	
Institution/Department :	
Mailing Address :	
Office Phone :	
Mobile phone :	

CO -INVESTIGATORS

	Name(s), Degree	Academic position and Affiliation
1.		
2.		
3.		
4.		
5.		
6.		

FUNDING INFORMATION

Check all of the appropriate boxes for funding sources for this research, including pending funding source(s).

☐ Extramural ☐ University ☐ College

☐ Department ☐ Other: Self-funding

Grant or Contract :	
Sponsor :	
Contract / Grant No. (if available) :	
Contract / Grant Title :	

Please provide one complete copy of the Materials & Methods of the proposal submitted to the sponsor with this application.

Has this protocol been previously reviewed by the REC Committee?

☐ No

☐ Yes REC No.: . . . . . .

CLASSIFICATION (click all that applies)

☐ Human (Please specify)

O Experimental O Observational O Medical / Dental Records

☐ Laboratory (e.g., Biology, Pathology, Materials, etc.)

☐ Animal

☐ Others (specify).

THE PROJECT INVOLVES THE USE OF: (Click all that applies)

☐ Investigational Drug(s)/Substance(s)

☐ Approved Drug(s)/Substance(s)

☐ Approved/ Investigational Device(s)

☐ Radioactive Agents Used In Humans

☐ Additional X-Ray Procedures

☐ Psychological Tests

☐ Questionnaire(s)

☐ Interviews

☐ Discarded Human Tissues/Fluids

☐ Use of Fetal and Abortus Tissues

☐ Surgical Procedures (Biopsy, etc.). Please Explain: . . . . . .

☐ Dental Procedures

☐ Medical/Dental Record Review/Archives

☐ Photographs/Videotaping/Audiotaping

☐ Collection of Specimens (a) (complete section below)

☐ Other (Please Explain): . . . . . .

(a) For studies collecting specimens, please specify what is to be collected

☐ Blood

O Separate Draw for the Purpose of this Research

O Additional Draw during Routine Diagnostic Testing

O Amount per Draw: . . . . . Total Amount: . . . . . .

☐ Urine

☐ Tissue

☐ Other, specify . . . . . .

TYPES OF HUMAN SUBJECTS

TYPE	AGE RANGE	NUMBER	SOURCE
Adult Patients (≥18 years)			
Adult Normal / Healthy Subjects (≥18 years)			
Minor Patients (< 18 years)			
Minor Normal / Healthy Subjects (< 18 years)			
Pregnant Women			
Subjects with Substance Abuse			
Prisoners			
Subjects with Disabilities			
Medical / Dental Students			
Employees			
No Subjects will be enrolled			
Others			

TYPES OF ANIMALS

Type	Species	Age range	Number

TIMELINES

Expected duration of the entire study : 3 months		
Expected Starting date of the study :		

RISKS AND BENEFITS

Does the research involve any possible risks or harms to subjects? ☐ No ☐ Yes

If yes, independent scientific review may be required to determine if scientific merit justifies this risk.

APPLICANT CERTIFICATION

I confirm that to the best of my knowledge the information provided in this document is true and accurate. Consistent with my role in this research, I (we) will:

• Conduct the study according to applicable human research protection laws, regulations and Good Clinical Practices, the approved protocol and consent form.

• Conduct the study consistent with the applicable ethical norms (e.g., principles of Declaration of Helsinki, Belmont Report, Tri-Council Policy Statement on Research Involving Humans).

• Accept the authority of, and will abide by, the decisions of this REC-FD as the board of record.

• Comply with REC-FD requirements, including timely filing of progress reports, end of study reports, or other documents as required by the REC-FD.

• Provide a copy, upon request, of the written plan between the sponsor and the investigator that addresses medical care for research subjects with a research-related injury in order for the REC-FD to determine consistency with the language used in the informed consent document.

• Acknowledge the right of the REC-FD to conduct an audit of the study documentation and to observe the consent process, with appropriate notice

• Not initiate changes to the research without prior REC-FD review and approval, except where necessary to eliminate an immediate hazard to subjects.

• Report immediately to the REC any unanticipated problems in the research, significant protocol deviations, or changes increasing the risk to subjects or affecting significantly the conduct of the trial.

• Report promptly all adverse reactions that are both serious and unexpected, and new information that may affect the safety of the subjects or the conduct of the trial, or subjects' willingness to participate in the research.

• Report promptly any findings of serious or continuing non-compliance detected during any monitoring activities that could affect the safety of participants or influence the conduct of the study.

• Report promptly any routine and urgent reports of data and safety monitoring.

• Report promptly

- Findings that emerge after the study has ended that directly affect the safety of past participants and were not anticipated at the time that the study was designed or conducted, and

- Proposed mechanisms for communication of the findings to participants.

• Acknowledge that the study documentation, retained by the REC-FD, may be inspected by regulatory authorities (e.g., Ministry of Health, Saudi FDA) or accrediting bodies, and be available for audit by sponsor-appointed auditors who have a legal right of access to confidential information relating to the study.

Corresponding Investigator (Name and Signature)	Date

Delegate Co-Investigator (Name and Signature)	Date