Note: To avoid any problems when filling out the form, please download the file to your desktop and make sure you have Acrobat Reader.

Application for Clinical Studies			
Principal Investigator (PI):		Position of the PI:	
Collage:		Department:	
Phone/Mobile:		E-mail address:	
Co- Investigators:			
Sponsor (Project No):			
Title of the study (English):			
Title of the study (Arabic):			
Aims of the study (English):			
Aims of the study (Arabic):			

The job title of the researcher and how it relates to the data used:	
Study duration:	
Sample Size: (including control subjects)	
Where will study be conducted? (List of participating centres):	
Has this study been approved by any IRB/REC? (In case of "YES', please specify and attach the letter of approval)	◉ Yes ○ No (Specify:
Has this study been submitted for review by any IRB/REC? (If Yes, please specify and mention the name of contact person and his/ her contact Details)	◉ Yes ○ No (Specify:
Drugs/Device Use:	
A Saudi Food and Drug Authority approved drug or medical device	○ Yes ○ No
Certificates:	
Good Clinical Practice (GCP) Course	○ Yes ○ No
Research ethics course from King Abdulaziz City for Science and Technology	○ Yes ◉ No
This research project is: (Check all that applies)	
○ Single site study / MD / Master Thesis.	
○ Multi-center study (Specify):	
○ National Collaborative project (Specify):	
○ International collaborative project (Specify):	
◉ Others (Specify):	

What is the type of the research?	
◉ Clinical study: (Specify the phase)	I ◉ II ○ III ○ IV ○
○ Interventional study: (Specify the phase)	I ○ II ○ III ○ IV ○ ◉ Specify:
○ Observational Descriptive Study (Case report, Case series, Survey)	
○ Observational Analytic study (Cross-sectional, Case-control, Cohort)	
○ Diagnostic test evaluation	

Does this study include? (Check all that applies)
☐ Human Subject
☐ Genetic testing/ Storing or Banking
☐ Human embryo research
☐ Stem cell research
☐ Biological specimens' collection/storing / banking
☐ Invasive Techniques

Request is being made for an exploited review?
◉ Yes ○ No
Please justify:

How to save data:

Data retention period:

How to destroy data:

List any expected financial support to the subjects:
List any expected ethical concern to the subjects:
List the expected risks of the study to the subjects:
List the potential benefits, if any, to the subjects:
The risks are reasonable to the potential direct benefits to the subjects, if any, or to the knowledge to be gained?
◯ Yes ◯ No
Indicate whether this study will contain dangerous/biohazards materials?
◯ Yes (Specify: ◯ No
Indicate whether this study will involve vulnerable subjects?
◯ Yes (Specify: ◯ No

- Date of Submission:
- Signature of the PI:

Please attach the following:

-The complete research proposal and study questionnaires.
-The CV of the principal investigator and all co-investigators.
-A valid certificate of completion of the scientific research ethics course from King Abdulaziz City for Science and Technology.