**Application for Clinical Studies**

|  |  |
| --- | --- |
| Principal Investigator (PI) |  |
| Position of the PI |  |
| Department\ Collage |  |
| Phone/ Mobile |  |
| E-mail address |  |
| Sponsor (Project No.) |  |
| Co- Investigators |  |

| Title of the study (English & Arabic) |
| --- |
|  |
| Aims of the study (English & 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 |
| 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 |
| **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**[ ]**  Other **[ ]**

 **(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

|  |
| --- |
|  |

* Financial: List any expected financial support to the subjects

|  |
| --- |
|  |

* Ethical Concern: List any expected ethical concern to the subjects

|  |
| --- |
|  |

* Risks: List the expected risks of the study to the subjects

|  |
| --- |
|  |

* Benefits: 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 enclose your proposal.

*Research Ethics Committee at Najran University*

* Received by:
* Date of Receiving:
* Study id Number: