**Application for Clinical Studies**

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| --- | --- |
| 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) |
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|  |
| Aims of the study (English & Arabic) |
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| --- | --- |
| 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

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How to save data

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Data retention period

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How to destroy data

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* Financial: List any expected financial support to the subjects

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

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

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* Benefits: List the potential benefits, if any, to the subjects

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* 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: