RESEARCH CENTER

PROPOSAL FORM

Please read <u>instructions</u> and edit your proposal's sections <u>inside the specified box</u>.

SECTION 1: SUBMISSION INFORMATION

1-Submission status:

☐ First submission. ☐ Second submission. ☐ Third submission

2- Institute of affiliation for the Principal investigator…….

3- Funded: ☐ No ☐ Yes, if funded, amount of budget ☐

4-Type of research:

☐ Clinical activity ☐ Diagnostic/laboratory ☐ Academic degree

☐ Basic science ☐ others

5- Any supporting collaborators: technical, logistic support

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6- Does the project involve collection or use of human tissue or blood?

☐ Yes ☐ No

7-Does the project involve uses of stored human tissue or blood?

☐ Yes ☐ No

8-Will lab tests be done outside KSA?

☐ Yes ☐ No

9-Will there be any invasive procedures to the human body?

☐ Yes ☐ No

10-Will any substance or drug be introduced into or applied to participants'?

☐ Yes ☐ No

11-Will there any use of data from patients' records?

☐ Yes ☐ No

SECTION 2: PROPOSAL FORM SUMMARY

1		Title of the proposal:
2		Principal investigator Name……..Office Ext……..…..Mobile……..E-mail…….
2		Department/institution to which the PI affiliated……. Name and contact information…….
3	3.1	Co- investigator (**1**)……... Contact information……..
	3.2	Co- investigator (**2**)……. ……. Contact information……..
	3.3	Co- investigator (**3**)……... Contact information……..
4		Is the research proposal submitted to elsewhere……..... If so, to which institute or organization, and what kind of support expected.....
5		Is the proposal reviewed by other IRB? Yes……No…….…..If yes, IRB approval form enclosed……
6		Applicant's signature Date…….signature……...…
7		Department/Institutional of affiliation endorsement Head of department/institution Name……...……Title……..…Date……..Signature…….

SECTION 3 DETAILED PROPOSAL

1- Abstract:

- Write briefing of the proposal (**150 words**).

Abstract:

2- Background:

Gives idea about the health problem/the topic at the national, regional and global level. Indicating in the first paragraph what you are **aiming** to do the study. Then review previous studies **(Literature review)**, presenting the literature as part of the background text, not separate sub-title. Report what has been written about the topic in the literature? Then **statement of the problem and justification of the study**. Finally, address the **significance**, by writing about the cost effect and the knowledge gap if any.

Background should not be less than 500 words.

Background:

3- Aim and objectives:

Aim: (stating your goals and what you are targeting and aiming to achieve in general). The broad general intentions to be accomplished through the following objectives.

- **Objectives):** (state the details of each objective that will finally lead to achieve the study target and goals, you can also add secondary objectives other than the main ones and that might be studied during the course of your study). These objectives Should be precise measurable.

Aim: **Objectives of the Study:**

4- Methodology (materials and methods):

- **Study design:** explain the design approach for the study; is it interventional or non-interventional study? Is it cross-sectional or longitudinal study? Is it prospective or retrospective/case-control study?
- **Study Area/Setting:** describe the area, place or setting where the study will be conducted, whether hospital setting (inpatient/outpatient) or community-based. Description of the health facilities, health personnel.
- **Study Subjects:** demographic profile of targeted subjects, accessible subjects, recruitment process, Inclusion Criteria of participants and exclusion criteria of the participants.
- **Sample size calculation and sampling technique:** mention the formula or software applied for sample calculation, with statistical Justification.
- **Ethical Considerations:**
    - Describe how the right to self-determination is preserved during the study (is the participant informed about the study, and do they have the right to withdraw from the study at any point of the study without any consequences).
    - Describe how participants' right to privacy and dignity is preserved (freedom of a person to determine the time, extent, and circumstances under which his or her private information is shared of withheld.
    - Describe how the anonymity and confidentiality of participants is maintained (when patients are involved in the study directly) and how is the confidentiality of the data collected maintained (when the study involves the collection or retrieval of data).

- Describe how right to fair treatment is preserved (how participants are fairly selected, distributed and treated regardless of convenience, age, gender, race, socio-economic status.
- Describe how the right to protection from discomfort and harm is preserved (does the have any anticipated effects? temporary discomfort? unusual level of temporary discomfort? risk of parament damage? certainty of permanent damage?)
- Considering fulfilling the above rights, does the study require informed consent, if yes, complete the informed consent form and attach, **if a** separate informed consent is **not required,** request for a **"consent waiver"**.

Study design:

Study population:

Study Area/Setting:

Study Subjects:

Sample size calcuation and sampling technique:

Ethical Considerations:

5- Data management and statistical analysis plan:

- **Data collection plan:** description of how data will be collected, by whom.
- **Additional source of data and study instruments**: Data collection form with detailed variables, patient data records
- **Variables and measurements:** Describe data collection variables, stressing on how you will measure and report your outcome variables, the number of sections and the total number of question items. Describe the validation process of the instrument.
- **Data processing:** sorting, coding, manual or computer processing
- **Data management and statistical analysis plan**: describe data cleaning, what type of statistical analysis software will be used.

Data collection plan:

Additional source of data and study instruments:

Variables and measurements:

Data management and statistical analysis plan:

6- **Work plan:** Use standard template explaining when the study to commence, duration and time the study end.

Work plan:

7- **Budget:** (Personnel/ consumable items/ transportation/ field expenses, equipment, transportation).

Budget details:

Any other funding agency

8- **References: S**hould be recent published articles and should be presented in the same order of their information in the text. Follow standard referencing styles). **Should be around 30 and not to be more than 50.**

SECTION 4: INFORMED CONSENT

Attach an informed consent (when required, it should be written in details)

SECTION 5: DECLARATION

1. Declaration by Principal Investigator

I agree to accept responsibility and accountability for all the ethical, scientific and technical conduct of this research, and I will be committed to submit annual progress reports for the research center and IRB, and a final report at the end of my study. I understand that if the protocol for this research changes in any way I must inform the research center and IRB.

Name of the principal investigator.....Signature.....Date.....

2. Declaration by head of department/institute to which the PI is affiliated

I have read the application and to the best of my knowledge and belief, it is accurate and appropriate for this research to be conducted in this department I give my consent for the application to be forwarded to the concerned IRB.

Name……Signature……..Institute……...Date……..

SECTION 6: APPENDECES

1. Attach the data collection form (questionnaire)
2. Attach CVs for all the research team (PI and co-investigators)
3. Attach a copy of the consent form, if applicable.
4. A copy of valid NCBE certificate