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| **KSU-IRB Form 019-E\_PROPOSAL FORM FOR NON-INTERVENTIONAL STUDIES****Version 4.0 dated May 2024** |
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| **Research Project Title:** |  |
| **Primary Investigator:**   |  |
| **College/Department:** |  |
| **Email Address:** |  |
| **Contact No. (Mobile):** |  |

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| **APPLICATION CHECKLIST: (Please READ and ✔ the appropriate boxes)** |
| ☐ | The submitted proposal should be detailed as per IRB requirements. |
| ☐ | All co-investigators should sign the proposal and make sure that their names and titles are correct. For students, names should match with your passport as required by SCFHS. |
| ☐ | Informed Consent Form (for online survey or face-to-face questionnaire) or waiver of consent for using samples from unidentified donor/patient. |
| ☐ | Copy of survey questionnaire or data collection sheet. |
| ☐ | Copyright permission for the use of study tools.  |
| ☐ | Approval/Notification to the involved department (other than the investigator’s department) for retrospective data collection or collecting materials from archive. |
| ☐ | For Master or PhD Student: Letter from Supervisor or Deanship of Graduate Studies confirming the research project as part of the thesis. |
| ☐ | Copy of investigator’s CV in KSU-IRB Template. |
| ☐ | Signed and dated Declaration of Conflict of Interest  |
| ☐ | Bio-Ethics Certificate of each study member*,* free online through National Committee of Bioethics (NCBE) at King Abdulaziz City of Science & Technology. (MANDATORY) [**https://ncbe.kacst.edu.sa/en/researchers/**](https://ncbe.kacst.edu.sa/en/researchers/)  |
| ☐ | Brief description of the role of each investigator. |
| ☐ | Signed Certificate of Confidentiality |
| ☐ | IRB review fee (if applicable as per memo of the Central IRB of the University). |

**For Multicenter Studies:**

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| ☐ | Approved version of the Informed Consent Form  |
| ☐ | Data Sharing Agreement/Collaborative Research Agreement from other sites |
| ☐ | Approval from other sites’ Ethics Committees/IRB, or administration |

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| **ABSTRACT** (Background, objectives, and methods not more than 150 – 200 words) |
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| **RESEARCH SIGNIFICANCE**(Please describe briefly how this study will contribute to existing knowledge in the field) **(not more than 200 words).** |
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| **RESEARCH OBJECTIVES****أهداف البحث** |
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| **LITERATURE REVIEW****أدبيات البحث** |
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| **RESEARCH METHODOLOGY****منهجية البحث** |
| **Study Design:** **Study Setting:** **Study Duration:** **Target Population:** **Sample Size with Sample Power Calculation*:*** *(Describe the statistical methods for determining the sample size for the study. (1) Provide information needed to validate your calculations - i.e. values for all parameters used in calculations (2) Document feasibility to enroll and follow the necessary numbers of subjects).***Recruitment Procedures:** **Inclusion Criteria:** **Exclusion Criteria:****Study Variables:** **Study Procedures:** **Data Collection Method/Data Source:** *(Describe the various sources of data for the study and means of collecting the data, including source documents and CRFs. Explain how you will first record the data, whether it will be onto hardcopy data collection forms or entered directly into an electronic system such as REDCap, or a combination of both methods).***Questionnaires/Data Sheets from other authors**: (Please specify if the questionnaires are adapted from other authors and provide its copyrights permission to use, or state in the methodology that the study tool is with open access for academic and research purpose).**Confidentiality and Ethical Considerations:** **Statistical Analysis**: *(Summarize the overall statistical approach to the analysis of the study)* |

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| **REFERENCES****المراجع** |
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| **RESEARCH INVESTIGATORS INFORMATION** |
| **Name** | **Academic Title** | **Department/College** | **Role in the Study** | **Signature** |
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| **RESEARCH TIME SCHEDULE**  |
| **Months** (should always start with one (1) as first month after IRB approval | **Activities** | **S. No** |
| **12** | **11** | **10** | **9** | **8** | **7** | **6** | **5** | **4** | **3** | **2** | **1** |
|  |  |  |  |  |  |  |  |  |  |  |  | Submission & Ethical Approval | **1** |
|  |  |  |  |  |  |  |  |  |  |  |  | Consent Process & data Collection | **2** |
|  |  |  |  |  |  |  |  |  |  |  |  | Data Management / Data Analysis | **3** |
|  |  |  |  |  |  |  |  |  |  |  |  | Manuscript Writing | **4** |
|  |  |  |  |  |  |  |  |  |  |  |  | Publication to a Journal | **5** |

**Certificate of Confidentiality**

Ensures the confidentiality of research participant’s data andbiological material obtained either prospectively or from existing record, under strict privacy and security throughout the study duration, publication and at any public presentation.

Principal Investigator will disclose the custodianship of the study material, with (first) and (second) or if applicable, (third) party, who shares the same, or a part, inside or outside the Kingdom of Saudi Arabia, as stated in the submitted protocol. Patient Information Sheet/Informed Consent Form, should have clear description of the information shared.

The privacy must ensure:

* Secured Access to data and bio samples of research subject
* Security on subject’s data and bio samples
* Secured electronic data access with user password
* De-identification of research subject’s personal information at publication or public presentation
* Compliance on ‘duration’ of archiving and storage location specified in protocol, agreed and signed

**Conflict of Interest**

The researcher(s) must declare any potential conflict of interest that could affect the outcome of the proposed research in any form like any financial or other ties of the investigator(s) or a member of his/her family to any party directly or indirectly involved in the field of study such as: holding stocks or shares, receiving educational or other research grant, employment opportunity, any gifts of any kind (career development opportunity, speaking arrangements, publication opportunity, providing advisory and consultancy services, board memberships, personal considerations or relationships, promises of any of the above. Please check the following box if applicable.

I hereby acknowledged that, I have read and understood this agreement and agree to be bound by its terms.

**Principal Investigator Signature:**

**Date:**