

**Application Form:**

**Application Form:**

- Departmental Research Committee Approval
- Budget Sheet Details
- Pharmacy Sheet
- Biological Hazards Section
- To include in the detailed description box:

*Introduction may include background information related to the research topic (Importance of the topic), the purpose in carrying out this research and the Importance of potential (expected) findings.*

*Methodology may include:*

- 1. List of collaborating Centers and the coordinating center.*
- 2. Duration of the study*
- 3. Inclusion Criteria and Exclusion Criteria, which will be used in selecting the research participants*
- 4. Registration (If Applicable)*
- 5. Randomization Process*
- 6. Data gathering methods*
- 7. Procedures, Designated Central Laboratories (If Applicable)*
- 8. Follow-up (If Applicable)*
- 9. Safety and Efficacy Parameters*
- 10. Expected Outcome*
- 11. Sample Size*
- 12. Statistical Methods*
- 13. participant confidentiality*
- 14. References/ Literature Review Section*
- 15. List of all investigators' Work Plan and Responsibilities*

**Consent Form in Word Format:**

- English Version
- Arabic Version
- Version Number and Date
- Contact Person(s) (Section J)
- Others: \_\_\_\_\_

**Related Documents:**

- Nursing Research Approval (for Nursing research project - [jbeer@kfshrc.edu.sa](mailto:jbeer@kfshrc.edu.sa))
- Case Report Form (CRF) / Data Collection Sheet (including date and version number) must be validated if translated from another language
- CV of Principal Investigator (PI) & Co- Principal Investigator
- GCP Certificates of all Investigators. Please find link: <https://gcp.nidatraining.org/>
- Copy of two (2) major literatures/references articles mentioned in the Literature Review Section
- Subject Recruitment Advertisements/Information (If Applicable)
- Invitation Letter to Participants if the study is questionnaire, interview, or survey (If Applicable)
- Questionnaire (on letter head paper including date and version Number) (If Applicable)
- Interview Questions (on letter head paper including date and version Number) (If Applicable)
- Bio-Medical Engineering Department Clearance If a medical device will be you used.
- Pathology and Laboratory Department clearance on the application If a lab technician will be assigned, or the study includes non-routine blood works.
- Pharmacy Department approval for medication interventions on pharmacy sheet.
- Establishment of special Research Clinic to meet the patients (If Applicable)

- For any study that involves sending biological samples, e.g., urine, blood, tissue, etc., outside the Kingdom of Saudi Arabia, you need to complete a form to notify the Saudi National committee of Medical and Bioethics and sign a Material Transfer Agreement before sending out any sample. ([bioethics.kacst.edu.sa/intro\\_2\\_e.aspx](http://bioethics.kacst.edu.sa/intro_2_e.aspx))
- For any clinical trial sponsored by other than a Saudi Government Agency, you need to ensure that the sponsor has registered the trial and obtained the approval of SFDA, as required, before commencing the study. ([sfda.gov.sa/Ar/home/Topis/regulations](http://sfda.gov.sa/Ar/home/Topis/regulations))
- For Biostatistician Assistance please contact (Ext. 66218) email- [J1513915@kfshrc.edu.sa](mailto:J1513915@kfshrc.edu.sa)
- For Clinical Research Coordinator Assistance or IRB Clinic Services please fill attached form and send through email to ([HawazinA@kfshrc.edu.sa](mailto:HawazinA@kfshrc.edu.sa) )

**Thank you.**

**Office of Research Affairs**

**Research Centre - Extension# 63539 / MBC-J04**