

**Application Form:**

- Departmental Research Committee Approval
- Pharmacy Sheet (If Applicable)
- Budget Sheet Details (if Sponsored or includes a non-routine test or procedure )
- Biological Hazards Section (If Applicable)
- To complete the Waiver of Consent section if study is retrospective
- 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 (If Applicable)
  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 Minimum 5 (Preferable recent ones)
  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))
- Collaborative/Clinical Trial / Material transfer Agreement(s) (To discuss with Sponsor Research Section MCD: 40530 – Email: [lalsalmi@kfshrc.edu.sa](mailto:lalsalmi@kfshrc.edu.sa))
- Ethical Approval Letter
- A letter of Protocol Approval from university/ supervisor
- Letter of Invitation to the KFSHRC-J PI to Participate in the study (from research owner institution)
- Copy of Original Protocol submitted to the University and other related documents e.g. CRF, Consent Form...etc.
- Case Report Form (CRF) / Data Collection Sheet including date & version number (If Applicable) 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
- Invitation Letter to Participants for Questionnaire, surveys or Interviews (if applicable)
- Questionnaire, surveys or Interview questions including date & version number (If Applicable) must be validated if translated from another language
- 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.
- 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))*

**Office of Research Affairs**  
**Research Centre**  
**Extension# 63539 / MBC-J04**  
**Thank you.**