## □ Application Form:

- Departmental Research Committee Approval
- □ Pharmacy Sheet (If Applicable)
- $\square$  Budget Sheet Details (if Sponsored or includes a non-routine test or procedure )
- □ Biological Hazards Section (If Applicable)
- 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 Minimum 5 (Preferable recent ones)
  - 15. List of all investigators' Work Plan and Responsibilities

## Related Documents:

- □ Nursing Research Approval (for Nursing research project jbeer@kfshrc.edu.sa)
- □ Collaborative Agreement(s) (To discuss with Sponsor Research Section MCD: 40530 Email: <u>lalsalmi@kfshrc.edu.sa</u>)
- □ Ethical Approval Letters from Collaborating institution.
- □ Letter of Invitation to the PI to Participate (from collaborating institution)
- □ Copy of original protocol and other related documents e.g. CRFs...etc. from collaborating institution
- □ Case Report Form (CRF) / Data Collection Sheet (including date & version number) <u>must be</u> <u>validated if translated from another language</u>
- □ CV of Principal Investigator (PI) & Co- Principal Investigator
- □ GCP Certificates of all Investigators including the PI from the collaborative center. Please find link: <u>https://gcp.nidatraining.org/</u>
- □ Copy of two (2) major literatures/references articles mentioned in the Literature Review Section
- □ Deposit the IRB Funds Allocation (S.R 7,000) before the initial review for sponsoring research in the Research Centre account (If Applicable)
- □ Establishment of special Research Clinic to meet the patients (If Applicable)
- For Biostatistician Assistance please contact (Ext. 66218) email- <u>J1513915@kfshrc.edu.sa</u>
- For Clinical Research Coordinator Assistance or IRB Clinic Services please fill attached form and send through email to (HawazinA@kfshrc.edu.sa)

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