

**Application Form:**

- Departmental Research Committee Approval
- Budget Sheet Details
- Waiver of Consent Form section to be filled
- 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

**Related Documents:**

- Nursing Research Approval (for Nursing research project - [jbeer@kfshrc.edu.sa](mailto:jbeer@kfshrc.edu.sa))
  - Collaborative/Clinical Trial Agreement(s) (To discuss with Sponsor Research Section MCD: 40530 – Email: [lalsalmi@kfshrc.edu.sa](mailto:lalsalmi@kfshrc.edu.sa))
  - Copy of Original Protocol and all related documents from the Sponsor
  - List of submitted Documents
  - CV of Principal Investigator PI & Co- Principal Investigator
  - Data Collection Sheet or Case Report Form (CRF) (including date and version number & must be validated if translated from another language)
  - Copy of two (2) major literatures/references articles mentioned in the Literature Review Section
  - GCP Certificates of all Investigators. Please find link: <https://gcp.nidatraining.org/>
  - Deposit the IRB Funds Allocation (S.R 7,000) before the initial review for sponsoring research in the Research Centre account
  - Establishment of special Research Clinic to meet the patients (If Applicable)
- 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**