☐ Application Form:
☐ Departmental Research Committee Approval
☐ Waiver of Consent Form section to be filled
\square 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:
 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 - <u>jbeer@kfshrc.edu.sa</u>) □ 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
☐ CV of Principal Investigator PI & Co- Principal Investigator
☐ GCP Certificates of all Investigators . Please find link: https://gcp.nidatraining.org/
• For Biostatistician Assistance please contact (Ext. 66218) email- J1513915@kfshrc.edu.sa
 For Clinical Research Coordinator Assistance or IRB Clinic Services please fill attached form and send

Thank you.

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through email to (HawazinA@kfshrc.edu.sa)