

Application Form:

- Font Size (Arial – 11) / Paragraph Spacing (1.5)
- Signatures, contacts or ID numbers on the Application Form Cover Page (*page 3*)
- Duration of the study
- Signature of Principal Investigator and date on all pages of the Application Form
- Departmental Research Committee Approval
(*It should be indicated if there is No Departmental Research Committee and signed by Department Chairman*)
- Departmental Approvals (*page 4*)
- Work Plan Responsibilities Section
- Literature Review Section Minimum 5 (preferable recent ones)
- Pharmacy Sheet
- Biological Hazards Section

Consent Form:

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

Related Documents:

- Cover Letter (Memo addressed to chairman of IRB)
- Nursing Research Approval (for Nursing research - gsedgewick@kfshrc.edu.sa)
- Budget Sheet Details
- Statement of Conflict of Interest
- Investigator's Assurance Form (*not in use yet*)
- Case Report Form (CRF) / Data Collection Sheet (Separated from the application form including date and version number) must be validated if translated from another language
- CV of Principal Investigator (PI)
- NIH Certificates for PI (<http://phrp.nihtraining.com/users/login.php>) (or the PI has one publication or more during the past five years).
- Invitation Letter to Participants.
- Copy of two (2) major literatures/references
- Subject Recruitment Advertisements/Information
- Questionnaire (Separated from the application form on letter head paper including date and version number)
- Interview Questions
- Bio-Medical Engineering Department approval If a medical device will be you used.
- Pathology and Laboratory Department approval If a lab technicians will be you assigned, or the study includes blood works.
- Pharmacy Department approval for medication interventions.
- Collaborative Institutional Training Initiative (*Optional*) www.citiprogram.org

Do you need assistance from a Clinical Research Coordinator?

- No** **Yes (if Yes follow instructions below)**

Before approval of IRB you may send your request for a consultation via email to ebawazeer@kfshrc.edu.sa (Ext. 63537/mcd 41160)

After approval of the IRB, if you need assistance from The Clinical Research Coordinator please fill out the attached- **CRC- REQUEST FORM**

Electronic Copy of Protocol and All Associated Documents (please send to HawazinA@kfshrc.edu.sa)

This checklist should be sent to us together with your research project submission.

Thank you.