INSTITUTIONAL REVIEW BOARD
RESEARCH CENTRE

New Proposal Submission
INDUSTRY STUDY - CHECKLIST

☐ ***Application Form:***

- ☐ Font Size (Arial – 11) / Paragraph Spacing (1.5)
- ☐ Signatures, contacts or ID numbers on the Application Form Cover Page *(page 3)*
- ☐ 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*)
- ☐ Work Plan Responsibilities Section
- ☐ Literature Review Section Minimum 5 (preferable recent ones)
- ☐ Duration of the study
- ☐ Departmental Approvals *(page 4)*
- ☐ Pharmacy Sheet
- ☐ Biological Hazards Section

☐ ***Consent Form*:**

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

☐ ***Related Documents:***

- ☐ Original Protocol
- ☐ Original Consent Form
- ☐ Clinical Trial Agreement
- ☐ Certificate of Insurance
- ☐ Investigator's Brochure
- ☐ Related SAE Reports / SUSAR
- ☐ CV of Principal Investigator
- ☐ Cover Letter (Memo addressed to chairman of IRB)
- ☐ Invitation to Collaborate
- ☐ Statement of Conflict of Interest
- ☐ Investigator's Assurance Form
- ☐ Copy of two (2) major literatures/references
- ☐ Study Drug Information
- ☐ Budget Sheet
- ☐ 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
- ☐ NIH Certificates for PI and Co-PI (http://phrp.nihtraining.com/users/login.php) (or the PI has one publication or more during the past five years).
- ☐ Questionnaire (Separated from the application form on letter head paper including date and version number)
- ☐ Subject Recruitment Advertisements/Information
- ☐ EC/IRB Approval Letters from participating institutions
- ☐ 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.
- ☐ Deposit the IRB Funds Allocation (S.R 7,000) before the initial review for sponsoring research in the Research Centre account
- ☐ 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.

Office of the Institutional Review Board
Research Centre
Extension# 63539 / MBC-J04