INSTITUTIONAL REVIEW BOARD
RESEARCH CENTRE

New Proposal Submission
INDUSTRY STUDY - CHECKLIST

☐ ***Application Form:***

- ☐ Departmental Research Committee Approval
- ☐ Pharmacy Sheet (If Applicable)
- ☐ 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*

☐ ***Consent Form in word format*:**

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

☐ ***Related Documents:***

- ☐ Nursing Research Approval (for Nursing research project - jbeer@kfshrc.edu.sa)
- ☐ Collaborative/Clinical Trial / Material transfer Agreement(s) (To discuss with Sponsor Research Section MCD: 40530 – Email: lalsalmi@kfshrc.edu.sa)
- ☐ Copy of Original Protocol
- ☐ Copy of Original Consent Form
- ☐ Certificate of Insurance *(If Applicable)*
- ☐ Invitation Letter to Participants if the study is questionnaire, interview, or survey (If Applicable)
- ☐ PDF Copy of two (2) major literatures/references from the references list
- ☐ Related SAE Reports / SUSAR *(If Applicable)*
- ☐ Study Drug Information (*If Applicable)*
- ☐ CV of Principal Investigator PI & Co- Principal Investigator
- ☐ Copy of Case Report Form (CRF) / Data Collection Sheet (including date & version number) must be validated if translated from another language
- ☐ GCP Certificates of all Investigators. Please find link: https://gcp.nidatraining.org/

☐ Copy of Questionnaire *(If Applicable)*
☐ Copy of Subject Recruitment Advertisements/Information *(If Applicable)*
☐ EC/IRB Approval Letters from participating institutions *(If Applicable)*
☐ Bio-Medical Engineering Department Clearance If a medical device will be you used.
☐ Pathology and Laboratory Department Clearance on the application If a lab technician will be assigned, or the study includes non-routine blood works.
☐ Pharmacy Department approval for medication interventions on pharmacy sheet.
☐ 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)
☐ List of submitted Documents by the Sponsor

- *For any study that involves sending biological samples, e.g., urine, blood, tissue, etc., outside the Kingdom of Saudi Arabia, you need to complete a form to notify the Saudi National committee of Medical and Bioethics and sign a Material Transfer Agreement before sending out any sample. (bioethics.kacst.edu.sa/intro_2_e.aspx)*

- *For any clinical trial sponsored by other than a Saudi Government Agency, you need to ensure that the sponsor has registered the trial and obtained the approval of SFDA, as required, before commencing the study. (sfda.gov.sa/Ar/home/Topis/regulations)*

- *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