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| 1. **Administrative Information** | | | | | | | | | | | | | | | | | | | |
| **Request Date:** |  | | | | | | | | | **IRB Log No.** (*to be filled by KFMC IRB*)**:** | | | | | | |  | | |
| **Study Title:** |  | | | | | | | | | | | | | | | | | | |
| **Hospital / Center / University:** | | | | | |  | | | | | | **Department:** | | |  | | | | |
|  | | | **Name** | | | | | | | | **Email** | | | | | **Phone** | | | **Fax** |
| **Principal Investigator:** | | |  | | | | | | | |  | | | | |  | | |  |
| **Co-Investigator(s):** | | |  | | | | | | | |  | | | | |  | | |  |
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| **Study Coordinator:** | | |  | | | | | | | |  | | | | |  | | |  |
| **Contact Person:** | | |  | | | | | | | |  | | | | |  | | |  |
| \* Place a double asterisk **(\*\*)** after the name of each person authorized to obtain Informed Consent. | | | | | | | | | | | | | | | | | | | |
| **Status of PI:** | Consultant Faculty | | | | | | | | | | | | | | | | | | |
| Other (please specify): | | | | | | | | | | | | | | | | | | |
| **Faculty Sponsor:** | | |  | | | | | | | | | | | | | | | | |
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| 1. **Conflict of Interest** | | | | | | | | | | | | | | | | | | | |
| Do you or any of the Investigators and Immediate Family have any Financial Interest related to the study, the research drug and/or device or with the sponsor or provider of the study article? | | | | | | | | | | | | | Yes (the Principal Investigator and each of the Investigators has attached a Financial Disclosure Form)  No | | | | | | |
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| 1. **Study** | | | | | | | | | | | | | | | | | | | |
| ***Summary*** | | | | | | | | | | | | | | | | | | | |
| Summarize you study | |  | | | | | | | | | | | | | | | | | |
| *The summary should be written in language intelligible to a moderately educated, non-scientific layperson. It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, and a discussion of the expected results. The length should be at least one half of a page and no more than one page. You should not refer the reader to the attached protocol.* | | | | | | | | | | | | | | | | | | | |
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| ***Type*** | | | | | | | | | | | | | | | | | | | |
| Type of Study | | | | Double-blind  Single-blind  Open-label | | | | | | | | Pilot  Observational (design):  Other: | | | | | | | |
| Phase of Study | | | | N/A (not a clinical trial)  Phase 1  Phase 2  Phase 3 | | | | | | | | Phase 4  Unknown  Other: | | | | | | | |
| Study Includes | | | | Questionnaire/survey  Chart review  Registry/database | | | | | | | | Blood draw  Specimens to be obtained in the future (specify): | | | | | | | |
| Gene Transfer/DNA  NA: | | | | Genetic research (specify):  Recombinant DNA | | | | | | | | KFMC Bio-Safety Committee approval attached\* | | | | | | | |
| *\* If your study uses recombinant DNA, it must be approved by the KFMC Bio-Safety Committee before it receives IRB approval.* | | | | | | | | | | | | | | | | | | | |
| Radiation  NA: | | | | Radioactive material is being used in this study (specify):  KFMC Radiation Safety Committee approval attached\* | | | | | | | | | | | | | | | |
| *\* If your study uses radioactive material, it must be approved by the KFMC Radiation Safety Committee before it receives IRB approval.* | | | | | | | | | | | | | | | | | | | |
| Has this study been submitted previously? | | | | | | | | With a different title: Yes No | | | | | | With a different PI: Yes No | | | | | |
| Has this protocol been, or will it be, submitted to another IRB? | | | | | | | Yes No | | **If yes**, give name and location of IRB: | | | | | | | | | | |

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| 1. **Funding Sources** | | | | | | | | | | | |
| Funding | | Internal \*\* | | External \* | | | | | | | No Funding |
| Funding Status | | Planned | | Pending | | | | | | | Funded |
| External Funding Sources \* | | Government grant (specify agency and grant/award #):  Industry contract (specify company(ies)):  Investigator-Initiated Industry-Initiated  Cooperative groups; specify:  Sub-contract (specify):  Foundation grant (specify):  Other (specify): | | | | | | | | | |
| KFMC Funding Sources \*\* | | Departmental (specify):  PI funded (specify):  Other (specify): | | | | | | | | | |
|  | |  |  | | | | | | | | |
| 1. **Sites and Study Duration** | | | | | | | | | | | |
| Study taking place at | | Single center **(KFMC)**  Multi-center I am the PI of multi-center trial  Other (specify): | | | | | | | | | |
| Study Site(s) | | **KFMC** | | | | |  | | | | |
| **Permission** | | For study outside my department, permission by responsible site authority attached:  NA: | | | | | | | | | |
| **Study Duration** | | Estimated Start Date: | | | | | Estimated Completion Date: | | | | |
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| 1. **Investigational Devices** | | | No devices (skip this section) | | | | | | | | |
| This study includes | | A significant risk device  A non-significant risk device | | | | | | | | | |
| *“Significant risk” and “non-significant risk” are FDA classifications. If the study is being done for potential US registration, research on a significant risk device must be performed under an IDE.* | | | | | | | | | | | |
| Device Name | |  | | | | Manufacturer/Sponsor | | | |  | |
| Device will be provided by | | Sponsor at no additional charge (not billable to subject or insurance)  Hospital **supply**  Other (specify): | | | | | | | | | |
| IDE # | | N/A | | | | | Yes (specify IDE #): | | | | |
| FDA restriction is detailed in protocol | | Yes | | | | | No | | | | |
|  | |  |  | | | | | | | | |
| 1. **Investigational Drugs** | | | No drugs (skip this section) | | | | | | | | |
| This study includes | | A drug approved for this indication and population  A drug for off-label use | | | | | | An investigational drug  A placebo | | | |
| Drug Name | |  | | | Manufacturer/Sponsor | | | |  | | |
| Generic Name | |  | | | Name of Supplier | | | |  | | |
| Mechanism of Action | |  | | | Indication | | | |  | | |
| Location of Drug Supply | |  | | | Known Drug Interactions | | | |  | | |
| Method/Route of Administration | |  | | | Dosage Strength(s) | | | |  | | |
| IND #  [US FDA jurisdiction only] | | N/A  Yes (specify IND #):  If this is an Investigator’s IND #; it expires:       \* | | | | | | | | | |
| *\* If an Investigator’s IND is indicated, the FDA letter must be attached to this form and the 30-day expiration date provided above.* | | | | | | | | | | | |
| Drugs will be provided by | Sponsor at no additional charge (not billable to subject or insurance)  Hospital  Other (specify): | | | | | | | | | | |
| Investigational Pharmacies | KFMC Pharmacy  ***NOTE:*** PI cannot keep medication at his clinic; it must be dispensed through the pharmacy. | | | | | | | | | | |

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| 1. **Data & Safety Monitoring** | | | | | |
| All studies at KFMC involving human subjects are required to have adequate data and safety monitoring. For non-blinded studies, the principal investigator can accept oversight. For blinded studies requiring full review, an independent reviewer or Data and Safety Monitoring Board (DSMB) may be required. A Data and Safety and Monitoring Plan must be appropriate to the level of risk to subjects, study design, objectives and procedures. | | | | | |
| Who will do the data and safety monitoring for this study?  *This role is distinct from the study monitor* | | | Principal Investigator  Principal Investigator’s Designee:  Study Sponsor; does the sponsor have a DSMB in place for this study?  No  Yes; a copy of its membership and charter including a description of the planned meeting frequency and how information will be distributed to investigators is provided\*  Other: | | |
| *\* If electronic copy of these documents is available, may provide by email to IRB Administrative Coordinator (*[*institutionalreviewboard@kfmc.med.sa*](mailto:institutionalreviewboard@kfmc.med.sa)*).* | | | | | |
| Primary data safety and monitor contact information | | | Name:  Telephone:  Email:  Qualifications:  Does the data and safety monitor have a conflict of interest:  No Yes; describe: | | |
| The number of subjects screened/enrolled will be monitored | | | Yes  No | Drop outs will be monitored | Yes  No |
| Primary and secondary efficacy endpoints will be monitored | | | Yes  No | Adverse events will be monitored using an accepted scale | Yes  No |
| Frequency of monitoring | | | Every 12 months coinciding with the IRB renewal period  Every 6 months  Every 3 months  Other: | | |
| Interim analysis will take place | | | No  Yes; describe: | | |
| Insert or attach any additional information regarding Data and Safety Monitoring for this protocol | | |  | | |
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| 1. **Application Submission Checklist** | | | | | |
| Yes | No | NA | Clinical Study Cover Sheet | | |
| Yes | No | NA | Protocol, including current amendments/revisions (see §13 for requirements) | | |
| Yes | No | NA | Case report form / data collection instruments | | |
| Yes | No | NA | Draft Informed Consent Form | | |
| Yes | No | NA | Diaries, questionnaires, etc. if applicable | | |
| Yes | No | NA | Recruitment material (including telephone scripts), if applicable | | |
| Yes | No | NA | Research grant, if applicable | | |
| Yes | No | NA | Investigator’s brochure, if applicable | | |
| Yes | No | NA | Package insert, if applicable | | |
| Yes | No | NA | Current (signed and dated) CVs and training forms for the PI and all study personnel involved with obtaining informed consent or collecting study data | | |

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| 1. **Investigator’s Responsibilities Checklist** | | | | | |
| The following are the minimum responsibilities of Principal Investigators. Check off each item to indicate that you have carefully read, understand, and accept your responsibilities. | | | | | |
|  | I, the Principal Investigator, acknowledge and accept my responsibility for protecting the rights and welfare of human research subjects. | | | | |
|  | If I intend to involve human research subjects in my research, I will be responsible for obtaining IRB review and approval prior to the initiation of that research. | | | | |
|  | I am responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, as required. | | | | |
|  | All signed consent documents will be retained in a manner approved by the IRB. | | | | |
|  | Unless otherwise authorized by the IRB, I am responsible for obtaining and documenting informed consent in accord with applicable regulations. | | | | |
|  | I shall be responsible for promptly reporting proposed changes in previously approved human subject research activities to the IRB. My proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to my subjects. | | | | |
|  | I will report to the IRB any unexpected (within 5 days) and serious events (within 48 hours by phone, in writing within 5 days) or other unanticipated problems involving risks to subjects or others within, of my first discovering it. | | | | |
|  | I will submit a progress report at least four weeks prior to the date at which the IRB has determined continuing review is required. If the progress report is not received by the due date, I understand that it cannot be guaranteed that my study will be reviewed before the expiration of the IRB approval date. If my study is not reviewed prior to the expiration date, all enrollment is suspended and I may not continue with the study for previously enrolled subjects except as approved by the IRB. | | | | |
|  | I have completed and will require my research team to complete an educational program on the protection of human subject research participants. | | | | |
|  | I will not begin any study activities prior to receiving Approval by the KFMC IRB. | | | | |
|  |  | | | | |
| **Principal Investigator’s Signature & Stamp** | | | | | |
| **Date** | |  | | | |
| **Print Name** | |  | | | |
| **Signature** | |  | | |  |
|  | | *I attest that the information contained herein is a true and accurate representation of my proposed study. I will abide by the requirements of the KFMC IRB in the conduct of this research study’s protocol.* | | | |
|  | | | | | |
| **Department Chairman and/or Section or Unit Head’s Signature(s) & Stamp** | | | | | |
| **Date** | |  | | | |
| **Department/Section/Unit** | |  | | | |
| **Print Name** | |  | | | |
| **Signature** | |  | | |  |
|  | | *I certify that the above-indicated investigator is a member of my department in good standing, has the resources necessary to carry out this research, and is qualified to be the principal investigator on the research study.* | | | |
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| **For Non-KFMC PI:** | | | | | |
| **Name of KFMC Sponsor:** | |  | **Department:** |  | |
| **Signature:** | |  | **Date:** |  | |

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| 1. **Description of the Study** | | | |
|  |  |  |  |
| **Protocol Categories** | | **Ck** | **NA** |
| Abstract | |  |  |
| 1. Introduction and background information | |  |  |
| 1. Objectives (specific aims) and rationale | |  |  |
| 1. Results of previous related research | |  |  |
| 1. Study methods and procedures (including frequency and duration of any tests) | |  |  |
| 1. Parameters to be measured | |  |  |
| 1. Resources required and documented availability | |  |  |
| 1. Role of key members | |  |  |
| 1. Study site(s) | |  |  |
| 1. Duration of study | |  |  |
| 1. Study population (include age, ethnicity, etc.) and rationale | |  |  |
| 1. Will vulnerable populations be involved | |  |  |
| 1. Vulnerable populations: Identify, justify, justify methodology, describe their protection | |  |  |
| 1. Number and age of subjects | |  |  |
| 1. Recruitment methods (advertisements included when applicable) | |  |  |
| 1. Inclusion/Exclusion criteria - equitable selection of subjects including:  * if women are excluded, justification is provided * if subjects under 21 are excluded, justification is provided | |  |  |
| 1. Role of subject and research procedures | |  |  |
| 1. Samples (e.g., blood, tissue, etc.) to be obtained and, for blood, volume, frequency, and route, e.g., venepuncture, venous catheter, arterial puncture, arterial catheter, cutaneous | |  |  |
| 1. Payment to volunteers | |  |  |
| 1. Justify use of a placebo, if applicable | |  |  |
| 1. If existing data will be used, specify the source and how the data will be retrieved, reviewed, coded, and stored. | |  |  |
| 1. Data analysis | |  |  |
| 1. Benefits to subject and to society (also in Informed Consent Document) | |  |  |
| 1. Risks to subjects and to society (also in Informed Consent Document) | |  |  |
| 1. How the study will be monitored | |  |  |
| 1. Any costs to subjects (also in Informed Consent Document) | |  |  |
| 1. Alternatives (also in Informed Consent Document) | |  |  |
| 1. Research materials, records, and confidentiality | |  |  |
| 1. Subject consent/assent or waiver or alteration of consent, and description of process | |  |  |