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| **Application for IRB Approval of Research Amendment** | | | | | | | | |
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| **Application Date:** | | 07 February 2021 | | **IRB Log No.:** | | | | **20-783** |
| **Category of Initial Review:** | | Exempt | | Expedited | | | | Full |
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| **INSTRUCTIONS TO PRINCIPAL INVESTIGATOR** | | | | | | | | |
| A research project must be carried out in accordance with the protocol approved by the IRB. Any changes in the project including, for example, changes in the study design, subject population, recruitment plans, advertising materials, research procedures, study duration, study instruments, study sites, or research personnel who are instrumental to the design or execution of the study, **must** be approved by the IRB ***prior to implementation***. This includes changes designed to reduce the risk to study subjects. | | | | | | | | |
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| *When submitting an application for amendment, submit only documents that are to be revised or are to be added. For example, if you are revising an advertisement, submit the advertisement only.* | | | | | | | | |
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| **ADMINISTRATIVE INFORMATION** | | | | | | | | |
| **Project Title:** | Comparative Study of Radiofrequency vs. CryoAblation of Genicular Nerves for Pain Management of Knee Osteoarthritis | | | | | | | |
| **Principal Investigator:** | | Dr. Salem Bauones | | | | | | |
| **Hospital / Center / University:** | | KFMC | | | **Department:** | | Medical Imaging Department | |
| **Email Address:** | | sbauones@kfmc.med.sa | | | **Telephone:** | |  | |
| **Co-Investigator(s) *(list all)*:** | | Dr. Maha Adosary  Dr. Aliya Alawaji  Dr. Osama Alshahya | | |  | | | |
|  | | | | | | | | |
| **Contact person for this study:** | | Dr. Salem Bauoned | | | | | | |
| **Email Address:** | | Sbauones@kfmc.med.sa | | | **Telephone:** | | 21788 | |
| **Study Personnel *(list all coordinators, data managers, etc.)*:** | | | | | | | | |
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| **Study Sponsor:** | | | | | | | | |
| Investigator-initiated (Departmental) | | | | | | | | |
| Foundation (specify): | | | | | | | | |
| KACST | | | | | | | | |
| Industry (specify): | | | | | | | | |
| Other (specify): KFMC | | | | | | | | |
|  | | | | | | | | |
| Single Center Trial | | | Multi-center Trial | | | PI of Multi-center Trial | | |
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| Proposed Length of Project: | | | FROM: March 2021 TO: March2023 | | | | | |
| Current Performance Period: | | | FROM:       TO: | | | | | |

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| **DESCRIPTION OF PROPOSED CHANGE(S)** | | | | | | |
| *Check all that apply:* | | | | | | |
|  | | Change in Currently Approved Protocol | | | | |
|  | | Change in Currently Approved Consent Form/Consent Procedures | | | | |
|  | | Advertisement | | | | |
|  | | DSMB Report | | | | |
|  | | Investigator's Brochure | | | | |
|  | | Change in Personnel (for added staff, **attach copy of training record**) | | | | |
|  | | Addition/Deletion of a Site | | | | |
|  | | Change in Conflict of Interest | | | | |
|  | | Other (specify): | | | | |
|  | | | | | | |
| *Check all that apply:* | | | | | | |
|  | | This change is administrative only (e.g., correct typographical errors, add or remove investigators or staff, etc.). | | | | |
|  | | This change does not increase risks to participants enrolled in the study. | | | | |
|  | | This change may increase risks to participants enrolled in the study. | | | | |
|  | | This change does not necessitate revision of the consent form document. | | | | |
|  | | Subjects already enrolled will be re-consented. | | | | |
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| **Attach** 2 copies of the proposed change(s) to an existing document (*include the entire document, not just relevant pages*): **Copy 1** should identify the change(s) in **bold** to facilitate IRB review. **Copy 2** should be a “clean copy.” For example, in MS Word® this would include: 1) A printout with “track changes” set to show all edits and comments; and, 2) A printout with changes accepted to show the proposed final document. If the amendment is an additional study document, e.g. a new advertisement, a single copy is sufficient. | | | | | | |
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| **SUMMARY OF CHANGES FROM THE PRINCIPAL INVESTIGATOR** | | | | | | |
| Summarize or list the change(s) and why it is being made. Provide a copy of the sponsor's formal notice of a change or revised protocol, if applicable. | | | | | | |
| 1 | Additional of co-author | | | | | |
| 2 | Methodology: “We are targeting patients >40 years of age with native knee and grade 3 or 4 Kellgren-Lawrence classification for osteoarthritis. Patients with systemic or local infection, radiating pain, oncology cases, rheumatoid patients and those who are not fit for total knee arthroplasty (uncooperative or refusal) are excluded.” | | | | | |
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| **INVESTIGATOR’S ASSURANCE** | | | | | | |
| This request reflects the status of the protocol. | | | | | | |
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| **Principal Investigator’s Signature** | | |  | | **Date** | |