Appendix 2

Consent Form

You are invited to participate in a clinical trial to investigate the long term efficacy and safety of pulsed low frequency magnetic field therapy. The study will be conducted by Prof. Fuad Abdulla, Dr. Saad AlSaadi, Prof. MIR Sadat-Ali, Dr. Fahd AlKhamis, Mr. Hani Alkhawaja and Dr. Serigne Lo (all are affiliated with Imam Abdulrahman Bin Faisal University). The study will be conducted at the department of physical therapy, King Fahd Hospital of the University. Participants in the study will be randomly assigned into two groups: group 1 will receive pulsed low frequency magnetic field, hot packs and back exercises while group 2 will receive sham pulsed low frequency magnetic field (i.e. no magnetic field), hot packs and back exercises. Participants are asked to commit one hour three times per week for six weeks (the intervention period) then they will be asked to come for evaluation at 6, 12 and 24 weeks after the conclusion of the intervention. At each evaluation time you will be asked to rate the pain intensity in your back using an 11 points scale and you will be asked to fill questionnaires to evaluate your quality of life, disability level due to the back pain, psychological status, functional level, effectiveness of intervention received, sleep quality and level of fatigue.

During the intervention period will be asked to lie on a mattress for 20 minutes (which may generate a magnetic field or no magnetic field) then hot packs for 20 minutes and back exercises for 20 minutes. You have been selected to participate in this clinical trial because you have chronic low back pain.

Pulsed low frequency magnetic field has no known side effects, however, all participants will be monitored for any type of side effects. If side effects develop or your symptoms get worse during the study you will be given appropriate medical care till the situation is resolved. You may not benefit directly from this research, however, if the pulsed low frequency magnetic field therapy is proven to be effective it will help patients with chronic low back pain. Your participation in this study is on a voluntary basis, you have the right to withdraw from the study at any time without having to provide any reasons for that. Refusal to participate or withdrawal from the study will not affect your rights to the care you are eligible to.

All data collected will be strictly confidential, only researchers involved in this project will have access to your data. All data collected will be coded and analyzed collectively so no participant can be identified when the results are published or presented in conferences. The study is funded by deanship of research at Imam Abdulrahman Bin Faisal University.

If you have any questions or concerns please do not hesitate to contact the trial principal investigator Prof. Fuad Abdulla by phone at 13-3331308 or by e-mail faabdullah@iau.edu.sa

I, _____, voluntarily consent to participate in this clinical trial as described above. I have had a chance to ask questions of the researchers, and have had any questions answered to my satisfaction.

_____ _____

Participant Signature Witness Signature

_____

Researcher Signature

_____

Date