

Institutional Review Board

مجلس المراجعة المؤسسي

IRB Registration Number with KACST, KSA: H-01-R-059

October 10, 2017

IRB Log Number: 17-0131

Project title: Computer-controlled delivery versus syringe delivery of local anesthetic injections for therapeutic treatment

Category of Approval: EXPEDITED

Dear Mehdiya Haider,

Thank you for submitting your proposal to the PNU Institutional Review Board. Your proposal was evaluated considering the national regulations that govern the protection of human subjects. The IRB has determined that your proposed project poses minimal risk to the participants. Therefore, your proposal has been deemed **EXPEDITED** from IRB review. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of the department in PNU or an external institution to commence data collection.

Please be informed that in conducting this study, you as the Principal Investigator are required to abide by the rules and regulations of the Government of Saudi Arabia, the PNU/IRB policies and procedures, and the ICH Good Clinical Practice guidelines. You also need to notify the IRB as soon as possible in the case of any amendments to the project, termination of the study, any serious unexpected adverse events, or any event or new information that may affect the benefit/risk ratio of the proposal. For any proposed changes in your research protocol, please submit a Request for Modification form to the PNU IRB. Please be aware that changes to the research protocol may prevent the research from qualifying for expedited review and require submission of a new IRB application or other materials to the PNU IRB.

Please be advised that regulations require that you submit a progress report on your research every 6 months. Please refer to the protocol number denoted above in all communication or correspondence related to your application and this approval. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

We wish you well as you proceed with the study. Should you have additional questions or require clarification of the contents of this letter, please contact me.

Sincerely yours,



Dr. Ebtissam AlMadi

Chairman, Institutional Review Board (IRB)

Princess Nourah bin Abdulrahman University, Riyadh, KSA

Tel: + 966 8240861

E-mail: irb@pnu.edu.sa



10 OCT 2017