

IRB Registration Number with KACST, KSA: H-01-R-012
IRB Registration Number with OHRP/NIH, USA: IRB00010471
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

July 18, 2019

IRB Log Number: 19-343

Department: Surgical Oncology

Category of Approval: EXEMPT

Dear Dr. Alam Ara Shafi and Dr. Fatema AlMushawah,

I am pleased to inform you that your submission dated July 7, 2019 for the study titled '**Correlation between Margin Width and Time to Local and Systemic Recurrence of Ductal Carcinoma in Situ**' was reviewed and was approved according to Good Clinical Practice guidelines. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

If you have any further questions feel free to contact me.

Sincerely yours,

Omar Kasule



Prof. Omar H. Kasule

Chairman, Institutional Review Board (IRB)

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