King Hussein Cancer Center	مركز الحسين للسرطان
Institutional Review Board	اللجنة المؤسسية

Dear Dr. Hikmat Abdel Razeq,

In reference to the proposal entitled: "**Multicenter first-line metastatic open-label prospective phase II trial evaluating the combination of Palbociclib (CDK 4/6 Inhibitor) and hormone therapy (Letrozole or Anastrozole) in women with luminal, HER2 negative advanced breast cancer: Evaluation of the prediction of individual treatment efficacy using infrared laser spectroscopy analysis on liquid biopsies (Quantum Optics)**" Proposal No. 21 KHCC 137

You are kindly informed that the IRB has reviewed and approved the following document(s):

1. Request for Renewal, submission date: 10/Sep/2023

The Request for Renewal was approved by convened IRB review.

If the study extends beyond one year you have to submit a **Renewal of Research Approval Form** and an interim update on the study. For any modifications on the approved proposal please complete the **Amendment to Approved Research Form**. At the end of the study, you are requested to complete **Study Closure/Termination Form.**

Please inform the IRB Office of any publications/ abstracts that may result from this study.

On behalf of KHCC IRB, I would like to wish you a successful study.

King Hussein Cancer Center
IRB Approval Date
13 SEP 2023
IRB Approval Expiration
12/9/2024

Date: 13/Sep/2023

Dr. Rawad Rihani
Deputy, Institutional Review Board
King Hussein Cancer Center

The IRB consists of members of medical and non medical background including public, lawyers, nurses and pharmacists. It is the policy of the IRB to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the IRB considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the IRB may request the principal investigator to provide an outcomes report, including information on follow up of participants.
KHCC-IRB is approved by JFDA and is compliant with GCP Guidelines and national Clinical Research Law (2011).