

NOTICE OF IRB APPROVAL – EXEMPT STATUS

To: Dr. Vanda Abi Raad
MD, Anesthesiology
School of Medicine

APPROVAL ISSUED: 17 June 2020
EXPIRATION DATE: 17 June 2022
REVIEW TYPE: EXEMPT CATEGORY D

Date: June 17, 2020

RE: **IRB #:** LAUMCRH.VA2.17/Jun/2020

Protocol Title: Evaluating the Validity of Virtual OSCEs in the Covid-19 Environment

Your application for the above referenced research project has been reviewed by the Lebanese American University, Institutional Review Board (LAU IRB). This research project qualifies as exempt under the category noted in the Review Type

This notice is limited to the activities described in the Protocol Exempt Application and all submitted documents listed on page 2 of this letter.

CONDITIONS FOR ALL LAU NOTICE OF IRB EXEMPTION DETERMINATION

LAU RESEARCH POLICIES: All individuals engaged in the research project must adhere to the approved protocol and all applicable LAU IRB Research Policies. **PARTICIPANTS** must NOT be involved in any research related activity prior to IRB notice date or after the expiration date.

EXEMPT CATEGORIES: Activities that are exempt from IRB review are not exempt from IRB ethical review and the necessity for ethical conduct.

PROTOCOL EXPIRATION: The LAU IRB notice expiry date for studies that fall under Exemption is 2 years after this notice, as noted above. If the study will continue beyond this date, a request for an extension must be submitted at least 2 weeks prior to the Expiry date.

MODIFICATIONS AND AMENDMENTS: Certain changes may change the review criteria and disqualify the research from exemption status; therefore, any proposed changes to the previously IRB reviewed exempt study must be reviewed and cleared by the IRB before implementation.

RETENTION: Study files must be retained for a period of 3 years from the date of project completion.

IN THE EVENT OF NON-COMPLIANCE WITH ABOVE CONDITIONS, THE PRINCIPAL INVESTIGATOR SHOULD MEET WITH THE REPRESENTATIVES OF THE IRB OFFICE IN ORDER TO RESOLVE SUCH CONDITIONS. IRB CLEARANCE CANNOT BE GRANTED UNTIL NON-COMPLIANT ISSUES HAVE BEEN RESOLVED.

If you have any questions concerning this information, please contact the IRB office by email at irb@lau.edu.lb

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The IRB operates in compliance with the national regulations pertaining to research under the Lebanese Minister of Public Health's Decision No.141 dated 27/1/2016 under LAU IRB Authorization reference 2016/3708, the international guidelines for Good Clinical Practice, the US Office of Human Research Protection (45CFR46) and the Food and Drug Administration (21CFR56). LAU IRB U.S. Identifier as an international institution: FWA00014723 and IRB Registration # IRB00006954 LAUIRB#1

Dr. Joseph Stephan
Chair, Institutional Review Board

DOCUMENTS SUBMITTED:

LAU IRB Exempt Protocol Application	Received 9 June 2020
Research Proposal Submission form & Supplemental sheet	Received 9 June 2020
CITI Training – Vanda Abi Raad	Cert.# 36120952 Dated 3 April 2020)
CITI Training – Nadia El Asmar	Cert.# 36744755 Dated 26 May 2020)
CITI Training – Sola Aoun Bahous	Cert.# 30892419 Dated 12 March 2019)
CITI Training – Nazih Youssef	Cert.# 26578464 Dated 24 March 2018)

