NOT HUMAN RESEARCH DETERMINATION

June 7, 2018

Marwan Sabban, PhD
American University of Beirut Medical Center
Email address: me00@aub.edu.lb

Dear Dr. Sabban:

On June 7, 2018 the IRB reviewed your emails received on May 21, 2018, May 24, 2018 and June 4, 2018 in regards to your activity entitled "Molecular assembly and regulation of connexion-containing junctional complexes in inflammatory bowel disease" stating that existing de-identified archived blocks will be used as part of this activity. The IRB also reviewed the letter from Hammoud hospital indicating that de-identified samples will be provided.

This is to draw your attention that for an activity to be considered "Human Research", it should involve "Human subjects".

The activity involves Human Subjects if either of the following is true:

- The investigator will gather data about living individuals through intervention or interaction.
  Or
- The investigator will gather data about living individuals that is private and identifiable.

As this activity does not fulfill the criteria of "human subjects" the IRB determined that the proposed activity is not "human research" as defined by DHHS and USFDA regulations.

Therefore, IRB review and approval by this organization is not required. Please note this determination applies to the activities described in your IRB submission only and does not apply should any changes be made. Changes to the activity may engage the organization in research by meeting the definition of human subject research. Therefore, please submit a request for re-determination of the status of the activity should you make any changes to the information reviewed by the IRB.

Approval by AUB-IRB cannot be mentioned in any publication as it is not applicable, and this letter can be used in case such an approval is inquired about by any journal editor.

The American University of Beirut and its Institutional Review Board, under the Institution's Federal Wide Assurance with OHRP, comply with the Department of Health and Human Services (DHHS) Code of Federal Regulations for the Protection of Human Subjects ("The Common Rule") 45CFR46, subparts A, B, C, and D, with 21CFR56; and operate in a manner consistent with the Belmont report, FDA guidance, Good Clinical Practices under the ICH guidelines, and applicable national/local regulations.

Sincerely,

Abeer Dakik, MSc.
Senior Regulatory Analyst/co-Administrator
Biomedical IRB

Cc: Ali K. Abu-Alfa, MD, FASN
Professor of Medicine
Director, Human Research Protection Program