

APPROVAL OF RESEARCH

June 13, 2013

Nada Melhem, PhD
American University of Beirut Medical Center
Email Address: melhemn@aub.edu.lb

Dear Dr. Melhem,

On June 13, 2013, the IRB reviewed the following protocol:

Type of Review:	Initial, Expedited
Project Title:	Etiological role of Norovirus in diarrhea and genotypic characterization of the virus
Investigator:	Nada Melhem
IRB ID:	FHS.NM.02
Documents reviewed:	<ul style="list-style-type: none">• The study proposal• The IRB application• The list of subjects whose parents approved to have their samples used for further research that was provided by Dr. Dbaibo on June 05, 2013 in response to IRB request on April 22, 2013

This is to grant you approval to the proposal; for a period **ending June 13, 2014** inclusive.

Before **April 13, 2014** or within 30 days of study close, whichever is earlier, you are to submit a completed "FORM: Continuing Review Progress Report" and required attachments to request continuing approval or study closure.

If continuing review approval is not granted before the expiration date of **June 13, 2014** approval of this research expires on that date.

Kindly note that this approval does not grant permission for contacting patients who were enrolled in previous studies, unless it is specified in the signed consent form or if the principal investigator or research team member has a primary patient-physician relationship. In all other circumstances, the IRB needs to grant approval for alternative mechanisms.

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,



Mona Nabulsi, MD
Vice Chairperson of the IRB

Cc: Fuad Ziyadeh, MD, FACP, FASN
Professor of Medicine and Biochemistry
Chairperson of the IRB

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