APPROVAL OF RESEARCH

June 29, 2015

Ammar Olabi, PhD
American University of Beirut
Email Address: ao01@aub.edu.lb

Dear Dr. Olabi,

On June 29, 2015 the IRB reviewed the following protocol.

Type of Review:	Follow up, Expedited
Project Title:	Sensory evaluation of commercial laxative solutions in Lebanon
Investigator:	Ammar Olabi
IRB ID:	NUT.AO.19
Documents reviewed:	• The IRB application • The study proposal • The English informed consent form (version received June 23, 2015) • The English oral script • The acceptability questionnaire • The descriptive questionnaire

This is to grant you approval to the study proposal, the English informed consent form (version received June 23, 2015), the English oral script, the acceptability questionnaire, the descriptive questionnaire; for a period **ending June 28, 2016 inclusive**.

Before **April 28, 2016** 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 28, 2016** 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.

Attached are stamped approved consent documents. Use copies of these documents to document consent.

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, FRCP
Professor of Medicine and Biochemistry
Chairperson of the IRB

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