

APPROVAL OF RESEARCH

April 20, 2012

Kassem Barada, MD
American University of Beirut Medical Center
Email Address: kb02@aub.edu.lb

Dear Dr. Barada:

Project Title:	Gross upper gastrointestinal bleeding in patients on anticoagulants and/or antiplatelet therapy: Endoscopic findings, management and clinical outcomes
Investigator:	Kassem Barada
IRB ID:	IM.KB.09
Documents reviewed:	<ul style="list-style-type: none">Your email dated April 18, 2012 in response to IRB letter dated April 16, 2012The English & Arabic oral scripts

On April 20, 2012 the IRB reviewed the above mentioned documents in an Expedited manner and found your response adequate.

This is to grant you re-approval to the study as well as approval to the English & Arabic oral scripts; for a period ending **April 20, 2013** inclusive.

Before **February 20, 2013** 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 **April 20, 2013** approval of this research expires on that date.

Kindly note this approval is granted to contact and obtain oral consent from the 37 subjects only. No further chart review is allowed prior to IRB notification and approval.

Updating the IRB regarding the outcome of the process is essential prior to proceeding.

Attached are stamped approved oral 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: Ibrahim Salti, MD, PhD
Chairperson of the IRB

Fuad Ziyadeh, MD
Co-Chairperson of the IRB

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