

Dear Dr Marie Merheb

November 26, 2013

Trial Number:	OBS13847
<i>Please quote this ref on all correspondence</i>	
Trial Title:	International Diabetes Management Practices Study wave 6 /IDMPS wave 6
Investigator Name(s):	Dr Marie Merheb
MLH code:	DM-2013-003

Thank you for submitting your application that was considered at the Ethics' Committee of **Mount Lebanon Hospital**. The following documents were reviewed:

1. Protocol: final version 1.0; code: GLA-NE-V1-F-30/10/2013; Date of final version: 02 October 2013.
2. Informed consent forms:
 - a. English: IC: EN-V1-NE-F-30/10/2013: Final version 1.0 dated 30 Sep 2013.
 - b. Arabic: IC: AR-EN (30/10/2013)-V1-NE-F-30/10/2013-Final version 1.0.
3. Case Report Form: GLA-NE-V1-F- 30/10/2013; Final version 1.0; dated 08/10/2013.

The Ethics' Committee approves the submitted documents. Approval is given on the understanding that the ICH GCP "Guidelines for Ethical Research Practice" are adhered to.

Please note that where approval is given by the Ethics' Committee that committee is part of **Mount Lebanon Hospital** and is delegated to act for **Mount Lebanon Hospital**.

Approval is given until the trial ends. Projects, which have not commenced within 6 months of original approval, must be re-submitted for Ethics' Committee approval. A yearly progress report will be submitted to the Ethics' Committee.

Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported immediately to the hospital EC.

The following are members of the Ethics Committee:

Position	Occupation/ Designation	Name
Chairman	Medical Director	Elie Gharios
Secretary	Urologist	Ghazi Sakr
Member	Attorney	Mrs. Joanne Kyrillos
Member	Gastroenterologist	Khailil Khoury
Member	Pulmonary and critical care specialist	Mirna Fares
Member	Endocrinologist	Marie Merheb
Member	Head Nurse	Maria Haddad
Member	Quality Manager	Talar Elmadjian
Member	Clinical Pharmacist	Maya Harb

The following are the voting members of the Ethics Committee:

Position	Occupation/ Designation	Name
Chairman	Medical Director	Elie Gharios
Secretary	Urologist	Ghazi Sakr
Member	Attorney	Mrs. Joanne Kyrillos
Member	Gastroenterologist	Khalil Khoury
Member	Pulmonary and critical care specialist	Mirna Fares
Member	Head Nurse	Maria Haddad
Member	Quality Manager	Talar Elmadjian

Dr. Elie Gharios
Chairman of Ethics Committee
Medical Director
General Manager
Honorary President of the Hospital
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Camille Chamoun Boulevard
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Elie Gharios, MD.
Honorary President, MLH
Medical Director, General Manager

November 8, 2013

RE: Sanofi Diabetes Management OBS13847

Dear Dr. Kanaan,

The Hammoud Hospital Institutional Review Board (IRB) which operates according to ICH GCP guidelines has reviewed the study request for "International Diabetes Management Practices Study wave 6/IDMPTS wave 6" in a meeting held on November 6, 2013.

The Committee reviewed the documents outlined below and approved Dr. Rafic Kanaan's (the PI) request to conduct this trial at HHUMC. The following members of the IRB were present at the meeting: Dr. Vito L. Tanzi (General Secretary), Dr. Ghassan Hammoud, Dr. Zena G. Hammoud (Deputy President), Dr. Tony Sweidi, Dr. Moh'd Mamlouk, Dr. Basem Shabb, Former Mayor Ahmad Kalash and Dr. Ahmad Zaatari (President). The principal investigator is not a member of this committee:

The committee received the following documents for approval:

1. The Final Version of the Study Protocol OBS13847
 - a. Protocol Number GLA-NE-V1-F-30/10/2013, Version Final 1.0 dated 02-Oct 2013
2. Patient Informed Consent Forms in English and Arabic
 - a. English: IC: EN-V1-NE-F-30/2013-Final version 1.0 dated 30 Sept 2013
 - b. Arabic: IC: AR-EN(30/10/2013)-V1-NE-F-30/10/2013-Final version 1.0

Sincerely,



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Institutional Review Board

Ain Wazein Hospital

Ain Wazein – El Chouf - Lebanon

Phone: +961 (5) 509 001 | Fax: +961 (5) 509 311

Email: irb@awh.org.lb

To : Dr. Husam Ghusn

From : IRB office, Ain Wazein Hospital

Date : November 15, 2013

Subject : Response to the protocol # CRU062: "International Diabetes Management Practices Study wave 6"

Thank you for submitting your research proposal. During the Institutional Review Board meeting on November 15, 2013, the committee members reviewed the protocol and submitted documents and voted to approve the study entitled "International Diabetes Management Practices Study wave 6" sponsored by Sanofi Aventis

The IRB approved the use of the following documents in the research:

- Protocol-GLA-NE-V1-F-30.10.2013
- Informed consent form AR-EN(30.10.2013)-V1-NE-F-30.10.2013
- Case report form GLA-NE-V1-F-30.10.2013
- IC-EN-V1-NE-F-30.10.2013
- Physician's questionnaire IDMP56_Final Version 1.0_September 2013

The approval granted is valid from November 15, 2013 until November 15, 2014. If you wish to continue your research after this date, you must complete and submit a Continuing Review Form 30 days before the end date of the study.

All involved investigators are responsible for making sure that the studies are conducted in accordance with the guidelines for Protecting Human Research Participants.

Please get back to us for any questions or concerns.

Conditions of Approval:

1. No subjects or subject related data may be involved in any study procedure prior to the IRB approval date or after the expiration date.
2. All unanticipated or serious adverse events must be reported to the IRB within 2 days.
3. All protocol modifications must be IRB approved prior to the implementation. This includes any change of investigator, site address, or protocol procedure.
4. All protocol deviations must be reported to the IRB within 5 working days.
5. All recruitment materials and methods must be approved by the IRB prior to being used.

Institutional Review Board Chairperson



Dr. Zouheir El Emad