



Date: December 27, 2015

Department of Healthcare Policy and Research
Weill Cornell Medical College – Qatar Cornell University
Qatar Foundation - Education City
Attention: Ms. May Al-Kassar

Dear Ms. May Al-Kassar,

This letter is in reference to the WCMC-Q's submission of the clinical trial study title "*Diabetes Intervention Accentuating Diet and Enhancing Metabolism (Diadem-I): A Randomised Controlled Trial Assessing The Impact of Low Calorie Diet and Activity on Body Weight and Glycaemia in Diabetes in Early Diabetes*". We acknowledge receipt of your submission dated December 8, 2015. We have completed our review of the below submitted documents, and have concluded that adequate information has been presented to protect the safety and wellbeing of participated subjects. Accordingly, this application is approved effective on the date of this letter.

Research proposal	Reviewed Document
NPRP 8-912-3-192	1.DIADEM-I_PROTOCOL_v2.3_29OCT15 2.ICF_DIADEM-I_v2.6_29OCT15 3.DIADEM-I-PIS_v2.2_26OCT15 4.DIADEM_15-00071_HRP-200 FORM_revised 26OCT15 5.DIADEM_15-00071_HRP-201 FORM 6.CRFBooklet_DIADEM-I_v1 7.CGMSBrochure 8.DVABrochure 9.GT3XBrochure 10.OneTouchBrochure 11.VicorderBrochure 12.FibroScanBrochure 13.FitmateBrochure 14.EQ-5D 15.FFQ 16.HADS 17.IPAQ 18.IWQOL-Lite 19.SIT-Q-7D 20.DIADEM-I-PIS_AR_v2.2_26OCT15 21.DIADEM-I_DeviceInfo_ENG_v1.1_26OCT15 22.DIADEM-I_DeviceInfo_AR_v1.1_26OCT15 22.15-00071- WCM-Q IRB- Approval Determination letter 24.HMC Signed Approval Letter 25.HMC Signed Approval Letter



Please be noted that the SCH provides approval for clinical trials that involves clinical investigation studies. Per SCH definition of clinical investigations, the following studies require SCH approval:

- 1 - A drug (e.g. new drug; or an approved drug used for a different indication); or combination of drugs; or
- 2 - A device; or
- 3 - A therapeutic intervention (such as stem cell transplant, gene transfer etc.)"

We appreciate your institutional compliance with SCH regulations. If you have any questions, please contact Mr. Nordin Fallouch, Clinical Research Specialist, at 974-4407-0981.

Sincerely yours,

Eman Sadoun MD
Manager
Biomedical Research Division
Healthcare Quality Department
Supreme Council of Health

