Date: September 18th, 2016

Hamad Medical Corporation - Director of IRB
Weill Cornell Medicine in Qatar - Director of IRB

Dear all,

This letter is in reference to the clinical trial titled "Intervention using vitamin D for Elevated urinary ALbumin in diabetes (IDEAL-2)"/ NPRP 4-1392-3-345, submitted on July 24th, 2016 by both Dr. Taheri, WCM-Q and Dr. Muhammad Asim, HMC and the recent submission of the establishment of Data Safety Monitoring Board (DSMB).

The study is sponsored by Qatar National Research Fund (QNRF).

Research proposal	Reviewed Document
16235/16	1) 15235_ Protocol_V2_20May16_129Pages 2) 15235_ Signed_Approval_Letter_23Jun16

Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of this clinical trial in Qatar. This support is conditioned by governing the following responsibilities:

- **It is HMC-Medical Research Center's responsibility to:**

1. Govern the MoPH-HMC assurance's terms of function.
2. Provide sufficient staff to support the IRB's review, recordkeeping, and trial monitoring.
3. Conduct on-site monitoring of the clinical trial, to ensure that:

   i - The rights and well-being of human subjects are protected.

   ii - The reported trial data are accurate, complete, and verifiable from source documents.

   iii - The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with Good Clinical Practice, and with applicable regulatory requirement(s).

- **It is the collaborative IRBs (HMC and WCM-Q)'s responsibility to:**

1. Protect the safety and wellbeing of research participants.
2. Protect the privacy and confidentiality of participants.
3. Provide one to one training to involved research staff.
4. Ensure that informed consents are in place.
5. Conduct periodic reviews throughout the trial's duration.
6. Conduct continuous monitoring during the conduct of the trials.
7. Report all unanticipated problems including adverse events to the MoPH.
8. Keep IRB meeting minutes, trial recordkeeping, etc. for inspection purposes.
9. Monitor the work conducted by the Data and Safety Monitoring Board.

- **It is the Data and Safety Monitoring assigned Board to**:

1. Periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy.
2. Make recommendations concerning the continuation, modification, or termination of the trial.
3. Ensure that the timeliness, completeness, and accuracy of the data submitted to them for review are sufficient for evaluation of the safety and welfare of study participants.
4. Report adverse events to the collaborative IRBs, QNRF, and MoPH.

- **It is the HMC's Principal Investigator (PI), Dr. Muhammad Asim's responsibility,** to ensure that this clinical trial is conducted in compliance with MoPH regulations and the principles of International Conference of Harmonization (ICH) - Good Clinical Practice (GCP) and to:

1. Protect the safety and wellbeing of participants.
2. Obtain informed consent from subjects or their legally authorized representative prior to initiation of research procedures.
3. Report all unanticipated problems, including adverse event(s) in accordance with the HMC-IRB's policy on reporting unanticipated problems including adverse events.
4. Conduct the research in accordance with the trial's protocols and the principles of research ethics.
5. Submit the protocol's amendments (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to HMC-IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the HMC-IRB as unanticipated problem.
6. Record and maintain all drug logistic.
7. Inform all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.

For any enquiries, please contact the Research Department via: irb@moph.gov.qa

Sincerely yours,

For Nordin Fallouch

Dr. Eman Sadoun
dresadoun@moph.gov.qa
Manager, Human Research
Ministry of Public Health