Date: August 3rd, 2016

Prof. Ibrahim Al Janahi
Executive Director of Research
Medical Research Center
Hamad Medical Corporation

Subject: Clinical Trial NPRP 8-311-3-062

Dear Prof. Al Janahi,

This letter is in reference to the HMC's submission of the clinical trial titled "Mechanisms of Glucosuria Induced Increase in HGP: Basic Mechanisms and Clinical Implications. Submission included Protocol 1: Elucidation of The Mechanisms Responsible for the Increase in HGP in Response to Glucosuria, and Protocol 3: Can GLP-1 Receptor Agonist, Exenatide, Prevent the Compensatory Increase in HGP in Response to Dapagliflozin and Produce Synergistic Reduction in Blood Sugar / NPRP 8-311-3-062".

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

Research proposal	submitted Document
15410/15	1) 15410_Signed_IRB_Approval_Letter_3May16 2) 15410_Protocol01_17Nov15_23pages 3) 15410_Protocol03_17Nov15_23pages 4) 15410_InformedConsent_Protocol01_11Nov15_08pages 5) 15410_InformedConsent_Protocol03_11Nov15_09pages 6) 15410_DSMBMembership_01page 7) 15410_DSMBMemo_03Dec15_01page 8) 15410_DSMBPlan_09Dec15_11pages

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

- **It is HMC-Medical Research Center 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.

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- **It is HMC-IRB'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 and QNRF.
8. Keep IRB meeting minutes, trial recordkeeping, etc. for inspection purposes.
9. Monitor the work conducted by the Data and Safety Monitoring Board.
10. Report adverse events to MoPH, and the Sponsor (QNRF).

- **It is the sponsor's responsibility to:**

1. Ensure that the initiation site visit of the study where the protocol, data collection instruction, and regulatory obligations are reviewed and shared among the site research team.
2. Work closely with the research team to ensure that execution of study protocols is in place.

- **It is the Data and Safety Monitoring Board's responsibility 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 IRB and the sponsor.

- **It is the HMC's Principal Investigator (PI), Dr. Muhammad Abdul-Ghani'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 perform, in collaboration with the sponsor, the initiation site visit of the study where the protocol, data collection instructions, and regulatory obligations are reviewed and shared among the site research team.

It is the PI's responsibility 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 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,

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