Date: February 7th, 2019

Dr. Amal Robay - WCM-Q Research Compliance Director
Ms. Manju Varghese - WCM-Q IRB Manager
Dr. Stephen Atkin - Principal Investigator

This letter is in reference to the clinical trial entitled **"A noninvasive monitor to predict hypoglycemia in diabetes patients"**, submitted on February 4th, 2019 by Weill Cornell Medicine-Qatar.

The study is sponsored by Qatar National Research Fund.

Research proposal	Documents initially reviewed
1370493-2	1) WCM-Q IRB Approval letter dated February 3, 2019 2) Advertisement - Advert version 1 dated 24Jan2019 - Phase 1 3) HRP-200 FORM - Initial Review Application - Phase 1 4) HRP-201 FORM - Research Personnel - Phase 1 5) Data Collection - Healthy volunteer screening form Version 1 dated 27Jan2019 - Phase 1 6) HRP-500 Form - Informed Consent Form Version 1 dated 31Jan2019 - Phase 1 7) HRP-504 - Protocol Version 1 dated 31Jan2019 - Phase 1

Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of this clinical trial. Please be noted that it is the institution, sponsor and the Principal Investigator (PI)'s responsibility, to ensure that this clinical trial is conducted in compliance with MoPH regulations and the principles of International Council on Harmonization (ICH) - Good Clinical Practice (GCP), and to ensure the below responsibilities are fulfilled.

The Principle Investigator, Dr. Stephen Atkin, should ensure the following:

1. The safety and wellbeing of participants are protected
2. The research is conducted in accordance with the local IRB-approved protocol, including the approved recruitment and informed consents.
3. All unanticipated problems, including adverse event(s) are reported in accordance with the IRB's policy on reporting unanticipated problems including adverse events
4. The protocol's amendments (e.g., protocol, recruitment materials, consent form, status of the study, etc.) are submitted to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate hazards to the subject(s).
5. All investigators and study staff listed on the project are well trained and informed of changes and unanticipated problems, including adverse events, involving risks to subjects or others
6. The continuing review submission to the IRB should be submitted with sufficient time to allow for IRB review and approval.
7. Adequate and accurate research records are kept for inspection purposes.
8. The confidentiality of data is maintained at all times

9. Upon request for monitoring and oversight of the research, research records are made available to MoPH and WCM-Q Monitor
10. All device logistic is maintained and recorded
11. When supervising the conduct of the research, the PI ensures that study personnel:

- are qualified by training and experience, and credentialed if necessary, to perform study-related tasks that have been assigned to them
- are aware of regulatory and policy requirements and standards for the conduct of human subjects research
- have a complete understanding of the details of the protocol relevant to the tasks they will be performing
- Follow the IRB-approved protocol
- are informed of any pertinent changes to the protocol during the conduct of the study and are educated or given additional training, as appropriate

It is WCM-Q and WCM-Q IRB's responsibility to:

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

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

Sincerely yours,

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