Date: March 12th, 2018

Professor Ibrahim Al Janahi - Executive Director of Research, Medical Research Center
Dr. Mohammed Hammoudeh - Chair of Hamad Medical Corporation IRB
Dr. Sadat Kamran - Principal Investigator

This letter is in reference to the clinical trial entitled **"A Placebo Controlled Trial to Determine the Effect of Ischemic Perconditioning on Blood Flow in Collateral Circulation Distal to Proximal Occlusion in Acute Stroke Patients"**, submitted on October 26th, 2017 by Hamad Medical Corporation.

The study is sponsored by Hamad Medical Corporation.

Research proposal	Documents initially reviewed
IRGC-02-SI-029	1) IRGC-02-SI-029_DeferredConsent_Eng_15Aug17_01Page 2) IRGC-02-SI-029_DSMBMembership_01Page 3) IRGC-02-SI-029_DSMBPlan_05Pages 4) IRGC-02-SI-029_ SchemeOfDelegation_22Aug17_03Pages 5) IRGC-02-SI-029_StudyDesign_Eng_23May17_01Page 6) IRGC-02-SI-029_CaseReportForm_Eng_16Aug17_03Pages 7) IRGC-02-SI-029_ InformedConsentPhaseI_Eng-Ara_22Aug17_07Pages 8) IRGC-02-SI-029_ InformedConsentPhaseII_Eng-Ara_22Aug17_07Pages 9) IRGC-02-SI-029_ InitialApplication_Eng_16Aug17_06Pages 10) IRGC-02-SI-029_ Protocol_Eng_12June17_18Pages

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 Conference on Harmonization (ICH) - Good Clinical Practice (GCP), and to ensure the below responsibilities are fulfilled:

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1. The safety and wellbeing of participants are protected
2. Research involving human subjects begins only after IRB review and approval
3. The research is conducted in accordance with the local IRB-approved protocol, including the approved recruitment and consent procedures
4. The elements of the Informed Consents are properly obtained and documented.

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5. All unanticipated problems, including adverse event(s) are reported in accordance with the IRB's policy on reporting unanticipated problems including adverse events

6. 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). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB as unanticipated problem

7. All investigators and study staff listed on the project are informed of changes and unanticipated problems, including adverse events, involving risks to subjects or others

8. The continuing review submission to the IRB should be submitted with sufficient time to allow for IRB review and approval and provide an opportunity for response by the Principal Investigator to any stipulations of the local registered IRB

9. When the research protocol ends, a final report is submitted to the IRB

10. Adequate and accurate research records are kept and retained

11. The confidentiality of data is maintained at all times

12. Upon request for monitoring and oversight of the research, research records are made available to MoPH and HMC Monitor

13. All drug logistic is maintained and recorded

14. 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 HMC and HMC-IRB's responsibility to:

1. Monitor the safety and wellbeing of research participants
2. Ensure that informed consents are documented and properly collected.
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

- **It is HMC Data and Safety Monitoring Board, assigned for this trial, responsibility to:**

1. Review the trial prior its implementation
2. Periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy
3. Make recommendations concerning the continuation, modification, or termination of the trial
4. 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
5. Report adverse events to HMC-IRB, the sponsor, and MoPH

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

Sincerely yours,

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