Date: January 12th, 2017

Professor David Barlow - Chair of Hamad Medical Corporation IRB
Dr. Zainab AbuBaker A A Al-Musleh- Principal Investigator

This letter is in reference to the clinical trial titled "A pilot study on benefits of Hijama cupping therapy in the treatment for Tinnitus, Sudden Sensory Neural Hearing Loss and Dizziness", submitted on October 26th, 2016 by Hamad Medical Corporation.

The study is sponsored by Hamad Medical Corporation.

Research proposal	Reviewed Document
13322/13	1) 13322_DizzinessHandicapInventory_Eng_02Pages 2) 13322_Dr.ZainabAdditionalClinicalPrivilegesApproval_30May16_01Page 3) 13322_EvaluationChart_Eng_01Page 4) 13322_FollowUpVisitSheet_Eng_01Page 5) 13322_HearingAssessmentChartforSSNHL_Eng_01Page 6) 13322_HijamaCertification_19Sept13-03Pages 7) 13322_HistorySheetFirstVisit_Eng_01Page 8) 13322_InformedConsent_Eng-Ara_15Aug16_06Pages 9) 13322_InitialApplication_05Jan16_06Pages 10) 13322_Protocol_RECD16Oct16_13Pages 11) 13322_SchemeOfDelegation_04Pages 12) 13322_SignedMemo_12Oct16_01Page 13) 13322_THIQuestionnaire_Eng_02Pages

Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of a pilot phase of this clinical trial, as per the protocol amended, with 25 participants. After completion of the pilot phase, a full report will be submitted to MoPH. 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 of Harmonization (ICH) - Good Clinical Practice (GCP), and to ensure the below responsibilities are fulfilled:

Dr. Zainab AbuBaker A A Al-Musleh's responsibility

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. When informed consent is required, it is obtained and documented before research participation begins

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. All anticipated problems including wound infection and blood transmission disease are reported to the IRB

7. The protocol's amendments (e.g., protocol, recruitment materials, consent form, status of the study, etc.) is 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

8. 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

9. 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

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

11. Adequate and accurate research records are kept and retained

12. The confidentiality of data is maintained at all times

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

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 the HMC-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 Department via: irb@moph.gov.qa

Sincerely yours,

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