Date: March 19, 2017

Professor David Barlow - Chair of Hamad Medical Corporation IRB
Dr. Mohamed Mostafa Arafa - Principal Investigator

This letter is in reference to the clinical trial titled "Antioxidants in male infertility: A clinical trial", submitted on February 16th, 2017 by Hamad Medical Corporation.

The study is sponsored by Fairhaven Health, LLC.

Research proposal	Reviewed Document
16351/16	1) 16351_CaseReportForm_AdverseEvent_01Mar16_01Page 2) 16351_CaseReportForm_PatientInformation_01Mar16_02Pages 3) 16351_CaseReportForm_Results_01Mar16_01Page 4) 16351_CaseReportForm_Screening_01Mar16_02Pages 5) 16351_CaseReportForm_Withdrawal_01Mar16_01Page 6) 16351_CertificateOfLiabilityInsurance_05Dec16_01Page 7) 16351_DelegationLog_02Pages 8) 16351_InformedConsent_Ara_01Mar16_06Pages 9) 16351_InformedConsent_Eng_01Mar16_06Pages 10) 16351_InitialApplication_08Jun16_06Pages 11) 16351_Protocol_12Dec16_16Pages

Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of this clinical trial, conditioned by the following:

1- Constitution of Data Safety and Monitoring Board (DSMB) Committee and or DSM plan.
2- Conducting additional laboratory tests of liver and kidney function before and after the trial.

Please be informed 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. Mohamed Mostafa Arafa'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. The informed consent 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 clearly presented to participants.
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 is:

I. Qualified by training and experience, and credentialed if necessary, to perform study-related tasks that have been assigned to them.
II. Aware of regulatory and policy requirements and standards for the conduct of human subjects research.
III. Understanding the details of the protocol relevant to the tasks they will be performing.
IV. Following the IRB-approved protocol.
V. 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 and the study protocols are clearly explained to participants.
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 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, the sponsor, and MoPH.

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

Sincerely yours,

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