Date: December 5th , 2016

Professor David Barlow - Chair of Hamad Medical Corporation IRB
Dr. Rayaz Malik - Chair of Weill Cornell Medicine in Qatar IRB
Dr. Dr. Ziad Kronfol- Principle Investigator

This letter is in reference to the clinical trial titled "Depression, Obesity and Inflammatory Markers (DOIM study)" - Aim 4 / NPRP 7-209-3-047, submitted on August 10th, 2016 by Weill Cornell Medicine in Qatar (WCM-Q).

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

Research project	Reviewed Documents
NPRP 7-209-3-047	1) 14-00099 Approval Determination 2) Beck Depression Inventory (Arabic) 3) Beck Depression Inventory (English) 4) Frequency, Intensity, and Burden of Side Effects Ratings (English) 5) Frequency, Intensity, and Burden of Side Effects Ratings (Arabic) 6) Hamilton Rating Scale for Depression (Arabic) 7) Hamilton Rating Scale for Depression (English) 8) HRP-200 FORM - Initial Review Application 9) HRP-201 FORM- Research Personnel 10) Protocol DOIM_resubmission-IRB April 13 final 11) ICF1DOIM_Mainstudy-IRB-stamped 12) ICF2DOIM_Pilotstudy-IRB-stamped 13) MINI International Neuropsychiatric Interview (Arabic) 14) MINI International Neuropsychiatric Interview (English) 15) Sheehan Disability Scale (Arabic) 16) Sheehan Disability Scale (English) 17) Young Mania Rating Scale (Arabic) 18) Young Mania Rating Scale (English)

Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of a pilot phase of this clinical trial with 25 participants from Qatar. This pilot phase needs the establishment of a Data and Safety Monitoring Board (DSMB). Please be noted that it is the institution, the funding body 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 that the below responsibilities are fullfilled:

Dr. Ziad Kronfol' 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- 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
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, the DSMB, and the sponsor
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 task.
    - 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
    - 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 IRBs' (Both WCMC-Q and HMC) 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.
10. Monitor the work conducted by the Data and Safety Monitoring Board.

- **It is the WCM-Q Data and Safety Monitoring Board registered under the registration number MOPH-WCMQ-DSMB-001 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 collaborative IRBs, QNRF, and MoPH.

After completion of the pilot phase, a full report shall be submitted to MoPH.
For any enquiries, please contact the Research Department via: irb@moph.gov.qa

Sincerely yours,

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