Date: February 26th, 2018

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

This letter is in reference to the clinical trial entitled **"A phase 4 open-label randomized controlled study comparing the effectiveness of adalimumab introduction and methotrexate dose escalation in subjects with Psoriatic arthritis (CONTROL)"**, submitted on November 20th, 2017 by Hamad Medical Corporation.

The study is sponsored by Abbvie.

Research proposal	Documents initially reviewed
16440/16	1) 16440_ADACartonCoverpage_Eng_01Pages 2) 16440_ADACartonQAT_Eng_01Pages 3) 16440_ADAPFSCoverpage_Eng_01Pages 4) 16440_ADAPFSQAT_Eng_01Pages 5) 16440_AE-non-CRF_Eng_15Jun16_01Pages 6) 16440_Brochure_Eng_22Sep16_01Pages 7) 16440_BrochureArabicTranslation_Eng-Ara_22Sep16_01Pages 8) 16440_DLQIQuestionnaire_Ara_Apr1992_02Pages 9) 16440_DLQIQuestionnaire_Eng_Apr1992_01Pages 10) 16440_eCaseReportForm_Eng_V1_17Aug16_289Pages 11) 16440_HAQ-DIQuestionnaire_Ara_15May06_02Pages 12) 16440_HAQ-DIQuestionnaire_Eng_AU1.0_02Pages 13) 16440_HumiraDosingDiary_Ara_V1_03May16_10Pages 14) 16440_HumiraDosingDiary_Eng_V1_03May16_10Pages 15) 16440_InformedConsent_Ara_V2_05Feb17_22Pages 16) 16440_InformedConsent_Eng_V2_05Feb17_22Pages 17) 16440_InformedConsentPregnantPartner_Ara_V1_31Oct16_06Pages 18) 16440_InformedConsentPregnantPartner_Eng_V1_31Oct16_05Pages 19) 16440_InitialApplication_Eng_16Oct16_06Pages 20) 16440_InsuranceCertificate_Eng_13Jul16_01Pages 21) 16440_InvestigatorBrochure_Eng_V22.1_17May16_459Pages 22) 16440_MTX15mgCartonCoverpage_Eng_01Pages 23) 16440_MTX15mgCartonCoverpagePen_Eng_01Pages 24) 16440_MTX15mgCartonPenQAT_Eng_01Pages 25) 16440_MTX15mgCartonQAT_Eng_01Pages 26) 16440_MTX20mgCartonCoverpage_Eng_01Pages 27) 16440_MTX20mgCartonCoverpagePen_Eng_01Pages 28) 16440_MTX20mgCartonPenQAT_Eng_01Pages 29) 16440_MTX20mgCartonQAT_Eng_01Pages 30) 16440_MTX25mgCartonCoverpage_Eng_01Page

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Research proposal	Documents initially reviewed
16440/16	31) 16440_MTX25mgCartonQAT_Eng_01Pages 32) 16440_MTX25mgPenCoverpage_Eng_01Pages 33) 16440_MTX25mgPenQAT_Eng_01Pages 34) 16440_MTXBlisterCoverpage_Eng_01Pages 35) 16440_MTXDosingDiary_Ara_V1_03May16_13Pages 36) 16440_MTXDosingDiary_Eng_V1_03May16_13Pages 37) 16440_PatientGlobalAssessmentofArthritis AS_Ara_V1_20May16_01Pages 38) 16440_PatientGlobalAssessmentofArthritis AS_Eng_V1_14Apr16_01Pages 39) 16440_PatientGlobalAssessmentOfDiseaseActivityVAS_Eng_V1_14Apr16_01Pages 40) 16440_PatientGlobalAssessmentOfDiseaseActivityVAS_Ara_V1_20May16_01Pages 41) 16440_Patient'sAssessmentOfPainVAS_Eng_V1_14Apr16_01Pages 42) 16440_Patient'sAssessmentOfPainVAS_Ara_V1_20May16_01Pages 43) 16440_PI-to-DrLetter_Eng_12Sep16_01Pages 44) 16440_PI-to-DrLetterArabicTranslation_Eng-Ara_12Sep16_01Pages 45) 16440_PI-to-PatientLetter_Eng_22Sep16_01Pages 46) 16440_PI-to-PatientLetterArabicTranslation_Eng-Ara_22Sep16_01Pages 47) 16440_Poster_Eng_12Sep16_01Pages 48) 16440_PosterArabicTranslation_Eng-Ara_12Sep16_01Pages 49) 16440_Protocol_Eng_V4_10Oct16_165Pages 50) 16440_PsAID9_Eng_V1_14Apr16_02Pages 51) 16440_PsAID9_Ara_V1_20May16_02Pages 52) 16440_ReminderSticker_Eng_18Aug16_01Pages 53) 16440_ReminderStickerArabicTranslation_Eng-Ara_18Aug16_01Pages 54) 16440_SAE-Non-CRF_Eng_22Feb13_08Pages 55) 16440_SAPS24Hours_Ara_V3_14Sep16_02Pages 56) 16440_SAPS24Hours_Eng_V3_15Jul16_02Pages 57) 16440_SchemeOfDelegation_Eng_30Oct16_02Pages 58) 16440_SF-36Questionnaire_Ara_V2_06Pages 59) 16440_SF-36Questionnaire_Eng_V2_06Pages 60) 16440_SubjectInformationCard_Ara_01Pages 61) 16440_SubjectInformationCard_Eng_01Pages

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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Dr. Samar Al Emadi' s reponsibilities:

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.) 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

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- 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 Abbvie, HMC and 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 Division at MoPH via: irb@moph.gov.qa

Sincerely yours,

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