Date: August 2nd, 2016

Prof. Ibrahim Al Janahi
Executive Director of Research
Medical Research Center
Hamad Medical Corporation

Dear Prof. Al Janahi,

This letter is in reference to the HMC's submission of the clinical trial titled "A Phase 2, Multi-Center, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of lulizumab pegol/BMS-931699 vs. Placebo on a Background of Limited Standard of Care in the Treatment of Subjects with Active Systemic Lupus Erythematosus". We acknowledge receipt of your submission dated May 31, 2016.

The study is sponsored by Bristol-Myers Squibb Research and Development.

Research proposal	Reviewed Document
15445/15	1) 15445_Addenduml_ListOfCentralLaboratories_Eng_1 Pages 2) 15445_AdditionalConsent_Site154_Ara_V1.1 _11 May16_7Pages 3) 15445_AdditionalConsent_Site154_Eng_V1.1 _11 May16_6Pages 4) 15445_CaseReport_Eng_17Nov15_1277Pages 5) 15445_eCaseRreportInstructions_Eng_V3_29Sept15_64Pages 6) 15445_ExternallySponsoredProjectResearchApplication_Eng_2Pages 7) 15445JACIT-F_Ara_V4_02Jan14_3Pages 8) 15445JACIT-F_Eng_V4_290ct14_3Pages 9) 15445JlowChart_Eng_V2_20Nov15_49Pages 10) 15445JnformedConsent_Site154_Ara_V1.1_11 May16_11 Pages 11) 15445JnformedConsent_Site154_Eng_V1.1_11 May16_11 Pages 12) 15445JnitialApplication_Eng_28Nov15_7Pages 13) 15445JnsuranceCertificate_Eng_06Dec15_2Pages 14) 15445JnvestigatorBrochure_Eng_V4_06Jul15_91 Pages 15) 15445_ListOfCountries_Eng_01 Dec15_1 Pages 16) 15445_MidstreamPregnancyKitlnstruction_Ara_2Pages 17) 15445_MidstreamPregnancyKitlnstruction_Eng_1 Pages 18) 15445_PaymentAcknowledegmenLAra_V1_ 01 Dec15_1 Pages 19) 15445_PaymentAcknowledegmenLEng_V1_ 01 Dec15_1 Pages 20) 15445_PregnancyKitlnsert_Ara_VLNov13_2Pages 21) 15445_PregnancyKitlnsert_Eng_V1_Nov13_2Pages 22) 15445_Protocol_Eng_V2_28Apr15_126pages 23) 15445_SchemeOfOelegation_Eng_2Pages

T: +974 44070000
P.O. Box: 42, Doha - Qatar
ت: ٤٤٠٧٠٠٠٠ ٩٧٤+
ص.ب: ٤٢، الدوحة - قطر
www.moph.qa

	24) 15445_SF36_Eng_V2_290ct14_6Pages 25) 15445_SF36Lebanon_Ara_V2_6Pages 26) 15445_SubjectAlertCard_Ara_V1_07Dec15_2Pages 27) 15445_SubjectAlertCard_Eng_V1_07Dec15_2Pages 28) 15445_SubjectContactInfo_Ara_V1_01 Dec15_1 Pages 29) 15445_SubjectContactInfo_Eng_V1_01 Dec15_1 Pages 30) 15445_VASSubjectGlobalAssess_AraJorGulC1Pages 31) 15445_VASSu bjectGlobaIAssess_Eng_V1.1_280ct14_1 Pages

Upon review of the submitted documents, the Ministry of Public Health (MoPH) supports the conduct of this clinical trial. This support is conditioned by governing the following responsibilities:

- **It is HMC-Medical Research Center to:**

1. Govern the MoPH-HMC assurance's terms of function.
2. Provide sufficient staff to support the IRB's review, recordkeeping, and trial monitoring.

- **It is HMC-IRB's responsibility to:**

1. Protect the safety and wellbeing of research participants.
2. Protect the privacy and confidentiality of participants.
3. Provide one to one training to involved research staff.
4. Ensure that informed consents are in place.
5. Conduct periodic reviews throughout the trial's duration.
6. Conduct continuous monitoring during the conduct of the trials
7. Report all unanticipated problems including adverse events to the MoPH and Bristol-Myers Squibb Research and Development.
8. Keep IRB meeting minutes, trial recordkeeping, etc. for inspection purposes.
9. Monitor the work conducted by the Independent Data Monitoring Committee.

- **It is the Independent Data Monitoring Committee'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, Bristol-Myers Squibb Research and Development, and MoPH.

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- **It is the HMC's Principal Investigator (PI), Dr. Samar Al Emadi'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).

It is the PI's responsibility to:

1. Protect the safety and wellbeing of participants.
2. Obtain informed consent from subjects or their legally authorized representative prior to initiation of research procedures.
3. Report all unanticipated problems, including adverse event(s) in accordance with the HMC-IRB's policy on reporting unanticipated problems including adverse events.
4. Conduct the research in accordance with the trial's protocols and the principles of research ethics.
5. Submit the protocol's amendments (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to HMC-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 HMC-IRB as unanticipated problem.
6. Record and maintain all drug logistic.
7. Inform all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.

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

Sincerely yours,

Dr. Eman Sadoun
dresadoun@moph.gov.qa
Manager, Human Research
Ministry of Public Health
T: 4407-0363