Kingdom of Saudi Arabia Ministry of Higher Education

King Saud University Code 034

College of Medicine & King Khalid University Hospital





المملكة العربية السعودية وزارة التعليم العالي حجامعة (الملك سعوى رمزها ٣٤٠ مكية الطب

Date:

03.12.2014

11.02.1436

التاريخ:

No.: 14/4464/IRB

الرقم:

To:

Prof. Mohammed El Mouzan

Department of Pediatrics

King Saud University College of Medicine

King Khalid University Hospital

Subject:

Research Project No. E-14-1329

Title:

"Characterization of Intestinal Microbiome in Saudi children with Celiac disease"

Dear Prof. El Mouzan,

This is in reference to your submitted proposal with the above-mentioned title, which was reviewed and discussed in the IRB Meeting 03 (Academic Year 1435-1436) held on 26 November 2014 (04 Safar 1436). Upon recommendation of the Research Committee and following the review of the IRB on the ethical and scientific aspects of the proposal, the project was **approved** and you are granted permission to conduct this study.

This approval is for a period of one (1) year commencing from the date of this letter with the following conditions:

Terms of Approval:

- 1. Modifications to Research/ Amendments to the approved project: any modifications to the research (including changes to the informed consent document(s) must receive IRB approval prior to implementation of the changes. Substantial variations may require new submission.
- 2. Annual Reports: continued approval of this project is dependent on the submission of annual reports. Please provide the IRB with an Annual Report determined by the date of your letter of approval.
- Monitoring: projects may be subject to an audit or any other form of monitoring by the IRB at any time.
- **4. Retention and storage of data:** the PI is responsible for the storage and retention of original data pertaining to the project for a minimum period of five (5) years.
- 5. Future correspondence: please quote the project number and project title above in any further correspondence.

In addition, you must file a **Progress Report** with the IRB every 6 months and a Final Report (Close-Out) when the study has been completed.

We wish you success in your research!

Thank you!

Sincerely yours,

Dr. Khalid M. Al-Faleh Chairman, Institutional Review Board King Saud University - College of Medicine P.O. Box 7805 Riyadh 11472 K.S.A Email: kfaleh@ksu.edu.sa

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