B.4 LOI2-BIO-20 IRB Approval Letter

OMB #: 0925-0647
Expiration Date: 01/31/2015

May 29, 2011

KJERSTI MARIE AAGAARD-TILLERY
BAYLOR COLLEGE OF MEDICINE
OB-GYN: ADMINISTRATIVE

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H-27393 - BIOSPECIMEN COLLECTION AND ANALYSIS IN THE NATIONAL CHILDRENS STUDY: METAGENOMIC ASSESSMENT OF THE MICROBIOME

APPROVAL VALID FROM 5/29/2011 TO 5/28/2012

Dear Dr. AAGAARD-TILLERY

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Minimal Risk IRB (Health Sciences)
12/6/2011

Submission ID number:	2011-0649
Title:	CONTRIBUTIONS OF THE MATERNAL-FETAL MICROBIOME INTERACTIONS AND CIRCULATING FETAL DNA FROM MATERNAL PLASMA AND CERVICAL AND VAGINAL FLUID - NCS Substudy
Principal Investigator:	MAUREEN DURKIN
Point-of-contact:	MARIE-NOEL SANDOVAL
IRB Staff Reviewer:	STACI LOWE

The convened MR IRB conducted a full review of the above-referenced initial application. The study was approved for the period of with the expiration date of 10/9/2012.

To access the materials approved by the IRB, including any stamped consent forms, recruitment materials and the approved protocol, if applicable, please log in to your ARROW account and view the documents tab in the submission's workspace.

If you requested a HIPAA waiver of authorization, altered authorization and/or partial authorization, please log in to your ARROW account and view the history tab in the submission's workspace for approval details.

Prior to starting research activities, please review the Investigator's Responsibility guidance, which includes a description of IRB requirements for submitting continuing review progress reports, changes of protocol and reportable events: http://arrowhelp.hsirbs.wisc.edu/content/investigator-responsibilities.

Please contact the IRB office at 608-263-2362 with general questions. For questions related to this submission, contact the assigned staff reviewer.