OMB # 0925-0647
EXPIRATION DATE: 1/31/2015

Yale University

Human Investigation Committee
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To: Andrew Dewan

From: Sandra L. Alfano, Pharm. D., FASHP, Chair, HIC-I

Date: 06/04/2010

HIC #: 1006006893

Title: Collection of Circulating Fetal DNA from Maternal Blood and from Cervical Fluid

The HIC is in receipt of your request for IRB review for your proposed study. We have determined that this study is not considered to be Human Subjects Research and does not require HIC review, pursuant to the Office of Human Research Protections (OHRP) definition of human subject, 45 CFR 46.102 (f), as follows:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention or interaction with the individual, or

(2) identifiable private information.

OHRP has issued guidance regarding Institutional Review board (IRB) review and approval processes for research involving coded private information or human biological specimens; this guidance can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.

The Guidance provides specific mechanisms by which coded information or specimens can fall outside of the definition of human subjects research. OHRP considers this guidance to apply not only to existing information and specimens but to materials to be collected in the future if the purpose of collection is for reasons other than the contemplated research project. The Guidance states that research does not involve human subjects if 1) the data or specimens were/will not be specifically collected for the current research project, and 2) there is a documented mechanism in place that prevents the investigator from obtaining access to identifiers. Examples of acceptable mechanisms include a simple Memorandum of Understanding between the provider and recipient that identifying information will neither be provided nor requested.

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.