



THE UNIVERSITY OF NEW MEXICO
HEALTH SCIENCES CENTER

Human Research Review Committee
MSC 08 4560 BMSB Room B71
1 University of New Mexico~Albuquerque, NM 87131-0001
(505) 272-1129 Facsimile (505) 272-0803
<http://hsc.unm.edu/som/research/hrrc/>

24-Sep-2010

Moore, Lisa
Obstetrics Gynecology OB GYN

SUBJECT: HRRC Determination of Exempt Status
HRRC#: 10-418
Study Title: Sonographically detected polyhydramnios and the associations with diabetes and fetal anomalies
Approved: 24-Sep-2010

Dear Dr. Moore:

The Human Research Review Committee (HRRC) has reviewed the above-mentioned research protocol and determined that this research is *exempt* from the requirements of Department of Health and Human Services (DHHS) regulations for the protection of human subjects as defined in 45CFR46.101(b) under category 4, based on the following:

1. HRPO Application received 081310

Because it has been granted exemption, this research project is not subject to continuing review. Also note that the Food and Drug Administration (FDA) regulations as defined in 21CFR50.1 and 21CFR56.101 do not apply to this research.

Changes to the Research: It is the responsibility of the Principal Investigator to inform the HRRC of any changes to this research. A change in the research may disqualify this project from exempt status. Reference the HRRC# and title in all documents related to this protocol.

Sincerely,

Mark Holdsworth, PharmD
Executive Chair
Human Research Review Committee