The University of Oklahoma
Health Sciences Center
INSTITUTIONAL REVIEW BOARD

IRB Number: 13298
Meeting Date: February 26, 2007
Approval Date: March 05, 2007

March 05, 2007

David Fields, Ph.D.
Dept of Pediatrics
940 N. E. 13th, CHO 2B2426
Oklahoma City, OK 73104-5066

RE: The impact of type 1 diabetes and being overweight on risk of future cardiovascular disease in children

Dear Dr. Fields:

The University of Oklahoma Health Sciences Center's Institutional Review Board (IRB) reviewed the above-referenced research protocol at its regularly scheduled meeting on February 26, 2007. It is the IRB's judgement that the rights and welfare of the individuals who may be asked to participate in this study will be respected; that the proposed research, including the process of obtaining informed consent, will be conducted in a manner consistent with the requirements of 45 CFR 46 or 21 CFR 50 & 56, as amended; and that the potential benefits to participants and to others warrant the risks participants may choose to incur.

On behalf of the IRB, I have verified that the specific changes requested by the convened IRB have been made. Therefore, on behalf of the Board, I have granted final approval for this study.

This letter documents approval to conduct the research as described:

IRB Application Dated: February 15, 2007
Protocol Dated: January 09, 2007
Recruitment flyer Dated: February 15, 2007 email
Consent form - Subject Dated: January 10, 2007
Priv - Research Auth 1 Dated: January 06, 2005
Survey Instrument Dated: February 15, 2007 Food Diary

As principal investigator of this protocol, it is your responsibility to make sure that this study is conducted as approved by the IRB. Any modifications to the protocol or consent form, initiated by you or by the sponsor, will require prior approval, which you may request by completing a protocol modification form.

It is a condition of this approval that you report promptly to the IRB any serious, unanticipated adverse events experienced by participants in the course of this research, whether or not they are directly related to the study protocol. These adverse events include, but may not be limited to, any experience that is fatal or immediately life-threatening, is permanently disabling, requires (or prolongs) inpatient hospitalization, or is a congenital anomaly, cancer or overdose. For multi-site protocols, the IRB must be informed of serious adverse events at all sites.

The approval granted expires on January 31, 2008. Should you wish to maintain this protocol in an active status beyond that date, you will need to provide the IRB with an IRB Application for Continuing Review (Progress Report) summarizing study results to date. The IRB will request a progress report from you approximately three months before the anniversary date of your current approval.

If you have questions about these procedures, or need any additional assistance from the IRB, please call the IRB office at (405) 271-2045 or send an email to irb@ouhsc.edu. Finally, please review your professional liability insurance to make sure your coverage includes the activities in this study.

Sincerely yours,

Vicki Lampley, M.D., M.P.H.
Vice Chair, Institutional Review Board

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