THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Office of Protocol Research

Institutional Review Board (IRB)
Unit 1437
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To: Michele Forman 05/26/2011
From: Veronica Roberts
CC: Beverly J. Gor, Ladia M. Hernandez, Lorna H. McNeill
MDACC Protocol ID #: 2010-0916
Protocol Title: Improving dietary assessment in pregnant women, infants, and children: The National Children's Study
Version: 03

Subject: Administrative IRB Approval -- Protocol 2010-0916

On Thursday, 05/26/2011, the Institutional Review Board (IRB) 4 chair or designee reviewed and approved your revision dated 05/09/2011 for Protocol 2010-0916

These Pages Include:

- Protocol Body -- Document header Date: 05/09/2011
- Abstract Page -- Document header Date: 05/09/2011
- Informed Consent(s) -- Document header Date: 05/09/2011
- Appendices -- Document header Date: 05/09/2011
- Collaborator(s) Page -- Document header Date: 05/09/2011

Revision included the following changes:
Revision response to contingencies from April 21, 2011 IRB4 meeting. Participants should be reconsented if there is a desire to do anthropometric measures on the children already enrolled. 404 Pediatric Risk Assessment - Research not involving greater than minimal risk. – Only 1 parent signature is required on Informed Consent Document. Consent updated to the new template.

The revision can now be implemented. Please inform the appropriate individuals in your department or section and the collaborators of these changes.

Please inform the appropriate individuals in your department/section and your collaborators of these revisions.

Please Note: This approval does not alter or otherwise change the continuing review date of this protocol.

In the event of any questions or concerns, please contact the sender of this message at (713) 792-2933.

Veronica Roberts 05/26/2011 02:29:22 PM

This is a representation of an electronic record that was signed and dated electronically and this page is the manifestation of the electronic signature and date:

Veronica Roberts
05/26/2011 02:28:42 PM
IRB 4 Chair Designee
FWA #: 00000363
OHRP IRB Registration Number: IRB 4 IRB00005015

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University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

Protocol Amendment Approval

18-Nov-2010

Investigator:	Dana Dabelea
Sponsor(s):	National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS~
Subject:	COMIRB Protocol 09-0563 Amendment
Effective Date:	16-Nov-2010
Title:	HEALTHY START

Amendment Description:

PAM007-1

Application Form: Protocol: Consent Form Revision: Documents Used with Subjects:

1. Extend the eligibility criteria for participation on Healthy Start to pregnant women < 23Weeks of gestation. This change is included in Protocol application: Page # 7 H- Human Subjects, numeral 6: Inclusion Criteria and in page # 8, I- Procedures, numeral 2. And in the study protocol pages #2.6 and 7.

2. Invite a random sample of participants (50% of those completing an IPV3) to bring their babies (4-6 months old) to The Children Hospital (TCH) CTRC for an in person visit (IPV4) to assess anthropometric measures (weight, length, skinfolds, circumferences) and body fat (using the Pea Pod measurement) . This addition is described in the Study Protocol pages # 8 and 9; in the protocol application page #8 I: Procedures numeral 2; and in Attachment U pages: 4,5,11 and 12. Description of IPV4 methods for the selected sample is included in the consent form Pages #3, and 7.Copies of highlighted and clean application protocol, attachment U, protocol, and consents are attached.

3. Increase incentives for completion of IPV1 from $40 to $60 and IPV3 from $20 to $40, and compensate $60 to those participants completing IPV4. This addition is reflected in the protocol application page #13 K Recruitment, numerals 4b and 4c; in the Healthy Start protocol Pages # 15 and 16. And in the consent pages #7. Copies of highlighted and clean protocol are attached.

4. When and if absolutely necessary, conduct visits I&2 in participant's home. This procedure will be done on case by case basis and only if participant can't absolutely come to the clinic for the study visits. COMRIB and OSHA procedures will be followed with phlebotomy and blood transportation, and interviewing. This is reflected in the protocol application G2 and J3; and in the protocol pg.15.

5. Conduct a pilot study on a convenience sample of N=50 Healthy Start participants to evaluate the feasibility, burden and data quality of collecting dietary data on pregnant women using the 24-hour recall method (ASA24) rather than or in conjunction with a food frequency method. This pilot work will inform the National Children's Study on what dietary data collection approaches to use. We are already colleting ASA24 recalls in Healthy Start participants, therefore, to accomplish this goal we would ask a sample of N=50 Healthy Start pregnant women who have completed an IPV1 to complete at home: 2 questionnaires on Acceptability of ASA24 recall (after the 2nd and third ASA24 recall) and a full food frequency questionnaire (after the third ASA24 recall). They would return these questionnaires to the study team when they are seen for their Healthy Start IPV2. This addition is reflected in the protocol application page #8 I: Procedures numeral 2, in the Healthy Start protocol Page s#7 and 8, and consent form Pages #2 and 7. Copies of highlighted and clean application protocol, Attachment A, protocol and consents as well as questionnaire and survey are attached. Participants completing this pilot study will be additionally compensated $ 25.

Documents Submitted and Approved:
1. Protocol application with attachments –Highlighted changes: application, Attachments A, D, E, F, G, H, I, J, M - Waiver of Consent, O - Waiver of HIPAA, P, Q, R, S, and U dated 11-5-10
2. Consent forms- English and Spanish - Highlighted changes and clean copies dated 11-5-10
3. Protocol- Highlighted changes and clean copy dated 11-5-10
4. ASA24 Acceptability Questionnaire # 1 and #2
5. NCS Food Frequency Questionnaire

Sincerely,
UCD Panel C

webIRB

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APPROVAL NOTICE
New Study

DATE:	3/15/2011
TO:	LENORE ARAB MEDICINE-GENERAL MEDICINE & HLTH SRVCS.
FROM:	ALISON MOORE Chair, SGIRB
RE:	IRB#10-001535 Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study Version: LOI-2-14

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. The UCLA IRB's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642 (IRB00004474).

Submission and Review Information

Type of Review	Full Board Review
Approval Date	3/15/2011
Expiration Date of the Study	1/10/2012
Funding Source(s)	1) NIH/NATIONAL INST OF CHILD HEALTH AND HUMAN DEVELOPMENT *Grant Title*: Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study *Grant Number*: LOI-2-14

Regulatory Determinations

-- The UCLA IRB waived the requirement for signed informed consent for the screening under 45 CFR 46.117(c)(2).

-- The UCLA IRB waived the requirement for obtaining the assent of the children under 45 CFR 46.116(d) for the entire study.

-- The UCLA IRB determined that the research meets the requirements of 45 CFR

46.404 for research involving children as subjects.

Documents Reviewed included, but were not limited to:

Document Name	Document Version #
Craigslist Text.Child Chinese CLEAN.pdf	0.01
Craigslist Text.Pregnant Indian CLEAN.pdf	0.01
Eligibility Screener Script (preschooler) .pdf	0.01
Flyer Pregnant Chinese CLEAN 2.28.11.pdf.pdf	0.01
Craigslist Text.Child Indian CLEAN.pdf	0.01
Consent form Pregnant women.pdf	0.01
Flyer Children Chinese CLEAN 2.28.11.pdf.pdf	0.01
Consent form preschoolers.pdf	0.01
Flyer Pregnant SouthEastIndian CLEAN 2.28.11.pdf.pdf	0.01
Flyer Pregnant Filipino CLEAN 2.28.11.pdf.pdf	0.01
Craigslist Text.Child Filipino CLEAN.pdf	0.01
Recruitment Flyer (Children Filipino) CLEAN.pdf	0.01
Eligibility Screener Script (pregnant).pdf	0.01
Craigslist Text.Pregnant Filipino CLEAN.pdf	0.01
Flyer Children South East Indian CLEAN 2.28.11.pdf.pdf	0.01
Craigslist Text.Pregnant Chinese CLEAN.pdf	0.01

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval
As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the

protocol to the IRB according to the OHRPP reporting requirements.

- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.