Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
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Aurora, Colorado 80045

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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

31-Jan-2011

Investigator:	Dana Dabelea
Sponsor(s):	National Institute of Diabetes and Digestive and Kidney Diseases/NIH/DHHS~
Subject:	COMIRB Protocol 09-0563 Amendment
Effective Date:	28-Jan-2011
Title:	HEALTHY START

Amendment Description:

PAM008-1

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

1. Conduct a pilot study on a convenience sample of N=50 Healthy Start newborn participants and N=50 infants age approximately 6 months to add ulnar length and lower leg length to the current anthropometric measurements to compare ulnar and length in children with length / height, weight and body mass index in Z -scores in diverse ethnic groups. This addition is reflected in the protocol application page #3 F: Performing Sites; page #8 I: Procedures- numeral 2a; and Page 13 K; Recruitment -numeral 4b. In the Healthy Star protocol Pages
#7, 8, 9, 10, 11, 15 and 16, and consent form Pages #3 and 7. Copies of highlighted and clean application protocol, Attachment A, HiPAA B, protocol and consents as well as questionnaires are attached.

Participants completing this pilot study will be additionally compensated $25.00

2. Additional questions are added to: Early Pregnancy Interview (EPI) and Postnatal Interview (PNI) questionnaires.

Documents Submitted and Approved:
1. Revised Protocol Application, Attachments A, D, E, F, G, H, I. J, M, P, Q, R, S, U dated 1-6-11
2. Revised highlighted/clean Protocol dated 1-6-11
3. Revised highlighted/clean Consent Forms (English/Spanish) dated 1-6-11
4. Revised highlighted/clean Post-Natal Interview (PNI)
5. Revised highlighted/clean Early Pregnancy Interview (EPI)

Review Comments:

NOTE:

By next Continuing Review, please explain the role of MD Anderson or remove reference to them in Section F in application.

Sincerely,
UCD Panel C

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: http://research.umn.edu/subjects/

05/03/2011

John H Himes
Epidemiology
Room 300 WBOB
1300 S 2nd St
Minneapolis, MN 55454

RE: "NCS Formative 26: Evaluation of Ulnar Length Measurement for Use in the National Children's Study"
IRB Code Number: **1104S98434**

Dear Dr. Himes:

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

IRB approval of this study includes the consent form and study posting, both received April 14, 2011.

The IRB would like to stress that subjects who go through the consent process are considered enrolled participants and are counted toward the total number of subjects, even if they have no further participation in the study. Please keep this in mind when calculating the number of subjects you request. This study is currently approved for 60 subjects. If you desire an increase in the number of approved subjects, you will need to make a formal request to the IRB.

For your records and for grant certification purposes, the approval date for the referenced project is April 18, 2011 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal; approval will expire one year from that date. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious unexpected adverse events should be reported to the IRB as they occur.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,

Christina Dobrovolny, CIP
Research Compliance Supervisor
CD/ks

CC: Deborah Engelhard, Wendy Hellerstedt, Emily Henning, Laurie Ukestad

webIRB

11000 Kinross Avenue, Suite 102
Los Angeles, CA 90095-1694

http://ohrpp.research.ucla.edu
GC-IRB: (310) 825-7122
M-IRB: (310) 825-5344

APPROVAL NOTICE
New Study

DATE:	4/6/2011
TO:	LENORE ARAB MEDICINE-GENERAL MEDICINE & HLTH SRVCS.
FROM:	ALISON MOORE Chair, SGIRB
RE:	IRB#10-001815 An Evaluation of Ulnar Length Measurement for use in the National Children's Study Version: PHYS-02-A

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	4/6/2011
Expiration Date of the Study	3/21/2012
Funding Source(s)	1) NIH/NATIONAL INST OF CHILD HEALTH AND HUMAN DEVELOPMENT *Grant Title*: An Evaluation of Ulnar Length Measurement for use in the National Children's Study *Grant Number*: PHYS-02-A

Specific Conditions for Approval

-- Until the UCLA IRB has received a copy of the approval notice from the lead site's Ethical Review Committee, no subjects may be contacted, recruited, or enrolled in this research study. Therefore, no related recruitment, screening or consent document(s) are stamped as approved and should not be used at this time. Once the approval notice has been received, the UCLA IRB will stamp these documents and issue an Approval Notice lifting this restriction. The approval notice from the lead site should be submitted to the IRB as an amendment.

Regulatory Determinations

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

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 category 4 and 7.

-- The UCLA IRB determined that the research meets the requirements of 45 CFR 46.404 for research involving children as subjects.

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

Documents Reviewed included, but were not limited to:

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.

South Dakota State University

SDSU

Office of Research/Human Subjects Committee
SAD Room 124
Box 2201 SDSU
Brookings, SD 57007

November 15, 2010

To: Lee Weidauer and Bonny Specker, E.A. Martin Program in Human Nutrition

Project title: Anthropometry in Children: An investigation into different methods of length and limb measurement in children from birth to 5 years.

Approval #: IRB-1011011-CR

Thank you for bringing your protocol to the Human Subjects Committee. The Committee approved the project at its duly convened meeting on November 9, 2010. The Committee classified this activity as no greater than minimal risk, and your final protocol (11/15/10) was approved using expedited review.

The one-year approval of your project will be dated starting 11/15/10. If you need to extend the study beyond one year, please submit a request for continuing approval prior to the project end date of 11/14/11. If you modify your study, changes must be proposed and approved prior to implementation. Expedited review will be used for all protocol changes. At the end of the project please inform the Committee that the study is complete.

If there are any unanticipated problems involving risks to subjects or others, please immediately contact the SDSU Research Compliance Coordinator.

If I can be of any other assistance, don't hesitate to let me know.

Sincerely,

Norm

Norman O. Braaten
Research Compliance Coordinator

INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

IRB: IRB_00045951

PI: Laurie Moyer-Mileur

Title: Anthropometry in Children: An investigation into different methods of length and limb measurement in children from birth to 5 years

This New Study Application has been reviewed and approved by a University of Utah IRB convened board. The convened board approved your study as a Greater Than Minimal risk study on 2/9/2011. Federal regulations and University of Utah IRB policy require this research protocol to be re-reviewed and re-approved within 1 year from the approval date.

Your study will expire on 2/8/2012.
Any changes to this study must be submitted to the IRB prior to initiation via an amendment form.

APPROVED DOCUMENTS

Protocol Summary
Clean Protocol Summary 1.27.11

Parental Permission Forms
ParentalPermissionw/DXAClean2.14.11
ParentalPermissionClean2.14.11

Grant Application
LOI3-PHYS-02-B- Utah

Other Documents
Recruitment Flyer PDF Blck/Wht
SDSU Consent no DXA Form
SDSU Consent with DXA Form

Click IRB_00045951 to view the application and access the approved documents.

Please take a moment to complete our customer service survey. We appreciate your opinions and feedback.