



Date: May 31, 2011

To: Pamela R. Wood, M.D.
Dept. of Pediatrics,
F 3725 3rd Fl, Center for Children and Families, CSR
UTHSCSA, MC 7808

From: Institutional Review Board

Subject: **Expedited Approval of a Modification to Ongoing Research (Amendment)**

Protocol Number: HSC20110139H

Title: Tools for screening pulmonary function in the National Children's Study

Funding Type: HHS (NIH-CDC); **Sponsor:** NIH-Diabetes/Digestive/Kidney Diseases; **Grant Title(s):** NCS-Tools for screening pulmonary function; **Grant #:** HHSN267200700006C/WA No. 5 LOI13-PHYS-01-B

Dear Principal Investigator,

Your request to modify this study (amendment), dated May 20, 2011, was reviewed by the Institutional Review Board on May 27, 2011 and approved.

In addition to the amendment form the following documents were reviewed: Signature Assurance Sheet; Form B - General Information; Form B-2 - Personnel List; Form D - HSC Consent, 1 English ICD Lamar County (new); Form L - Recruitment Material; Form M - Data Collection Instrument(s); **Other:** Form H-1 Translation Certification; Form L Lamar County Parent Letter; Form L Lung Study Flyer Lamar County Head Start; Form L Lung Study Flyer Lollypop Daycare; Form M Baseline Quest; Form M Spanish Baseline Quest; Form M Spanish Pulmonary Function Testing; Form M Spanish Specialist visit Questionnaire; Form M Specialist visit Questionnaire, UT Centralized IRB Review Notification to Relying Organization Intent to Submit for Centralized Review (signed 05-23-11).

Summary of the main modifications to your study: Added Lamar County as a study site with Dr. Deborah Cherry as Principal Investigator for that site; added a consent form, two flyers and a parent letter for Lamar County; added study staff from UTHSC Tyler; submitted Spanish translation for 3 questionnaires; and revised 2 questionnaires.

The attached informed consent document(s) digitally stamped with **IRB APPROVED May 27, 2011** must be used.

Affiliated institutions which are engaged in this research: UTHSCSA UTHSCS-Tyler

Sincerely,

Senior IRB Coordinator

cc: Debbie Fielder
University of Texas Health Science Center at Tyler
debbie.fielder@uthct.edu

Please retain this document in your IRB correspondence file

Institutional Review Board Office | Mail Code 7830 | 7703 Floyd Curl Drive | San Antonio, Texas 78229-3900
210.567.2351 | Fax 210.567.2360 | <http://research.uthscsa.edu/irb> | FWA00005928 | IORG0000312