## Youngblood, Marston E Jr

**From:** IRB <irb_no_reply@mailserv.grad.unc.edu>
**Sent:** Friday, February 18, 2011 4:40 PM
**To:** LaVange, Lisa M
**Cc:** Youngblood, Marston E Jr
**Subject:** IRB Notice

A paper copy of the approval memo and any relevant documents are being mailed today.

**To**: Lisa Lavange
Biostatistics
CB:8030

**From**: Public Health-Nursing IRB

**Approval Date**: 2/18/2011
**Expiration Date of Approval:** 2/17/2012

**RE**: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
**Submission Type**: Renewal
**Expedited Category**: 7.Surveys/interviews/focus groups,2.Minimal blood draw,3.Noninvasive bio-specimens,4.Noninvasive clinical data
**Study #:** 07-1003
**Study Title**: Hispanic Community Health Study
**Sponsors:** National Heart Lung and Blood Institute

This submission has been approved by the above IRB for the period indicated.

**Study Description:**
The Collaborative Studies Coordinating Center (CSCC) is the Data and Statistical Coordinating Center for the Hispanic Community Health Study (HCHS). This study is designed to document health status in four Hispanic communities around the United States and to obtain baseline measures of pulmonary function, cardiovascular function, metabolic status, oral health, and measures of neurocognitive and psychological functioning. Approximately 16,000 adults of 18 to 74 years, will be enrolled at four centers over a 36 month period, and will be followed for 36 months to assess health outcomes.

The CSCC does not directly enroll or directly contact any HCHS participants. It is responsible for coordinating the administration of the multi-center study, designing, developing and maintaining a data management system that provides appropriate confidentially and security for subjects' data in the study database (described in detail in section A.4.10), overseeing quality assurance and quality control of study procedures such as by hosting training sessions and performing site monitoring visits, subcontracting for the procurement of study medication and placebo, producing all study data reports, including those for study monitoring by the Observational Study Monitoring Board (created by NHLBI), and for generating the statistical analysis for manuscript publication of the study.

**Regulatory and other findings:**
This research meets criteria for a waiver of consent entirely according to 45 CFR 46.116(d).

**Investigator's Responsibilities:**
Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

**IF YOU SUBMITTED ON PAPER,** enclosed are stamped copies of approved consent documents and other recruitment materials (when applicable). You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise. **IF YOU SUBMITTED ONLINE (Behavioral IRB Only),** your approved consent forms and other documents are available online at http://irbis.unc.edu.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented (use the modification form at ohre.unc.edu/forms). Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at https://irbis.unc.edu/irb.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40CFR 26 (EPA), where applicable.

CC: Marston Youngblood Jr, Biostatistics

IRB Informational Message—please do not use email REPLY to this address