THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097

TO: Lloyd Chambless
Biostatistics
CB:8030

FROM: Public Health-Nursing IRB

RH/DT
Authorized signature on behalf of IRB

APPROVAL DATE: 6/08/2007

EXPIRATION DATE OF APPROVAL: 6/06/2008

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Initial
Expedited Category: 7.Surveys/interviews/focus groups
Study #: 07-1003

Study Title: Hispanic Community Health Study

This submission has been approved by the above IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

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.

When applicable, enclosed are stamped copies of approved consent documents and other recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

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). Should any adverse event or unanticipated problem involving risks to subjects or others occur it must be reported immediately to the IRB using the adverse event form at the same web site.

Study Description:
The Collaborative Studies Coordinating Center (CSCC) is the Data and Statistical Coordinating Center for the Hispanic Community Health Study. This multi-center observational health 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 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.

Details:
This research meets criteria for a waiver of consent entirely according to 45 CFR 46.116(d).

Call the IRB at 966-3113 if you have any questions. You can now access IRB status information at https://my.research.unc.edu/.

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), and 21 CFR 50 & 56 (FDA), where applicable.

The University of North Carolina at Chapel Hill holds a Federal Wide Assurance approved by the Office for Human Research Protections, Department of Health and Human Services (FWA # 4801).

CC:
Marston Youngblood Jr, Biostatistics, CB:8030 137 E Franklin St Ste 203, Study Coordinator