UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Initial Review – Expedited Review
Conditional Approval

December 19, 2013

Martha L. Daviglus, MD, PhD
Medicine
1819 W. Polk Street, Ste 312-D
M/C 672
Chicago, IL 60612
Phone: (312) 413-0739 / Fax: (312) 996-9911

RE: Protocol # 2013-1261
"Hispanic Community Health Study - Study of Latinos, Visit 2"

Dear Dr. Daviglus:

Members of Institutional Review Board (IRB) #3 reviewed and conditionally approved your research protocol under expedited review procedures [45 CFR 46.110(b)(1) on December 19, 2013.

Conditional IRB approval of HCHS/SOL study – Visit 2 study granted for the data collection forms and the protocol, consent, and HIPAA documents cited below.

Please be reminded to submit final versions of study materials prior to initiation of Visit 2 cohort, including but not limited to English and Spanish consent and authorization forms, recruitment/contact materials for Visit 2, and data collections instruments. Stamped IRB-approved informed consent forms and Authorizations will be released following the approval of these final versions of the study materials.

Please note the following information about your approved research protocol:

Protocol Approval Period: December 19, 2013 - December 19, 2014
Approved Subject Enrollment #: 4137
Additional Determinations for Research Involving Minors: These determinations have not been made for this study since it has not been approved for enrollment of minors.
Performance Sites: UIC
Sponsor: NHLBI/NIH
PAF#: 2013-01631
Grant/Contract No: NHLBI-HV-13-06
Grant/Contract Title: Hispanic Community Health Studies - Studies of

Latinos - SOL Field Centers

Research Protocol(s):

a) Manual 1, Visit 2 Study Protocol, General Description and Study Management, October 15, 2013 - Version 1.01
b) Manual 2 Field Center Procedures for Visit 2, September 30, 2013, Version 1.0
c) HCHS/SOL Visit 2, Manual 7, Biospecimen Collection and Processing, Sept 27th, 2013 - Version 1.0

Informed Consent:

a) HCHS/SOL 2nd visit, Version 2.0 12-01-2013

HIPAA Authorization:

a) HCHS/SOL 2nd visit, Version 2.0, 12-01-2013

Your research meets the requirements for expedited review under the following categories:

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or

diagnosis).
(7) Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
12/19/2013	Initial Review	Expedited	12/19/2013	Approved (Conditional)

Please remember to:

→ **Use only the IRB-approved and stamped consent document(s) enclosed with this letter when enrolling new subjects.**

→ Use your **research protocol number** (2013-1261) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
"**UIC Investigator Responsibilities, Protection of Human Research Subjects**"
(http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS office at (312) 996-1711 or me at (312) 413-3788. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Rachel Olech, B.A., CIP
Assistant Director, IRB # 3
Office for the Protection of Research Subjects

Enclosure:
1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**

cc: George T. Kondos, Medicine, M/C 715
OVCR Administration, M/C 672