Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Science at the heart of medicine

Institutional Review Board

Yeshiva University
FWA #00000140

Montefiore Medical Center
FWA #00002558

North Bronx Healthcare Network
FWA #00009807

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http://www.einstein.yu.edu/irb

Notification of Approval

Date: January 15, 2014

Principal Investigator
Robert Kaplan

Study Title:	Visit 2 of the Hispanic Community Health Study/Study of Latinos		
Grant Title:	Hispanic Community Health Study - Study of Latinos - Field Center		
IRB #:	2013-2749	**Reference #:**	001443
Type of Submission:	Submission Response for Initial Review Submission form		
Approval Date:	01/15/2014	**Expiration Date:**	01/14/2015

The above titled submission was reviewed and approved by expedited review under 45 CFR 46.110 and 21 CFR 56.110 as the research fits into the following categories:

Category 2(b): Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture 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.
Category 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.

This submission was approved with the following stipulations:

- Use only IRB stamped copies of the consent form(s) in your research. Do not use expired consent forms.
- A fully translated foreign language informed consent document must be approved by the Einstein IRB prior to enrolling non-English speaking participants.
- The HIPAA Authorization was incorporated into the approved consent.

All changes to a study must receive IRB approval before they are implemented. The only exception to the requirement for prior IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(b)(4), 21 CFR 56.108(a)). In such cases, report the actions taken as a reportable event.

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

Expiration Notice: IRB approval for this study is limited to the period specified above. In order to gain re-approval, you must submit a Progress Report prior to the expiration of the study. When the research is completed, submit a final Progress Report. The iRIS system will generate an email notification 60 days prior to the

expiration of this study's approval. However, it is your responsibility to ensure that a Progress Report has been submitted by the required time.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.