



Office for Human Research Protections  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, Maryland 20852  
Telephone: 240-453-8132  
FAX: 240-453-6909  
E-mail: [Kristina.Borrer@hhs.gov](mailto:Kristina.Borrer@hhs.gov)

June 12, 2012

Joseph Walsh, Jr., Ph.D.  
Vice President for Research  
Northwestern University  
Office of Research  
633 Clark Street  
Rebecca Crown Center - Room 2-232  
Evanston, IL 60208-1108

**RE: Human Research Protections Under Federalwide Assurance FWA-1549**

**Research Project: The Hispanic Community Health Study / Study of Latinos (HCHS/SOL)**

**Principal Investigator: Martha Daviglus, M.D., Ph.D.**

**HHS Protocol Number: N01HC65236-11**

Dear Dr. Walsh:

Thank you for your October 19, 2011 report in response to our September 9, 2011 request that Northwestern University evaluate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on our review of your response, we make the following determinations:

**A. Determinations regarding the above-referenced research**

- (1) The complainant alleged that changes to research were initiated without IRB review and approval, in violation of HHS regulations at 45 CFR 46.103(b)(4)(iii). Specifically, the complainant alleged that some subjects were enrolled who did not meet the inclusion criteria. We note that your investigation did not reveal any evidence that recruiters knowingly recruited subjects who did not meet the inclusion criteria. It was noted that subjects may have misinformed recruiters about their race, age or place of residence, or that subjects may have moved after the initial study visit. However, the protocol allows for subjects to provide this information

without proof, and it was decided that, if researchers later learned or suspected that that a subject did not, or not longer, met the inclusion criteria, “the subject’s study visits should be completed in order to foster goodwill within the community and among the families, but the data for these subjects should be excluded.” Subjects who resided in the recruitment area at the time of recruitment but subsequently moved will still be followed as described in the protocol. Based on the information provided in your report, we have determined that this allegation of noncompliance is unproven.

- (2) The complainant alleged that some subjects were enrolled and interviewed prior to signing an informed consent document, in violation of HHS regulations at 45 CFR 46.117(a) and (c). We note that the October 6, 2008 meeting minutes stated “it also appeared that the study staff was asking potential subjects to follow a few procedures in an informational packet that is distributed before informed consent is obtained...The primary reviewer noted that the pre-screening recruitment packet asks potential subjects to fast for a blood draw and asks diabetics to discontinue their medications before the first visit, but only until the blood draw is done” and that the study was started before IRB review and approval of a human subjects protocol (over 200 subjects were enrolled before this was discovered). We note that the study was thoroughly reviewed at a convened meeting of the IRB and waiver of documentation of informed consent was granted for the procedures prior to the exam when this was discovered. Therefore, while the allegations appear to be founded, the noncompliance was detected and corrected prior to OHRP’s involvement in this matter.
- (3) The complainant alleged that there was failure to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, as required by HHS regulations at 45 CFR 46.111. Specifically, the complainant alleged that consent was obtained from subjects while in a group. We note the following from your response: “Through the study audit it was revealed that occasionally subjects who were family members (e.g., spouses) preferred to provide consent together, because family members were recruited together and /or some were wary of research.” We also note that the protocol describes many activities that take place in groups, including “Social meetings quarterly or every six months with participants will assist in building cohesiveness among and between participants and members of the research team” and described the study as being “family-oriented.” Based on the information provided in your report, we have determined that this allegation of noncompliance is unproven.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

Page 3 of 3  
Joseph Walsh, Jr., Ph.D.-- Northwestern University  
June 12, 2012

We appreciate the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.  
Director, Division of Compliance Oversight

cc:

Ms. Eileen Yates, IRB Manager, Quality Assurance and Training, Northwestern University (NU)

Dr. Darren Gitelman, Chairperson, NU IRB #1

Dr. Thomas Holly, Chairperson, NU IRB #2

Dr. Jonathan Goldman, Chairperson, NU IRB #3

Dr. Michael Roloff, Chairperson, NU IRB #4

Dr. Frank Palella, Chairperson, NU IRB #5

Ms. Maureen Moran, Chairperson, NU IRB #6

Dr. Martha Daviglius, NU

Dr. Sherry Mills, National Institutes of Health (NIH)

Mr. Joseph Ellis, NIH

Dr. Susan B. Shurin, Acting Director, National Heart, Lung, and Blood Institute