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at CHAPEL HILL

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December 15, 2008

Martha Daviglus, MD, Ph.D.  
Northwestern University  
Feinberg School of Medicine  
Department of Preventive Medicine  
680 N. Lake Shore Drive, Suite 1102

Re: HCHS/SOL Monitoring Visit Report

Dear Dr. Daviglus,

Attached please find the monitoring visit report prepared by the HCHS/SOL Collaborative Studies Coordinating Center at the University of North Carolina at Chapel Hill. It summarizes the findings of the monitoring visit conducted on November 10 – 12, 2008 by Coordinating Center (CC) representatives Marston Youngblood and Paula Gildner. This report describes observations made by the CC representatives that will aid your site in complying with all study procedures and protocols and includes both recommendations and action items for both the Chicago Field Center and the CC.

The last page of the report summarizes the list of action items for your Field Center and for the CC. We request an immediate response (within 1 week) to three action items under “Clinic” as they are outstanding issues since the last site visit. For all other comments/action items, we request a response addressing potential corrective actions within two weeks of receipt of this memo in keeping with the Site Visit Procedures recently approved by the Steering Committee.

The HCHS/SOL CC would like to thank the Chicago Field Center staff for their willingness to accommodate the schedules of the Coordinating Center personnel during the visit. We understand the burden this type of visit places on staff, and the staff demonstrated their professionalism throughout the process. We commend you and your staff’s patience and cooperation.

Sincerely,

Marston Youngblood

Paula Gildner

CC Lisa LaVange, Ph.D., Director Coordinating Center  
Diane Catellier, Dr.PH, HCHS/SOL Co-Investigator  
Gerado Heiss, MD, Ph.D., HCHS/SOL Co-Investigator

Attachment

	Center Name	Chicago
	Date of Visit	11/12/08 – 11/13/08
<b>HCHS/SOL MONITORING VISIT REPORT</b>		
<b>Principal Investigator:</b>	Martha Daviglius, MD, PhD	
<b>Study Site address:</b>	Department of Preventive Medicine 680 N. Lake Shore Drive, Suite 1102 Chicago, IL 60611	
<b>Date of previous visit:</b>	04/22/08 – 04/24/08	
<b>HCHS/SOL Coordinating Center monitor(s) present:</b>	Marston Youngblood, MA, MPH Paula Gildner, MPH	
<b>Key Study Site personnel present:</b>	Karen Mancera-Cuevas, Clinic Manager Catalina Ramos, Recruitment Coordinator	

### General Comments

The clinic at Preventive Health is fully stable and well equipped to handle a full clinic. This was proven during the visit when the clinic saw 10 participants on the day of the monitoring visit. On this day, staff were able to maintain the clinic flow while keeping participants engaged and well attended. However, one limitation of scheduling more than 8-9 participants on one day is that some time intensive procedures like audiometry require a second visit in order to obtain a complete baseline examination.

Recruitment efforts at the Chicago Field Center have improved due to the implementation of changes in the organizational structure at the site. In the field, recruiters are well versed in recruitment methods and protocol.

### RECRUITMENT

1. General		YES	NO	N/A
<b>Manual/Scripts</b>	Hard copies of manuals and scripts are available			X
<b>Staffing/ Certification</b>	a. Recruitment staff is HCHS/SOL certified b. Log of certified recruiters is on file and up-to-date c. Documents for certification are on record and up to date.	X X X		
<b>Protocols</b>	a. HCHS/SOL recruitment protocol as defined by study manual is followed b. Scripts are followed c. Study wide data management system is used correctly	 X X	X	

#### Comments/Actions

Although current recruitment staff is certified, it is recommended that future certification documentation be sent to the Coordinating Center in a timely and organized fashion.

#### Protocols

Per the approved scripts for recruitment, recruitment staff should make a point to verify the address with the respondent at time of recruitment. Due to different unit layouts at each address and recruiting in the evening hours, identifying the unit to be screened can prove to be challenging. It is recommended that recruitment staff comply with study protocol and confirm the address with the respondent at the door.

Furthermore, it is an IRB violation to ask any questions of person(s) under 18 years of age. If the age of the respondent is questionable, recruitment staff should request to speak with a household member who is 18 years of age or older.

In addition, recruiters are also asking persons who have agreed to participate if they are pregnant or have diabetes. Although these questions are part of the Participant Safety Screening form, the recruiter is not formally

recording the responses directly on the form. It is recommended that if recruiters ask these questions, he/she formally records the response on the Participant Safety Screening form.

**Actions**

1. **Verify address at time of screening**
2. **If warranted by the situation, ask to speak to a person in the household age 18 years or older.**
3. **Record responses to questions on an approved form (in this case, the Participant Safety Screening Form).**

<b>2. Recruitment Forms</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
<b>Storage of forms</b>	Forms and confidential information are kept in a locked cabinet, accessible only to HCHS/SOL recruitment staff	<b>X</b>		
<b>Recruitment Flow</b>	Work flow follows protocol and is completed in a timely fashion	<b>X</b>		
<b>Household Screening/Roster (HSR)</b>	a. HSR is completed correctly	<b>X</b>		
	b. Specs are followed for the proper use of selection p and cut-point c values	<b>X</b>		
	c. Follow through with ELE is complete	<b>X</b>		
<b>Screen Call Tracking (SCT)</b>	a. Number of call/visits is adequate	<b>X</b>		
	b. Final status code uses are used appropriately		<b>X</b>	
<b>Individual Eligibility (ELE)</b>	a. ELE is completed correctly		<b>X</b>	
	b. Scheduling of clinic visits is completed	<b>X</b>		
<b>Drop Point Selection Worksheet (DPS)</b>	a. DPS is correctly used			<b>X</b>
	b. Selected unit/address is screened by recruiter			<b>X</b>

**Comments/Actions**

Household Screening/Roster (HSR)

During observation of field staff, it was noted that field staff are adding a question to the Household Screening Form (HSRB) after he/she has reviewed the selection p and cut-point c values as instructed in the form. Recruiters are then asking how many 45 – 74 year olds live in the household. The Household Screening form has been approved study wide and is the accepted form to use in the field. It is recommended that recruiters follow the structure of the form and the scripts as approved and do not add any questions.

An audit of the household screening files was performed during the site visit. Due to remodeling of the work area recruitment files have been relocated to a set of locked file cabinets in Dr. Giachello's office. Files are now organized by date and physical household address instead of the former filing order of household ID number and recruitment team. The HSRB pilot study households which had the most complete final screening status on the date of the site visit were chosen for the audit. Out of 120 household files that were reviewed two notable errors were detected: 1) household C2226939 completed by staff ID 227 was incorrectly excluded when the probability of selection was mis-interpreted (it was below the cut-point) and the 18-44 year old household members were reported as "not selected", and 2) household C2047828 had a screening code on the SCT indicating no one could be contacted, but the matching HSR indicates two people in the household were eligible and selected. These types of errors on the roster and contact status forms indicate that at times recruiters were not correctly applying the new screening protocol.

Other inconsistencies noted on screening forms were the following: 1) C2060345 (staff ID 234), SCT completed indicating eligible HH that refused to participate. However, roster rows on HSR were incomplete for case code of individuals screened, 2) C2053593 also had a SCT case code of eligible but refused to participate and incomplete matching roster row data for 2 individuals listed on the HSR, 3) C2048369 was closed as "unable to contact" within 7 days of the start of screening with only one weekend day contact (staff ID 238), 4) C2047567 was also closed in 7 days by staff ID 238, noting that name on buzzer was not Hispanic, and 5) Although noted that there was direct access to door bells, other households closed too quickly (within 13 days time) include C2068154 (staff ID 232) and C2229094 (staff ID 238), and also C2304540 and C2181162 each closed by staff ID 227 after 12 days time and included only one weekend contact for each case.

Note that the staff IDs listed above are the final IDs listed on the forms. It was apparent during the audit that the site is continuing to use the practice of using multiple recruiters to visit a single address. With this practice, it is

impertinent that detailed information of attempts to contact a household be documented. The error rate and deviation from proper use of the screening forms detected in the audit is higher than desired. Direct examination of the paper records by supervisory staff is recommended so that corrective feedback can be provided immediately.

**Individual Eligibility (ELE)**

As noted while in the field with recruiters, ELE forms are not always being administered to the individual but by proxy. Study protocol requires the form to be administered directly to the participant so that information given by the household “gatekeeper” can be confirmed. Administration of this form directly to the participants confirms his/her self identification as Hispanic/Latino, thus the eligibility to participate in the study.

**Actions**

1. **Unless approved, do not add questions to existing recruitment screening form, specifically the HSRB.**
2. **After rostering at the household level, contact possible participant directly to administer the Individual Eligibility form.**
3. **Immediate refresher training on use of the SCT with the new HSRB is strongly recommended.**
4. **The recruitment supervisor should randomly audit all recruiters for accuracy in their use of screening codes for households and completeness of household rosters.**

<b>3. Database/Scheduling</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
<b>Database</b>	Database works effectively and well for project needs			<b>X</b>
<b>Scheduling</b>	Clinic visits are scheduled with follow-up for no-shows	<b>X</b>		
<b>Comments/Actions</b> Local database will need modification to import completed records from the mini-tablet pcs that will be used by the recruiters starting in December 2008.				

**CLINIC**

<b>1. Number of Incomplete Visits</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
If applicable, were incomplete visits discussed with appropriate staff to minimize them when possible? (If yes, describe suggestions to minimize them below).				<b>X</b>
<b>Comments/Actions</b>				

<b>2. IRB and Regulatory Authority, Regulatory Binder</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
a.	IRB approved of all required study documentation	<b>X</b>		
b.	UNC has received all required study documentation	<b>X</b>		
<b>Comments/Actions</b>				

<b>3. Informed Consent</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
HCHS/SOL study informed consent has been approved, properly documented and signed for each participant		<b>X</b>		
<b>Comments/Actions</b> The most current approved study wide version of the informed consent is still being reviewed by the Principal Investigator and has not been submitted to IRB.				

**HCHS/SOL IRB Approval of Current Consent Form and Protocol**

<b>IRB Approval Dates</b>	
<b>Consent Form Approval Dates</b> mm/dd/yyyy	<b>IRB Protocol Amendment Approval Date</b> mm/dd/yyyy
12/21/2007	1/28/2008 (HIPPA), 2/28/2008 (final forms)

4. Staff Training/Certification		YES	NO	N/A
<b>Certification</b>	a. Staff is HCHS/SOL certified b. Log of certified staff/clinicians is maintained c. Documents for certification are on record and up to date	X X X		
<b>Blood draw certification</b>	Staff certification is in compliance with Appendix 10, Manual 2	X		
<b>Medication use certification</b>	Staff are certified in implementing and documenting medication use	X		
<b>Comments/Actions</b> The project manager keeps an updated log of certified staff and corresponding documentation. The project manager gladly gave a copy of staff's certification records for review by CC staff.				

5. Participant files		YES	NO	N/A
	a. HCHS/SOL participant files are properly organized and complete b. Files are stored properly c. Source documents are stored properly	X X X		
<b>Comments/Actions</b>				

6. Observation of clinic visit		YES	NO	N/A
<b>General</b>	Clinic set up and flow of participants for examination works well	X		
<b>Informed Consent</b>	Informed consent is delivered and its meaning is explained in full	X		
<b>Participant Safety Screening (PSE/PSS)</b>	Form is administered using the proper techniques for general interviewing, or form is fully reviewed with participant	X		
<b>General Interview Techniques</b>	Forms are properly administered (following protocols) by certified staff	X		
<b>Procedures (Including: Anthropometry, Blood Pressure, and ABI, etc...)</b>	Correct HCHS/SOL procedures are followed as instructed in manual of procedures	X		
<b>Comments/Actions</b> On the day of the visit, the clinic was at full capacity with 10 participants. The clinic flow was well organized and moved smoothly.  Informed consent was administered properly with all questions that were raised being answered correctly by staff explaining the consent.  General Interview Techniques Review of Quality Control Report, October 2008 identified some outlying data. Data was reviewed with the project manager, and participant files were reviewed to confirm data collected was correctly recorded by staff.  Procedures It is suggested that clinic staff use the actual questionnaires or facsimiles to record measurements and then enter the data into the DMS to speed up accurate data capture and reduce participant wait times.  Base on a data query, one QC Anthropometry procedure was not performed as instructed. Staff should be instructed to perform these QCs procedures as selected by the DMS for QC re-measurement (C6006267). <b>Action(s)</b> <b>1. Instruct staff to record measurements of clinic data on an actual questionnaire and then enter into the DMS (i.e. ANTA) instead of using scrap paper or napkin.</b>				

**2. Instruct staff to perform QC re-measurement when prompted by the DMS.**

<b>7. Manuals, Forms, and Logs</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
<b>Manuals</b>	Up to date hard copies of Manuals of Procedures (MOPs) are available in clinic room(s)		<b>X</b>	
<b>Forms</b>	Up to date forms are available in clinic room(s)		<b>X</b>	
<b>Logs</b>	Logs are maintained in a central location and updated as instructed in the manual of procedures	<b>X</b>		
<b>Procedure</b>	Procedure logs are updated on a regular basis	<b>X</b>		
<b>Equipment</b>	Maintenance and calibration logs for equipment are updated per protocols outlined in manual of procedures	<b>X</b>		
<b>Actical Monitor</b>	Tracking log is updated and maintained to insure proper handling of equipment	<b>X</b>		
<b>Sleep Monitor</b>	Tracking log is updated and maintained to insure proper handling of equipment	<b>X</b>		

**Comments/Actions**

**Manuals**

Although hard copies of manuals are in a central location, it is recommended that binders with hard copies of pertinent study manuals be kept in each clinic room.

**Forms**

Hard copies of all up to date questionnaires and question by question instructions need to be available in each clinic room. Spanish language scripts also need to be readily available in all clinic rooms.

**Logs**

All logs are well maintained and up to date. Chicago staff have done well designing and organizing log updating procedures.

**Action(s)**

- 1. Make hard copies of pertinent manuals available in each clinic room.**
- 2. Make hard copies of all questionnaires and question by question instructions available in each clinic room. In addition, Spanish translations of scripts were sent to each site. Scripts need to be available to staff while conducting procedures.**

<b>8. Clinical Laboratory</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
a.	Visit to the blood collection and processing area	<b>X</b>		
b.	Procedures for collection, labeling, handling, storage and shipping of samples has been followed according to HCHS/SOL protocols	<b>X</b>		
c.	Was the fasting glucose procedure conducted properly? (fasting pre-blood draw, no eating, smoking between pre-post glucose administration period, glucose refrigerated)	<b>X</b>		
d.	Procedures for packaging and shipping of samples have been followed	<b>X</b>		
e.	Study laboratory equipment has been maintained and calibrated as required (Backup plan for freezer, thermometers for freezer and refrigerator)	<b>X</b>		

**Comments/Actions**

Per recommendation by the HCHS/SOL central lab, CC monitoring checked the setting for the centrifuge speed. The centrifuge speed should be set for 3000 rcf (not 3000 rpm). At time of the visit, the centrifuge speed was set at rpm NOT rcf. However, it was brought to the monitor's attention that the manual does not clearly explain the preferred setting. The CC will follow-up with the central lab on inserting language in the manual that clearly explains the centrifuge setting.

In addition, the central lab requested the CC monitor check that sites have a sound procedure to verify participant IDs before collecting the 2 hr post OGTT sample. Chicago has two lab technicians that allow for the QC of labeling of tubes.

While at the clinic, questions arose about the QC sample and a short sample draw. The CC will follow-up with the central lab and the operations committee to provide protocol on how the site should handle this situation.

**Action**

1. **CC follow-up with central lab about speed of centrifuge.**
2. **CC follow-up with central lab and the operations committee about the QC sample and a short sample draw.**

9. Data Management	YES	NO	N/A
a. Electronic record system is working properly	X		
b. Use of data management system or data entry with no issues	X		
c. Use of study website with no issues	X		
<b>Comment(s)/Action(s)</b>			

10. Changes at the Site and Other Issues	YES	NO	N/A
a. Any change in site staff or staff roles has been properly documented	X		
b. Any change in clinic facilities has been properly documented			X
c. Any change in study equipment has been properly documented			X
<b>Comment(s)/Action(s)</b>			

11. Monitoring Visit Follow-up	YES	NO	N/A
a. Follow-up letter sent to Principal Investigator	X		
b. At the site visit, immediate feedback was given with the appropriate field center personnel (Project Manager, Clinic Manager, Recruitment Manager, etc...). Explain.	X		
<b>Comments/Actions</b>			

**Proposed date of next HCHS/SOL monitoring visit:**

**TBD**

**Comments/Action items for HCHS/SOL Field Center:**

**Recruitment**

1. Verify address at time of screening
2. If warranted by the situation, ask to speak to a person in the household age 18 years or older.
3. Record responses to questions on an approved form (in this case, the Participant Safety Screening Form).
4. Unless approved, do not add questions to existing recruitment screening form, specifically the HSRB.
5. Record responses to questions on an approved form (in this case, the Participant Safety Screening Form).
6. After rostering at the household level, contact possible participant directly to administer the Individual Eligibility form.
7. Immediate refresher training on use of the SCT with the new HSRB is strongly recommended.
8. The recruitment supervisor should randomly audit all recruiters for accuracy in their use of screening codes for households and completeness of household rosters.

**Clinic**

1. Instruct staff to record measurements of clinic data on a questionnaire and then enter into the DMS.
2. Make hard copies of pertinent manuals available in each clinic room.
3. Make hard copies of all questionnaires and question by question instructions available in each clinic room. In addition, Spanish translations of scripts were sent to each site. Scripts need to be available to staff while conducting procedures.

**Comments/Action items for HCHS/SOL Coordinating Center:**

1. CC will follow-up with central lab about speed of centrifuge.
2. CC follow-up with central lab and the operations committee about the QC sample and a short sample draw.



Marston Youngblood  
HCHS/SOL Monitor

12/15/08

Date



Paula Gildner  
HCHS/SOL Monitor

12/15/08

Date