



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

SCHOOL OF PUBLIC HEALTH
DEPARTMENT OF BIostatISTICS T 919.962.2073
COLLABORATIVE STUDIES COORDINATING CENTER F 919.962.3265
137 E FRANKLIN STREET, SUITE 203
CAMPUS BOX 8030
CHAPEL HILL, NC 27514-4145
HCHSAdministration@mail.escc.unc.edu

June 18, 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 Coordinating Center at the University of North Carolina at Chapel Hill. It summarizes the findings of the monitoring visit conducted on April 22 – 24, 2008 by Coordinating Center (CC) representatives Marston Youngblood and Paula Gildner. The goal of the monitoring visit is to promote and insure protocol compliance and adherence to study procedures. This report describes observations made by the CC representatives that will aid your site in complying with study procedures and protocols and includes recommendations and action items for both the Chicago Field Center and the CC.

The HCHS/SOL CC would like to thank the Chicago Field Center staff for their professionalism and willingness to accommodate the schedules of the CC representatives during the visit. In addition, the usefulness of allowing the CC to act as a “dummy participant” and observe the full clinic visit is invaluable to us and to the study as a whole. We commend your patience and cooperation during this process.

In addition to thanking the entire Chicago Field Center staff, we would like to extend special thanks to Dr. Aida Giachello, PhD, Co-Investigator, Claudia Chambers, Interim Project Coordinator, Sue Giovanazzi, Clinic Manager, and Jeannie Concha, Recruitment Manager for their efforts in accommodating our needs. The CC also appreciates the effort demonstrated by the Chicago Field Center staff to maintain the high quality of data collection necessary to ensure the integrity of the HCHS/SOL.

It is our goal to provide sites with the monitoring visit report in a timely manner, and we apologize that this report was not issued to the site earlier. Please feel free to contact the CC in regards to this monitoring visit report.

Sincerely,

Marston Youngblood

Paula Gildner

CC Aida Giachello, Ph.D. HCHS/SOL Co-Investigator
Lisa LaVange, Ph.D., HCHS/SOL Principal Investigator
Diane Catellier, Dr.PH, HCHS/SOL Co-Investigator
Gerado Heiss, MD, Ph.D., HCHS/SOL Co-Investigator

Attachment

	Center Name	Northwestern University
	Date of Visit	04/22/08 – 04/24/08
HCHS/SOL MONITORING VISIT REPORT		
Principal Investigator:	Martha Daviglius, MD, PhD	
Study Site address:	Department of Preventive Medicine 680 N. Lake Shore Drive, Suite 1102 Chicago, IL 60611	
Date of previous visit:	n/a	
HCHS/SOL Coordinating Center monitor(s) present:	Marston Youngblood, MA, MPH Paula Gildner, MPH	
Key Study Site personnel present:	Aida Giachello, PhD, Co-Investigator Claudia Chambers, Interim Project Coordinator Sue Giovanazzi, MS, Clinic Manager Jeannie Concha, PhD, Recruitment Coordinator	

General Comments

The Chicago field center is fully operational in two clinics at different physical locations (CommunityHealth and Northwestern Department of Preventative Medicine) for the conduct of the baseline examination protocol with trained staff in place. Clinic staff are well prepared, organized, and are capable of handling a full schedule of HCHS/ SOL participants. Recruitment staff are well trained, and their recruitment efforts are productive in generating referrals for the clinic. The recruiters currently face a number of challenges in the enrollment of study participants. However, the staff is learning to overcome such obstacles. With the hiring of more recruitment staff, Chicago should be able to meet study goals.

RECRUITMENT

1. General		YES	NO	N/A
Manual/Scripts	Hard copies of manuals and scripts are available	X		
Staffing/ Certification	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		
Protocols	a. Follow HCHS/SOL recruitment protocols as defined by study manual b. Use of scripts c. Use of data management system	X X X		
Comments/Actions	Chicago recruiters are facing many challenges in their recruitment efforts. With time, experience, and creative thinking in the application of the study recruitment protocol the recruitment team will become better versed in executing of the sample design as it is applied to their local community. The hiring of more recruitment staff should help to full any gaps in coverage that currently exist with the field screening of households.			

2. Recruitment Forms		YES	NO	N/A
Storage of forms	Forms and confidential information are kept in a locked cabinet, accessible only to HCHS/SOL recruitment staff	X		
Recruitment Flow	Work flow follows protocol and is completed in a timely fashion	X		
Household Screening/Roster (HSR)	a. Completed correctly b. Follow specs for the proper use of selection p and cut-point c	X X		

	c. Follow through with ELE	X		
Screen Call Tracking (SCT)	a. Number of call/visits is adequate b. Final code use	X	X	
Individual Eligibility (ELE)	a. Completed correctly b. Scheduling of clinic visits	X	X	
Drop Point Selection Worksheet (DPS)	a. Correct use b. Selected unit/address screened	X X		
Comments/Actions				
Storage of forms At the time of the visit, the space used for recruitment activities at UIC is under renovation. Storage space for forms is limited. However, once renovations are complete, there will be ample space for the archival of all recruitment related forms in secure file cabinets.				
A random subsample of case folders for approximately 5% of the households was selected for review by the coordinating center representatives. Closed screening cases were selected at random from each of 3 recruitment teams and spanned the period from February 27 to April 12, 2008. The results of the review are noted below.				
HSR and SCT – The predominant times for household contacts in this sample as recorded on the forms was from late morning to late afternoon (approximately 11:30am to 4:30pm). The corresponding days of the week in this early sample did not include weekends. The likelihood of successfully screening individuals that work during normal business hours and the contact days and times seen in the random sample is low. The site reported that screening on Saturday had recently been initiated. The number of calls/visits reported on the worksheet for the SCT was limited in some cases, with some addresses closed after only 3 visits over 5 days time (C2286571) or even 5 visits over 10 days time (C2190228, C2298055). We recommend that household screening be left open for 1 to 4 weeks so that individuals who are out of town for a brief time would have a greater chance of being screened. The CC representative will send the recruitment manager a list of cases with short closure dates of 10 days or less.				
ELE- The recruiters need to complete and key the Individual Eligibility forms (ELE) using an individual level ID for persons screened at the person level <i>after</i> the roster of the household is finished. ELE forms should be completed for each person who either has a pending status or who passes the preliminary household screen based on the household respondent interview (case code 6 or 7). ELEs are missing from the central database for individuals who are deemed ineligible at the individual level. The coordinating center cannot compute accurate person level response rates without an unbiased entry of ELEs.				
Action(s)				
<ol style="list-style-type: none"> 1. Household screening needs to extend to early evening and include weekends, if possible. 2. The guidelines for suggested number of attempts to contact a HH should be followed more closely, i.e. up to 4 times for a home visit and up to 10 – 12 calls unless a hard refusal is given. These contacts can take up to a 4 week period to complete. 3. The recruiters need to key ELE forms, using individual level IDs, administered to individuals who screened out when individual eligibility was determined. 				
CC				
<ol style="list-style-type: none"> 1. CC to send list of too short closure times to recruitment manager. 				

3. Database/Scheduling		YES	NO	N/A
Database	Database works effectively and well for project needs		X	
Scheduling	Clinic visits are scheduled and follow-up for no-shows	X		
Comments/Actions				
The database management system used to tracking household recruitment work flow is a locally developed software application with many features for controlling the assignment of cases to recruiters and generating local management reports. The system appears to work well for most functions. However, one severe limitation of the				

system controlling the household case load and screening system is the inability to routinely assign an individual level ID for all people who are screened with an ELE form and determined to be ineligible.

Scheduling – We suggest that the site consider the sharing of efforts between clinic staff and recruiters in the area of re-scheduling missed appointments. At the time of the site visit the recruitment team seemed hard pressed to cover an adequate number of households that need to be screened each week in order to generate eligible scheduled participants. Assignment to the recruiters of additional duties that could be done by clinic staff dilutes the coverage needed for recruitment.

Action(s)

1. Consider development of an alternate action plan for re-scheduling clinic no shows in a way that reduces burden on the recruitment staff.
2. Modify database application for tracking households and people to be more flexible in assignment of individual level IDs.

CLINIC

1. Number of Incomplete Visits	YES	NO	N/A
If applicable, were incomplete visits discussed with appropriate staff to minimize them when possible? (If yes, describe suggestions to minimize them below).			X
Comments/Actions Staff were instructed on the use of missing form and missing field flag options in the study DMS to specifically note when an entire form or part of a form is missing.			

2. IRB and Regulatory Authority, Regulatory Binder	YES	NO	N/A
a. IRB approved of all required study documentation	X		
b. UNC has received all required study documentation	X		
Comments/Actions None			

3. Informed Consent	YES	NO	N/A
HCHS/SOL study informed consent has been approved, properly documented and signed for each participant	X		
Comments/Actions None			

HCHS/SOL IRB Approval of Current Consent Form and Protocol

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

4. Staff Training/Certification	YES	NO	N/A
Certification			
a. Recruitment staff is HCHS/SOL certified	X		
b. Log of certified staff/clinicians	X		
c. Documents for certification are on record and up to	X		

	date.			
Blood draw certification	Staff certification is in compliance with Appendix 10, Manual 2	X		
Medication use certification	Staff are certified in implementing and documenting medication use	X		
Comments/Actions Certification – a. Although on record, logs and documentation were not well organized, making them difficult to review. It is recommended that a log of staff certification is on file and staff files include all proper certification documentation.				
Action(s) 1. Organize certification files by staff member and include all pertinent certification documentation.				

5. Participant files	YES	NO	N/A
a. HCHS/SOL participant files are properly organized and complete	X		
b. Files are stored properly	X		
c. Source documents are stored properly	X		
Comments/Actions a. A very neat and organized filing system for participant paperwork is in place. File labels are printed the night before, in full preparation for the clinic visit. Files are 3 sided, allowing for loose paperwork to be neatly stored.			
Action(s)			

6. Observation of clinic visit	YES	NO	N/A
General	Clinic set up and flow of participants for examination works well	X	
Informed Consent	Informed consent is delivered and its meaning is explained in full	X	
Participant Safety Screening (PSE/PSS)	Form is administered using the proper techniques for general interviewing, or form is fully reviewed with participant	X	
General Interview Techniques	Forms are properly administered (following protocols) by certified staff	X	
Procedures (Includes: Anthropometry, Blood Pressure, ABI, and Biospecimen Collection)	a. Correct HCHS/SOL procedures are followed as instructed in manual of procedures (comments below on individual procedures)	X	
	b. Study measurement equipment has been maintained and calibrated as required	X	
Comments/Actions General – The Chicago Field Center benefits from the ability to maintain two HCHS/SOL clinic locations. The clinic at Northwestern is set up to create an efficient flow through clinic procedures that uses minimal movement between stations for the clinic participant. At CommunityHealth the layout is not as ideal due to space limitations and time sharing of that site. However, the efficient and well-trained staff should be able to adapt to the challenges of participant flow during the examination. Due to limited work space, good organization will be the key to clinic flow. At CommunityHealth, the spirometry station is set up in the hallway outside of the staff room. It was suggested that the station be moved or a screen be installed to provide more privacy, thus increasing the participant's level of comfort while performing the lung function test. Informed consent – The delivery of the informed consent was concise and succinct. Procedures – Although procedures were correctly followed, some participant contact time could be saved by			

having clinicians record information into the DMS after the procedure is completed, i.e. Anthropometry and Blood Pressure. Equipment in some clinic rooms was not in close proximity to the computer station for recording of information into the DMS so time was lost walking back and forth between the computer workstation and the participant while measures were being obtained. 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. For instance, while the participant is resting for 5 minutes prior to the sitting blood pressure, that is the perfect opportunity to enter anthropometry data. Medication coding should always be initiated while the participant is at another exam station (dental, audiometry, etc.) to also reduce waiting time.

Action(s)

1. **Move or install a screen for spirometry to provide privacy for participants.**
2. **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.**

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

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 – Some logs were being transferred from one clinic location to another. It is suggested that logs for each piece of equipment stay at the location where the piece of equipment is housed, eliminating the need to transfer the logs from one location to the next.

Actical and Sleep Monitor – Electronic logs have been set up to track the monitors. These logs are very nicely designed and well organized. In attempts to ensure the actical monitor is returned, the staff has placed a contact sticker on the back of the monitor. Although a good idea, the CC was not sure if the manufacturer of the device would allow the patent and medical device approval information located on the back of the monitor to be covered. The CC will follow-up with an inquiry to the manufacturer.

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.**

CC

1. **Contact manufacturer of actical device about using a contact label on back of device.**

8. Clinical Laboratory	YES	NO	N/A
a. Visit to the blood collection and processing area	X		
b. Procedures for collection, labeling, handling, storage and shipping of samples has been followed according to HCHS/SOL protocols	X		
c. Was the fasting glucose procedure conducted properly? (fasting pre-blood draw, no eating, smoking between pre-post glucose administration period, glucose refrigerated)	X		
d. Procedures for packaging and shipping of samples have been followed	X		
e. Study laboratory equipment has been maintained and calibrated as required (Backup plan for freezer, thermometers for freezer and refrigerator)	X		
Comments/Actions If a clinic visit terminates without a blood draw, then a BIOA form is still expected to be completed to alert both the coordinating center and the central laboratory that no specimens were obtained.			
Action(s) 1. Complete a Biospecimen Collection form on all participants regardless if the blood draw occurred.			

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		
Comment(s)/Action(s) Although no major issues exist with the DMS, the CC has requested that clinic staff enter the administrative date of collection and staff ID fields for the Personal Identifier Form (IDE/IDS) for participants and set the other fields to unresolvable. By setting the remaining fields to unresolvable, queries are avoided. The process of setting the rest of a form to unresolvable in the DMS was explained to Louis Martos. He is going to instruct clinic staff on this process in the DMS.			
Action(s) 1. Complete administrative data on the Personal Identifier Form and set the other fields to “unresolvable”, thus diminishing possible queries.			

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
Comment(s)/Action(s) Staff – the site has had some minor changes in staff. It is requested that an updated list of staff be sent to the CC. Clinic facilities – The Chicago Field Center is fortunate to have two clinic locations for their HCHS/SOL participants. In order to track clinic use and possible sources of intracenter variability between clinics, the CC recommends that the clinic manager keep track of clinic activity in a simple EXCEL file, using participant ID, date and location and send this file periodically to the coordinating center so that the information can be used in the routine quality control analysis for the study. This information will help to guide future practices in the clinics.			

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...).	X		
Comments/Actions None			

Proposed date of next HCHS/SOL monitoring visit:

TBD

Comments/Action items for HCHS/SOL Field Center:

Recruitment

1. Contact with households needs to extend to early evening and include weekends.
2. Although exception will occur, staff should attempt to follow recruitment guidelines and visit a house up to 4 times and call 10 – 12 times at different times of the day/evening and including weekends before declaring the case closed. This procedure may take up to 3 weeks or more to complete.
3. ELE forms are missing in the database for participants who screen out at the person level and need to be keyed using individual level IDs so that accurate, unbiased, estimates of response rates can be computed.
4. Consider development of an alternate action plan for re-scheduling clinic no shows in a way that reduces burden on the recruitment staff.

Clinic

1. Maintain up to date log and file(s) on certification of staff members.
2. Move or install a screen for spirometry to provide more privacy for participants.
3. Instruct staff to record measurements of clinic data on a questionnaire and then enter into the DMS.
4. Make hard copies of pertinent manuals available in each clinic room.
5. 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.
6. Complete a Biospecimen Collection form (BIOA) on all participants regardless if the actual blood draw occurred.
7. Complete administrative data on the Personal Identifier Form and set the other fields to “unresolvable”, thus diminishing possible queries.

Action items for HCHS/SOL Coordinating Center:

1. CC to send list of too short closure times to recruitment supervisor.
2. Contact manufacturer of actual device about use of a contact label on back of device.



Marston Youngblood
HCHS/SOL Monitor

6/17/08
Date



Paula Gildner
HCHS/SOL Monitor

6/17/08
Date