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at CHAPEL HILL

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July 07, 2008

Sylvia Smoller, PhD
Einstein College of Medicine
Epidemiology & Population Health
1300 Morris Park Avenue, Room 1312A
Bronx, NY 10461

Re: HCHS/SOL Monitoring Visit Report

Dear Dr. Smoller,

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 June 3 – 5 2008 by Coordinating Center (CC) representatives Paula Gildner and Franklyn Gonzalez. 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 representative that will aid your site in complying with study procedures and protocols and includes recommendations and action items for both the Bronx Field Center and the CC.

The HCHS/SOL CC would like to thank the Bronx Field Center staff for their professionalism and willingness to accommodate the schedule of the representatives from the CC during the visit. The kindness of the Bronx Field Center staff was greatly appreciated. In addition, the usefulness of allowing the CC to observe a participant through the 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 Bronx Field Center staff, we would like to extend special thanks to Rosalyn Graves, Clinic Manager, and Madeline Crespo, Recruitment Manager for their efforts in accommodating our needs.

Please feel free to contact the CC with any questions or concerns in regards to the monitoring visit report.

Sincerely,

Paula Gildner

CC Robert Kaplan, PhD, HCHS/SOL Co-Investigator
Yvonne Raiford, Project Manager
Lisa LaVange, PhD, HCHS/SOL Principal Investigator
Diane Catellier, Dr.PH, HCHS/SOL Co-Investigator
Gerardo Heiss, MD, PhD, HCHS/SOL Co-Investigator
Marston Youngblood, MA, MPH, Project Manager

Attachment

	Center Name	Bronx
	Date of Visit	06/03/08 – 06/05/08
HCHS/SOL MONITORING VISIT REPORT		
Principal Investigator:	Sylvia Smoller, PhD	
Study Site address:	HCHS/SOL Bronx Clinic 1 Fordham Plaza Bronx, NY 10458	
Date of previous visit:	n/a	
HCHS/SOL Coordinating Center monitor(s) present:	Paula Gildner, MPH Franklyn Gonzalez, MS	
Key Study Site personnel present:	Rosalyn Graves, RN, Clinic Manager Madeline Crespo, Recruitment Coordinator	

General Comments

Bronx field center is a fully functional clinic that is prepared for the conduct of study baseline examination protocol with trained staff. Clinic staff are ready to work toward creating a clinic that is effectively run and operated. Bronx recruiters are well prepared and well trained. They have overcome many challenges in their recruitment efforts. With the hiring of additional recruiters, the Bronx should have no problems reaching their recruitment 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. 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				
Staffing/Certification – The recruitment manager at the Bronx has hired a very competent recruitment staff. She has trained the staff so that they are well prepared to go into the field to meet recruitment goals. She has also devised a hiring plan that will facilitate the Bronx having a full team of qualified recruiters. The Bronx has also hired a data entry person for recruitment.				
With the numbers of recruiters projected to increase, the Bronx field center will need to think of ways in which to house all recruiters and a data entry person in the allotted work space.				

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. HSR is completed correctly b. Specs are followed for the proper use of selection p and cut-point c values c. Follow through with ELE is complete	X X X		
Screen Call Tracking (SCT)	a. Number of call/visits is adequate b. Final status code uses are used appropriately	X X		

Individual Eligibility (ELE)	a. ELE is completed correctly b. Scheduling of clinic visits is completed	X	X	
Drop Point Selection Worksheet (DPS)	a. DPS is correctly used b. Selected unit/address is screened by recruiter	X X		
<p>Comments/Actions</p> <p>Storage of forms The Bronx has a filing system in place where files are arranged numerically under only the HH ID, making it difficult to look up an individual level ID if the HH ID is unknown. In addition, the filing cabinet is limited in space, so the Bronx will need to think of an archival system.</p> <p>A random subsample of case folders for approximately 15% of the households was selected for review by the coordinating center monitor. The results are noted below.</p> <p>HSR – In a few instances the administrative information on the form was not completed and entered into the DMS. As good research practice, all fields should be completed on paper and entered into the DMS. Examples are: B1043672, B1067007, and B1067619.</p> <p>The use of selection p and cut-point c for household screening is performed correctly.</p> <p>SCT – a. The hard copy documentation of the SCT demonstrated that recruiters are using study protocol with the number of visits. A review of those cases closed within a 1-week period showed that times were variable with the standard number of 4 attempts to contact the household.</p> <p>SCT – b. The final codes on the SCT were used as outlined by study protocol. However, a few HH files were not able to be located during the review, B1000381 and B1102100. It was not determined at time of visit if the files had been filed incorrectly or were being processed by a member of the recruitment team.</p> <p>ELE – a. As with all forms, it is important that recruiters complete all information on the individual eligibility (ELE) form including administrative information. Due to the filing system, a thorough review of the ELE forms proved to be difficult. In addition, the number of ELE forms in the DMS seems to be rather limited. It is recommended that the recruitment manager review study protocol to make sure that any person on the HSR roster who is eligible or whose eligibility is pending should have an ELE form. The recruiters need to complete and key the ELE forms using a participant ID for all persons who are screened at the person level <i>after</i> the household rostering stage 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. ELE forms are missing from the central database for individuals who screen out as ineligible. The coordinating center cannot confirm accurate person level response rates without entry of all ELE forms into the study data management system.</p> <p>DPS – Completed Drop Point Selection Worksheets (DPS) should be in the file for the household in which it was used. In one such instance, the DPS worksheet could not be located.</p> <p>Additional notes There was a lengthy discussion about the implementation of the handheld devices. Key points that were raised by the Bronx field center were:</p> <ul style="list-style-type: none"> • Participant Safety Screener should be on the handheld • Recruiters do not go out in pairs, so the number of handheld devices available is important • Devices should be pilot tested <p>Action(s)</p> <ol style="list-style-type: none"> 1. Recruitment team should follow the protocol for completing an Individual Eligibility Form (ELE) for individuals listed on the HSR roster with a case code of 6 or 7. 2. Administrative information for forms must be completed on the hard copy documentation AND entered into the DMS. 3. Using individual level IDs, recruiters need to key ELE forms administered to individuals who screened out when individual eligibility was determined. 				

CC
1. Consider generating a report that will allow for continuous monitoring by recruitment manager.

3. Database/Scheduling		YES	NO	N/A
Database	Database works effectively and well for project needs	X		
Scheduling	Clinic visits are scheduled with follow-up for no-shows	X		
Comments/Actions Data base – The Bronx is using a database management system that has 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.				

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 The check on the completeness of questionnaires and procedures revealed a variety of cases of incomplete visits. However, working with Bronx staff it was discovered that much of the information was saved in local mode. The data were then transferred to the study wide data management system. Bronx staff should be aware of data being saved in local mode and should perform a periodic check to see if any data have been stored and not uploaded.				

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
09/10/2007	

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

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

Staffing for the Bronx field center does not appear to be optimal. With only 3 med techs and 3 interviewers, the Bronx may want to think about the possibility of hiring more clinic staff.

Although staff were either trained at central training or trained on-site, there is no training documentation (only a log of trained staff). It is recommended that the clinic manager keep all training documentation in staff files.

Action(s)

- 1. Clinic manager maintain files with source documentation of staff certification.**

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

Participant files are stored properly. However, they are being filed by participant last name rather than ID. Name change, duplicate names, and the diversity of the use of last name may create issues in discerning participants in the future. At time of review there were 3 participants who had the same first and last name. It is suggested to use the unique HCHS/SOL individual identifier for filing.

Although a system is in place for filing source documentation, some hard copy documentation of procedure results could not be located in the participant files at the time of this review. It is recommended that all source documents be filed in a secure and consistent manner with the participant folder. Examples: B5000729, B50001185.

Action(s)

- 1. Securely and consistently file any source documentation in participant's file.**

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 (Including: Anthropometry, Blood Pressure, and ABI, etc...)	Correct HCHS/SOL procedures are followed as instructed in manual of procedures	X		

Comments/Actions

General – The clinic is well set up and staff is prepared to execute the individual exam components. At the time of the visit, the daily schedule was being developed as participants arrived. A schedule template adjusted for the number of participants seen in clinic on a given day accommodating a 4 to 8 person case load might help to facilitate the clinic flow schedule that is developed on a daily basis.

In addition, each member of the team was given a schedule. However, there seemed to be times where there was some confusion amongst staff as to the location of the participant or the next procedure the participant should be

completing. Although the clinic schedule for the day was full, participants were left waiting in the hallways while staff figured out the next procedure to be completed. In order to alleviate such confusion, it is suggested that the daily schedule be posted near the administrative office so that everyone can review the schedule. This system may help to diminish any confusion about each participant's clinic visit and the components he/she has completed.

Informed consent – The informed consent was delivered to 7 clinic participants that showed up for their appointment. Although informed consent was delivered and explained in full, the explanation to the group as a whole may prove to be ineffective for conveying the details of the participant burden. Some individuals seem to have a better understanding of the process than others. It seems like the delivery of the informed consent would be better in pairs or in a small group of 3 individuals.

In addition, the staff delivering the informed consent explained the need for the study to collect social security information. Some participants were visibly alarmed by this prospect. The lead staff delivering the information about SSN never mentioned that its provision was voluntary. Another staff stepped in to clarify. We recommend that staff be re-trained on key points in the informed consent and delivering those points to participants in a clear manner.

Participant Safety Screener – Since the form is not administered by clinic staff, we recommend that the form be reviewed before each clinic visit so that staff can be fully knowledgeable about any safety concerns for participation and plan the examination flow accordingly.

General Interview Techniques – A participant was followed through his full clinic visit. The following observations of general interview techniques were noted:

- a. Questions of standardized interviews were not always read correctly or as they appear on the screen.
- b. Scripted introductions to questions were often skipped.
- c. Questions were inadvertently skipped; some times responses were filled in by interviewer, other times they were left blank.
- d. Response categories were not always read to participant; thus questions were changed to be in an open-ended format.
- e. Interviewer lead respondent in some cases by reading only those response categories that may apply.
- f. Interviewer some times inferred responses from participant's answers without probing, when an exact response category was not chosen by participant.
- g. Questions that are gender specific were completed although they were not applicable to the participant.

Response binders should be used in order to facilitate the administration of questionnaires, and staff should implement the question by question instructions available for each questionnaire. Although the response "don't know/refuse" is considered part of the response categories, it is recommended that this response not be read to participants.

In addition, there seemed to be lack of familiarity with the data management system by the staff administering questionnaires.

Based on these observations, the study protocol was always not followed completely.

Procedures – Most procedures followed protocol and were administered in a timely fashion. However, spirometry procedures were not followed per the manual. While doing the spirometry procedure, participants must use a nose clip. This step is not optional.

It is recommended that the clinic manager observe study technicians to make sure that each clinician is following exact protocols outlined for each procedure.

Action(s)

- 1. Any person administering questionnaires needs to be re-trained on general interview techniques**

**and review protocol on general interviewing techniques in Manual 2.
2. Clinic manager should closely observe procedures by study technicians.**

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 available in the clinic manager’s office, copies of the manual of procedures for the study and specific procedures need to be in each clinic exam room.

Forms – Copies of forms and question by question instructions need to be in each clinic exam room.

Logs/Procedures/Equipment – Logs for observation, procedures and equipment calibration are not maintained or are not up to date. The following logs are to be utilized by the clinic manager and/or clinic staff:

Manual 2

1. Observation and equipment checklist (Appendix 1)
2. Observation of general interview techniques (Appendix 2)
3. Observation of anthropometry (Appendix 3)
4. Observation of blood pressure and ABI measurement (Appendix 4)
5. Simultaneous ABI (Appendix 5)
6. Observation of biospecimen collection (Appendix 6)
7. Anthropometry Equipment Calibration (Appendix 8)
8. Daily Spirometer Leak and Volume Check (Appendix 12)

Manual 5

9. ECG Directory Log (Manual 5, Appendix 5)

Actical and Sleep Monitor – Electronic logs have been set up to track the monitors. These logs are very nicely designed and well organized. At time of visit, recruitment staff was responsible for picking up equipment. For the future, the field center might consider hiring a courier or other type of service for equipment pick-up.

During the exit interview the physical activity monitor (actical) was explained to the participant at the time of the visit. However, the participant was not asked to wear the monitor until the following day. Although not directly stated in the manual, it is suggested that the participant put the monitor on before leaving the clinic. This practice might help to improve the quality of the data received.

Action(s)

1. **A copy of the appropriate manual of procedures should be available in each exam room.**
2. **Copies of the forms/questionnaires and question by question instructions should be available in each exam room.**
3. **Maintain observation, procedure and equipment calibration logs as outlined in the study manual of procedures.**

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 During the time of the visit, a representative from the lab was present and will provide a detailed report to the Field Center on the lab.			

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) The DMS has many shortcuts that are outlined in the user's guide, i.e. date fill – F2, Full screen – F11. The clinic staff should review these routine shortcuts and use them when seeing participants. As mentioned previously, at times local mode was used to collect data, unbeknownst to the staff. Periodic checks of local mode should be conducting in order to insure that all data has been uploaded to the study wide data management system. In addition, a few items were requested by data management staff as outlined below. Action(s) CC <ol style="list-style-type: none"> 1. Allow sites to generate a report to help them resolve missing items on a regular basis. 2. Develop a report where sites can run a query by Staff ID so they can regulate activities of clinic staff. 3. Consider uploading the clinic demographic distribution report daily as opposed to weekly. 4. Follow-up on generating a report of data entered by staff for the Weight History form, Q6 and Q7. 			

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) None			

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		
Comments/Actions None			

Proposed date of next HCHS/SOL monitoring visit:

TBD

Comments/Action items for HCHS/SOL Field Center:

Recruitment

1. Recruitment team should follow the protocol for completing an Individual Eligibility Form (ELE) for individuals listed on the HSR roster with a case code of 6 or 7.
2. Administrative information for forms must be completed on the hard copy documentation AND entered into the DMS.
3. Using individual level IDs, recruiters need to key ELE forms administered to individuals who screened out when individual eligibility was determined.

Clinic

1. Clinic manager maintain files with source documentation of staff certification.
2. Securely and consistently file any source documentation in participant's file.
3. Any person administering questionnaires needs to be re-trained on general interview techniques and review protocol on general interviewing techniques in Manual 2.
4. Clinic manager should closely observe procedures by study technicians.
5. A copy of the appropriate manual of procedures should be available in each exam room.
6. Copies of the forms/questionnaires and question by question instructions should be available in each exam room.
7. Maintain observation, procedure and equipment calibration logs as outlined in the study manual of procedures.

Action items for HCHS/SOL Coordinating Center:

1. Consider generating a report that will allow for continuous monitoring by recruitment manager.
2. Allow sites to generate a report to help them resolve missing items on a regular basis.
3. Develop a report where sites can run a query by Staff ID so they can regulate activities of clinic staff.
4. Consider uploading the clinic demographic distribution report daily as opposed to weekly.
5. Follow-up on generating a report of data entered by staff for the Weight History form, Q6 and Q7.



Paula Gildner
HCHS/SOL Monitor

6/30/08
Date