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at CHAPEL HILL

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April 21, 2008

Neil Schneiderman, Ph.D.
Department of Psychology, FLIPSE Building
5665 Ponce de Leon Boulevard, Room 408
PO Box 248185
Coral Gables, FL 33124

Re: HCHS/SOL Monitoring Visit Report

Dear Dr. Schneiderman,

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 April 01 – 03, 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 all study procedures and protocols and includes both recommendations and action items for both the Miami Field Center and the CC.

The HCHS/SOL CC would like to thank the Miami Field Center staff for their professionalism and willingness to accommodate the schedules of the Coordinating Center personnel during the visit. The kindness of the Miami Field Center staff was greatly appreciated. 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 Miami Field Center staff, we would like to extend special thanks to Dr. Marc Gellman, Project Manager, Nayomy Figueroa, Clinic Manager, and Brendaly Rodriguez, Recruitment Manager for their efforts in accommodating our needs. The CC also appreciates the effort demonstrated by the Miami Field Center staff to maintain the high quality of data collection necessary to the integrity of the HCHS/SOL.

Please feel free to contact either Marston Youngblood or Paula Gildner with any questions or concerns in regards to the monitoring visit report.

Sincerely,

Marston Youngblood

Paula Gildner

CC Marc Gellman, Ph.D., HCHS/SOL Project Manager
John Ryan, Dr. PH, HCHS/SOL Co-Investigator
Lisa LaVange, Ph.D., Director Coordinating Center
Diane Catellier, Dr.PH, HCHS/SOL Co-Investigator

Attachment

	Center Name	University of Miami
	Date of Visit	04/01/08 – 04/03/08
HCHS/SOL MONITORING VISIT REPORT		
Principal Investigator:	Neil Schneiderman, PhD	
Study Site address:	Behavioral Medicine Research Center, Clinical Research Building 1120 NW 14th Street Miami, FL 33136	
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:	Marc Gellman, PhD, Project Manager John Ryan, DrPh, Co-Investigator Nayomy Figueora, RN, Clinic Coordinator Brendaly Rodriguez, MA, Recruitment Coordinator	

General Comments

Miami field center is fully operational for conduct of study baseline examination protocol with trained staff in place. Clinic staff are well prepared and are capable of handling a full schedule of HCHS/ SOL participants. Recruitment staff are highly organized and their recruitment efforts are productive in generating referrals for the clinic although the number of scheduled visits are still under the goal of 30 persons per week at this early stage of the study. With the hiring of more recruitment staff, Miami will be able to meet that goal.

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 Staffing/Certification – Miami recruiters are knowledgeable and well-trained and with the hiring of more staff the Miami Field Center will easily meet recruitment goals. b. Although all recruiters are certified, a log of fully certified staff is not on record locally. Recruitment manager was notified and will begin to maintain a written log of certified recruiters. c. Documentation of certification checklist for recruitment and certification quiz for each certified recruiter is not on file. Recruitment manager was notified and will begin to maintain a written log of certified recruiters.				
Action(s) 1. Recruitment manager will maintain a log of certified recruiters and a folder with documentation of certification.				

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		X	
	b. Follow specs for the proper use of selection p and cut-point c	X		
	c. Follow through with ELE	X		
Screen Call Tracking (SCT)	a. Number of call/visits is adequate	X		
	b. Final code use	X		
Individual Eligibility (ELE)	a. Completed correctly	X		
	b. Scheduling of clinic visits	X		
Drop Point Selection Worksheet (DPS)	a. Correct use			X
	b. Selected unit/address screened			X

Comments/Actions

Storage of forms

Miami has in place a filing system that allows easy access by recruiters to possible participant forms and closed cases. An archival system will need to be developed in the future to accommodate the expected volume of case files generated by screening 7,500 households.

A random subsample of case folders for approximately 10% of the households was selected for auditing by the coordinating center monitors. The results are noted below.

HSR – a. In 2 of 12 cases there were discrepancies between the number of individuals reported to be living in a HH and the individuals on the roster. Recruitment staff needs to make sure they gather as much information on the individuals in the HH as possible. Example: M3066620 – Q2 and Q3 report 2 persons. Q5, roster, only one person listed. M3104902 missing final status codes for 2 persons on roster.

SCT – a. 1. The hard copy of the SCT needs to be completed in full before entering in the DMS. Although the data was entered into the DMS, the hard copy needs to show the final result code. Examples: M3063820 and M3104902. a. 2. The number of calls/visits reported on the worksheet for the SCT was limited in some cases. Although exception will occur, recruitment guidelines include up to 4 home visits or 10 – 12 phone calls at differing times of day/evening. This procedure may take up to a 2 week (or longer) period. These guidelines are especially important in trying to maximize the number of open HH cases and when the known selection p is actually less than cut-point c (a selected HH) which guarantees that the household would be invited to participate in the study. Example: M3112035, 3 attempts over 3 successive days and case was closed.

SCT – b. If a household invitation mailing was returned, recruitment staff has kept the letter on record and used the appropriate final case code on the SCT. This demonstrates good data archival practice, and these addresses should be visited by recruiters to confirm that address is not a working address.

ELE – a. If some individuals in a HH have scheduled a clinic visit, and others have not, then attempt to keep the door open to contact others in HH. Try to make re-contact if possible. Example: M3104902

Action(s)

- 1. Recruiters need to gather as much information as possible on individuals living in the household, i.e. gender, relationship and age.**
- 2. Hard copy documentation for forms must be completed in full AND entered into the DMS.**
- 3. Follow the guidelines for suggested number of attempts to contact a HH, 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 2 week period or more to complete.**

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

Scheduling – In order to keep track of cancellations, no-shows, etc. we recommend that the scheduler create a

report that can be reviewed by staff on a weekly basis. A report will allow the recruitment staff to follow-up with those individuals who do not show for their scheduled clinic visit.

Action(s)

1. **Print weekly report that identifies clinic no-shows, cancellations, etc...that will help recruitment staff follow-up with scheduling.**

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 majority of incomplete visits were due to protocol safety procedures for high fasting glucose. Appropriate procedures for referral and follow-up are being implemented.			

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
09/17/2007	

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 date.		X	
Blood draw certification	X		
Staff certification is in compliance with Appendix 10, Manual 2			
Medication use certification	X		
Staff are certified in implementing and documenting medication use			
Comments/Actions Certification – a. Although on record, logs and records were difficult to review. It is recommended that a log of staff certification is on file and files would include all proper certification documentation by staff member.			

Action(s)
1. Maintain up to date log and file(s) on certification of staff members.

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. During the visit participant files and loose paperwork were awkwardly transferred from clinician to clinician. Source documents could easily fall out and be lost. It is recommended that a protocol be devised for participant files and that source documents be labeled with participant ID, in case the documents were to get separated from the file. These documents include: Exam flow checklist, tympanometry tracings, Blood Pressure, etc...				
Action(s)				
1. Devise protocol for organization of participant file and documents during clinic visit.				
2. Coordinating Center to provide utility report for printing bar coded ID labels for participants				

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 – Although the clinic is well set up and staff is prepared to execute the individual exam components, there was some confusion observed during the initial triage at the beginning of the day when participants first start the actual clinical procedures. The clinic supervisor has developed a succinct system and schedule for participants, and the schedule is easily read. It is suggested that all staff review the clinic schedule for the day early on for last minute updates and/or changes so that their role for that day is clear.

In addition, the system that is in place to maintain clinic flow handles up to 5 participants. Another schedule will have to be in place to accommodate up to 6 participants, and on days when there might be overbooking, even more participants.

Lastly, the schedule for the clinic visits collects the personal contact information (IDE/IDS form) on participants very late in the day, i.e. after 1 pm. It is recommended that this critical information be gathered early in case of the need to end the clinic visit early.

Informed consent – Although informed consent was delivered and explained in full, the explanation may prove to be unnecessarily long a process for high SES literate participants. Content that took one hour to deliver would take 30 minutes or less for some participants if they can go at their own pacing. Experiences with more participants in the higher SES category will help to guide the decision for pacing the delivery of the informed consent to this subset of participants.

PSE/PSS – PSE was not explicitly reviewed or administered, and was not in the participant file. The form should be reviewed either on-line (DMS) or a hardcopy should be in the participant file.

General Interview Techniques – Clinicians need to follow protocols on administering questionnaires. Many clinical interviewers did not ask questions as they appear on the DMS and inferred answers. It is recommended that clinicians review protocols on administering questionnaires and strictly adhere to the protocols.

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 computer station for recording of information into the DMS so time was lost walking back and forth between the computer workstation and the participant.

Action(s)

1. Review on the DMS or hard copy OR administer the PSE/PSS during informed consent process.
2. Any person administering questionnaires needs to review protocol on general interviewing techniques and strictly adhere to this protocol.

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 – Dental staff raised some issues on the confusing information in the oral health manual with regard to referral recommendation. CC will follow-up with lead investigators to see if the most current guidelines are reflected in the manual, and send confirmation back to the Miami examiners.

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 were also not readily available in clinic rooms.

Action(s)

1. CC will follow-up with issues regarding question on Oral Health Manual and referral feedback.
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.

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 None			

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) b. Demographic report for pulmonary function cut and paste may have problems. CC to follow-up with parties involved. Field center staff were reminded that any records "open" for data entry must be saved and closed in order for the Demographic report to find data values and pass them along to the Spirometry software. The message, "NODATA", means the Medication Use form is incomplete or missing from the DMS.			
Comments/Actions 1. CC will follow-up with issues regarding the interaction between spirometry software and DMS			

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 manager will maintain a log of certified recruiters and a folder with documentation of certification.
2. Recruiters need to gather as much information as possible on individuals living in the household, i.e. gender and age.
3. Hard copy documentation for forms must be completed in full on paper AND entered into the DMS.
4. Although exception will occur, 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 before declaring the case closed. This procedure may take up to 2 weeks or more to complete.

5. Print weekly report that identifies clinic no-shows, cancellations, etc...that will help recruitment staff follow-up with scheduling.
6. 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.

Clinic

1. Maintain up to date log and file(s) on certification of staff members.
2. Devise protocol for organization of participant file and documents during clinic visit.
3. Review on the DMS or hard copy OR administer the PSE/PSS during informed consent process.
4. Any person administering questionnaires needs to review protocol on general interviewing techniques and strictly adhere to this protocol.

Action items for HCHS/SOL Coordinating Center:

1. CC will follow-up with issues regarding Oral Health Manual.
2. CC will follow-up with issues regarding interaction between spirometry software and DMS.



Marston Youngblood
HCHS/SOL Monitor

4/21/08

Date



Paula Gildner
HCHS/SOL Monitor

4/21/08

Date