



THE UNIVERSITY  
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at CHAPEL HILL

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June 20, 2008

Greg Talavera, MD, MPH  
Associate Professor, Graduate School of Public Health  
9245 Sky Park Ct., Suite 110  
San Diego, CA 92123

Re: HCHS/SOL Monitoring Visit Report

Dear Dr. Talavera,

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 May 12 – 16, 2008 by Coordinating Center (CC) representative 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 representative that will aid your site in complying with study procedures and protocols and includes recommendations and action items for both the San Diego Field Center and the CC.

The HCHS/SOL CC would like to thank the San Diego Field Center staff for their professionalism and willingness to accommodate the schedule of the representative from the CC during the visit. The kindness of the San Diego Field Center staff was greatly appreciated. In addition, the usefulness of allowing the CC to observe a volunteer 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 San Diego Field Center staff, we would like to extend special thanks to Ana Talavera, Project Manager, Johanne Hernandez, Clinic Manager, and Rosalinda Rodriguez, Recruitment Manager for their efforts in accommodating our needs. The CC also appreciates the effort demonstrated by the San Diego Field Center staff to maintain the high quality of data collection necessary to ensure the integrity of the HCHS/SOL.

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

Sincerely,

Paula Gildner

CC Ana Talavera, HCHS/SOL 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	San Diego
	Date of Visit	05/12/08 – 05/16/08
<b>HCHS/SOL MONITORING VISIT REPORT</b>		
<b>Principal Investigator:</b>	Greg Talavera, MD, MPH	
<b>Study Site address:</b>	HCHS/SOL San Diego Clinic Site 450 4th Street Chula Visita, CA 33136	
<b>Date of previous visit:</b>	n/a	
<b>HCHS/SOL Coordinating Center monitor(s) present:</b>	Paula Gildner, MPH	
<b>Key Study Site personnel present:</b>	Ana Talavera, MPH, Project Manager Johanne Hernandez, RN, Clinic Coordinator Rosalinda Rodriguez, Recruitment Coordinator	

### General Comments

The San Diego field center is operating a well run clinic that is prepared for the conduct of the baseline examination protocol with trained staff. Clinic staff are prepared and capable of handling a full schedule of HCHS/SOL participants. San Diego recruiters have faced many challenges that recruiters at other sites have not faced. Despite these challenges recruitment staff have remained strong. They are highly organized and their recruitment efforts are productive in generating clinic appointments.

### 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		
<b>Comments/Actions</b>	Staffing/Certification – San Diego recruiters are knowledgeable, well-trained and are equipped to meet recruitment goals.			

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

## Comments/Actions

### Storage of forms

San Diego has a filing system in place that is based upon the batch mailings. Within each batch, cases are filed by the final SCT code. The system allows for easy access to completed forms based on the knowledge of the SCT. Although not necessary, filing forms in a "loose" numerical order would help to locate a form when needed.

A random subsample of case folders for approximately 20% of the households was selected for review by the coordinating center monitor. The results are noted below.

HSR – a. In some cases there were discrepancies between what was recorded on the hard copy form and what was entered into the DMS. Staff needs to be careful to enter the exact information that is recorded on the hard copy form into the DMS. Examples: S4340315 – Hard copy Q1= ., DMS Q1= 1, S4042239 – Hard copy Q1= 1, Q2= 4, DMS Q1=., Q2= ., S4345604 – Hard copy Q1= ., DMS Q1= 0, S4193687 – Hard copy Q1= ., DMS Q1= 0, S4396892 – Hard copy Q1= ., DMS Q1= 0, S42277389 – Hard copy Q1= 1, DMS Q1=.

It is important that hard copy documentation is consistent with information entered into the data management system. This becomes even more important when recruitment data will be entered into the DMS by a data entry person and not actual recruiters. In order to alleviate the issue, it is recommended that the recruitment manager periodically reviews data entry and the work of the data entry person.

HSR – b. Recruitment staff are using the selection p and cut-point c values correctly and are finding that many HHs do not get selected using the current cut-point c value. The CC will inquire as to a projected date to change the cut-point value for mixed age HH in order to increase the number of HHs selected.

SCT – The actual study-wide hard copy of the Screen Call Tracking Worksheet (SCT) is not being used by recruitment staff. A modified version that captures all aspects of San Diego recruitment is being used. CC will follow-up with inquiry about the usage of a modified form. Although the version of the worksheet being used is acceptable, it is recommended that recruiters make apparent the data that will need to be entered into the DMS by the data entry person, i.e. highlight the information, circle in red pen, etc.... Clearly identifying the information is critical when the hard copy documentation is passed to a data entry person for entry into the study DMS.

SCT – b. There were some discrepancies on the usage of the final codes on the SCT. If a household had been contacted and any information was gathered on that household, the final case not should NOT be recorded as final code 3 – Able to contact, but HH refused to be screened; HH eligibility is unknown. The correct case code to be used in a situation where some screening information was gathered but not all is final case code 4 – Able to contact, but HH screening was never completed; HH eligibility is unknown. Although the final result in both situations is "eligibility unknown", the cases should not be considered the same. Examples: S4326971, S4324483, and S4395004 where Q1= 1, SCT final code= 3.

In other situations, the screening was actually completed and the final case code was reported as 3 – Able to contact, but HH refused to be screened; HH eligibility is unknown or as 4 – Able to contact, but HH screening was never completed; HH eligibility is unknown. Examples: S4394828 where the HH was eligible, selected, SCT final code= 3; and S4358277 where the HH was eligible and selected and the SCT final code= 4. Both of these cases demonstrate incorrect usage of the final case code for the households listed.

In addition, there was another situation where the HH screening was complete, but the HH was not selected. The final code given to the HH was 5 – Screening completed, HH not eligible. Based on the documentation, the correct final case code should be 6 – Screening completed, HH eligible and not selected. Based on this review, it is recommended that recruitment manager provides refresher training on the use of the final case codes for households.

ELE – a. It is important that recruiters complete all administrative information on the ELE. A report generated by the CC shows many instances where the "roster row letter" is missing. Examples: S8000104, S8000138, S8000145, and S8000153. As a part of good research practice, administrative information should be completed by person completing the form and entered into the DMS.

### Action(s)

1. Recruitment manager periodically reviews data entry and data entry person.

- 2. Recruitment manager to provide recruiters with refresher training on the use of the final case codes for households.
  - 3. Administrative information for forms must be completed on the hard copy documentation AND entered into the DMS.
- CC**
- 1. Follow-up at the CC about the use of a modified version of the SCT.
  - 2. Review changing of cut-point so more households can be accepted into the study and establish a target date if change is needed.

3. Database/Scheduling		YES	NO	N/A
<b>Database</b>	Database works effectively and well for project needs	X		
<b>Scheduling</b>	Clinic visits are scheduled and follow-up for no-shows	X		
<b>Comments/Actions</b>				
Data base – San Diego has designed a data base that effectively tracks clinic no-shows and actual participants. They can print a variety of reports to help manage clinic flow, no-shows, and equipment tracking.				
Scheduling – San Diego has a system in place that allows a lead recruiter to work with call backs, completing the ELE, and scheduling clinic visits. The system seems to be working for San Diego in scheduling clinic visits. Clinic no shows are being followed up by clinic staff, which helps decrease the burden placed on recruitment staff.				

**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
<b>Comments/Actions</b>			
None			

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		
<b>Comments/Actions</b>			
None			

3. Informed Consent	YES	NO	N/A
HCHS/SOL study informed consent has been approved, properly documented and signed for each participant	X		
<b>Comments/Actions</b>			
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
03/12/2008	

4. Staff Training/Certification		YES	NO	N/A
<b>Certification</b>	<ul style="list-style-type: none"> <li>a. Staff is HCHS/SOL certified</li> <li>b. Log of certified staff/clinicians is maintained</li> <li>c. Documents for certification are on record and up to date.</li> </ul>	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> None				

5. Participant files		YES	NO	N/A
	<ul style="list-style-type: none"> <li>a. HCHS/SOL participant files are properly organized and complete</li> <li>b. Files are stored properly</li> <li>c. Source documents are stored properly</li> </ul>	X		
<b>Comments/Actions</b> Participant files are well-organized and stored properly. However, the space for storage is rather limited. More storage space for participant files will be necessary as the clinic participant numbers increase.  From a DMS report, some information on participants was missing. Upon review of the participant file, the information was located. It is recommended that all information on the participant be entered into the DMS in a timely fashion.				

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 (Includes: Anthropometry, Blood Pressure, ABI, and Biospecimen Collection)</b>	<ul style="list-style-type: none"> <li>a. Correct HCHS/SOL procedures are followed as instructed in the manual of procedures (comments below on individual procedures)</li> <li>b. Study measurement equipment has been maintained and calibrated as required</li> </ul>	X		
<b>Comments/Actions</b> General – The clinic is well set up and staff is prepared to execute the individual exam components with the daily schedule posted near the administrative office. This system helps to diminish any confusion about each participant's clinic visit and the components he/she has completed. The clinic supervisor develops a succinct system and visit schedule for participants, and the schedule is easily read. However, much burden is placed on the clinic manager to develop a plan for each clinic day. In order to reduce burden to the clinic manager, a schedule template might be developed that would assist in developing a daily schedule. Exam component times are tracked by each clinician with a timer. This system works well for documenting actual time of the clinic visit.  Informed consent – Although informed consent was delivered and explained in full, the explanation may prove to be unnecessarily long for high SES or more literate participants. Content that took one hour to deliver could take 30 minutes or less for some participants if they can go at their own pace. Experience with more participants in the higher SES category will help to guide the decision for pacing the delivery of the informed consent. Training staff on recognizing the fine line that exists between a participant saying they have read the consent in full and understanding it in full is key.				

Participant Safety Screener – Since the form is not administered by clinic staff, the form must be reviewed before each clinic visit so that staff can be fully knowledgeable about any safety concerns.

General Interview Techniques – Clinicians have hard copies of questionnaires ready for use when there is a problem with the data management system. Clinicians need to follow guidelines on administering questionnaires as described below:

Questionnaires should be delivered in an even slow pace using non-neutral feedback. At times questionnaires were delivered in a very rapid voice and reinforcement was given with the word “correcto”, a non-neutral word. Also, response binders should be used in order to facilitate the administration of questionnaires, because the prompts reduce the repetition of responses, and the tendency to curtail or shape responses. It is suggested that staff who are administering interviews review the section on interview techniques in Manual 2.

Procedures – The protocol for some exam procedures was not followed strictly. Although the clinic manager has maintained the procedure observation checklist, it is recommended that the clinic manager continue to closely observe clinicians to make sure that each clinician is following exact protocols outlined for each procedure. One example is sitting blood pressure where the participant is asked to rest for a full five minutes before starting procedure. At the time of observation, this protocol was not explained to the participant nor did the participant rest.

Also, participant contact time could be saved by having clinicians record information into the DMS after the procedure is completed. 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. In addition, 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. Any person administering questionnaires needs to review the protocol on general interviewing techniques and adhere to this protocol.
2. The clinic manager should continue to closely observe procedures by each clinician.
3. Staff should be instructed to code medication while participant is at another exam station.

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

**Comments/Actions**

Manuals – Dental staff raised some concerns over incorrect data that might have been entered due to confusing information in the oral health manual with regard to referral recommendation. CC has been developing a plan for resolving the issue and will follow-up with a procedure to correct any inconsistent data.

Logs – Most logs are well maintained and up to date with the exception of the ECG Directory Log (Manual 5, Appendix 5). It is recommended to maintain the ECG Directory Log.

The Anthropometry Equipment log is in need of clarification. The technique as described in Manual 12, Appendix 8 for checking the measuring tape can be implemented but not with the range given. CC to follow-up with range outlined on the Anthropometry Equipment Calibration log.

Actical and Sleep Monitor – Electronic logs have been set up to track the monitors. These logs are very nicely designed and well organized. A courier has been hired to collect study equipment when necessary.

The site is administering the explanation of the instructions at different times. It was requested at the site that the Clinic Check Off Sheet be modified to allow for this procedure.

**Action(s)**

1. **ECG Directory Log (Manual 5, Appendix 5) should be maintained.**

**CC**

1. **CC will follow-up with issues regarding dental data and referral feedback.**
2. **Clarify range on Anthropometry Equipment Calibration Log (Manual 12, Appendix 8)**
3. **Modify CHK to allow for entering of time for explanation of take home monitors separately.**

<b>8. Clinical Laboratory</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
a. Monitor 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**

Blood collection and processing area – although the blood collection area is sufficient, the actual collection of the specimen seemed awkward. It is recommended that another small table or rolling cart be put in the room to add to the available work space for the technician.

**Action(s)**

1. **Provide additional work space for clinicians by placing another table or a rolling cart in the biospecimen collection room.**

<b>9. Data Management</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
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)**

Data Management System (DMS)

The site requested the ability to run a report that would give the information on the procedures and questionnaires that were completed by the participant. CC will follow-up and explain the use of the existing “Baseline Examination Completion Report”. Note that the user guide for reports was recently expanded and is available on the study website.

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.

<b>10. Changes at the Site and Other Issues</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
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

<b>11. Monitoring Visit Follow-up</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
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>			
None			

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

TBD

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

**Recruitment**

1. Recruitment manager should periodically review data entry and work of the data entry person.
2. Recruitment manager should provide recruiters with refresher training on the use of the final case codes for households.
3. Administrative information for forms must be completed in the hard copy documentation AND entered into the DMS.

**Clinic**

1. Any person administering questionnaires needs to review the protocol on general interviewing techniques and adhere to this protocol.
2. Clinic manager should continue to closely observe procedures by clinician.
3. Staff should be instructed to code medication while participant is at another exam station.
4. ECG Directory Log (Manual 5, Appendix 5) should be maintained.
5. Additional work space for clinicians should be provided by placing another table in the biospecimen collection room.

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

1. CC will follow-up about the use of a modified version of the SCT Worksheet.
2. CC will review changing of cut-point so more households can be accepted into the study.
3. CC will follow-up with issues regarding dental data and referral feedback.
4. Range for checking the measuring tape on Anthropometry Equipment Calibration Log (Manual 12, Appendix 8) will be clarified.
5. The CC will consider modifying CHK to allow for entering of time for explanation of take home monitors separately.

*Paula Gildner*

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Paula Gildner  
HCHS/SOL Monitor

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6/18/08  
Date