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at CHAPEL HILL

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MEMORANDUM

To: Observational Study Monitoring Board - HCHS/SOL
Copy: HCHS Principal Investigators. Project Office
From: Coordinating Center (Lisa LaVange, Gerardo Heiss, Diane Catellier and Marston Youngblood)
Date: May 21, 2008
Re: Materials for review prior to New York meeting

Enclosed please find materials for the upcoming meeting of the Observational Study Monitoring Board (OSMB) for the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) to be held in New York City on June 3, 2008. The meeting materials include:

- Agenda
- Report on Recruitment, Data Management, and Study Quality
- Responses to the OSMB comments dated April 15, 2008 concerning the study protocol

The HCHS/SOL was granted OMB approval on February 12, 2008, and recruitment commenced soon thereafter. The data cut-off date for the report included in this package was May 13, 2008. The report therefore reflects the first three months of recruitment activities and clinical examinations.

The report is divided into five sections:

- Section 1 provides a summary of household and person-level recruitment activities, including a brief description of the probability sampling design and recruitment protocol, as a refresher, and a comparison of observed versus expected rates for the various screening outcomes.
- Section 2 provides a summary of data collection and management activities, including process outcomes for the clinical interviews and examinations. Tabulations of missing forms and items as well as times to complete the various exam components are included.
- Section 3 contains the results of the quality control analyses completed to date.
- Section 4 provides summary statistics for selected baseline characteristics and clinical assessments. These data should be viewed as preliminary due to small sample sizes (250 completed clinical examinations across the four field centers). Future reports will contain more extensive analyses of baseline data. Also to be included in future reports are tables that monitor provisions to the informed consent by which study participants restrict the use or sharing of data.
- Section 5 provides templates for reports prepared for both participants and their medical providers as well as for alert notifications resulting from the clinical examinations.

Please let us know if you have any questions concerning this material. We look forward to meeting with you on June 3 in New York.

OBSERVATIONAL STUDY MONITORING BOARD

June 3rd, 2008 - Meeting Agenda

New York City - 70 Park Avenue Hotel

Murray Hill Meeting Room

June 3rd session, 8:00am - 5pm Eastern

(Continental breakfast and lunch buffet served)

Executive Session (Board Members only, Executive Secretary & NHLBI/NIH Representatives)

8:30am	Welcome and introductions	Chair, OSMB
	Review and approval of June 2007 minutes	Chair, OSMB
8:45am	Response to OSMB recommendations (June 2007)	Chair, OSMB
9:15am	Project updates	Project and Contract Officers,
	Break (if time)	

10:00 Full Session (Board Members, Investigators, Executive Secretary and NHLBI/NIH)

Introductions Chair, OSMB

10:00am	OSMB recommendations from June 2007 and SC Responses	Chair, OSMB
10:30am	Study overview and progress report	Chair, Steering Cmte
10:45am	Coordinating Center management report	PI, Coordinating Center
	- Sampling and recruitment	Chair, Sampling Cmte
	- Data collection protocol	Chair, Exam Cmte
	- Data management	Project Manager, CC
	- Reading center operations	PI, Coordinating Center
	- Quality assurance	Chair, QC Cmte
12:30pm	Buffet Lunch in meeting room	
1:00pm	Follow-up Exam / Endpoints	Chair, Endpoints Cmte
1:15pm	Field Center reports (10 minutes each)	PIs, Field Centers
2:00pm	Reporting of results to participants	Chair, Exam Cmte
2:15 pm	Community involvement	Chair, Community Reln.
2:45pm	Ancillary studies	Chair, Ancillary Studies
3:15pm	Publications	Chair, Publications Cmte
3:30pm	Plans and priorities	Chair, Steering Cmte

4 pm Executive Session (OSMB members, Executive Secretary, NHLBI/NIH representatives)

- Discussion and recommendations

Adjournment prior to 5pm

Expected Attendees at New York Meeting

NHLBI Observational Study Monitoring Board
Listing of Members (April, 2008)

Odilia I. Bermudez, PhD, MPH
Assistant Professor
Tufts University
Friedman School of Nutrition Science and Policy

Enrique Caballero, MD
Assistant Professor
Joslin Diabetes Center

Hannia Campos, PhD
Senior Lecturer on Nutrition
Harvard University School of Public Health
School of Nutrition

Gustavo Cruz, DMD, MPH
Assistant Professor and Director of Public Health
New York University
Department of Epidemiology and Health Promotion
College of Dentistry

Judy Dubno, PhD
Professor, Medical University of South Carolina
Department of Otolaryngology/ENT

George Howard, Dr.P.H.
Professor and Chairman of Biostatistics
University of Alabama at Birmingham

Martha Medrano, MD, MPH
Director of the Medical Hispanic Center of Excellence
University of Texas at San Antonio

Anne B. Newman, MD, MPH
University of Pittsburgh
Graduate School of Public Health

Jean L. Olson, MD, MPH
(Executive Secretary, HCHS/SOL OSMB)
NHLBI

Study Staff / PIs to present at OSMB

Project Office – National Heart, Lung and Blood Institute
Project Officer: Larissa Avilés-Santa, MD, MPH
Deputy Proj Officer: Paul Sorlie, PhD
Deputy Proj Officer: Lorraine M. Silsbee, MHS
Contracting Officer: Kristi E. Cooper
Contract Specialist: Elizabeth Zoller

Bronx Field Center
Sylvia Wassertheil-Smoller, PhD, FACE, FAHA [Chair of HCHS/SOL Publications Committee]

Chicago Field Center
Martha Daviglus, MD, PhD

Miami Field Center
Neil Schneiderman, PhD [Chair of HCHS/SOL Ancillary Studies Committee]
David Lee, PhD [Chair of HCHS/SOL Questionnaires Committee]
Brendaly Rodriguez [Chair of HCHS/SOL Community Relations Committee]

San Diego Field Center
Greg Talavera, MD, MPH [Chair of HCHS/SOL Steering Committee]

Coordinating Center
PI: Lisa LaVange, PhD [Chair of HCHS/SOL Sampling/Recruitment Committee]
Co-PI: Diane Catellier, PhD [Chair of HCHS/SOL Quality Control Committee]
Co-PI: Gerardo Heiss, MD, PhD [Chair of HCHS/SOL Exam Committee]
Co-Investigator: Lloyd Chambless, PhD
Co-Investigator: Wayne Rosamond, PhD [Chair of HCHS/SOL Endpoints Committee
Project Manager: Marston Youngblood
Administrative Coordinator: Jeff Oberhaus

Reading Center Principal Investigators if requested by OSMB

Additional Questions, Comments and Suggestions
from the HCHS/SOL OSMB
Since the June 21-22, 2007 Meeting

OSMB Recommendations, Questions and Suggestions are italicized in this font
Responses from the HCHS/SOL Steering Committee are in plain text in this font

April 15, 2008 -- The HCHS/SOL OSMB found the Steering Committee's response to be very complete, thoughtful and clear in addressing the Board's previous recommendations and suggestions.

The following specific comments address comments received from Board members.

1. Clarification on the Ultrasound substudy

The HCHS/SOL investigators propose:

The ancillary study investigators wish to clarify that this study will not measure the degree of stenosis in the carotid arteries (percent stenosis is not a measurement considered in the study protocol). Although visualizing the carotid beds will make it possible to detect extensive carotid atherosclerosis, neither the scanning nor the reading will follow a clinical protocol for determining luminal stenosis of the carotid arteries. Addressing the point raised by the Board, based on an assessment by the ancillary study PI and the reading center PI, the study participant will be notified of his/her results regardless of the findings of the ultrasound study. It is the field center PI who is responsible for the notification but she/he is not asked to agree with interpretations of the ultrasound image. The study participant's physician is contacted only if the participant has authorized sharing this information with the health care provider.

2. Oral exam component

The Oral exam component of the study is being conducted according to the contract issued by the National Institute of Dental and Craniofacial Research. It was specified that the HCHS/SOL exam be conducted in the same manner as the dental component of the NHANES studies run by the National Center for Health Statistics. While not all of the NHANES oral measures are included in the HCHS/SOL exam, those components that are included follow the NHANES protocol so that these data can be compared with national findings. The HCHS/SOL examiners are trained by and calibrated to a dentist who had been an examiner for the NHANES studies. We also conduct annual recalibration studies and the standard examiner visits each field center to provide quality assurance. Thus, all measures except one follow a standard protocol. The exception is the Oral Lesion component of the report. While past NHANES studies did contain a detailed measurement of oral lesions, they were not included in the HCHS/SOL study. However, as scientists conducting oral examinations we feel it is our ethical obligation to do a screening for suspicious oral lesions as a service for the study participant even though it is not a part of the study. Hygienists as well as dentists are trained to look for suspicious lesions although only dentists are allowed to diagnose. This process is similar to oral cancer screenings that may be provided to the public at wellness fairs and other venues. This same procedure was followed in the dental ancillary study that was part of the Atherosclerosis Risk In Communities (ARIC) study.
The study examination is much like a screening exam as radiographs and other diagnostics are

not available to the examiners. This is indicated on the recommendation sheet and we also indicate to participants that only their dentist can provide a complete exam. Because radiographs are not available and recording of incipient carious lesions are not in the protocol, it means that any caries calls made by the examiner are are caries that already mature and have progressed into the dentin. The recommendations sheet is a simplified version of the sheet that was used in the NHANES studies and uses the same algorithms to derive recommendations. Recommendation #4 is derived from the oral lesion screening when the examiner noted a suspicious soft tissue lesion that should be followed up by a dentist for a definitive diagnosis.

3. ***Alert reports. Include [also] immediate notification to designated contact person (or legal guardian) in addition to notification to his/her primary physician.***

The immediate notification includes the person designated by the study participant for this purpose. We anticipate that study participants will exercise the opportunity to have study results (and possibly other communications) directed to individuals of their choice. No reasons need to be given, since they may reflect language preference, literacy, power of attorney and others.

4. ***Indicate to whom are study results communicated.***

As above, field center personnel ask the study participant for instructions on who the study results should be sent to. Per study protocol, staff offers to send the report(s) to the study participant or his/her designee, and the participant is asked whether a copy of the report should be sent to the provider of health care identified by the participant. These choices are kept on record and the participant's decision to send study results to a health practitioner is recorded on the informed consent form and initialed by participant.

5. ***"Not Applicable" in the table about HTN actions is confusing; consider another heading.***

We have revised this table according to this recommendation.

6. ***ECG alert criteria should specify heart rate criteria in addition to rhythm and conduction criteria. These should be consistent with sleep study heart rate criteria.***

The ECG alert criteria are well established and widely used in other studies, several NHLBI sponsored cohort studies among them. The sleep heart rate criteria are consistent with guidelines from the American Academy of Sleep Medicine and represent the state of the science from sleep epidemiology research. It is not apparent to us how to achieve consistency in the heart rate criteria used by these fields of study.

7. ***LBBB is not emergent.***

Indeed, an LBBB is described as a potential emergency that should be confirmed by the HCHS/SOL physician while the study participant is on the premises. Action is taken at the discretion of the clinician.

8. ***Recommendations for immediate referral to MD for BP should be modified to say "recommend contact with MD" rather than "recommend being seen by an MD.".***

The text in the protocol manual has been modified to read "to consult with a physician"

9. Do joint replacements require antibiotic prophylaxis for an oral exam?.

The April 19, 2007 guidelines of the American Heart association and the American Dental Association do not specify antibiotic prophylaxis for an oral exam in individuals with a joint replacement as those guidelines focused on cardiovascular conditions. The orthopedics society has not yet revised their guidelines, so we continue to require antibiotic prophylaxis for joint replacements, which for this study means that participants with joint replacements do not receive the periodontal portion of the oral examination.

10. How were the referral values chosen for the wide range of measurements reported by HCHS/SOL?

Threshold and referral values are based on (and adhere to) guidelines where available. Similarly, the informational materials that accompany the report of results provided to the study participants makes use of educational material made available by professional societies, top the degree that this is possible.

Sleep studies. The Urgent Referral Values are based on guidelines developed by two of the largest sleep epidemiological studies - Sleep Heart Health Study and the Outcomes of Sleep Disorders in Older Men study. These initially were determined by consensus of sleep experts and reviewed by the safety monitoring boards of each of these studies. The criteria for quantifying disease severity are based on standard guidelines from the American Academy of Sleep Medicine. I can provide a reference if needed.

The criteria for hearing-related referrals are based on established guidelines (American-Speech-Hearing and language Association), published norms (tympanometric values) and clinical expertise. They have been used for more than 15 years in our two epidemiological studies of hearing loss.

Observational Study Monitoring Board Meeting Materials

June 3rd, 2008

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1. RECRUITMENT

Overview: Tables 1.1-1.4 present the results to date of both household and subject recruitment at each of the four HCHS/SOL Field Centers. Data collected via the recruitment forms and entered into the study data management system (DMS) provide the basis for these summaries. The Household Screening Contact Form (SCT) is the source of the final status code for households for which recruitment has been attempted. Distributions of these status codes are provided in Table 1.1, and summary response rates are provided in Table 1.2. The Individual Eligibility Form (ELE) contains the status of potential participants for whom additional screening and scheduling of appointments have been attempted. Distributions of these status codes are provided in Table 1.3. Distributions of participants attending the clinic are based on the Demographic Form (PIE) and are presented in Table 1.4.

Sample Design Recap: The HCHS/SOL study design is based on a probability sample of households in the target areas identified for each Field Center. The sample was selected in two stages. At the first stage, Census block groups were randomly selected from a frame of all block groups in the target areas, stratified by Hispanic concentration and SES (education $<$ vs. $\geq$ high school). At the second stage, households were randomly selected within block groups from a list frame of postal addresses obtained from a private vendor (Genesys). Oversampling was implemented at both stages of selection in order to improve the efficiency of the screening process. Block groups with a higher concentration of Hispanic households were sampled at a disproportionately higher rate at the first stage, and addresses for which a commercial list match yielded a Hispanic surname were selected at a disproportionately higher rate at the second stage. The final sample was randomly divided into three subsamples corresponding to the three years planned for recruitment. Therefore, each year's sample is representative of the Field Center target areas at the time the sample was selected (Fall 2007).

Recruitment: Recruitment began in early February following OMB approval. The recruitment protocol consists of three steps: (1) initial mailing to the selected addresses; (2) telephone screening (optional); and (3) in-person contacts. Following a quick screener to determine if the household was 'age/Hispanic eligible' (i.e., included at least one person who was Hispanic/Latino aged 18-74 years) and to classify the eligible households into two groups based on household members' ages (Group 1 = all eligible persons aged 45-74 years vs. Group 2 = any other combination of ages), subsampling was invoked to control the age distribution of study participants. The subsampling rates are specific to each field center and are based on the estimated age distributions of Hispanic households in that geographic area (source = CPS 2005). All households in Group 1 are selected (with probability = 1), and a fraction of those in Group 2 are selected. Initial subsampling rates for Group 2 households are 20.6%, 13.9%, 38.5%, and 11.5% for the Bronx, Chicago, Miami, and San Diego Field Centers respectively. Careful monitoring of the resulting age distributions is underway, in order to adjust these subsampling rates as needed.

The sample size of addresses to be selected was calculated based on various assumptions about the recruitment process under both a 'realistic' and 'worst' case scenario. A total of 95,780 addresses were selected in order to yield 14,359 households screened and 16,000 clinic participants (with 62.5% aged 45-74 years and 38.5% aged 18-44 years). The sample was randomly divided into three subsamples corresponding to the three years of recruitment. The first year's sample was then sent to the Field Centers, and the areas to be 'worked' in the first quarter were selected (purposively).

Household Screening Results: Table 1.1 provides a summary of household recruitment as of May 13. Overall contact was made with 82% of the 2,665 sampled addresses finalized to date, and screening interviews were completed with 87.9% of those contacted. The proportion of screened households that were age/Hispanic eligible was 69%, and of those, 43% were subsampled according to their age

distributions. Of the subsampled households, 73% agreed to participate in the study, and rosters of household members were obtained.

As a measure of recruitment progress thus far, a 'screening success rate' was computed as the product of the household screening rate and the conditional household response rate. Addresses for which no contact was made were assumed to result in legitimate households (not retail centers, offices, group homes, etc.) at the same rate that contacted households did. This imputation factor was used in computing the household screening rate. Overall, the screening success rate is 57% for these first three months of recruitment.

The in-text table below summarizes the key eligibility and response rates expected for recruitment (best case scenario) by Field Center versus the rates observed to date and reported in Tables 1.1 and 1.2.

	Bronx		Chicago		Miami		San Diego	
	Exp.	Obs.	Exp.	Obs.	Exp.	Obs.	Exp.	Obs.
Age/Hispanic Eligibility Rate	71%	64%	62%	45%	91%	77%	69%	81%
Age Subsampling Rate	40%	39%	31%	65%[1]	59%	57%	27%	28%
Screening Success Rate	66%	63%	64%	54%	62%	44%	65%	75%
Household Yield Rate[2]	19%	14%	12%	13%	33%	18%	12%	16%

[1]Note that age subsampling was not in effect in Chicago for 6 weeks of recruitment.
[2]Household Yield Rate = the number of households agreeing to participate divided by the total number of addresses finalized.

Participant Screening Results: Once a household agrees to participate and all age/Hispanic eligible members are listed on the roster, the recruitment staff attempt to contact each person individually to re-confirm eligibility (additional exclusion criteria include active duty military status, intent to move out of the area, and homebound status) and schedule a clinic visit. This person-level screening may take place in the home at the same time as the household screening interview or through a telephone call shortly thereafter. Completion of the individual screening form (ELE) and attendance at the scheduled clinic visit constitute the final recruitment milestones.

Table 1.3 provides the person-level screening results to date. Overall, screening was completed and eligibility confirmed for 89% of the 715 individuals for whom contacts were attempted, and 79% of those agreed to schedule a clinic visit. Of the 484 appointments scheduled thus far, 51% (248) have attended the visit as scheduled, 41% of the visits are still pending (scheduled clinic date past May 13), and 8% did not show up for the exam.

In terms of overall performance of person-level screening compared to what was expected, the sample design assumed that 70%-80% (worst to best case) of persons in households agreeing to participate would attend the clinic. If we assume that the clinic visits still pending are completed at the same rate as those whose dates have passed [248/(248+39) or 86%], then an estimated success rate defined as the proportion attending or soon to attend the clinic out of those for whom screening was attempted is 58% [(248+170)/715].

Figure 1.1 presents participant accrual, expected and observed, to date by Field Center and month. The expected rate was calculated based on the following assumptions:

- To achieve a per Field Center sample size of 4,000 over three years of recruitment, a rate of 1333 clinic visits per year is required, or approximately n=112 per month.
- Field Centers would begin recruitment with a few staff members and ramp up slowly; therefore recruitment rates of ¼ n, ½ n, and ¾ n were assumed for months 1-2, 3-4, and 5-6, respectively, such that sites would be recruiting at the target rate of n=112 per month by month 7.

Recruitment began in February, 2008, following OMB approval. Months represented in the graph are therefore defined as Feb. 15 – Mar 15; Mar 15 – Apr 15; and Apr 15 – May 15. Note however that not all sites were able to begin recruitment in February. For this report, different start dates were not incorporated for each site, but can be going forward.

Target Sampling Distributions: Table 1.4 provides demographic distributions for the 250 participants attending the clinic as of May 13 (note that ELE forms were not yet entered for 2 participants, hence the discrepancy between tables 1.3 and 1.4). The characteristics for which distributions are provided correspond to variables key to the sampling design. Additional demographic information is provided in Section 4 of the report (see Table 4.1). The subsampling of households according to age distribution has resulted in the intended target being met thus far, yielding 61% - 68% of subjects in the older age category (45-74 years) in three of the four Field Centers (expected rate = 62.5%). Note that the age subsampling procedure was not in effect in Chicago for 6 of the 12 weeks of recruitment reported, hence the younger than expected age distribution of participants in that Field Center (44% aged 45-74 years).

The distribution according to country-of-origin is fairly consistent with the target distributions expected for each Field Center. Note that block groups with a high concentration of persons from Central/South America were targeted for early screening in Miami, and a more even distribution between that group and Cubans is expected going forward. Note also that 9 of the 18 persons from the Bronx classified as 'Other' were from the Dominican Republic, also as expected. The fact that 22% of Bronx participants were from Central/South America was unexpected.

Oversampling was not invoked with respect to SES or gender. SES was included as a stratification variable in the first stage of sampling to ensure diversity in the study sample, but no target distribution was set. Note that gender is collected on the household roster, so as these data are processed, we will be able to investigate whether (clinic attendance) response rates vary by gender in the future.

Table 1.1 Household Recruitment Screening Status by Center (source SCT)

Result of Screening	Bronx (N=526)		Chicago (N=635)		Miami (N=788)		San Diego (N=716)		Overall (N=2665)	
	N	%	N	%	N	%	N	%	N	%
Households Finalized	525		630		788		716		2659	
Address not a household	30	5.7	85	13.5	42	5.3	28	3.9	185	7.0
Unable to contact after repeated attempts	54	10.3	106	16.8	136	17.3	7	1.0	303	11.4
HH Contacted	441	84.0	439	69.7	610	77.4	681	95.1	2171	81.7
Households Contacted	441		439		610		681		2171	
HH refused to be screened	47	10.7	66	15.0	93	15.3	46	6.8	252	11.6
HH screening never completed, eligibility unknown	1	0.2	0	0.0	7	1.2	2	0.3	10	0.5
HH screening completed	393	89.1	373	85.0	510	83.6	633	93.0	1909	87.9
Households interviewed	393		373		510		633		1909	
HH not age/Hispanic eligible	143	36.4	207	55.5	117	22.9	123	19.4	590	30.9
HH age/Hispanic eligible	250	63.6	166	44.5	393	77.1	510	80.6	1319	69.1
Households age/Hispanic eligible	250		166		393		510		1319	
HH not selected age subsample	153	61.2	59	35.5	171	43.5	366	71.8	749	56.8
HH selected age subsample	97	38.8	107	64.5	222	56.5	144	28.2	570	43.2
Households selected age subsampling	97		107		222		144		570	
HH refused to participate	21	21.7	25	23.4	82	36.9	26	18.1	154	27.0
HH agreed to participate	76	78.4	82	76.6	140	63.1	118	81.9	416	73.0

Based on data created on May 13, 2008.

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HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 1.2 Household Screening and Response Rates by Center (source SCT)

Result of Screening	Bronx (N=526)	Chicago (N=635)	Miami (N=788)	San Diego (N=716)	Overall (N=2665)
	%	%	%	%	%
Household screening rate*[1]	79.95	70.67	69.18	92.04	77.91
Conditional household response rate[2]	78.35	76.64	63.06	81.94	72.98
Screening success rate[3]	62.64	54.16	43.62	75.42	56.86
***Screening imputation factor[4]**	0.94	0.84	0.94	0.96	0.92

*Note:

(1) Household Screening Rate = the percentage of households screened among all addresses that were households. The denominator excludes addresses that were not households (e.g., vacant lots, retail centers) and includes a proportion of the households for which contact was not made (see Screening Imputation Factor defined in (4) below).

(2) Conditional Household Response Rate = the percentage of households agreeing to participate among all households screened, eligible, and selected.

(3) Screening Success Rate = the product of the Household Screening Rate and the Conditional Household Response Rate.

(4) Screening imputation factor = the number of households contacted divided by the number of addresses with known status (households contacted + addresses that were not households).

Based on data created on May 13, 2008.

HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 1.3 Scheduled and Completed Clinic Visits by Center (source ELE and visit forms)

Result of Screening	Bronx (N=122)		Chicago (N=137)		Miami (N=286)		San Diego (N=170)		Overall (N=715)	
	N	%	N	%	N	%	N	%	N	%
Persons Screened for Eligibility	120		130		284		170		704	
Unable to Contact or Refused Screen	0	0.0	1	0.8	38	13.4	33	19.4	72	10.2
Completed Screen and Ineligible	1	0.8	0	0.0	2	0.7	0	0.0	3	0.4
Completed Screen and Eligible	119	99.2	129	99.2	244	85.9	137	80.6	629	89.4
Eligible Persons	119		129		244		137		629	
Eligible and refuse Visit	0	0.0	3	2.3	56	23.0	72	52.6	131	20.8
Eligible and agree to Visit	119	100.0	126	97.7	188	77.1	65	47.5	498	79.2
Agree to Visit	119		126		188		65		498	
Appointment not Scheduled	1	0.8	3	2.4	10	5.3	0	0.0	14	2.8
Appointment Scheduled	118	99.2	123	97.6	178	94.7	65	100.0	484	97.2
Scheduled Appointments	118		123		178		65		484	
Attended Visit	53	44.9	54	43.9	98	55.1	43	66.2	248	51.2
Pending Clinic Visit	39	33.1	62	50.4	78	43.8	18	27.7	197	40.7
Past due Clinic Visit	26	22.0	7	5.7	2	1.1	4	6.2	39	8.1

Based on data created on May 13, 2008.

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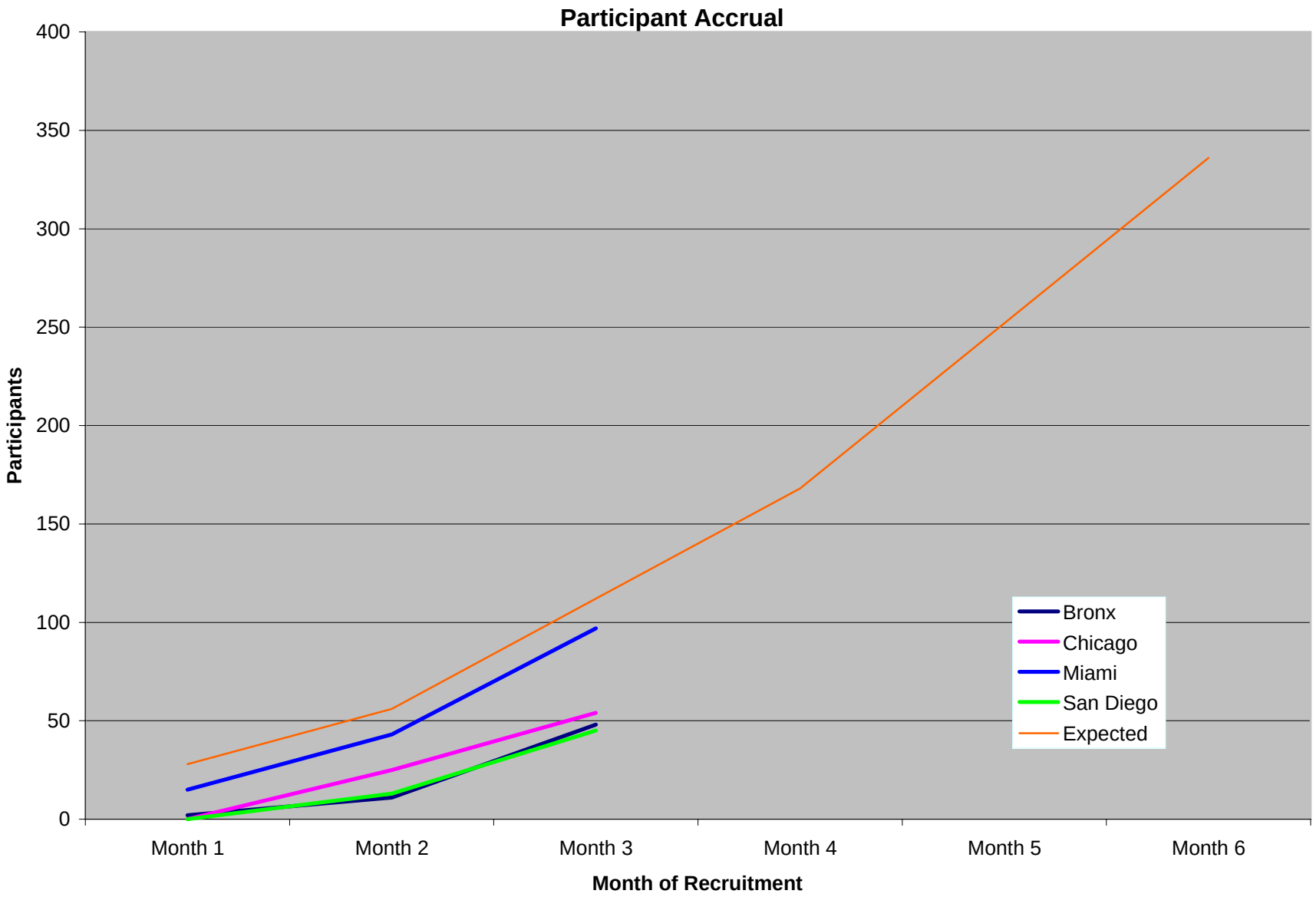
Participant Accrual
400
350
300
250
200
150
100
50
0
Participants
Month 1
Month 2
Month 3
Month 4
Month 5
Month 6
Month of Recruitment
Bronx
Chicago
Miami
San Diego
Expected

Table 1.4 Clinic Visit Participant Demographic Distribution by Center (source PIE)

Participant Characteristics	Bronx (N=51)		Chicago (N=55)		Miami (N=97)		San Diego (N=47)		Overall (N=250**)	
	N	%	N	%	N	%	N	%	N	%
Age Distribution										
a. Clinic Participants Ages 18-44	17	33.3	31	56.4	36	37.1	14	29.8	98	39.2
b. Clinic Participants Ages 45+	34	66.7	24	43.6	59	60.8	32	68.1	149	59.6
Hispanic/Latino Heritage*										
a. Central/South American	11	21.6	7	12.7	56	57.7	0	0.0	74	29.6
b. Cuban	0	0.0	1	1.8	28	28.9	2	4.3	31	12.4
c. Mexican	0	0.0	28	50.9	4	4.1	43	91.5	75	30.0
d. Puerto Rican	19	37.3	17	30.9	3	3.1	1	2.1	40	16.0
e. More than one of above	2	3.9	2	3.6	3	3.1	0	0.0	7	2.8
f. Other*	18	35.3	0	0.0	2	2.1	1	2.1	21	8.4
Education (SES surrogate)										
a. Less than High School Education	24	47.1	29	52.7	37	38.1	26	55.3	116	46.4
b. High School Education or Higher	27	52.9	24	43.6	58	59.8	19	40.4	128	51.2
Gender										
a. Female	35	68.6	34	61.8	58	59.8	32	68.1	159	63.6
b. Male	16	31.4	21	38.2	39	40.2	15	31.9	91	36.4

Note: *Other Hispanic / Latino heritage includes Spain (2), Caribbean Islands (6), Dominican Republic (9), U.S.A. (3).
**Total N for this table is number of demographic forms (PIE/PIS) with non-missing age.

Based on data created on May 13, 2008.

2. DATA MANAGEMENT

The following tables and figures summarize the recent baseline examination clinic visits for the Hispanic Community Health Study / Study of Latinos (HCHS/SOL). Data is current as of May 13, 2008 when the analysis files were created for this report from a "snapshot" of the shared study database. Data transfer from the field centers to the Coordinating Center occurs through the use of a web-based remote data entry application (the HCHS/SOL Data Management System). Administration of the interviews and capturing the results of the exam procedures for the study is through direct entry using the DMS. Electronic records from the reading centers are also uploaded directly into the database once expert over-reads or interpretations are complete, and the individual study is designated for transfer to the Coordinating Center (e.g. diet recall, ECG, pulmonary function, sleep).

Table 2.1 presents the completion of baseline examination visits since March, 2008. There are 257 participants in the course of completing the baseline examination. Of that number, 250 had complete (all forms present) or partially complete (1 or more forms absent) questionnaire batteries. Another 7 individuals had minimal amount of information present and were categorized as missing/pending submission of forms. The presence of exam procedure forms and reading center records provide the counts for "Exam Procedure" where 250 individuals have complete or partially complete procedural forms in the database. The HCHS/SOL steering committee designated a core subset of examination procedures and questionnaires in order to prioritize collection of data if the participant was unable to complete the full protocol visit. Core questionnaires and procedures are jointly present for 74% participants seen to date. (Note, arrival of some core procedure records is still pending transfer from central agencies to the Coordinating Center).

Table 2.2 displays the completion rate for the 22 form questionnaire battery by field center. The overall presence of individual forms is uniformly high across centers with most forms collected at a rate of 95% or higher.

Table 2.3 shows the completion rate for the 7 procedure forms captured directly into the DMS software from each field center. The overall presence of individual procedures forms is extremely high across centers with most forms collected at a rate of 98% or higher.

Table 2.4 presents the rates of missing items from the questionnaire battery by center. The DMS software tracks the occurrence of validly missing fields (e.g. skip patterns, confirmed blank fields or unknowns) in the study data. Questionnaires designed with highly structured response patterns (e.g. items designed for Likert scale scoring) have significantly fewer missing items compared to forms with predominantly open ended text field response patterns (e.g. the participant identifier form). Note the difference missing item response rates in two centers that are making use of the DMS item status flags to explicitly denote validly missing vs. two centers that do not. The Coordinating Center is in the process of bringing online an automated query and resolution report in the DMS so that the field centers can self-check completeness of forms as they are collected in real time.

Table 2.5 looks at rates of missing items from the procedure results that are entered directly into the DMS by field center technicians. The rate of missing items is minimal (0 to 1%) lower except for some audiometric forms (8 to 9%) where some measurements are expected to be missing due to the nature of those test procedures (e.g. no response threshold at a given frequency). The audiometry reading center graders conduct remote over-reads of all components of this portion of the exam using a special interface developed by the Coordinating Center for their use.

Tables 2.6 through 2.17 are a series of analyses that look in-depth at the administration times for the questionnaire battery and the baseline procedures. The time course of the clinic visit is tracked for each participant on a check-off sheet which provides the capability to note start and stop times for each component of the HCHS/SOL baseline examination. The steering committee was concerned about the length of the examination and the resulting participant burden so these analyses are provided to quantify how long an "average" visits takes and if that varies from the time predicted during protocol development. The time taken by participants in changing clothes and a snack/lunch break are included in with the procedures to improve the overall estimate of the length of the visit. Overall average time for administration of the questionnaires is 131 minutes and 236 for the procedures.

Table 2.18 compares the duration of a HCHS/SOL visit by the same subgroups provided in earlier tables (2.6 to 2.17) that highlights the differences by center, age, gender, and education. It is important to note that the neurocognitive test battery and ankle / brachial pressures are only obtained from participants age 45 and older, so age-related differences are confounded by the study protocol.

Table 2.19 presents summary times for an abbreviated, priority, subset of questionnaires and procedures called the "core" examination visit. The reduced content core visit cuts approximately 3 hours of time from the length of the full protocol clinic visit.

Tables 2.20 and 2.21 compare the expected times for the questionnaires and procedures in the baseline visit to the actual observed times reported by the field centers. Overall there is a difference of 14 minutes longer in practice for administration of the questionnaire battery and 9 minutes longer for the exam procedures compared to the expected times.

Table 2.22 computes the duration of the baseline visit in a slightly different manner from previous tables. The duration of the visit is computed here using the "clock in" time at the start of administration of informed consent to the participant to the "clock out" time at the end of the exit interview. The average duration of the visit computed in this way accounts for more down time and breaks that occurs outside of explicit administration time for a specific questionnaire or procedure. The average length of the clinic computed in this fashion is approximately 430 minutes (around 7.25 hours).

Table 2.1 Completion of Baseline Exams by Center

Baseline Examination Visits	Bronx (N=54)		Chicago (N=56)		Miami (N=99)		San Diego (N=48)		Overall (N=257)	
	N	%	N	%	N	%	N	%	N	%
Questionnaire battery										
a. Complete	44	81.5	49	87.5	69	69.7	38	79.2	200	77.8
b. Partial	7	13.0	6	10.7	28	28.3	9	18.8	50	19.5
c. Missing/Pending	3	5.6	1	1.8	2	2.0	1	2.1	7	2.7
Exam Procedure										
a. Complete	36	66.7	50	89.3	75	75.8	20	41.7	181	70.4
b. Partial	15	27.8	5	8.9	22	22.2	27	56.3	69	26.9
c. Missing/Pending	3	5.6	1	1.8	2	2.0	1	2.1	7	2.7
Full Protocol Visit										
a. Complete	35	64.8	45	80.4	67	67.7	18	37.5	165	64.2
b. Partial	16	29.6	10	17.9	30	30.3	29	60.4	85	33.1
c. Missing/Pending	3	5.6	1	1.8	2	2.0	1	2.1	7	2.7
Full Core Visit										
a. Core Questionnaires	49	90.7	51	91.1	91	91.9	42	87.5	233	90.7
b. Core Procedures	40	74.1	51	91.1	92	92.9	20	41.7	203	79.0
c. Complete Core Qx and Procedures	39	72.2	47	83.9	86	86.9	19	39.6	191	74.3

Definitions: Complete = all forms (or procedures) are present per data collection schedule
Partial = at least one form (or procedure) is missing
Full protocol visit = Complete questionnaire battery + Complete exam procedures
Missing/Pending = forms and/or procedures not present – minimal information exists

Based on data created on May 13, 2008.
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Table 2.2. Form level Completion Rates for Baseline Questionnaires by Center

Interview Forms	Field Center: Bronx (n=54)		Chicago (n=56)		Miami (n=99)		San Diego (n=48)	
	# Present	% Present	# Present	% Present	# Present	% Present	# Present	% Present
ALEA - Alcohol use	53	98.1	56	100.0	97	98.0	47	97.9
DBEA - Dietary behavior	53	98.1	55	98.2	97	98.0	47	97.9
ECEA - Economic	53	98.1	56	100.0	98	99.0	47	97.9
HCEA - Health Care	51	94.4	55	98.2	98	99.0	45	93.8
HEEA - Hearing exam Qx	50	92.6	56	100.0	97	98.0	46	95.8
HHEA - Hearing history	50	92.6	54	96.4	94	94.9	44	91.7
IDEA - Personal identifiers	54	100.0	53	94.6	98	99.0	42	87.5
MHEA - Medical history	53	98.1	55	98.2	96	97.0	47	97.9
MUEA - Medical use	54	100.0	56	100.0	98	99.0	48	100.0
NEEA* - Neurocognitive	35	94.6	25	100.0	62	98.4	33	97.1
OCEA - Occupation	51	94.4	55	98.2	96	97.0	45	93.8
OHEA - Oral Health	50	92.6	55	98.2	82	82.8	46	95.8
PAEA - Physical Activity	53	98.1	55	98.2	97	98.0	47	97.9
PIEA - Personal information	53	98.1	55	98.2	98	99.0	47	97.9
RSEA - Respiratory history	51	94.4	56	100.0	97	98.0	46	95.8
SCEA - Sociocultural	53	98.1	55	98.2	97	98.0	47	97.9
SFEA - SF -12	53	98.1	55	98.2	96	97.0	47	97.9
SLEA - Sleep history	51	94.4	55	98.2	96	97.0	45	93.8
SNEA - Social network	51	94.4	55	98.2	98	99.0	46	95.8
TBEA - Tobacco use	53	98.1	56	100.0	97	98.0	47	97.9
WBEA - Well being	51	94.4	55	98.2	98	99.0	46	95.8
WHEA - Weight history	49	90.7	55	98.2	93	93.9	46	95.8
Overall	1125	96.1	1183	98.5	2080	97.1	1001	96.1

Based on data created on May 13, 2008.
Note: * Denominator for neurocognitive battery (NEE) is number of participants over age 44.

Table 2.3 Form level Completion Rates for Baseline Procedures by Center

Exam Related Forms	Field Center							
	Bronx (n=54)		Chicago (n=56)		Miami (n=98)		San Diego (n=47)	
	# Present	% Present	# Present	% Present	# Present	% Present	# Present	% Present
ABPA* - Ankle brachial pressures	37	100.0	25	100.0	62	100.0	33	100.0
ANTA - Anthopometry	53	98.1	56	100.0	98	100.0	47	100.0
AUDA - Audiometry	51	94.4	56	100.0	97	99.0	46	97.9
BIOA - Biospecimen collection	52	96.3	56	100.0	98	100.0	47	100.0
OTOA - Otoscopy	49	90.7	56	100.0	97	99.0	46	97.9
SBPA - Sitting blood pressure	54	100.0	56	100.0	98	100.0	47	100.0
TYMA - Tympanometry	50	92.6	56	100.0	97	99.0	45	95.7
Overall	346	95.8	361	100.0	647	99.5	311	98.7

Based on data created on May 13, 2008.
Note: *Denominator for ankle brachial pressures is number of participants over age 44.

Table 2.4 Rates of Missing Items for Questionnaires by Center

Interview Forms	Center							
	Bronx (n=54)		Chicago (n=56)		Miami (n=99)		San Diego (n=48)	
	# Missing	% Missing	# Missing	% Missing	# Missing	% Missing	# Missing	% Missing
ALEA - Alcohol use	0	0.0	1	0.2	1	0.1	6	1.1
DBEA - Dietary behavior	0	0.0	20	2.8	0	0.0	0	0.0
ECEA - Economic	1	0.2	6	1.3	1	0.1	3	0.8
HCEA - Health Care	1	0.0	0	0.0	0	0.0	14	0.6
HEEA - Hearing exam Qx	0	0.0	0	0.0	0	0.0	1	0.1
HHEA - Hearing history	0	0.0	0	0.0	0	0.0	0	0.0
IDEA - Personal identifiers	435	7.3	212	3.6	7136	66.2	2819	61.0
MHEA - Medical history	0	0.0	16	0.2	58	0.5	5	0.1
MUEA - Medical use	12	0.1	39	0.3	114	0.6	31	0.3
NEEA - Neurocognitive	0	0.0	30	5.0	0	0.0	1	0.1
OCEA - Occupation	18	0.4	6	0.1	35	0.4	5	0.1
OHEA - Oral Health	0	0.0	1	0.0	1	0.0	4	0.1
PAEA - Physical Activity	6	0.2	5	0.1	61	0.9	55	1.8
PIEA - Personal information	3	0.2	8	0.4	16	0.4	14	0.8
RSEA - Respiratory history	18	0.5	44	1.1	183	2.7	57	1.8
SCEA - Sociocultural	1	0.1	0	0.0	2	0.1	0	0.0
SFEA - SF -12	0	0.0	0	0.0	4	0.3	1	0.2
SLEA - Sleep history	0	0.0	0	0.0	45	1.0	0	0.0
SNEA - Social network	0	0.0	0	0.0	0	0.0	2	0.5
TBEA - Tobacco use	1	0.1	0	0.0	2	0.1	0	0.0
WBEA - Well being	1	0.1	0	0.0	28	1.3	2	0.2
WHEA - Weight history	17	2.2	61	6.9	165	11.1	56	7.6
Overall	514	0.9	449	0.7	7852	7.4	3076	6.0

Based on data created on May 13, 2008.

Table 2.5 Rates of Missing Items for Baseline Procedures by Center

Exam Related Forms	Center							
	Bronx (n=54)		Chicago (n=56)		Miami (n=98)		San Diego (n=47)	
	# Missing	% Missing	# Missing	% Missing	# Missing	% Missing	# Missing	% Missing
ABPA* - Ankle brachial pressures	0	0.0	0	0.0	0	0.0	11	1.9
ANTA - Anthopometry	0	0.0	13	1.7	5	0.4	3	0.5
AUDA - Audiometry	131	8.6	157	9.4	230	7.9	119	8.6
BIOA - Biospecimen collection	10	0.1	54	0.5	145	0.8	77	0.9
OTOA - Otoscopy	1	0.1	16	1.8	0	0.0	0	0.0
SBPA - Sitting blood pressure	0	0.0	1	0.1	1	0.1	1	0.1
TYMA - Tympanometry	0	0.0	5	0.5	5	0.3	0	0.0
Overall	142	0.9	246	1.5	386	1.3	211	1.5

Based on data created on May 13, 2008.

Table 2.6 Average Completion Time for Questionnaires by Center

Interview Forms	Bronx (N=51)		Chicago (N=55)		Miami (N=98)		San Diego (N=47)		Overall (N=251*)	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ALEA - Alcohol use	2	0.2	2	0.2	7	4.5	4	0.6	4	1.7
CLEA - Claudication	2	0.2	1	0.2	2	0.7	2	0.2	2	0.3
DBEA - Dietary behavior	5	1.3	5	1.0	5	1.3	13	2.3	6	0.8
ECEA - Economic	4	0.7	4	0.3	3	0.2	4	0.3	4	0.2
HCEA - Healty Care	7	1.3	5	0.6	4	0.3	6	0.6	5	0.3
HHEA - Hearing history	6	0.5	4	0.5	9	0.6	4	0.2	7	0.3
IDEA - Personal identifiers	8	0.5	5	0.5	9	1.4	13	0.9	9	0.6
MHEA - Medical history	9	0.8	9	0.5	10	0.6	10	0.8	10	0.3
MUEA - Medication and Suppliment use	6	0.9	8	1.3	10	0.8	12	1.7	9	0.6
NEEA - Neurocognitive	18	0.6	18	2.0	17	0.9	17	0.3	18	0.5
OCEA - Occupation	8	0.5	8	0.6	7	0.3	9	0.7	8	0.3
OHEA - Oral Health	5	1.1	12	2.0	10	0.8	7	1.4	9	0.6
PAEA - Physical Activity	5	0.8	5	0.3	6	0.6	9	1.4	6	0.4
PIEA - Personal information	6	0.5	7	1.2	7	0.5	8	0.6	7	0.4
RSEA - Respiratory history	9	0.5	7	0.3	9	0.4	9	0.5	9	0.2
SCEA - Sociocultural	7	0.4	8	0.6	8	0.8	8	0.4	8	0.4
SFEA - SF - 12	5	0.5	6	0.5	5	0.3	6	0.4	5	0.2
SLEA - Sleep history	7	0.5	7	0.3	7	0.3	11	2.1	8	0.4
SNEA - Social network	2	0.2	2	0.2	2	0.2	3	0.7	3	0.2
TBEA - Tobacco use	3	0.2	3	0.3	5	1.3	4	0.4	4	0.5
WBEA - Well being	4	0.3	4	0.2	4	0.2	5	0.3	4	0.1
WHEA - Weight history	4	1.4	3	0.2	3	0.3	3	0.3	3	0.3
Overall Questionnaires	109	5.0	118	4.9	141	6.6	146	5.1	131	3.2

*Note: N based on number of exam checklist forms (CHK) present with tracking information for start and end times

Based on data created on May 13, 2008.

Table 2.7 Average Completion Time for Baseline Procedures by Center

Exam Procedures	Bronx (N=51)		Chicago (N=55)		Miami (N=98)		San Diego (N=47)		Overall (N=251)	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ABPA - Ankle brachial pressures	9	0.5	15	1.5	20	1.2	17	1.2	16	0.7
ANTA - Anthropometry	7	0.4	9	0.4	11	0.7	9	0.6	9	0.3
Audiometry Exam Battery*	25	1.4	30	1.7	36	1.9	35	1.4	32	1.0
BIOA - Biospecimen collection	7	0.6	29	3.3	17	0.9	25	3.1	19	1.1
INIA - Oral/Dental Exam	17	1.7	33	2.0	22	1.3	25	1.2	24	0.9
SBPA - Sitting blood pressure	8	0.3	12	0.5	11	0.5	10	0.6	11	0.3
Spirometry	10	0.8	14	0.8	16	1.6	12	1.0	14	0.7
ECG	9	1.4	16	0.6	20	0.9	18	1.2	16	0.6
Post-Glucose Load draw	3	0.5	6	0.6	3	0.2	6	0.9	4	0.3
Diet recall past 24 hrs.	40	1.9	41	1.9	38	1.4	43	2.4	40	0.9
Consent, etc.	26	1.5	20	1.0	48	1.6	32	1.7	35	1.1
Changing clothes	10	2.2	12	0.6	11	1.3	13	2.1	12	0.6
Snack and/or lunch	17	3.7	17	1.6	23	1.7	20	3.4	20	1.1
Activity monitor instructions	18	1.6	13	1.4	16	1.1	13	2.2	15	0.7
Exit Interview	4	1.2	13	0.9	16	1.0	14	1.5	14	0.7
Overall Procedures	164	5.8	252	6.7	273	6.2	215	6.5	236	4.2

Note: N based on number of exam checklist forms (CHK) present with tracking information for start and end times

*HEEA - Hearing Ex, AUDA - Audiometry, OTOA - Otoscopy, TYMA - Tympanometry.
Based on data created on May 13, 2008.

Table 2.8 Average Completion Time for English Questionnaires by Center

Interview Forms	Bronx (N=12)		Chicago (N=17)		Miami (N=4)		San Diego (N=8)		Overall (N=41)	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ALEA - Alcohol use	2	0.4	2	0.4	2	0.3	4	1.4	2	0.3
CLEA - Claudication	1	0.6	1	0.3	1	0.6	1	0.6	1	0.2
DBEA - Dietary behavior	8	4.7	4	1.2	4	1.2	15	7.0	7	2.0
ECEA - Economic	3	0.4	3	0.4	4	2.0	4	0.7	4	0.3
HCEA - Healty Care	3	0.4	4	0.6	4	0.3	7	3.0	4	0.6
HHEA - Hearing history	7	1.2	4	0.7	8	2.0	4	0.5	5	0.6
IDEA - Personal identifiers	7	1.0	5	1.0	6	0.5	11	1.1	7	0.6
MHEA - Medical history	7	0.8	7	0.8	7	1.2	8	2.7	7	0.6
MUEA - Medication and Suppliment use	3	0.8	10	3.6	5	1.8	8	2.8	7	1.8
NEEA - Neurocognitive	18	0.7	17	4.0	16	-	17	0.6	17	2.0
OCEA - Occupation	7	0.9	7	1.2	5	1.5	7	1.1	7	0.7
OHEA - Oral Health	4	0.7	15	4.3	6	0.6	4	0.4	9	2.0
PAEA - Physical Activity	4	0.5	5	0.6	6	1.5	8	1.2	5	0.5
PIEA - Personal information	7	0.7	7	1.3	8	1.4	7	1.2	7	0.6
RSEA - Respiratory history	9	1.2	7	0.4	9	2.2	9	1.1	8	0.5
SCEA - Sociocultural	8	0.6	10	1.4	10	2.0	6	0.9	8	0.7
SFEA - SF - 12	3	0.3	5	0.7	10	4.9	5	0.8	5	0.5
SLEA - Sleep history	6	1.5	7	0.5	6	2.2	11	2.9	8	0.8
SNEA - Social network	2	0.3	2	0.4	2	0.6	4	2.1	3	0.5
TBEA - Tobacco use	3	0.3	3	0.3	2	0.9	4	0.7	3	0.2
WBEA - Well being	4	0.9	5	0.5	6	2.2	5	0.5	5	0.4
WHEA - Weight history	10	6.6	2	0.2	4	2.5	3	0.9	4	1.8
Overall Questionnaires	106	10.5	120	10.5	90	29.1	119	7.8	113	6.1

Based on data created on May 13, 2008.

Table 2.9 Average Completion Time for Baseline Procedures Where English is Preferred Language by Center

Exam Procedures	Bronx (N=12)		Chicago (N=17)		Miami (N=4)		San Diego (N=8)		Overall (N=41)	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ABPA - Ankle brachial pressures	9	2.2	13	1.8	19	3.5	17	7.3	13	1.5
ANTA - Anthropometry	6	0.5	8	0.7	8	2.1	9	1.1	8	0.4
Audiometry Exam Battery*	27	1.7	28	2.4	31	12.0	37	4.2	30	1.7
BIOA - Biospecimen collection	9	1.6	39	9.1	15	-	27	4.2	26	5.0
INIA - Oral/Dental Exam	22	3.7	35	5.0	18	2.6	22	2.0	27	2.7
SBPA - Sitting blood pressure	9	0.5	13	0.7	11	2.3	11	0.8	11	0.5
Spirometry	8	1.1	13	1.6	10	2.6	9	0.8	11	0.9
ECG	8	0.7	17	1.5	25	2.3	19	2.0	15	1.1
Post-Glucose Load draw	3	0.9	7	1.2	3	-	7	2.9	6	0.8
Diet recall past 24 hrs.	37	3.0	39	2.5	45	5.2	33	6.0	38	1.8
Consent, etc.	33	3.8	17	1.5	43	8.5	31	4.7	27	2.2
Changing clothes	10	0.5	12	0.8	-	-	10	-	11	0.7
Snack and/or lunch	21	4.9	14	2.3	19	1.5	17	-	16	1.9
Activity monitor instructions	18	3.5	10	0.8	11	1.3	14	1.0	13	1.3
Exit Interview	5	0.0	14	1.6	11	1.3	11	1.6	12	1.1
Overall Procedures	180	11.4	253	12.7	206	43.7	207	10.4	218	8.9

*HEEA - Hearing Ex, AUDA - Audiometry, OTOA - Otoscopy, TYMA - Tympanometry.
Based on data created on May 13, 2008.

Table 2.10 Average Completion Time for Spanish Questionnaires by Center

Interview Forms	Bronx (N=37)		Chicago (N=38)		Miami (N=92)		San Diego (N=39)		Overall (N=206)	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ALEA - Alcohol use	2	0.2	2	0.3	8	4.7	4	0.6	5	2.1
CLEA - Claudication	2	0.3	1	0.2	2	0.7	2	0.3	2	0.4
DBEA - Dietary behavior	4	0.8	5	1.3	5	1.4	13	2.5	6	0.9
ECEA - Economic	4	1.0	4	0.4	3	0.2	4	0.4	4	0.2
HCEA - Healty Care	8	1.8	5	0.8	4	0.3	6	0.6	5	0.4
HHEA - Hearing history	6	0.6	4	0.6	9	0.6	5	0.3	7	0.3
IDEA - Personal identifiers	8	0.6	5	0.6	9	1.4	13	1.0	9	0.8
MHEA - Medical history	10	1.1	9	0.7	10	0.6	10	0.8	10	0.4
MUEA - Medication and Suppliment use	6	0.8	7	1.0	10	0.9	13	1.8	9	0.6
NEEA - Neurocognitive	19	0.8	18	2.2	17	0.9	17	0.4	18	0.6
OCEA - Occupation	8	0.6	8	0.7	7	0.4	10	0.8	8	0.3
OHEA - Oral Health	5	1.4	10	2.1	10	0.8	7	1.7	9	0.7
PAEA - Physical Activity	5	1.2	5	0.4	6	0.6	9	1.7	6	0.5
PIEA - Personal information	6	0.6	7	1.7	7	0.5	9	0.7	7	0.4
RSEA - Respiratory history	9	0.5	8	0.4	9	0.5	9	0.5	9	0.3
SCEA - Sociocultural	6	0.5	6	0.5	8	0.9	8	0.5	8	0.4
SFEA - SF - 12	5	0.7	6	0.7	5	0.3	6	0.4	5	0.2
SLEA - Sleep history	7	0.5	7	0.5	7	0.3	10	2.5	8	0.5
SNEA - Social network	2	0.3	2	0.3	2	0.2	3	0.7	3	0.2
TBEA - Tobacco use	3	0.2	3	0.3	5	1.4	4	0.4	4	0.6
WBEA - Well being	4	0.3	4	0.2	4	0.2	5	0.3	4	0.1
WHEA - Weight history	3	0.3	3	0.2	3	0.3	3	0.3	3	0.2
Overall Questionnaires	109	5.9	117	5.4	143	6.8	152	5.6	134	3.7

Based on data created on May 13, 2008.

Table 2.11 Average Completion Time for Baseline Procedures Where Spanish is Preferred Language by Center

Exam Procedures	Bronx (N=37)		Chicago (N=38)		Miami (N=92)		San Diego (N=39)		Overall (N=206)	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ABPA - Ankle brachial pressures	9	0.4	15	2.1	20	1.2	17	1.1	17	0.8
ANTA - Anthropometry	7	0.6	9	0.5	11	0.7	9	0.6	10	0.4
Audiometry Exam Battery*	25	1.8	31	2.2	36	2.0	35	1.4	33	1.1
BIOA - Biospecimen collection	6	0.7	24	2.1	17	0.9	23	4.3	17	0.9
INIA - Oral/Dental Exam	16	2.0	33	1.8	22	1.3	25	1.3	23	0.9
SBPA - Sitting blood pressure	8	0.4	12	0.7	11	0.5	10	0.7	10	0.3
Spirometry	11	1.0	14	0.9	16	1.7	13	1.2	14	0.9
ECG	10	1.9	16	0.6	20	0.9	17	1.4	17	0.7
Post-Glucose Load draw	3	0.6	6	0.7	3	0.3	6	0.9	4	0.3
Diet recall past 24 hrs.	39	2.1	42	2.5	38	1.5	46	2.5	40	1.0
Consent, etc.	24	1.4	21	1.3	49	1.7	33	1.8	36	1.2
Changing clothes	8	2.7	12	0.9	11	1.3	14	2.5	11	0.7
Snack and/or lunch	11	4.9	18	2.1	23	1.7	21	4.3	21	1.3
Activity monitor instructions	18	1.7	13	1.9	17	1.1	13	2.4	16	0.8
Exit Interview	5	1.6	12	1.0	17	1.1	15	1.8	15	0.8
Overall Procedures	158	7.0	252	8.0	277	6.2	217	7.5	240	4.8

*HEEA - Hearing Ex, AUDA - Audiometry, OTOA - Otoscopy, TYMA - Tympanometry.
Based on data created on May 13, 2008.

Table 2.12 Average Completion Time for Questionnaires by Age Groups and SES

Interview Forms	Less Than High School Diploma				At Least High School Diploma			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ALEA - Alcohol use	2.8	0.4	2.4	0.3	10.2	7.9	2.8	0.3
CLEA - Claudication	0.9	0.2	1.6	0.2	2.3	1.5	1.8	0.2
DBEA - Dietary behavior	5.5	1.3	8.2	2.1	3.6	0.9	7.4	1.2
ECEA - Economic	3.5	0.3	4.2	0.5	3.4	0.2	3.6	0.3
HCEA - Healty Care	4.3	0.6	6.4	0.8	4.5	0.6	5.5	0.5
HHEA - Hearing history	4.7	0.5	6.1	0.5	7.3	0.8	7.5	0.6
IDEA - Personal identifiers	8.6	1.0	9.3	0.7	7.1	0.5	10.1	1.9
MHEA - Medical history	7.0	0.5	10.8	0.7	8.4	0.7	10.6	0.6
MUEA - Medication and Suppliment use	7.1	1.2	9.7	0.9	8.3	1.7	9.7	0.8
NEEA - Neurocognitive	21.5	11.5	18.6	0.9	10.9	3.4	17.2	0.5
OCEA - Occupation	7.3	0.6	7.3	0.5	8.1	0.5	8.0	0.5
OHEA - Oral Health	6.4	0.6	9.3	1.5	11.3	1.7	7.1	0.7
PAEA - Physical Activity	5.9	0.5	7.0	1.1	5.0	0.3	5.9	0.8
PIEA - Personal information	6.5	0.6	7.5	0.5	6.7	0.5	7.1	0.5
RSEA - Respiratory history	8.3	0.5	8.7	0.4	8.5	0.6	8.7	0.4
SCEA - Sociocultural	7.3	0.5	7.4	0.4	7.7	0.9	8.5	0.9
SFEA - SF - 12	5.2	0.4	5.6	0.4	4.9	0.3	5.6	0.5
SLEA - Sleep history	8.3	0.7	7.1	0.4	8.2	1.2	7.9	0.9
SNEA - Social network	2.0	0.2	2.5	0.2	2.7	0.5	2.8	0.3
TBEA - Tobacco use	3.1	0.3	3.3	0.3	5.4	2.2	3.9	0.3
WBEA - Well being	4.4	0.3	4.3	0.2	4.1	0.2	4.5	0.3
WHEA - Weight history	2.8	0.3	3.2	0.2	2.1	0.2	4.4	0.9
Overall Questionnaires	109.5	4.0	135.7	4.9	125.8	10.8	143.6	3.9

Based on data created on May 13, 2008.

Table 2.13 Average Completion Time for Baseline Procedures by Age Groups and SES

Exam Procedures	Less Than High School Diploma				At Least High School Diploma			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ABPA - Ankle brachial pressures	1.0	-	16.5	0.8	11.4	3.4	16.4	1.1
ANTA - Anthropometry	8.5	0.5	9.1	0.5	9.9	0.9	9.5	0.6
Audiometry Exam Battery*	28.1	1.7	33.9	1.5	31.1	2.9	33.2	1.5
BIOA - Biospecimen collection	22.1	3.7	17.5	2.0	17.6	1.7	17.8	2.1
INIA - Oral/Dental Exam	27.7	1.6	23.4	2.1	24.0	1.5	23.0	1.4
SBPA - Sitting blood pressure	11.5	0.7	10.2	0.5	10.3	0.5	10.8	0.5
Spirometry	11.8	0.7	12.4	1.0	14.7	2.4	15.6	1.3
ECG	14.5	0.9	19.2	1.5	15.6	0.9	15.5	0.8
Post-Glucose Load draw	5.4	0.7	3.1	0.4	4.0	0.5	4.6	0.5
Diet recall past 24 hrs.	35.4	2.1	42.2	1.9	37.1	1.6	42.2	1.7
Consent, etc.	26.2	1.9	38.9	2.1	35.6	2.6	36.3	1.9
Changing clothes	10.2	1.2	12.5	1.5	10.8	1.1	12.1	1.0
Snack and/or lunch	23.2	3.1	19.7	1.7	18.2	2.6	20.1	1.9
Activity monitor instructions	13.7	1.9	17.5	1.7	15.4	1.4	14.1	1.0
Exit Interview	13.0	2.0	15.5	1.5	14.4	1.3	14.3	0.9
Overall Procedures	225.9	9.2	239.9	8.1	233.7	9.1	246.1	7.3

*HEEA - Hearing Ex, AUDA - Audiometry, OTOA - Otoscopy, TYMA - Tympanometry.
Based on data created on May 13, 2008.

Table 2.14 Average Completion Time for Spanish Questionnaires by Age Groups and SES

Interview Forms	Less Than High School Diploma				At Least High School Diploma			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ALEA - Alcohol use	2.7	0.5	2.5	0.4	12.7	10.3	2.8	0.3
CLEA - Claudication	0.9	0.2	1.6	0.2	2.7	1.8	1.8	0.2
DBEA - Dietary behavior	5.5	1.6	8.7	2.3	3.9	1.1	6.1	1.0
ECEA - Economic	3.4	0.3	4.3	0.6	3.5	0.3	3.5	0.3
HCEA - Healty Care	3.8	0.3	6.5	0.9	4.8	0.8	5.9	0.6
HHEA - Hearing history	5.0	0.6	6.3	0.5	8.1	1.0	7.4	0.6
IDEA - Personal identifiers	8.6	1.2	9.5	0.8	7.1	0.6	11.0	2.3
MHEA - Medical history	7.3	0.6	11.2	0.7	8.9	0.9	10.6	0.6
MUEA - Medication and Suppliment use	7.8	1.6	9.6	0.9	8.3	1.7	9.9	0.9
NEEA - Neurocognitive	21.5	11.5	18.6	1.0	14.4	3.6	16.8	0.4
OCEA - Occupation	7.9	0.6	7.4	0.6	8.1	0.6	8.0	0.5
OHEA - Oral Health	6.1	0.5	9.6	1.6	11.3	1.8	6.8	0.4
PAEA - Physical Activity	6.0	0.5	7.2	1.2	5.2	0.4	6.1	1.0
PIEA - Personal information	6.4	0.7	7.4	0.5	6.9	0.6	7.0	0.5
RSEA - Respiratory history	8.6	0.7	8.7	0.4	8.3	0.7	9.1	0.5
SCEA - Sociocultural	7.5	0.5	7.3	0.5	7.5	1.1	8.4	1.1
SFEA - SF - 12	5.7	0.4	5.6	0.4	5.0	0.3	5.6	0.5
SLEA - Sleep history	7.8	0.4	7.1	0.4	8.6	1.5	8.1	1.1
SNEA - Social network	2.0	0.2	2.6	0.2	2.9	0.6	2.6	0.3
TBEA - Tobacco use	3.1	0.3	3.2	0.3	6.2	2.9	4.1	0.3
WBEA - Well being	4.3	0.3	4.3	0.2	4.0	0.2	4.4	0.3
WHEA - Weight history	3.0	0.4	3.3	0.2	2.0	0.2	3.6	0.4
Overall Questionnaires	112.1	4.5	138.9	5.0	133.7	13.7	144.1	4.4

Based on data created on May 13, 2008.

Table 2.15 Average Completion Time for Baseline Procedures Where Spanish is Preferred Language by Age Groups and SES

Exam Procedures	Less Than High School Diploma				At Least High School Diploma			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ABPA - Ankle brachial pressures	1.0	-	17.0	0.9	12.0	4.0	17.0	1.3
ANTA - Anthropometry	9.0	0.6	9.3	0.5	10.9	1.2	9.6	0.7
Audiometry Exam Battery*	27.3	1.6	34.6	1.6	32.4	3.6	33.3	1.8
BIOA - Biospecimen collection	17.6	2.0	17.7	2.0	16.8	1.7	16.5	1.6
INIA - Oral/Dental Exam	28.1	1.9	22.2	1.9	24.0	1.7	22.1	1.5
SBPA - Sitting blood pressure	11.2	0.9	10.1	0.5	10.2	0.6	10.9	0.6
Spirometry	12.0	0.7	12.5	1.1	16.3	3.0	16.4	1.5
ECG	15.1	1.1	19.3	1.6	16.0	1.1	15.4	0.8
Post-Glucose Load draw	4.9	0.7	3.0	0.3	3.8	0.6	4.4	0.5
Diet recall past 24 hrs.	37.3	2.6	41.0	1.9	36.6	1.9	43.1	2.0
Consent, etc.	28.1	2.4	40.0	2.2	37.4	3.0	37.5	2.1
Changing clothes	9.7	1.4	12.1	1.7	10.6	1.2	12.6	1.4
Snack and/or lunch	24.4	3.9	19.9	1.8	18.8	3.1	21.7	2.2
Activity monitor instructions	13.4	2.4	17.6	1.7	15.5	1.7	15.1	1.1
Exit Interview	13.5	2.5	15.9	1.6	14.7	1.5	14.9	1.1
Overall Procedures	228.2	11.4	242.5	8.4	242.4	10.5	250.4	8.6

*HEEA - Hearing Ex, AUDA - Audiometry, OTOA - Otoscopy, TYMA - Tympanometry.
Based on data created on May 13, 2008.

Table 2.16 Average Completion Time for English Questionnaires by Age Groups and SES

Interview Forms	Less Than High School Diploma				At Least High School Diploma			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ALEA - Alcohol use	3.4	0.6	1.0	0.4	1.5	0.3	2.7	0.8
CLEA - Claudication	0.9	0.4	1.0	0.6	0.4	0.2	1.9	0.4
DBEA - Dietary behavior	6.1	2.5	2.5	0.9	2.5	0.3	12.8	4.9
ECEA - Economic	3.6	0.7	3.5	0.3	2.9	0.3	4.3	0.6
HCEA - Healty Care	5.6	2.2	5.0	1.5	3.2	0.4	4.1	0.7
HHEA - Hearing history	3.9	0.7	4.8	0.6	4.8	1.0	6.8	1.4
IDEA - Personal identifiers	8.5	2.0	5.5	1.5	7.0	0.9	6.5	0.9
MHEA - Medical history	6.4	0.9	6.5	2.6	6.6	0.6	9.3	1.3
MUEA - Medication and Supplement use	4.1	0.9	7.0	2.1	8.4	4.9	8.0	2.2
NEEA - Neurocognitive	-	-	18.0	2.0	2.0	2.0	19.1	2.0
OCEA - Occupation	5.7	1.4	5.0	1.8	8.1	1.1	8.0	1.1
OHEA - Oral Health	6.3	1.6	7.0	1.5	11.3	4.5	8.3	3.8
PAEA - Physical Activity	6.1	1.3	4.5	1.0	4.3	0.7	5.2	0.7
PIEA - Personal information	6.8	1.2	9.0	0.9	5.8	0.7	7.6	1.6
RSEA - Respiratory history	7.4	0.9	7.3	0.8	8.9	1.3	7.3	0.7
SCEA - Sociocultural	6.9	1.2	10.0	1.7	8.4	1.7	9.2	1.1
SFEA - SF - 12	4.0	0.5	7.0	2.8	4.7	0.7	5.9	1.2
SLEA - Sleep history	9.3	2.5	6.8	0.3	7.0	1.4	6.8	0.8
SNEA - Social network	2.0	0.4	1.5	0.3	2.1	0.4	3.8	1.4
TBEA - Tobacco use	3.2	0.5	3.7	0.3	2.3	0.4	3.2	0.5
WBEA - Well being	5.1	0.7	5.7	1.8	4.2	0.6	4.9	0.8
WHEA - Weight history	2.3	0.9	2.8	0.5	2.4	0.4	8.9	5.9
Overall Questionnaires	101.5	9.1	93.8	20.7	100.3	10.2	140.8	9.5

Based on data created on May 13, 2008.

Table 2.17 Average Completion Time for Baseline Procedures Where English is Preferred Language by Age Groups and SES

Exam Procedures	Less Than High School Diploma				At Least High School Diploma			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
ABPA - Ankle brachial pressures	-	-	14.2	0.7	9.5	9.5	13.8	2.1
ANTA - Anthropometry	7.0	0.8	8.6	1.9	6.6	0.5	8.8	0.9
Audiometry Exam Battery*	29.2	5.0	31.3	4.7	26.7	2.6	32.7	2.1
BIOA - Biospecimen collection	36.1	12.7	26.5	20.5	20.1	5.1	24.0	9.4
INIA - Oral/Dental Exam	26.0	3.6	47.3	18.2	24.2	3.4	24.5	3.1
SBPA - Sitting blood pressure	12.1	1.1	12.0	1.8	10.5	0.9	10.3	0.6
Spirometry	10.1	1.2	11.8	1.7	9.4	1.7	12.3	2.0
ECG	13.4	2.1	20.6	3.4	14.1	1.9	16.2	2.2
Post-Glucose Load draw	7.9	1.4	5.3	3.3	4.6	1.1	6.2	2.5
Diet recall past 24 hrs.	30.2	2.9	46.8	4.3	38.8	2.7	39.4	3.5
Consent, etc.	20.3	3.0	24.2	3.0	29.3	4.6	30.8	4.2
Changing clothes	11.8	0.5	11.5	1.5	11.4	2.5	10.7	0.7
Snack and/or lunch	17.2	5.1	16.7	6.2	16.4	3.3	14.1	3.1
Activity monitor instructions	15.3	2.9	11.7	3.5	15.0	2.7	9.6	1.2
Exit Interview	11.6	2.0	13.3	4.4	13.5	2.3	11.0	1.8
Overall Procedures	216.3	17.0	232.6	42.8	205.5	16.7	226.3	11.1

*HEEA - Hearing Ex, AUDA - Audiometry, OTOA - Otoscopy, TYMA - Tympanometry.
Based on data created on May 13, 2008.

Table 2.18 Summary Times for Overall Examination Visit

Subgroup	Questionnaires			Examination Procedure			Overall Visit		
	Median	Mean	s.e.	Median	Mean	s.e.	Median	Mean	s.e.
Overall Centers									
Bronx	107	108	4.9	163	164	5.8	274	272	8.8
Chicago	116	117	4.8	254	252	6.7	362	368	10.0
Miami	129	133	7.7	273	273	6.2	414	406	11.0
San Diego	140	143	6.0	212	215	6.5	363	358	9.1
Age 18-44									
Females	103	109	4.1	225	228	8.1	330	338	10.0
Males	104	121	18.1	225	228	10.2	335	349	24.8
Age 45+									
Females	131	134	5.6	239	238	6.7	378	371	8.9
Males	138	139	4.6	257	251	8.9	406	390	11.3
Education									
Less than H.S	125	119	5.1	236	235	6.2	359	353	8.5
H.S. and Above	125	134	5.2	240	241	5.7	367	375	8.9

Based on data created on May 13, 2008.

Table 2.19 Summary Times for Core Examination Visit

Subgroup	Questionnaires			Examination Procedure			Overall Visit		
	Median	Mean	s.e.	Median	Mean	s.e.	Median	Mean	s.e.
Overall Centers									
Bronx	58	58	3.0	71	71	3.3	129	130	5.2
Chicago	60	63	3.3	96	105	4.1	157	167	6.0
Miami	71	74	6.9	102	100	4.5	176	173	8.5
San Diego	79	80	3.2	88	91	4.3	168	169	6.0
Age 18-44									
Females	53	55	2.4	84	85	3.3	135	140	4.5
Males	53	65	17.2	86	77	11.1	134	141	21.5
Age 45+									
Females	75	75	4.3	98	100	3.0	177	175	5.1
Males	78	81	2.8	101	102	4.1	180	181	5.5
Education									
Less than H.S	69	65	3.8	93	96	3.1	157	160	5.0
H.S. and Above	64	74	4.6	94	93	3.6	161	167	6.3

Based on data created on May 13, 2008.

Table 2.20 Observed vs. Expected Questionnaire Completion Times

Interview Forms	Observed Time	Expected Time	Difference (Obs-Exp) Mean	s.e	Average Deviation (abs(Obs-Exp)/n)
ALEA - Alcohol use	4	2	2	1.74	1.74
CLEA - Claudication	2	2	-0	0.34	0.32
DBEA - Dietary behavior	6	3	3	0.77	0.75
ECEA - Economic	4	2	2	0.18	0.18
HCEA - Healty Care	5	4	1	0.32	0.29
HHEA - Hearing history	7	4	3	0.30	0.27
IDEA - Personal identifiers	9	7	2	0.64	0.59
MHEA - Medical history	10	7	3	0.33	0.28
MUEA - Medication and Suppliment use	9	6	3	0.56	0.48
NEEA - Neurocognitive	18	16	2	0.53	0.47
OCEA - Occupation	8	7	1	0.26	0.18
OHEA - Oral Health	9	5	4	0.64	0.61
PAEA - Physical Activity	6	5	1	0.42	0.38
PIEA - Personal information	7	9	-2	0.35	0.27
RSEA - Respiratory history	9	9	-0	0.23	0.15
SCEA - Sociocultural	8	7	1	0.37	0.33
SFEA - SF - 12	5	5	0	0.21	0.17
SLEA - Sleep history	8	6	2	0.42	0.40
SNEA - Social network	3	2	1	0.16	0.15
TBEA - Tobacco use	4	3	1	0.52	0.50
WBEA - Well being	4	4	0	0.12	0.09
WHEA - Weight history	3	2	1	0.30	0.29
Overall Questionnaires	131	117	14	3.24	2.65

Based on data created on May 13, 2008.

Table 2.21 Observed vs. Expected Procedure Completion Times

Exam Procedures	Observed Time	Expected Time	Difference (Obs-Exp) Mean	s.e	Average Deviation (abs(Obs-Exp)/n)
ABPA - Ankle brachial pressures	16	17	-1	0.68	0.46
ANTA - Anthropometry	9	8	1	0.32	0.25
Audiometry Exam Battery*	32	22	10	0.96	0.86
BIOA - Biospecimen collection	19	12	7	1.15	1.00
INIA - Oral/Dental Exam	24	22	2	0.87	0.65
SBPA - Sitting blood pressure	11	11	-0	0.26	0.18
Spirometry	14	15	-1	0.73	0.59
ECG	16	14	2	0.57	0.46
Post-Glucose Load draw	4	2	2	0.26	0.23
Diet recall past 24 hrs.	40	45	-5	0.91	0.60
Consent, etc.	35	15	20	1.10	1.05
Changing clothes	12	16	-4	0.57	0.39
Snack and/or lunch	20	10	10	1.12	1.02
Activity monitor instructions	15	10	5	0.72	0.66
Exit Interview	14	8	6	0.66	0.59
Overall Procedures	236	227	9	4.21	2.60

Based on data created on May 13, 2008.

Table 2.22 Average Duration* of the Baseline Visit by Subgroup

Subgroup	Duration of Baseline Visit (hours)				
	Min	Max	Median	Mean	s.e.
Overall Centers					
Bronx	275	530	390	379	25.0
Chicago	150	527	411	402	10.3
Miami	113	575	427	426	8.8
San Diego	280	646	483	480	11.0
Age 18-44					
Females	257	560	412	408	7.7
Males	160	465	384	369	13.3
Age 45+					
Females	113	646	464	451	10.8
Males	150	575	477	462	12.2
Less than H.S	160	646	428	434	8.8
H.S. and Above	113	577	427	430	8.2
Date of Visit					
March-April	113	646	432	435	7.1
May	160	540	412	410	10.0

*Duration = Elapsed time in minutes from Informed Consent to end of Exit Interview

Based on data created on May 13, 2008.

3. QUALITY CONTROL

Tables 3.1 – 3.2
To estimate the reliability of laboratory and anthropometric measurements, some participants provided an additional sample of blood or urine, or had anthropometric measurements repeated by a second technician on the same visit. The same technician obtains replicate biospecimen samples by either (1) drawing 2nd tube of blood or sample, or (2) dividing urine into 2 separate containers. These additional QC specimens are labeled with a *phantom* participant ID that is indistinguishable from other ID numbers, so that the laboratory is blinded to the QC process. The sampling rate for replicate measurements is at least 5% ($n \geq$ 12 out of the approximately 250 participants with completed clinic visits).

The statistics in Tables 3.1 and 3.2 (a-e) that are most relevant are those that quantify the degree of measurement error. The total variance of the study data (σ_T^2) can be partitioned into two components: the measurement error component (σ_e^2) and the true variation between and within individuals in the study population (σ_b^2), so that $\sigma_T^2 = \sigma_b^2 + \sigma_e^2$. Because the QC specimens were collected at the same time, the true value for the original and QC measurement should be identical, and any differences between the two specimen measurements is attributed to the laboratory measurement process. Therefore, the square root of measurement error component (σ_e^2) is referred to in the report as the "Lab SD". A reliability coefficient $R = \sigma_b^2 / \left(\sigma_b^2 + \sigma_e^2 \right)$ close to 1 suggests that only a small proportion of the total variance due is due measurement error (or laboratory) variation. The coefficient of variation (CV) is a measure of within-specimen variation expressed as a percentage of the mean, CV = $100 * \sigma_e / \mu$. For example, if the mean cholesterol value for all QC replicates is 250 mg/dl and the measurement error variation is 15 mg/dl, then the CV is 6%. Assuming the cholesterol values are normally distributed about 250 mg/dl, a CV of 6% means that 95% of the time the reported value will fall between 220 and 280 (within 2 SD). The limitation of the CV is that it shows how well the laboratory can measure a specimen with a cholesterol value of 250, but not a specimen with a value of 100 or 500. The reliability coefficient does a better job of quantifying measurement error across the range of observed values. The statistics under the "Difference" column indicate whether there is evidence of a systematic difference between measurements obtained from the original and QC specimens. Again, since the specimens were obtained at the same time, we would not expect to see any systematic difference in measurements.

As the reliability of a measurement decreases, power to detect a given effect of the measurement on a response also decreases (assuming a constant sample size). Because power is so compromised for reliabilities below 0.60, analyses for this study should focus on variables with reliability coefficients of 0.60 or higher. Ideally, we would like all reliabilities to be above 0.80.

The reliability coefficients for all of the anthropometric measures are excellent (0.98 or higher). Similarly, all but a few laboratory measurements have reliabilities above 0.85. Those that are below 0.85 have mean values that are close to 0. In such circumstances, the reliability statistic is not very meaningful.

Table 3.3 and Figure 3.1
The spirometry QC procedures involve assigning quality grades for FEV_1 and FVC (quality codes) based on the number of acceptable maneuvers. The QC grades are assigned as follows:

A = 3-acceptable curves, plus largest and second largest value within 100 ml
B = 2-acceptable curves, plus largest and second largest value within 150 ml
C = 2-acceptable curves, plus largest and second largest value within 200 ml
D = 1 acceptable curve plus no end of test requirement for FVC QF
F = no acceptable curves

We have provided a subset of QC results from the Spirometry Reading Center based on data from 229 participants in the attached report. Table 3.3 shows the average quality grade for FEV_1 (green) and FVC (red) by field center, where the codes have been converted these numeric values as follows: A=4, B=3, C=2, D=1, F=0. It is important to note that almost a year had elapsed between training and the beginning of clinic exams. As a result, each of the field centers will receive a booster training. This booster training has already occurred at Miami and San Diego – and thus, is a likely explanation for the higher mean quality grades at those field centers. Chicago and the Bronx will have received their booster training by the end of May, 2008.

The top graph of Figure 3.1 shows the trends of average FVC and FEV_1 quality scores over the course of the study thus far. The bottom part of the graph shows the percentage of participants with non-repeatable tests (quality grades D and F) over time. Quality grades of C or better are usable for analysis, while grade F is not (grade D may or may not be used). The goal is to keep the proportion of non-repeatable tests below 10% throughout the study. Although we have not quite met this goal, we expect to see improvements on this metric after the site visits to Chicago and the Bronx.

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Table 3.1 Reliability of Anthropometric Measurements

	QC Pairs						Difference				
	N	Outliers removed	Mean	Lab SD (1)	Reliab (2)	CV (3)	Mean	95% CI		Prop > 0	pval (4)
Standing height in cm (ANTA2)	12	0	156.8	0.29	1.00	0.2	0.00	-0.24	0.24	0.50	1.000
Weight (kg) (ANTA4)	12	0	70.8	0.05	1.00	0.1	0.01	-0.04	0.05	0.50	1.000
Fat (%) (ANTA5)	12	0	33.2	0.97	0.99	2.9	0.53	-0.21	1.28	0.63	0.727
Impedance (ohms) (ANTA6)	12	0	548.8	5.42	1.00	1.0	1.00	-3.49	5.49	0.56	1.000
Fat mass (kg) (ANTA7)	11	0	22.0	0.10	1.00	0.5	0.17	-0.19	0.54	0.43	1.000
Lean body mass (kg) (ANTA8)	11	0	45.8	0.10	1.00	0.2	-0.17	-0.50	0.17	0.50	1.000
Total body water (kg) (ANTA9)	11	0	33.5	0.07	1.00	0.2	-0.12	-0.35	0.12	0.50	1.000
Waist Girth (cm) (ANTA10A)	12	0	95.0	1.63	0.98	1.7	0.00	-1.36	1.36	0.40	1.000

Outliers (diff > 3 SD) excluded unless row label is preceded by *
(1) Standard deviation = square root (within-subject variance)
(2) The reliability coefficient is an estimate of the correlation between repeated measurements
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs
(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

Based on data retrieved at the CC on May 14, 2008
Created by HC002601 (AGH) on 14MAY08 14:49

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Table 3.2a Reliability of laboratory measurements (Tubes 1 & 2)

Variable		QC Pairs N	QC Pairs Outliers removed	QC Pairs Mean	Lab SD (1)	Reliab (2)	CV (3)	Difference Mean	Difference 95% CI		Difference Prop > 0	Difference pval (4)
LABA66	Total cholesterol	18	0	211.0	3.88	0.99	1.8	0.39	-2.21	2.99	0.50	1.000
LABA67	Triglycerides	18	0	156.1	4.09	1.00	2.6	-1.67	-4.30	0.97	0.29	0.143
LABA68	HDL cholesterol	18	0	51.7	0.75	1.00	1.4	-0.33	-0.81	0.14	0.27	0.227
LABA69	LDL cholesterol	18	0	128.1	3.25	0.99	2.5	1.00	-1.13	3.13	0.59	0.629
LABA74	Alanine aminotransferase	18	0	31.2	0.82	1.00	2.6	0.33	-0.19	0.86	0.70	0.344
LABA75	Aspartate aminotransferase	18	0	26.1	1.12	0.99	4.3	-0.72	-1.39	-0.05	0.29	0.180
LABA76	Serum creatinine	18	0	0.8	0.05	0.95	5.7	-0.02	-0.05	0.01	0.35	0.332
LABA82	Iron	18	0	80.7	3.17	0.99	3.9	-1.17	-3.22	0.89	0.40	0.607
LABA83	Total Iron Bindind Capacity	18	0	345.3	11.13	0.95	3.2	-2.78	-10.1	4.59	0.38	0.454
LABA84	Transferrin saturation	18	0	24.2	0.67	1.00	2.8	-0.22	-0.66	0.21	0.40	0.754
LABA91	High-sensitivity CRP	17	1	2.0	0.06	1.00	3.1	0.18	-0.24	0.59	0.27	0.118

Outliers (diff > 3 SD) excluded unless row label is preceded by *
(1) Standard deviation = square root (within-subject variance)
(2) The reliability coefficient is an estimate of the correlation between repeated measurements
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs
(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

Based on data retrieved at the CC on May 14, 2008
Created by HC002602a (AGH) on 19MAY08 13:29

HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 3.2b Reliability of laboratory measurements (Tube 3)

Variable		QC Pairs N	QC Pairs Outliers removed	QC Pairs Mean	Lab SD (1)	Reliab (2)	CV (3)	Difference Mean	Difference 95% CI		Difference Prop > 0	Difference pval (4)
LABA1	White blood count	28	1	6.5	0.47	0.90	7.3	0.32	-0.13	0.78	0.68	0.108
LABA2	Red blood count	28	1	4.7	0.14	0.88	3.0	-0.11	-0.21	-0.00	0.35	0.169
LABA3	Hemoglobin (Hgb)	28	1	13.5	0.44	0.93	3.2	-0.39	-0.75	-0.03	0.33	0.152
LABA4	Hematocrit	28	1	40.2	1.41	0.86	3.5	-1.11	-2.07	-0.16	0.32	0.087
LABA5	Mean corpuscular volume	29	0	85.7	0.73	0.99	0.9	-0.31	-0.68	0.05	0.25	0.146
LABA6	Mean corpuscular Hgb	28	1	28.9	0.27	0.99	0.9	-0.20	-0.44	0.04	0.41	0.523
LABA7	Mean corpuscular Hgb conc.	28	1	33.5	0.35	0.96	1.0	-0.06	-0.33	0.21	0.60	0.424
LABA8	Red cell distribution width	28	1	13.9	0.10	1.00	0.7	0.07	-0.03	0.17	0.56	0.804
LABA9	Platelet count	28	1	259.5	17.00	0.94	6.6	12.45	-15.7	40.62	0.52	1.000
LABA10	% neutrophils	28	1	53.5	4.83	0.78	9.0	0.90	-2.55	4.34	0.50	1.000
LABA11	% lymphocytes	27	2	33.4	2.61	0.91	7.8	-0.45	-3.48	2.58	0.55	0.832
LABA12	% monocytes	28	1	7.9	1.09	0.65	13.9	-0.41	-1.06	0.23	0.22	0.031
LABA13	% eosiniphils	28	1	3.7	0.55	0.96	14.8	0.10	-0.29	0.50	0.50	1.000
LABA14	% basophils	27	1	0.7	0.36	0.60	49.9	-0.14	-0.42	0.14	0.43	1.000
LABA23	Neutrophil count	28	1	3.5	0.54	0.78	15.7	0.22	-0.16	0.61	0.69	0.076
LABA24	Lymphocyte count	28	1	2.2	0.33	0.76	15.1	0.08	-0.15	0.32	0.57	0.664
LABA25	Monocyte count	28	1	0.5	0.07	0.70	14.8	0.00	-0.04	0.05	0.50	1.000
LABA26	Eosinophil count	28	1	0.2	0.04	0.95	17.7	0.01	-0.02	0.04	0.50	1.000
LABA27	Basophil count	27	1	0.0	0.03	0.55	109.5	-0.01	-0.03	0.01	0.40	1.000
LABA72	Glycosylated Hgb	28	1	6.4	0.11	1.00	1.7	0.06	-0.13	0.25	0.33	0.688

Outliers (diff > 3 SD) excluded unless row label is preceded by *
(1) Standard deviation = square root (within-subject variance)
(2) The reliability coefficient is an estimate of the correlation between repeated measurements
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs
(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

Based on data retrieved at the CC on May 14, 2008
Created by HC002602b (AGH) on 19MAY08 13:29

HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 3.2c Reliability of laboratory measurements (Tube 4 & 5)

Variable		QC Pairs N	QC Pairs Outliers removed	QC Pairs Mean	Lab SD (1)	Reliab (2)	CV (3)	Difference Mean	Difference 95% CI		Difference Prop > 0	Difference pval (4)
LABA70	Glucose, fasting	13	1	103.1	3.29	0.98	3.2	4.07	-6.58	14.73	0.42	0.774
LABA73	Insulin, fasting	13	0	15.1	2.25	0.92	14.9	-0.15	-1.95	1.65	0.56	1.000

Outliers (diff > 3 SD) excluded unless row label is preceded by *
(1) Standard deviation = square root (within-subject variance)
(2) The reliability coefficient is an estimate of the correlation between repeated measurements
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs
(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

Based on data retrieved at the CC on May 14, 2008
Created by HC002602c (AGH) on 19MAY08 13:33

HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 3.2d Reliability of laboratory measurements (Tube 10)

Variable		QC Pairs N	Outliers removed	Mean	Lab SD (1)	Reliab (2)	CV (3)	Difference Mean	95% CI		Prop > 0	pval (4)
LABA71	Glucose, post OGTT	14	0	126.6	3.27	1.00	2.6	0.36	-2.15	2.86	0.58	0.774
LABA90	Insulin, post OGTT	14	0	117.7	11.53	0.99	9.8	4.57	-3.94	13.08	0.67	0.388

Outliers (diff > 3 SD) excluded unless row label is preceded by *
(1) Standard deviation = square root (within-subject variance)
(2) The reliability coefficient is an estimate of the correlation between repeated measurements
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs
(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

Based on data retrieved at the CC on May 14, 2008
Created by HC002602d (AGH) on 19MAY08 13:33

HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 3.2e Reliability of laboratory measurements (Urine)

Variable		QC Pairs N	QC Pairs Outliers removed	QC Pairs Mean	Lab SD (1)	Reliab (2)	CV (3)	Difference Mean	Difference 95% CI		Difference Prop > 0	Difference pval (4)
LABA79	Urine creatinine	14	1	127.2	2.95	1.00	2.3	4.20	-3.76	12.16	0.50	1.000
LABA80	Urine microalbumin	19	1	58.2	3.58	1.00	6.2	-6.90	-19.0	5.17	0.30	0.344
LABA81	Albumin/creatinine ratio	19	1	42.2	2.83	1.00	6.7	-4.72	-13.5	4.03	0.37	0.359

Outliers (diff > 3 SD) excluded unless row label is preceded by *
(1) Standard deviation = square root (within-subject variance)
(2) The reliability coefficient is an estimate of the correlation between repeated measurements
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs
(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

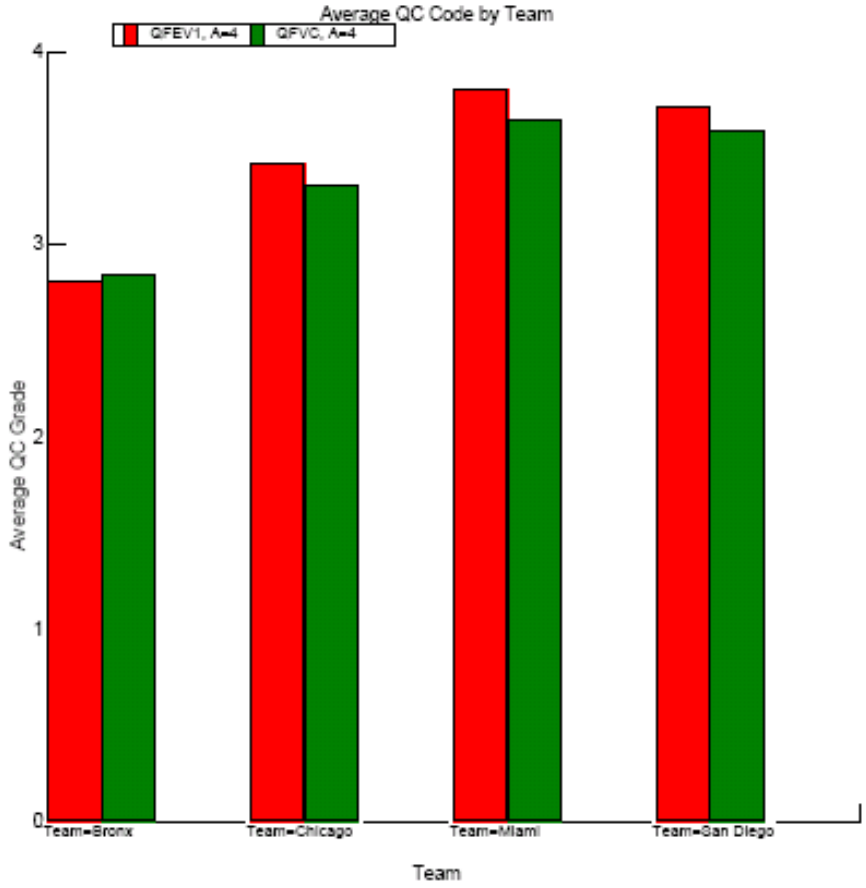
Based on data retrieved at the CC on May 14, 2008
Created by HC002602e (AGH) on 19MAY08 13:33

HCHS/SOL Observational Study Monitoring Board Report for May 2008

Table 3.3 Spirometry Quality Scores by Center (3/1/08 to 5/5/08)

From: 3/1/2008 To: 5/5/2008
All IDs selected

Team	NTests	AQFVC	AQFEV1
Bronx	31	2.84	2.81
Chicago	29	3.31	3.41
Miami	94	3.65	3.81
San Diego	53	3.58	3.72



4. DESCRIPTIVE STATISTICS

Section 4 presents illustrative summary statistics of the HCHS/SOL participants examined to date. In subsequent management reports this section will be expanded to build a profile of the demographic, social, behavioral and physical attributes of the HCHS/SOL examinees. Interview items and physical measurements will be included in this section to reflect input from the OSMB and the Steering Committee. At this point the number of observations in most strata of the tables shown in this section is too small to allow for interpretation.

The degree to which the examinees meet the study design expectations of demographic and country of origin characteristics are shown in Table 4.1. Marital and employment status, income and education levels are also summarized in this table.

Selected items from the self reported medical history are summarized in Table 4.2. Self reported respiratory history items are shown in greater detail in Table 4.3. The number of reported signs and symptoms attributed to allergies is sufficiently high to warrant a data quality inquiry. Smoking habits and reported alcohol consumption are summarized in Table 4.4 and 4.5. Responses to the hearing history questionnaire are shown in Table 4.6.

Summary statistics of the examinee's anthropometric indices are shown by age and gender in Table 4.7. The (average) seated blood pressure values as well as the systolic pressure measurements for the ankle/brachial index are presented in Table 4.8. Mean values of fasting time, blood chemistry and hemogram results are shown in Table 4.9. Tables 4.10 and 10b present the number of pulmonary function tests in this data snapshot and the percent indicative of airflow obstruction; the number of useable post-bronchodilator studies and their response; and mean values of the observed and predicted test results.

Table 4.11 provides summary statistics of the sleep study performance and of selected sleep study measurements, by gender and age. Neurocognitive study test results are summarized by gender in Table 4.12, while depression and quality of life scores are summarized in Table 4.13.

Table 4.1 Participant Demographics by Center

Baseline Characteristic	Bronx (N=52)		Chicago (N=56)		Miami (N=95)		San Diego (N=47)	
	N	%	N	%	N	%	N	%
Age								
18-44	17	32.7	31	55.4	36	37.9	14	29.8
45+	34	65.4	24	42.9	59	62.1	33	70.2
Gender								
Male	16	30.8	21	37.5	38	40.0	15	31.9
Female	35	67.3	34	60.7	57	60.0	32	68.1
Race								
American Indian	6	11.5	3	5.4	6	6.3	2	4.3
Asian/Pac Islands	0	0.0	0	0.0	0	0.0	1	2.1
Black or African American	6	11.5	1	1.8	4	4.2	0	0.0
White	13	25.0	15	26.8	38	40.0	16	34.0
Multi-racial	6	11.5	5	8.9	16	16.8	9	19.2
Unknown/refused	20	38.5	30	53.6	31	32.6	19	40.4
Hispanic / Latio Heritage								
Central American	11	21.2	7	12.5	54	56.8	0	0.0
Cuban	0	0.0	1	1.8	28	29.5	2	4.3
Mexican	0	0.0	28	50.0	4	4.2	43	91.5
Puerto Rican	19	36.5	17	30.4	3	3.2	1	2.1
Multi-Heritage Hispanic	2	3.9	2	3.6	3	3.2	0	0.0
Other Hispanic Heritage*	18	34.6	0	0.0	2	2.1	1	2.1

*Note: Other Hispanic heritage includes Spain (2), Caribbean Islands (6), Dominican Republic (9), U.S.A. (3)

Based on data created on May 13, 2008.

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(CONTINUED)

Table 4.1 Participant Demographics by Center

Baseline Characteristic	Bronx (N=52)		Chicago (N=56)		Miami (N=95)		San Diego (N=47)	
	N	%	N	%	N	%	N	%
Marital Status								
Single	22	42.3	15	26.8	22	23.2	9	19.2
Married/ with a partner	15	28.9	29	51.8	49	51.6	29	61.7
Separated/Divorced	10	19.2	7	12.5	19	20.0	5	10.6
Employment Status								
Working full time	19	36.5	25	44.6	40	42.1	15	31.9
Employed part time	8	15.4	10	17.9	14	14.7	10	21.3
Not Employed	16	30.8	20	35.7	39	41.1	20	42.6
Income								
Less than $30K	39	75.0	30	53.6	70	73.7	27	57.5
Over $30K	11	21.2	22	39.3	19	20.0	20	42.6
Education								
Less than High School	24	46.2	29	51.8	35	36.8	26	55.3
High School and Higher	27	51.9	24	42.9	58	61.1	19	40.4

Based on data created on May 13, 2008.

Table 4.2 Medical History (self report) by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
High BP/Hypertension	10	15.6	49	52.7	0	0.0	22	39.3
High Cholesterol	13	20.3	57	61.3	3	9.4	27	48.2
Angina	0	0.0	6	6.5	1	3.1	3	5.4
Heart Problems	5	7.8	13	14.0	3	9.4	4	7.1
a. Heart Attack	1	20.0	2	15.4	0	0.0	2	50.0
b. Heart failure	0	0.0	2	15.4	0	0.0	2	50.0
c. Rheumatic Heart Disease	0	0.0	3	23.1	0	0.0	0	0.0
d. Atrial Fibrillation	0	0.0	1	7.7	0	0.0	1	25.0
e. Other	4	80.0	9	69.2	3	100.0	3	75.0
Heart Procedure (ie. angio, Stent, bypass)	0	0.0	1	1.1	0	0.0	2	3.6
Stroke	0	0.0	2	2.2	0	0.0	2	3.6
Mini-stroke/TIA	1	1.6	3	3.2	0	0.0	1	1.8
Neck: angio/surgery	0	0.0	1	1.1	0	0.0	1	1.8
Aortic Aneurism, AAA, etc.	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Anteriolar Disease	1	1.6	5	5.4	1	3.1	3	5.4
Diabetes	6	9.4	23	24.7	1	3.1	13	23.2
Kidney Problems	10	15.6	16	17.2	3	9.4	8	14.3
Liver Disease	7	10.9	10	10.8	2	6.3	6	10.7
a. Hepatitis								
A	3	42.9	2	20.0	0	0.0	4	66.7
B	1	14.3	1	10.0	0	0.0	0	0.0
C	0	0.0	2	20.0	1	50.0	1	16.7
b. Cirrhosis	1	14.3	0	0.0	0	0.0	2	33.3
c. Other	2	28.6	3	30.0	0	0.0	2	33.3

Based on data created on May 13, 2008.
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Table 4.2 Medical History (self report) by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
Heartburn	24	37.5	44	47.3	16	50.0	27	48.2
Acid Regurgitation	22	34.4	48	51.6	15	46.9	22	39.3
Migraines	14	21.9	18	19.4	5	15.6	1	1.8
Blood Clot (leg/lung)	0	0.0	4	4.3	0	0.0	1	1.8
Joint Swelling	5	7.8	28	30.1	3	9.4	8	14.3
Sleep Disorder	6	9.4	22	23.7	2	6.3	10	17.9
a. Insomnia	4	66.7	21	95.5	1	50.0	10	100.0
b. Restless legs	2	33.3	9	40.9	2	100.0	2	20.0
c. Narcolepsy	0	0.0	0	0.0	1	50.0	0	0.0
d. Apnea	1	16.7	3	13.6	0	0.0	1	10.0
e. Other	1	16.7	3	13.6	1	50.0	1	10.0
Cancer/Malignancy, Tumor	0	0.0	8	8.6	0	0.0	2	3.6
Hysterectomy	1	1.6	12	12.9	-	-	-	-
Menopause Reached	3	4.7	67	72.0	-	-	-	-
Ever Pregnant	48	75.0	85	91.4	-	-	-	-
Birth Control med use (ever)	38	59.4	51	54.8	-	-	-	-
Other female hormonal meds (currently)	1	1.6	6	6.5	-	-	-	-

Based on data created on May 13, 2008.

Table 4.3 Respiratory History (self report) by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
Symptoms in past 12 months								
Cough - general	11	16.9	12	13.3	2	6.1	13	23.6
Cough - waking	7	10.8	9	10.0	1	3.0	8	14.6
Phlegm from chest - general	6	9.2	11	12.2	1	3.0	8	14.6
Phlegm from chest - waking	6	9.2	11	12.2	1	3.0	8	14.6
Past History of Any								
Wheezing/Whistling - general	22	33.9	28	31.1	5	15.2	16	29.1
Wheezing/Whistling - short of breath	9	13.9	14	15.6	1	3.0	8	14.6
Indoor allergies								
a. Cough/wheeze	14	21.5	17	18.9	2	6.1	8	14.6
b. Sneeze/Watery Eyes	33	50.8	34	37.8	8	24.2	19	34.6
Outdoor allergies								
a. Cough/wheeze	14	21.5	15	16.7	1	3.0	6	10.9
b. Sneeze/Watery Eyes	23	35.4	29	32.2	7	21.2	14	25.5
Chronic Sinusitis	5	7.7	15	16.7	3	9.1	10	18.2
Shortness of breath - walking	31	47.7	45	50.0	3	9.1	19	34.6
Resp. Illness - days missed (work or school, past 12 months								
a. None	49	75.4	67	74.4	30	90.9	36	65.5
b. 1-5 days	10	15.4	3	3.3	3	9.1	5	9.1
c. 6-15 days	2	3.1	2	2.2	0	0.0	0	0.0
d. 16 days or more	1	1.5	0	0.0	0	0.0	0	0.0
e. Not applicable	3	4.6	17	18.9	0	0.0	14	25.5

Note: Symptoms are asked in the context of 4+ days/week for the last 3 months within the past year.

Based on data created on May 13, 2008.

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Table 4.3 Respiratory History (self report) by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
Asthma -ever	13	20.0	17	18.9	3	9.1	7	12.7
a. Asthma - currently	8	12.3	8	8.9	2	6.1	3	5.5
b. Asthma - med treatment	6	9.2	9	10.0	1	3.0	2	3.6
Physician Diagnosis								
a. Asthma	11	16.9	15	16.7	3	9.1	5	9.1
b. (Broncho)/Pneumonia	6	9.2	9	10.0	1	3.0	8	14.6
c. Chronic Bronchitis	1	1.5	5	5.6	1	3.0	5	9.1
d. COPD/emphysema	2	3.1	3	3.3	0	0.0	3	5.5
COPD/emphysema req. medical trt	0	0.0	2	2.2	0	0.0	1	1.8
e. Active TB	1	1.5	5	5.6	0	0.0	3	5.5
TB req. medical treatment	1	1.5	3	3.3	0	0.0	3	5.5

Based on data created on May 13, 2008.

Table 4.4 Alcohol and Tobacco Use History by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
Alcohol Use								
Drinking Status								
a. Current	32	49.2	30	32.3	18	54.6	30	52.6
b. Former	21	32.3	36	38.7	13	39.4	25	43.9
i. Quit for health reasons or MD advice	2	9.5	8	22.2	2	15.4	9	36.0
c. Never	11	16.9	27	29.0	2	6.1	2	3.5
Heavy Drinking (4+ for females, 5+ for males in a two-hour period)								
a. Every day	0	0.0	0	0.0	0	0.0	0	0.0
b. 5-6 days/week	0	0.0	0	0.0	0	0.0	1	1.8
c. 3-4 days/week	1	1.5	0	0.0	0	0.0	1	1.8
d. 2 days/week	3	4.6	2	2.2	0	0.0	1	1.8
e. 1 day/week	2	3.1	2	2.2	1	3.0	2	3.5
f. 2-3 days/month	7	10.8	4	4.3	3	9.1	2	3.5
g. 1 day/month	3	4.6	3	3.2	2	6.1	0	0.0
h. Less than once/month	3	4.6	5	5.4	1	3.0	1	1.8
i. Never	12	18.5	14	15.1	11	33.3	22	38.6
Tobacco Use								
Cigarette Smoking Status								
a. Current	9	13.9	13	14.0	11	33.3	16	28.1
b. Former	7	10.8	19	20.4	3	9.1	20	35.1
c. Never	49	75.4	60	64.5	19	57.6	21	36.8
Pipe Smoking, Ever	0	0.0	1	1.1	1	3.0	6	10.5
Cigar Smoking, Ever	2	3.1	0	0.0	2	6.1	3	5.3

Based on data created on May 13, 2008.

Table 4.5 Alcohol/Tobacco History - Average Consumption by Age and Gender

Response (Self-Report)	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
Alcohol Use								
1. Weekly Usage								
a. Red Wine (glass)	0.2	0.1	0.3	0.1	0.3	0.2	0.7	0.2
b. White Wine (glass)	0.1	0.0	0.1	0.1	0.1	0.1	0.2	0.1
c. Beer (glass, bottle, can)	2.3	0.9	1.8	0.6	2.5	0.9	4.6	1.1
d. Liquor, Spirits, Mixed Drinks	2.6	1.6	0.5	0.3	0.8	0.3	1.4	0.8
e. Overall Drinks Per Week	5.1	1.9	2.6	0.6	3.7	1.0	6.8	1.4
Tobacco Use								
2. Cigarettes/day								
a. Daily Smokers	10.2	3.1	13.9	2.9	13.0	3.4	12.9	3.5
b. Some Days Smokers	1.3	0.3	3.3	2.4	2.8	0.7	2.3	1.3
3. Smoking Lifetime - Cigarettes/day	6.8	1.6	12.2	2.7	8.9	2.7	11.7	1.8

Based on data created on May 13, 2008.

Table 4.6 Hearing History (self report) by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
Hearing without aid								
Excellent	25	39.1	23	26.1	15	46.9	12	22.6
Good	31	48.4	33	37.5	16	50.0	22	41.5
Have a little trouble	7	10.9	14	15.9	0	0.0	10	18.9
Have moderate trouble	1	1.6	12	13.6	1	3.1	8	15.1
Have a lot of trouble	0	0.0	6	6.8	0	0.0	1	1.9
Deaf	0	0.0	0	0.0	0	0.0	0	0.0
Embarrassed meeting new people								
No	57	89.1	68	77.3	29	90.6	48	90.6
Sometimes	1	1.6	10	11.4	0	0.0	3	5.7
Yes	2	3.1	9	10.2	0	0.0	2	3.8
Frustrations talking to family								
No	53	82.8	70	79.6	29	90.6	47	88.7
Sometimes	5	7.8	11	12.5	0	0.0	5	9.4
Yes	2	3.1	6	6.8	0	0.0	1	1.9
Feel handicapped by hearing problem								
No	59	92.2	73	83.0	28	87.5	49	92.5
Sometimes	0	0.0	7	8.0	1	3.1	3	5.7
Yes	1	1.6	7	8.0	0	0.0	1	1.9
Problems cause difficulty visiting friends, relatives, or neighbors								
No	54	84.4	77	87.5	28	87.5	49	92.5
Sometimes	5	7.8	5	5.7	1	3.1	3	5.7
Yes	1	1.6	5	5.7	0	0.0	1	1.9

Based on data created on May 13, 2008.

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Table 4.6 Hearing History (self report) by Age and Gender

Baseline Characteristic	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	N	%	N	%	N	%	N	%
Problems cause arguments with family members								
No	53	82.8	80	90.9	28	87.5	48	90.6
Sometimes	3	4.7	5	5.7	0	0.0	4	7.6
Yes	4	6.3	2	2.3	1	3.1	1	1.9
Hearing limits/hampers personal or social life								
No	55	85.9	74	84.1	29	90.6	46	86.8
Sometimes	4	6.3	4	4.6	0	0.0	6	11.3
Yes	1	1.6	9	10.2	0	0.0	1	1.9
Ever worn hearing aid								
No	62	96.9	83	94.3	32	100.0	51	96.2
Yes	2	3.1	5	5.7	0	0.0	2	3.8
Don't Know/refused	0	0.0	0	0.0	0	0.0	0	0.0

Based on data created on May 13, 2008.

Table 4.7 Anthropometric Measures by Age and Gender

Measurement	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
Height standing (cm)	156.9	0.91	154.7	0.76	168.9	1.41	168.7	0.98
Weight (kg)	74.0	2.24	71.4	1.33	80.6	2.91	80.3	1.72
Self Reported Weight (kg)	75.5	2.58	72.4	1.52	80.8	2.65	82.0	1.77
Body Mass Index (kg/m2)**	30.1	0.83	29.8	0.51	28.3	1.02	28.2	0.54
Fat (%)	37.3	1.55	38.0	0.76	26.6	1.69	28.7	1.07
Impedance (Ohms)	557.6	11.73	533.1	10.16	516.4	19.79	495.7	9.71
Fat mass (kg)	27.8	1.52	27.9	0.95	22.2	2.11	24.1	1.35
Lean body mass (kg)	45.1	0.65	43.6	0.63	58.4	1.44	56.5	0.89
Total body water (kg)	33.0	0.48	31.8	0.46	42.8	1.05	41.3	0.65
Waist girth (cm)	96.6	1.85	98.3	1.13	95.8	2.27	99.8	1.58
Hip girth (cm)	106.4	1.51	106.5	1.10	101.2	1.79	101.8	1.04
Waist / Hip ratio	0.9	0.01	0.9	0.01	0.9	0.01	1.0	0.01

Based on data created on May 13, 2008.

Table 4.8 Sitting Blood Pressure and Ankle Brachial Pressures by Age and Gender

Measurements	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
Sitting Blood Pressure (average of 3)								
Systolic Blood Pressure	112.9	1.9	131.9	2.0	118.2	1.5	128.5	2.2
Diastolic Blood Pressure	71.7	1.4	76.2	1.1	72.2	1.5	75.0	1.4
Pulse	68.1	1.1	66.5	1.0	67.1	1.8	66.9	1.4
Ankle Brachial Pressures*								
Right brachial Systolic (mm HG)	-	-	130.4	2.3	-	-	125.9	3.4
Right dorsalis pedis systolic (mm HG)	-	-	133.0	2.4	-	-	131.5	3.1
Right posterior tibial systolic (mm HG)	-	-	134.1	2.3	-	-	133.7	3.6
Left posterior tibial systolic (mm HG)	-	-	133.5	2.0	-	-	134.8	2.9
Left dorsalis systolic (mm HG)	-	-	133.5	2.0	-	-	134.8	2.9
Left brachial systolic (mm HG)	-	-	129.1	2.1	-	-	128.1	2.5
Ankle Brachial Index (average left, right)	-	-	1.05	0.01	-	-	1.07	0.01

*Note: Ankle brachial pressures obtained only for participants age 45 and older.

Based on data created on May 13, 2008.

Table 4.9 Clinical Laboratory Results by Age and Gender

Laboratory Test Results	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
Fasting time (hrs)	14.2	0.5	15.8	0.6	14.1	0.6	13.7	0.3
Total Cholesterol (mg/dL)	174.4	5.1	217.5	4.8	195.7	8.8	203.0	7.4
LDL-Cholesterol (mg/dL)	99.7	3.7	136.0	4.0	124.7	6.4	118.0	5.8
HDL-Cholesterol (mg/dL)	53.8	2.5	51.5	1.2	40.9	1.5	43.3	1.9
Triglycerides (mg/dL)	104.4	8.9	150.1	7.6	156.6	22.2	227.5	39.1
Glucose - fasting (mg/dL)	101.1	5.2	109.6	3.5	98.1	2.5	123.9	8.0
Glucose - 2 hrs after glucose load	120.3	7.0	149.4	9.2	107.4	8.0	118.0	8.5
Glycosylated Hemoglobin %	5.6	0.2	6.1	0.1	5.7	0.2	6.3	0.2
Albumin / Creatinine (mg/g)	32.6	13.6	46.7	19.4	5.9	0.9	89.4	49.5
Serum creatinine	0.8	0.0	0.8	0.0	1.0	0.0	1.2	0.1
White Blood Count (WBC) (x103/L)**	6.8	0.2	6.1	0.2	6.8	0.4	6.8	0.3
Red Blood Count (RBC) (x1012)**	4.6	0.1	4.6	0.0	5.2	0.1	5.0	0.1
Hemoglobin (g/dL)	13.3	0.2	13.5	0.1	15.4	0.2	14.9	0.2
Hematocrit (%)	39.5	0.5	40.2	0.3	45.4	0.5	43.7	0.5
Mean Corpuscular Volume (MCV)	85.7	0.9	88.3	0.6	88.2	0.9	88.5	0.9
Mean Corpuscular Hemoglobin (MCH)	28.5	0.4	29.6	0.2	30.0	0.3	30.2	0.3
Mean Corpuscular Hemoglobin (Concentration (MCHC) (g/dL)	33.2	0.2	33.5	0.1	34.0	0.2	34.1	0.2
Red Cell Distribution Width (RDW) (%)	13.9	0.2	13.7	0.1	13.2	0.1	13.4	0.2
Platelet Count (x 109/L)**	263.1	7.9	247.0	6.6	224.8	9.8	229.3	9.1

Based on data created on May 13, 2008.

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Table 4.10 Pulmonary Function Results by Age and Gender

Pulmonary Test Results	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
Number of Total Maneuvers	6.3	0.3	5.4	0.2	5.3	0.3	6.1	0.3
Number of Acceptable Maneuvers	5.2	0.3	4.6	0.2	4.3	0.2	4.9	0.2
Test Results								
FVC (L)	3.4	0.1	2.8	0.1	4.5	0.1	3.9	0.1
FEV_1 (L)	2.8	0.1	2.2	0.1	3.7	0.1	3.1	0.1
FEV_1/FVC (%)	83.4	0.7	78.6	0.9	82.3	0.8	79.2	1.1
Predicted Values								
FVC (%)	95.2	2.5	93.4	1.7	93.1	2.6	90.9	2.2
FEV_1 (%)	94.1	2.6	92.4	2.0	92.8	2.5	92.4	2.2

Based on data created on May 13, 2008.

Table 4.10a Post-Bronchodilator Pulmonary Function Test Results by Gender

Pulmonary Function Measurement	Females		Males	
	N	%	N	%
Useable PFT Studies	124	99.2	72	100.0
Airflow Obstruction (FEV1/FVC < 0.70)	10	8.1	2	2.8
Useable post-bronchodilator studies	11	8.8	2	2.8
COPD (FEV1/FVC < 0.70 after BD)	6	54.6	2	100.0
Bronchodilator responsive	11	100.0	2	100.0

Based on data created on May 13, 2008.

Table 4.11 Sleep Study Results by Age and Gender

Sleep Monitor Measurements	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
Overall Study Quality	2.7	0.3	3.4	0.2	2.7	0.5	3.3	0.2
Total Time in bed (hrs.)	5.0	0.4	6.1	0.3	5.1	0.5	6.1	0.4
Total valid recording time (hrs.)	5.0	0.4	6.1	0.3	5.1	0.5	6.1	0.4
Baseline Oxygen (SpO2)	97.8	0.2	97.5	0.2	97.6	0.3	96.9	0.3
Percentage sleep time with SpO2 < 90%	0.2	0.1	0.7	0.2	1.2	1.0	1.8	0.7
Lowest Oxygen During Sleep	88.6	0.9	86.8	0.7	87.7	1.9	84.3	1.1
Mean Oxygen During Sleep	96.9	0.1	96.4	0.1	96.6	0.3	95.8	0.2
Apnea / Hypopnea Index (AHI) 3% desat. events/hour	2.1	0.9	6.0	1.4	3.1	1.5	10.3	2.5

Based on data created on May 13, 2008.

Table 4.12 Neurocognitive Function by Gender

Test Result	Females		Males	
	Mean	s.e.	Mean	s.e.
Number Correct Six-item screener	5.4	0.1	5.3	0.1
Spanish/English Verbal Learning Test				
Words recalled Trial 1	5.5	0.2	5.3	0.3
Words recalled Trial 2	8.6	0.3	7.5	0.3
Words recalled Trial 3	9.9	0.3	8.4	0.4
Words recalled Trial 5	8.7	0.3	7.1	0.5
Word Fluency				
Letter F	8.9	0.5	9.3	0.5
Letter A	8.2	0.4	9.2	0.6
Total Correct Symbols (DSST)	31.6	1.5	28.8	1.8

Note: Test battery is administered only if participant is age 45 or older.

Based on data created on May 13, 2008.

Table 4.13 Depression and Quality of Life by Age and Gender

Scored Test Result	Females				Males			
	Ages 18-44		Ages 45+		Ages 18-44		Ages 45+	
	Mean	s.e.	Mean	s.e.	Mean	s.e.	Mean	s.e.
CESD-10 summary score	6.8	0.8	8.0	0.7	3.8	0.6	5.5	0.7
SP-12v2 Aggregate Scores								
Physical Health score (PCS)	0.1	0.1	-0.6	0.1	0.0	0.1	-0.3	0.1
Mental Health score (MCS)	-0.5	0.1	-0.5	0.1	0.3	0.2	-0.1	0.1

Based on data created on May 13, 2008.

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5. PARTICIPANT SAFETY

Procedures are in place at the Coordinating Center to retrieve from the database the results that are reported to the study participants and to present them to field each field center in a secure area of the study website within 24 hours of receipt. The flow of results to field centers and from the study sites to their examinees started on May 22nd. This management report presents shell tables that will be populated in future reports from the data flowing through this process. The frequency of results referred to a study participant for consideration by his/her medical practitioner as well as summary statistics reflecting the action taken by the field centers will be presented by measurement, study site, and the degree of urgency attached to the items reported. These are outlined in table 5.1 and 5.3.

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Table 5.1 Study Results Referred to Medical Practitioners by Center and Gender

Study Results Referred	Bronx				Chicago				Miami				San Diego			
	Women		Men		Women		Men		Women		Men		Women		Men	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Glucose meter reading																
Glucose - fasting																
Glucose - 2 hrs after glucose load																
Glycosylated Hemoglobin																
Total Cholesterol																
LDL-Cholesterol																
HDL-Cholesterol																
Triglycerides																
Seated blood pressure																
Ankle-Brachial Ratio																
ECG																
Estimated GFR																
Albumin / Creatinine																
Serum creatinine (alert only)																
White Blood Count																
Red Blood Count																
Hemoglobin																
Hematocrit																
Platelet Count																
Hepatitis A serology																
Hepatitis B*																
Hepatitis C serology																
Lung function tests																
Oral Health Exam																
Audiometry																

Based on data created on May 13, 2008.

Table 5.1 Study Results Referred to Medical Practitioners by Center and Gender

Study Results Referred	Bronx				Chicago				Miami				San Diego			
	Women		Men		Women		Men		Women		Men		Women		Men	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sleep Study																
Other																

* Combinations of positive Hepatitis B Core Antibody; Hepatitis B Surface Antigen; Hepatitis B Surface Antibody

Based on data created on May 13, 2008.

Table 5.2 Study Results Referred to Medical Practitioners by Completion Status

Study Results Referred	Bronx (N)		Chicago (N)		Miami (N)		San Diego (N)	
	n	% Notified	n	% Notified	n	% Notified	n	% Notified
Glucose meter reading								
Glucose - fasting								
Glucose - 2 hrs after glucose load								
Glycosylated Hemoglobin								
Total Cholesterol								
LDL-Cholesterol								
HDL-Cholesterol								
Triglycerides								
Seated blood pressure								
Ankle-Brachial Ratio								
ECG								
Estimated GFR								
Albumin / Creatinine								
Serum creatinine (alert only)								
White Blood Count								
Red Blood Count								
Hemoglobin								
Hematocrit								
Platelet Count								
Hepatitis A serology								
Hepatitis B*								
Hepatitis C serology								
Lung function tests								
Oral Health Exam								

Based on data created on May 13, 2008.

Table 5.2 Study Results Referred to Medical Practitioners by Completion Status

Study Results Referred	Bronx (N)		Chicago (N)		Miami (N)		San Diego (N)	
	n	% Notified	n	% Notified	n	% Notified	n	% Notified
Audiometry								
Sleep Study								
Other								

* Combinations of positive Hepatitis B Core Antibody; Hepatitis B Surface Antigen; Hepatitis B Surface Antibody

Based on data created on May 13, 2008.

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Table 5.3 Study Result Alert Notifications by Field Center and Timeliness of Completion

Alert Notifications	Bronx (N)		Chicago (N)		Miami (N)		San Diego (N)	
	N (%)	Days Mean, range	N (%)	Days Mean, range	N (%)	Days Mean, range	N (%)	Days Mean, range
Glucose meter reading								
Glucose - fasting								
Glucose - 2 hrs after glucose load								
Triglycerides								
Seated blood pressure								
ECG								
Estimated GFR								
Albumin / Creatinine								
Serum creatinine								
White Blood Count								
Red Blood Count								
Hemoglobin								
Platelet Count								
Hepatitis A serology								
Hepatitis B*								
Hepatitis C serology								
Oral Health Exam								
Audiometry								
Sleep Study								
Other								

* Combinations of positive Hepatitis B Core Antibody; Hepatitis B Surface Antigen; Hepatitis B Surface Antibody

Based on data created on May 13, 2008.

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