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The Hispanic Community Children's Health Study/Study of Latino Youth (SOL Youth): Design, objectives and procedures

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Abstract

Purpose—This paper describes the design and methodology of the SOL Youth study, a multicenter study of Hispanic/Latino children living in the US.

Methods—Participants are children aged 8–16 years whose parents/legal guardians participated in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), a large community-based cohort study of Hispanic/Latino adults living in the US.

Results—Between 2012 and 2014, 1600 children recruited from 4 field centers (Bronx, Chicago, Miami and San Diego) will undergo a 3.5 hour examination to collect biospecimens, obtain anthropometric measures, blood pressure, fitness level, dietary intake, and physical activity. Psychosocial and environmental characteristics are assessed by questionnaire. Primary study aims are to examine associations of youth's lifestyle behaviors and cardiometabolic risk factors with (1) youth's acculturation and parent-child differences in acculturation; (2) parenting strategies, family behaviors, and parental health behaviors; and (3) youth's psychosocial functioning.

Conclusions—SOL Youth will determine the prevalence and distribution of obesity-promoting lifestyle behaviors, cardiometabolic risk profiles and novel biomarkers associated with obesity and insulin resistance. This paper describes the study methodology and considers advantages and limitations of embedding a cohort of children within a well characterized cohort of adults.

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INTRODUCTION

Hispanic/Latino children are disproportionately affected by the obesity epidemic¹ and are at high risk of developing diabetes and other cardiometabolic disorders. Recent national data indicate that obese adolescents have a higher burden of cardiovascular disease (CVD) risk factors compared to normal weight adolescents.² Findings from cohort studies suggest that adverse levels of cardiovascular risk factors measured in childhood track into young adulthood.^{3–5} Furthermore, the prevalence of pre-diabetes in youth has dramatically increased in recent years.² While the number of CVD risk factors increases with category of weight, a substantial proportion of normal weight youth (37%) have at least one CVD risk factor. Boys are at higher cardiometabolic risk, but the factors associated with this disparity are unknown.^{2,6,7} In addition, the prevalence of metabolic syndrome and its components is high among overweight Hispanic/Latino children.⁸ Thus, Hispanic/Latino children may be at high risk of living with chronic conditions throughout their lifespans. Despite the broad socio-cultural heterogeneity of the Hispanic/Latino population in the U.S.,⁹ current knowledge about risk and protective factors is based mostly on studies limited to Mexican-American individuals.¹⁰

The biological, behavioral and environmental factors that place Hispanic/Latino children at risk for cardiometabolic disorders are complex. One factor that may play a unique role in Hispanic/Latino youth is acculturation—a concept that describes the degree of integration to a dominant culture by members of a minority group. Studies suggest that Hispanic/Latino youth born outside of the US have lower risk of obesity as compared with those who are US-born or who moved to the US at a young age.^{11–14} Although acculturation is cited as a risk factor for obesity in Hispanic/Latino adults, this association is less clear in youth.^{11,12,14,15} Variation in findings may be attributable to the limited set of measures used to capture acculturation (many studies rely solely on language preferences or country of birth) or because few studies have simultaneously evaluated the joint influence of parental acculturation and youth acculturation on the health risk profile of youth. Until a comprehensive set of measures are used to capture acculturation in youth and their caregivers, the contribution of acculturation on the established risk factors for cardiometabolic diseases cannot be determined. Lower parental educational achievement and living in poverty have been documented as risk factors for increased cardiometabolic burden in youth.^{16,17} However, the pathways explaining these inequalities are not well understood, as most of the studies in youth do not include comprehensive assessments of behavioral, psychosocial, familial and biological factors.^{2,16–21}

The Hispanic Community Children's Health Study/Study of Latino Youth (SOL Youth) was launched in April 2011 as an ancillary study to the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) to address this knowledge gap. By examining the children of participants enrolled in HCHS/SOL, the largest population-based cohort study of Hispanic/Latino adults living in four regions of the U.S: Bronx, NY, Chicago, Miami, and San Diego, new and unprecedented findings are anticipated. The specific aims of the SOL Youth study are:

1. To investigate the influence of youth acculturation and parent-child differences in acculturation on youth's lifestyle behaviors and cardiometabolic risk profiles;
2. To examine associations of parenting strategies, family behaviors and parent lifestyle behaviors on youth's lifestyle behaviors and cardiometabolic risk profiles; and
3. To investigate the influence of youth's psychosocial functioning on youth's lifestyle behaviors and cardiometabolic risk profiles.

The objective of this manuscript is to describe the design, sampling methods, and data collection procedures for the SOL Youth study.

MATERIALS AND METHODS

Study participants

The population source for the SOL Youth study is a population-based sample of Hispanic households whose adult members are enrolled in the NIH-initiated HCHS/SOL cohort study. HCHS/SOL is a population-based cohort study of 16,415 Latino adults (ages 18–74 years) who were selected using probability sampling from four US cities (Chicago, IL; Miami, FL; Bronx, NY; San Diego, CA). The aims of HCHS/SOL are to identify risk factors associated with cardiovascular disease, and other chronic conditions. Baseline data collection for the HCHS/SOL study was carried out between 2008 and 2011. HCHS/SOL cohort participants are contacted annually to update their event status. Details about the methodology and protocols of HCHS/SOL are published elsewhere.²²

SOL Youth Eligibility—Children living with at least one parent or legal guardian who participated in HCHS/SOL are eligible for SOL Youth. A biological relationship between the youth and the HCHS/SOL participant is not required. Eligibility further required that the child: (1) lives at least 5 days/week and 9 months/year with the HCHS/SOL parent or legal guardian; (2) age 8 to 16 years at the time of the baseline examination; and (3) has no known serious physical or cognitive comorbidities that would interfere with his/her ability to complete a clinic visit. All eligible children in the household were invited to participate. Our goal is to recruit an equal number of boys and girls, and youth aged <11 years vs. 11 years. The projected numbers of participants by ancestry of origin is expected to reflect the diversity of the main HCHS/SOL study. Table 1 displays the anticipated distribution of ancestry of origin across field centers.

Recruitment procedures

Recruiters from each field center mail letters to all HCHS/SOL participants describing the main goals and procedures of the SOL Youth Study and alerting them that a member of the research staff would call shortly to describe the study. The letter also includes a child-friendly informational flier. Recruiters from each field center call HCHS/SOL participants to find out if they have a child within the target age range, verify individual eligibility, and invite participation. Parents/guardians are asked to accompany their children to the visit, provide written consent and to complete additional assessments not included in their HCHS/SOL examination. If a HCHS/SOL participant has more than one eligible child, all who are qualified are enrolled. The number of children per household is accounted for in analyses.

Visits are scheduled in the morning to enable collection of overnight fasting blood samples. To minimize missed school days, clinical examinations are primarily scheduled on Saturdays and on weekdays when children are not in school. To increase participation rates, clinic appointment letters are mailed and reminder calls are made the day before the scheduled appointment to confirm the visit or reschedule for another day. Because transportation is often a barrier to participation in research in many underserved communities, participants are reimbursed for their transportation expenses. A tracking system documents recruitment progress, monitors enrollment and response rates.

Overview of the clinic examination and measures

Study participation includes three components: 1) an initial clinical examination lasting up to 3.5 hours; 2) 7-days of wearing a physical activity monitor; and 3) a repeated 24-hour dietary recall to be completed on the telephone. Prior to the clinical examination, parents are

instructed to have their children fast for at least 10 hours prior to the examination and to wear light clothing and comfortable shoes. Parents are asked to bring all medications currently being taken by their children. Parents are also informed that their own height and weight will be assessed and that they would be asked to complete some questionnaires.

The informed consent process takes place at each field center research clinic according to the guidelines of each site's Institutional Review Board (IRB), by personnel specifically trained in this process. Before the start of any data collection, parents and children provide written consent or assent. Two field centers (Bronx and San Diego) require children older than 12 years old to sign a consent form instead of an assent. Child assent/consent is obtained separately from that of parents. Both the parental informed consent form and the consent form for children over 12 years of age were structured to allow parents and children the opportunity to agree or to refuse to certain components of the examination (e.g., acquiring and storing child's DNA, use of their information in future studies).

The list of study questionnaires administered to youth and their parents is provided in Table 2. We selected questionnaires that would capture the constructs needed to address our primary study aims, including potential confounders or effect modifiers of our hypothesized associations. The majority of questionnaires were selected because they were validated for use in this age group in previous studies. However, when validated questionnaires were not available we assembled individual questions from multiple studies to create our questionnaire. All questionnaires were pilot tested in age-appropriate samples prior to finalizing for administration in the SOL-Youth study. All questionnaires, with the exception of pubertal status, depressive and anxiety symptoms, tobacco and alcohol use in adolescents aged 12 and older, are interviewer administered.

The examination protocol allows some flexibility in the order of administration of study components, and provides the option of completing the examination on a second visit (within a month) if the family could not stay for the full 3.5 hours in a given day. A set of core components (identified in Table 2 by "C") was identified to prioritize examination elements that were critical for the study specific aims and staff was cross-trained in the different components of the protocol. These strategies were implemented to optimize local efficiency in staffing and provide the ability to conduct examinations on multiple children (and their parents) concurrently.

The clinical examination includes phlebotomy, anthropometry (Tanita Body Composition Analyzer TBF-300A, wall-mounted stadiometer, Gulick anthropometric tape), seated blood pressure (OMROM HEM-907XL), fitness test (step test),²³ pubertal stage (Pubertal Development Scale),²⁴ and study questionnaires. Youth are also asked to wear an activity monitor for a week (ActiCal, MiniMiter Respironics). Table 3 describes the study components and approximate time required to collect each measurement. Parents also answer questions regarding their child's medical history and medications use. Anthropometric measures are also obtained from the parents to update the measurements obtained during their HCHS/SOL examination.

At the end of the examination, staff provides the child and parent with instructions on how the child should wear the activity monitor and when to return it. Each child receives at least \$25 in gift certificates and/or cash as compensation for their time. Parents receive an additional minimum of \$25 following completion of the second dietary recall and the return of the physical activity monitor. Actual reimbursement amounts were permitted to vary across field centers consistent with PI's experience on previous successful recruitment efforts. Staff mail parents a report of study findings of clinical relevance and a brief interpretation of their child's values based on current pediatric guidelines (weight status,

blood pressure, glucose, lipids, and depressive symptoms). Each field center maintains a network of social and clinical resources in the community for referring children to appropriate services as needed.

Selection of Measures

The selection of study measures was guided by a comprehensive theoretical framework informed by Social Cognitive Theory,^{25,26} described in a companion paper by Ayala et. al (submitted to *Annals of Epidemiology*). Obesity and insulin resistance were selected as the primary outcomes of the study because they are important public health problems in Latino youth.^{18,27} Study variables and their instruments were selected to provide a comprehensive overview of the major determinants of cardio-metabolic risk and included physiological, psychosocial, cultural, familial, and behavioral variables (Table 2). Complete characterization of parents' own risk profile is available from the HCHS/SOL baseline examination.²²

The study planned to use existing Spanish translations of validated instruments. Instruments that lacked an existing version in Spanish were translated by a certified translator and reviewed by the study's Translation Subcommittee.

Reading centers

Central Laboratory—The central laboratory is responsible for developing the protocol and training for specimen collection and processing. Blood specimens obtained by venipuncture are processed at the collection site immediately after drawing according to a standardized protocol. Serum, plasma, and packed cells are frozen at -70°C and shipped to the central laboratory on a weekly basis. Components of the laboratory assessment are listed in Table 4. Frozen specimens (serum, plasma, packed cells for DNA isolation) are stored in a repository at the central laboratory for future biomarker measurements.

Nutrition Reading Center—Two 24-hr dietary recalls are obtained from each child, with parental assistance if needed, to assess dietary intake using the Nutrition Data System for Research (NDSR) software developed by the University of Minnesota. The initial recall, conducted in person at the clinic examination, is followed by a second recall, conducted by telephone within a month of the first recall. The nutrition reading center developed the protocols and is responsible for the centralized training, processing and quality control of the dietary data. A comprehensive database of Hispanic foods initially developed for the parent HCHS/SOL study provides a rich set of standardized recipes and food formulations.

Data management, quality assurance/control, and statistical analysis

The University of North Carolina at Chapel Hill Collaborative Studies Coordinating Center is the study's coordinating center (CC) for SOL Youth and is responsible for the data management and quality assurance procedures for the study. In collaboration with all study sites, the CC developed a comprehensive data capture and management system along with quality control and quality assurance programs to ensure rigorous and high quality data collection and adherence to the study protocols. Data is entered at the sites into a standardized, industry-compliant web-based data management system (DMS) and transmitted to the CC. Results from the Central Laboratory and the Nutrition Reading Center is transferred via the DMS to the CC at regular intervals throughout the study. Timely transmission of data allows study investigators to address laboratory alert values as they become known. The DMS provided each field center the ability to generate a variety of reports pertaining to recruitment, data quality, specimen tracking and completion of results letters. Quality control activities included monitoring protocol adherence by direct observation of selected procedures, audio-taping interviews, and repeatability studies. The

CC will also guide the analytical approach, which will include calculating sample weights for estimating prevalence of risk factors and cardiometabolic profile. Generalized estimating equations (GEE) models with compound symmetric working covariance or multilevel models with a random intercept per household will be used to account for within-family correlations that arise from including more than one child per household.²⁸⁻³⁰ Dyadic analyses will also be conducted to examine the reciprocal influence of youth and parental factors on youth cardiometabolic risk profile.³¹

Cohort Retention

By building upon an ongoing longitudinal cohort study of adults (HCHS/SOL), SOL-Youth is able to cost-effectively recruit participants and will be able to follow participants more effectively compared to studies that are not affiliated with an established adult cohort. Each field center offers a child-friendly atmosphere and pays special attention to the needs of children and parents to enhance the study experience. In collaboration with HCHS/SOL, participants receive quarterly newsletters, which highlight a member of the research team, discuss progress of the study, provide information on a health topic of potential interest to participants, and include a brief insert designed specifically for SOL-Youth. In addition, participants receive birthday and holiday cards from study personnel.

To facilitate follow-up of participants who may have moved or changed phone numbers since the baseline examination, all participants are asked to provide the names and contact information of at least three people who are not members of their household and who would know how to contact them in case they moved. In addition, each participant is provided with a postage paid change-of-address card at the time of their initial visit and a phone number to call to provide updated contact information.

Although the SOL Youth study is currently funded as a cross-sectional study, the study design and operations are intended to facilitate future studies including repeated examinations. The above mentioned cohort retention efforts are expected to yield a high retention and follow-up rate for future examinations. Of the HCHS/SOL adult participants who have now been followed for three years, 90% have been successfully contacted, and follow-up rates of over 80% have been obtained in each field center.

Study governance and oversight

SOL Youth is a collaborative study using a multiple principal investigator (PI) approach. The scientific and operational direction for the study was provided by a Steering Committee made up of the PI's from each of four field centers, the coordinating center and the two reading centers. The Steering Committee is led by a Chair whose appointment rotated annually among PI's from the field centers. The Steering Committee is charged with implementing and overseeing all study policies and procedures. Subcommittees were created with the charge of guiding selection of measures and instruments, and preparing manuals for each procedure, including aspects related to quality assurance/control. All study materials are approved by the Steering Committee by majority vote. The Steering Committee held weekly conference calls during the first year of the study, and bi-weekly thereafter. In-person meetings take place annually.

Institutional review boards (IRBs) provide human subject-related oversight at each field center. Additionally, the study falls under the oversight of the Observational Studies Monitoring Board (OSMB) for HCHS/SOL study at the federal level, which monitors participant burden, safety, and progress.

Dissemination plans

The findings of SOL Youth will have broad scientific interest and immediate public health applicability. A multifaceted approach will be utilized to disseminate study findings to both professional and lay communities that includes presentation in professional and community meetings, publication in peer reviewed journals, and coordination with each university's media relations staff and NIH/NHLBI to provide press releases about main findings for publication in Spanish and English language media and newspaper outlets. Furthermore, the data collected for this study will be included in the main HCHS/SOL study's limited-use database maintained by the CC and will be made available to the public according to terms agreed to between NHLBI and the SOL Youth study. As part of the HCHS/SOL database, SOL Youth will provide phenotypic and behavioral information for examining a whole range of intergenerational differences in future investigations.

DISCUSSION

SOL Youth is one of the largest and most comprehensive studies on cardiometabolic health in a diverse sample of Hispanic/Latino children living in four areas of the United States. The study will provide valuable information about cultural, behavioral, and familial influences on risks for obesity and cardiometabolic abnormalities. Because the SOL Youth study is embedded within a longitudinal cohort study of adults, parental behavioral and phenotypic data are integrated with the children's data. This provides an innovative and unique opportunity to document biological and environmental influences on important health outcomes. Because both studies have stored DNA samples, future studies can take full advantage of the rich dataset to address genetic factors and gene-environment interactions. SOL Youth is highly efficient from the perspective of recruitment because participating families have been involved with HCHS/SOL study staff and investigators for a number of years and are in active follow-up.

Notable strengths of SOL-Youth include population-based methods to recruit participants, a multicenter design with four field centers that allows for the recruitment and collection of data from multiple Hispanic/Latino groups; and a comprehensive characterization of both individual youth and parental factors that includes health status, lifestyle behaviors, and psychosocial characteristics. Our approach will allow us to tease apart the complex concept of acculturation and its influence on cardiometabolic risk profile. In addition, collecting similar data from both youth and parents will allow us to conduct dyadic analyses and examine the reciprocal influence of youth and parental factors on youth cardiometabolic risk profile. Another unique contribution of SOL Youth study is comprehensive assessments of both boys and girls. Hispanic/Latino boys are reported to be at high risk of obesity and cardiometabolic risk.^{2,6,7,32,33} However, little is known about the factors associated with this disparity. Information collected in SOL Youth about boy's lifestyle patterns, mental health functioning, and body image perceptions may help elucidate this issue. Lastly, the inclusion of novel biomarkers (e.g. biomarkers of endothelial function) shown to increase the risk of diabetes and cardiovascular disease in adults will help us understand better the natural history of these associations by examining the role of obesity and metabolic syndrome on these biomarkers in a younger population.

Despite all these advantages, the study is not free of limitations. The most important is that HCHS/SOL was designed to oversample people 45 years and older and under sample those between 18 and 44 years of age. Thus, HCHS/SOL participants are less likely to have younger children in their household than would an unselected group of Hispanic adults. While this may present a limitation for generating prevalence estimates for health behaviors and cardiometabolic risk factors in the sample, we are applying the sample weights generated from the parent study to any estimates of prevalence. Furthermore, we do not feel

that the sampling strategy presents a limitation in the interpretation of our hypothesis testing on the association of acculturation, psychosocial factors and family functioning with cardiometabolic risk factors. The estimates of effect that we generate should be internally valid and there is no reason to assume that the external validity of the relationships between factors would be compromised based on the selected age distribution. HCHS/SOL was conducted in areas with high Hispanic/Latino concentration, thus, the sample does not capture rural or suburban areas or areas where Latinos are a small minority. Household rosters collected for families participating in the HCHS/SOL adult cohort did not record the exact ages of children living in the households. Thus, recruitment efforts are time consuming, as we had limited prior knowledge of which households contained children in the target age range, but participation rates are expected to be higher than traditional community-based samples. SOL Youth is currently a cross-sectional study that does not permit us to study how risk factors are associated with changes in body weight and cardiometabolic disease over time. In anticipation of seeking funding for a follow-up study, we have implemented cohort-retention procedures that will allow future examination of longitudinal associations. Additional contributions to the scientific community are anticipated in SOL Youth, as a resource for future ancillary studies that could use measured phenotypes, behaviors, and stored specimens to answer new scientific questions that may emerge in the field.

Conclusions

Embedding a youth study within an existing adult cohort has numerous logistic and scientific advantages as described in this paper. This approach uses an existing infrastructure that decreases the costs of enrollment and retention efforts while providing a unique opportunity to examine the influence of multiple parental and familial factors on youth cardiometabolic risk profile. SOL Youth is designed to provide a comprehensive characterization of the cardiometabolic health of Latino youth, and will help gain a better understanding of risk and protective factors associated with cardiometabolic risk. Findings from SOL Youth will have public health relevance, guiding the tailoring of cardiovascular health promoting interventions in this population.

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Table 1
 Expected demographic distribution of children in the SOL Youth study per field center (N = 1,600)

Hispanic/Latino Background	Bronx (N = 400)	Chicago (N = 400)	Miami (N = 400)	San Diego (N = 400)	All (N = 1600)
Cuban	1%	1%	57%	0%	14%
Central American	5%	10%	25%	2%	11%
Dominican	33%	1%	2%	0%	9%
Mexican-American	5%	58%	1%	93%	39%
Puerto Rican	44%	19%	2%	1%	17%
South American	5%	9%	12%	1%	7%
Mixed/other	5%	4%	3%	2%	3%

Table 2

Measurements and Core Components (C) included in the SOL Youth Exam

Measures	Child	Parent (New)	Parent (from HCHS/SOL) ³⁴
Demographic, Socio-Economic, and Health insurance status (C)	Birth date, sex, race/ethnicity, Latino background	Household composition	Birth date, sex, Latino background
	Grade in school	Child's health insurance ³⁵	Income, education attainment, occupation
	Employment (adolescents) ³⁵		Educational attainment
Anthropometry (C)	Height, weight	Height, weight	Height, weight
	Waist and hip circumferences	Waist and hip circumferences	Waist and hip circumferences
	Percent body fat	Percent body fat	Percent body fat
Laboratory (C)	Lipid panel (total, HDL-C, triglycerides, LDL-C)		Lipid panel
	Fasting glucose, insulin and HbA1C		Fasting glucose, insulin and HbA1C
	CRP and other inflammatory markers		CRP
Lifestyle behaviors	24-hr dietary recalls and dietary supplements (C): one in person and a second one over the phone.	Family meal patterns ³⁶	24-hr dietary recalls and dietary supplements
	Away-from-home foods, ³⁷ food eating practices with TV ³⁶	Food purchasing ³⁸	Away-from-home foods
	Smoking and alcohol status and susceptibility (adolescents) ^{39,40}		Smoking status Alcohol intake
	Sleep duration (weekdays and weekends) ⁴¹		Sleep duration and quality
	7-day accelerometry, physical activity ⁴² questionnaire ⁴³ (C)		7-day accelerometry, physical activity questionnaire
Examination	Cardiorespiratory fitness (step test) ²³		ECG findings
	Blood pressure (seated)(C)		Blood pressure
	Pubertal development questionnaire ²⁴		
Acculturation (C)	Acculturation scales, ^{44,45} place of birth, age at arrival, years living in the US, ethnic identity, ⁴⁶ acculturative stress ⁴⁷	Acculturation scales, ^{44,45} ethnic identity, ⁴⁶ acculturative stress ⁴⁷	Acculturation scale, familismo, ethnic identity, discrimination, language of preference, country of birth, age at arrival, years living in the US
Personal and family medical history (C)		Child's general health and chronic conditions (asthma, diabetes, hypertension, hypercholesterolemia, cancer, attention deficit disorder) ⁴⁸	General health status and chronic conditions
		Child's medication use ³⁴	Medication use
		General health of the child's 1° relatives	Family history of CVD in 1° relatives
Family and home environment	Parenting strategies (C), ⁴⁹ parenting practices for eating and physical activity (C), ⁵⁰ dietary and physical activity support (C), ^{51,52} workout equipment at home, ^{53,54} family functioning (C) ⁵⁵⁻⁵⁷	Parenting strategies (C), ⁴⁹ parenting practices for eating and physical activity (C), ⁵⁰ dietary and physical activity support, ^{51,52} foods in the home, ⁵⁸ food security, ⁵⁹ family functioning (C) ⁵⁵⁻⁵⁷	

Measures	Child	Parent (New)	Parent (from HCHS/SOL) ³⁴
Mental Health and body image	Depressive symptoms, ⁶⁰ anxiety ⁶¹ (C)		Depressive symptoms, anxiety
	Disordered eating, ⁶² body image, ⁶² social attitudes towards weight ⁶³		
	Social support for healthy eating and physical activity ⁶⁴		
School and neighborhood environment	School food environment, ⁶⁵ after-school environment ⁶⁶	School type, ³⁵ neighborhood SES, ⁶⁷ food and physical activity environment, ⁶⁸ barriers to activity in neighborhood ⁶⁹	

Table 3

Components of the SOL Youth Examination

	Child	Parent/guardian
Exam Component	Average time (min)	Average time (min)
Fasting Block (children, adults are not fasting)	60	40
Reception & informed consent/assent process.	25	25
Anthropometry	10	10
Seated Blood Pressure	15	-
Phlebotomy	05	-
Snack	05	05
Procedures, flexible sequence	55	10
Fitness Step Test	10	-
24-hr dietary recall, supplements	45	10*
Interviews, flexible sequence (with breaks)	80	80
Child Medical history	-	5
Child Medications	-	5
Visit Termination	20	30
Exit interview & Incentive	10	10
Feedback report (BMI, blood pressure, depressive symptoms)**	-	10
Activity monitoring instructions	10	10

* Confirms child responses if needed

** A second feedback report is later mailed to parents listing laboratory values and interpretation

Table 4

Components of the SOL Youth laboratory assessment

Glucose and insulin-related metabolic parameters	Fasting glucose, fasting insulin, hemoglobin A1C
Lipid profile	Total cholesterol, LDL-cholesterol, HDL- cholesterol, triglycerides
Markers of inflammation, endothelial function and obesity-related cytokines	von Willebrand factor (vWF) and e-selectin; high sensitive C reactive protein; adiponectin, interleukin-6, Plasminogen activator inhibitor, tumor necrosis factor-alpha
Stored specimens	Multiple aliquots of frozen serum, plasma, and packed cells for DNA