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Teen-LABS MOP
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Section 1 – Study Overview

Adolescent Bariatrics: Assessing Health Benefits and Risks (Teen-Longitudinal Assessment of Bariatric Surgery [Teen-LABS])
The Teen-LABS consortium is made up of five clinical centers and a data coordinating center. The goal of Teen-LABS is to facilitate coordinated clinical, epidemiological, and behavioral research in the field of adolescent bariatric surgery, through the cooperative development of common clinical protocols and a bariatric surgery database that will collect information from participating clinical centers performing bariatric surgery on teenagers. Teen-LABS will help pool the necessary clinical expertise and administrative resources to facilitate the conduct of multiple clinical studies in a timely, efficient manner. Also, the use of standardized definitions, shared clinical protocols, and data-collection instruments will enhance investigators' ability to provide meaningful evidence-based recommendations for patient evaluation, selection, and follow-up care.

In addition to investigating surgical outcomes, another broader goal of Teen-LABS is to better understand the etiology, pathophysiology, and behavioral aspects of severe obesity in youth and how this condition affects human beings over time.

The consortium was funded in June 2006. The investigators have collaboratively developed a core database and shared clinical protocols, and subject enrollment began in early 2007. This NIDDK website has detailed information on general ancillary studies policies and procedures. Further information about Teen-LABS and its specific policies are available on the Teen-LABS website. The study has a well-defined process for online submission of ancillary studies for review by the Teen-LABS Ancillary Studies Committee. The policy and online proposal submission site may be found at: http://www.Teen-LABS.org

Purpose of the Study
To facilitate and accelerate research in Bariatric Surgery, the National Institute of Diabetes & Digestive, and Kidney Diseases (NIDDK) established the Longitudinal Assessment of Bariatric Surgery consortium (LABS). The LABS research project, as originally conceived, focused only on adult participants undergoing bariatric surgery. However, an ancillary studies mechanism was also established to support other related research projects. Teen-LABS is one such related project. The primary goal of this observational Teen-LABS study is to collect baseline characteristics and postoperative outcomes of adolescents who are undergoing bariatric surgery in an effort to assess safety and efficacy of bariatric surgery. By mirroring LABS data collection in adolescents, the Teen-LABS study will also allow us to estimate the relative merits of early surgery compared to delayed surgery for extremely obese youth. This comparison will lead to a better understanding of the plasticity of important medical and psychosocial obesity-related comorbidities. Moreover, this study will provide critical scientific information to inform clinical decision-making regarding appropriate timing of bariatric surgery. In the 3rd cycle of funding for this project (2016-2022), several additional long-term research aims have been added, all in general alignment with the original aims of the project to assess efficacy and safety of bariatric surgery when performed in adolescent years.

Specific Aims and Design Synopsis:
Specific Aim 1:

Aim 1: Assessment of mid-term (5 year) outcomes of adolescent compared to adult bariatric surgery, assessment of long-term (10 year) outcomes of adolescents bariatric surgery, and assessment of differences in outcome for RYGB and SG procedures performed in adolescence.

Aim 2: To assess long term safety by measurement of bone mineral density in the surgical cohort, with comparisons to similarly obese non-surgical control participants

Exploratory Aim 3: To evaluate cognitive functioning and behavioral constructs during the first decade following adolescent bariatric surgery. In particular, cognitive function, cognitive control, affect regulation, reward processing, risk taking behaviors (including problems with alcohol), and problematic eating behaviors will be assessed.

Aim 4: To obtain and store biospecimens (serum, plasma, and whole blood) from adolescents for research related to the aims of this study, and for future use by this consortium and ancillary studies for research into the pathophysiology of obesity and obesity related health problems.

For more details, see full protocol document, revised October 2018.

Data Safety Monitoring Information: Provided in the Teen-LABS Dropbox, accessible by direct invitation or by using the following link:
https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QqOmBPyGpEzChIZla?dl=0

Data Safety Monitoring Charter (DSMC)

Data Safety Monitoring Plan (DSMP)

Section 2 – Scheduling and Visits

2.1 Enrollment Procedures.
Prior to implementing this protocol, the principal investigator must have the protocol and consent form approved by the Institutional Review Board (IRB) for Human Research at each participating institution. For adolescents, all eligible patients should be recruited.

2.1.1 Enrollment.
For the initial cohort, once an adolescent had been approved for surgery, the surgeon Co-Investigator at adolescent centers screened patients for eligibility. If the adolescent was willing to participate, met criteria, and gave written informed consent, they were enrolled into the Teen-LABS study. Consent/ Assent was given for study participation, access to all medical records, submission of biospecimens, DNA, liver tissue, and for future contact for participation in any additional research studies. The original signed consent form was placed into the participant's research binder and a copy was placed in their medical records.

The original study cohort of 242 adolescent participants were recruited between 2007 and 2011. To further compare the participants who had Vertical Sleeve Gastrectomy (SG) surgery after Teen-LABS enrollment closed, we will enroll 38 additional SG participants in this third cycle of funding to permit adequately powered comparisons of important outcomes between SG and RYGB participants. Our power analysis indicates that additional 38 SG participants would be sufficient for these purposes. To maximize the long-term (5-10 year) SG follow-up visits in the 2016-2022 extension period, and to maintain uniformity with our consecutive enrollment methodology, we will sequentially recruit individuals meeting inclusion criteria. We will screen the operative log at two study sites, Cincinnati Children's Hospital Medical Center and Nationwide Children's Hospital Medical Center, who performed SG in the years of 2012-2015 to identify potential new SG participants. We will sort potential participants in the screening list by date of SG surgery and consecutively recruit these individuals. Recruitment phone calls and letters will be used, as well as recruitment using typical means by which the clinical team maintains contact with these individuals including routine clinic visits, as available. After enrollment, data that map to Teen-LABS core baseline variables and early postoperative measures (weight/height, comorbidities, laboratory data, and surgical complications) at the timepoints typically collected by Teen-LABS (e.g., baseline, 30d, 6mo, and annual) will be abstracted from medical records. Major healthcare utilization self- reported events (operations, other procedures, or hospitalizations) during or following bariatric surgery will also be abstracted so that potential complications of surgery or of underlying medical conditions can be analyzed. An in-person research visit will then be conducted to collect a complete annual visit research dataset, identical to the annual in-person full visits conducted for all other TL participants. In this manner, all 38 new enrollees will be eligible to contribute long-term (≥5 year outcomes) data by 2018, and will be serially studied every year during this project period (2016-2022).

We will also be enrolling "Control" participants at Cincinnati Children's, Nationwide Children's and Texas Children's where the ***Dual energy-x-ray absorptiometry (DXA)*** machines "Hologic Discovery" model to measure bone health are capable of measuring participants of a higher weight range. Physiologic increases in bone mass and density (BMD) typically occur throughout childhood and into the 3rd decade of life. Bone mass and density are relatively stable in the 3rd to 5th decades of life and slowly decline thereafter. Weight is a strong determinant of BMD at all ages, and weight reduction is associated with reduced BMD. Bariatric surgery is associated with bone loss in the short term due, in part, due to weight loss. There is concern that bariatric surgery in adolescence may adversely affect bone health over the *long-term.* Even small annual declines in BMD are important as they accumulate over decades and increase fracture risk later in life. This is particularly salient for adolescents who undergo bariatric

surgery as they have life-long "exposure" to their altered anatomy. We will **test the hypothesis that bone mineral density will be lower following both RYGB and SG procedures compared to BMI-similar controls.**

- An **Enrollment Form** will be completed to record participants who are enrolled into Teen-LABS. This form reports whether participants provided consent to Teen-LABS, along with date of consent. If the patient does not consent, the reason is reported.

Written informed consent will be obtained from all participants, former and new, according to the guidelines established by the Institutional Review Board at CCHMC and each specific site. All study procedures will be explained and performed using English language and participants must comprehend the English language to participate. The informed consent form is a means of providing information about the study to a prospective participant and allows for an informed decision about participation in the study. All participants must read, sign, and date a consent form before entering the study or undergoing any study-specific procedures.

2.1.2 Study Procedures for Participants:
Initial and Perioperative (Day of Operation to 30 day postoperative) Data Elements.
At each adolescent site, patients will be enrolled only after they have been approved by the clinical team to undergo bariatric surgery, meet study eligibility criteria, and agree to participate in Teen-LABS by signing an informed consent. Primary and alternative contact information, including the names, addresses and telephone numbers of two contacts and their primary care physician will be requested. Permission will be requested to contact the alternative contacts when the participant becomes unreachable during the study period; where local regulatory approval allows permission will also be sought to use the subject's social security number to locate him or her in the event of a missed visit.

The principal investigator and research staff will attempt to determine why consent is not provided when eligible participants refuse to participate. At those sites where IRB permits, the adolescent who declines participation in Teen-LABS will be asked to consent to having age, gender, race, ethnicity, height and weight recorded and stored in a de-identified manner. The information from patients who decline to participate in the study will be compared to those who do consent to ascertain the generalizability of Teen-LABS results.

Data collection forms and questionnaires will be obtained electronically from the Teen-LABS DCC by each clinical site in portable document format (PDF) for printing and completion. The Site Coordinator will determine which measures (including study laboratory analyses and psychosocial measures) <u>are not obtained</u> during routine preoperative assessment by the clinical team and insure that these elements are collected for the research study. The Teen-LABS pre-operative evaluation, including relevant updated data collection, will be completed through patient assessments, including chart review, self-administered forms and interview with the patient as necessary. Laboratory values, medication and co-morbidity information will be updated within 90 days of surgery; and weight and other physician measures obtained again within 30 days of surgery via the anthropometrics form. The pre-operative evaluation and update (if applicable) forms will be transmitted to the Teen-LABS DCC using the data entry system developed by the Teen-LABS DCC. After performing the bariatric operation, the Teen-LABS operative form will be completed and the data transmitted to the Teen-LABS DCC. Patients or, when necessary, an alternative contact (if agreed to by the patient as noted above) will be contacted no less than 30 days after surgery to ask about post-operative events occurring within 30 days of the Bariatric surgery. The research coordinator will also review patients' medical records to determine if a reportable outcome event occurred.

Some details of the Teen-LABS pre-operative enrollment form, operative and post-operative data collection forms are listed below. The pre-operative evaluation update form includes a subset of the data collected at the initial pre-operative evaluation. All the forms are provided in the Teen-LABS Dropbox, accessible by direct invitation or by using the following link: https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QgOmBPyGpEzChIZla?dl=0

Teen-LABS Participants with Learning Disabilities
Teen-LABS Participants with Learning Disabilities who need caregivers to complete forms should only exclude the BB, SF36, BDI, IWQOL but all others should be completed. Complete the OFF protocol form for the following behavior forms that will not be completed due to the patient's learning disability: BB, SF36, BDI, IWQOL, SBQ, Cognitive Measures.

Enrollment Elements: Enrollment forms and Informed Consent Tracking Form.
These elements are collected upon Enrollment into the study and participant identifier (alpha-numeric code) and date of consent to participate in Teen-Labs are sent to DCC the day completed.

Baseline Evaluation Data Elements
These elements will be optimally collected within 30 days prior to operation.

- Month and year of birth, gender, height, weight, race, ethnicity
- Anthropometrics and vital signs (Anthropometrics Form)
- Nutritional supplements prescribed for postoperative period
- Fitness (400 meter corridor walk,)
- Most recent laboratory values and medications (within 90 days)
- Planned procedure, planned approach, previous obesity surgery
- Whether or not the planned procedure is a revision/reversal of prior bariatric procedure
- Comorbidities (T2DM, ischemic heart disease, hypertension, congestive heart failure, sleep apnea, history of deep vein thrombosis/pulmonary embolus, asthma, functional status, pulmonary hypertension, urinary incontinence, sleep hygiene)
- Psychosocial assessments
    - BDI-II and if indicated BDI Action Plan
    - Sent to DCC on the day completed and scored
- Smoking history, other conditions possibly affecting outcomes
- Preoperative weight loss program characteristics
- Weight history

Operative Data Elements
These elements are collected by the surgeon immediately after the surgical procedure.

- Date of surgery
- Operative times
- Procedure(s) performed
- Whether a resident or trainee was present
- Method of surgical procedure
- Whether concurrent procedures were performed
- Test of anastomosis
- Deep vein thrombosis prophylaxis
- Intra-operative fluids administered
- Anesthesia risk-derived classification
- Whether post-operative anticoagulation was ordered
- Adverse intra-operative events
- Lowest reported or known body temperature

30-day Post-Operative Outcome Elements
These data will be collected within a desired window of 30-55 days. If patient cannot be reached within this window, the objective elements of the form which can be completed by chart review without patient input will be collected by coordinator.

- Source(s) of information
- Length of hospital stay (days)
- Discharge location
- Whether the surgical wound edges opened
- Whether the wound edges separated and required packaging or bandaging
- Date of death, if applicable
- Re-hospitalization(s), if applicable
- 30-day post-operative outcomes, i.e., abdominal re-operation, tracheal re-intubation, tracheostomy, endoscopy, placement of percutaneous drain, anticoagulation therapy for presumed/confirmed deep vein thrombosis, anticoagulation therapy for presumed/confirmed pulmonary embolus, other events requiring intervention
- Supplement adherence
- Primary caregiver demographics, weight, height

30 Day Status/Visit for Teen-LABS
The 30 day health assessment (is not a protocol mandated "visit"). Health status information can be collected either in person or by phone.
Situation A: If coordinator is aware of planned visit between 30-45 days, wait for visit and collect info in person. Even if a patient has visited or contacted the clinical center before day 30, do not fill out 30 day data collection form until day 30 at the earliest, but using all clinical status information available.
Situation B: If coordinator not aware of planned visit between days 30-45, then coordinator calls ASAP after day 30 to obtain all information by phone, and begins requesting records from outside hospitals/clinics/ERs if applicable.
Situation C: If unsuccessful in reaching patient by day 45, coordinator can continue to attempt to reach patient or await an in-person visit until day 55 to obtain the data. If still unable to obtain data by day 55, coordinator completes 30 day form regardless, based on a review of office chart and hospital chart at facility where surgery was performed or any other affiliated facility relevant to the care of the patient as appropriate, provided this data acquisition is not in violation of any local, state, or federal regulations or policy.

Six, Twelve, and Twenty-Four Month and Annual Post-operative Outcome Elements.
These data will be collected within a designated window of time around the 6, 12, and 24 month and annual anniversary. The desired window for the 6 month time point will be 30 days before or after, and the window around the annual time points will be 60 days of the anniversary date. Please see Timepoints table later in this section for forms to be completed at annual visits past 24 months.

- Updated contact information
- Anthropometrics (Anthropometrics Form)
- Nutritional supplements prescribed for postoperative period
- Fitness (400 meter corridor walk, Stepwatch physical activity monitoring)
- Most recent vital signs, laboratory values, medications (within 90 days)
- Comorbidity reassessment
- Psychosocial self-assessment forms
- Smoking status, Other conditions possibly affecting outcomes
- Healthcare utilization

- Supplement adherence

A screening log will be kept on patients who do not consent to participate in Teen-LABS. If participant does not want to consent to participate in the study but is willing to share personal data information collected in the screening log will be:

- Reason for refusal
- Age
- Height and weight
- Gender
- Race and ethnicity

All participants will be reimbursed for completing visits, as outlined below. If a participant is unable to complete a full visit, the reimbursement amount will be prorated.

Study Visit	For completion of Self-Assessment Questionnaires	For completion of Physical Measurements	For completion of Blood Draw & Urine Collection	For completion of Phone Interview	Total Maximum Participant Amount Possible (for full study visit)
5 year full visit	$50.00	$120.00	$90.00	n/a	**$**260.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
6 year full visit	$50.00	$130.00	$100.00	n/a	**$**280.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
7 year phone call	$25.00	n/a	n/a	$25.00	**$**50.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
8 year full visit	$50.00	$140.00	$110.00	n/a	**$**300.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
9 year phone call	$25.00	n/a	n/a	$25.00	**$**50.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
10 year full visit	$50.00 $50.00 psych	$150.00	$120.00	n/a	**$**370.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
11 year phone call	$30.00	n/a	n/a	$30.00	**$**60.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
12 year phone call	$35.00	n/a	n/a	$35.00	**$**70.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
13 year phone call	$40.00	n/a	n/a	$40.00	**$**80.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
14 year phone call	$45.00	n/a	n/a	$45.00	**$**90.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
15 year phone call	$50.00	n/a	n/a	$50.00	**$**100.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00

Prorated reimbursement schedule for new SG being recruited 2017-2019:

Study Visit	For completion of Self-Assessment Questionnaires	For completion of Physical Measurements	For completion of Blood Draw & Urine Collection	For completion of Phone Interview	Total Maximum Participant Amount Possible (for full study visit)
3 year full visit	$50.00	$100.00	$70.00	n/a	$220.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
4 year full visit	$50.00	$110.00	$80.00	n/a	$240.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
5 year full visit	$50.00	$120.00	$90.00	n/a	$260.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
6 year full visit	$50.00	$130.00	$100.00	n/a	$280.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
7 year phone call	$25.00	n/a	n/a	$25.00	$50.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
8 year full visit	$50.00	$140.00	$110.00	n/a	$300.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
9 year phone call	$25.00	n/a	n/a	$25.00	$50.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
10 year full visit	$50.00 $50.00 psych	$150.00	$120.00	n/a	$370.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00

In addition, some eligible participants may receive compensation for travel to the study site and may be provided for all current participants continuing in the study for the full annual study visits (years 5, 6, 8, and 10) that occur after June 2009 and for new 2017-2019 SG for full annual study visits. The compensation will be based on the federally allowable reimbursement for automobile use, based on round trip distance from the participant's home to the clinical center. The compensation schedule is below:

- Round trip travel from home to center up to 125 miles: $25 compensation
- Round trip travel from home to center 126-250 miles: $100 compensation
- Round trip travel from home to center 251-375 miles: $150 compensation
- Round trip travel from home to center 376-500 miles: $200 compensation

Round trip travel from home to center over >500 miles: $250 compensation

- For a Quest visit $25 compensation is given for mileage from home to the outpatient lab.

Participants continuing in the study who live >250 miles round trip from the center may also be reimbursed for reasonable lodging costs up to $150.00 per visit for full study visits in years 2, 3, 4, 5, 6, 8, and 10. SG who live >250 miles round trip from the center may also be reimbursed for reasonable lodging costs up to $150.00 per visit for full study visits (visits 1, 2, and 4).

If a DXA scan is done, participants will receive a one-time reimbursement of $100.00.

The non-surgical cohort for DXA comparison will be reimbursed $100.00 for their one–time visit but will not be given gas or mileage or hotel compensation.

2.2 Data Collection Flow is based on the Timepoints listed below.

TL data collected (rows) at years (columns)*		5	6	7	8	9	10	11	12	13	14	15
	Surgeon/Coordinator Completed											
ANTH	Anthropometrics	x	X		X		x					
ANTH	Blood Pressure	x	x		X		x					
MWE	400 Meter Walk Eligibility Form	x	X		X		x					
MWF	400 Meter Walk Data Collection Form	x	X		X		x					
CAF	Comorbidity Assessment - Follow-up	x	X		X		x					
HC	Healthcare Utilization Form	x	X	x	X	x	x	x	x	x	x	x
CLAB FH	Central Lab - Fresh	x	X		X		x					
CLAB_FZ	Central Lab - Frozen	x	X		X		x					
ICT	Informed Consent Tracking form	x	X	x	X	x	x	x	x	x	x	x
BDI2S	Beck Depression Inventory Scoring & Action Plan	x	X		X		x					
SHORT	Short Form	x	X	x	X	x	x	x	x	x	x	x
AE	Adverse Events											
INF	Inactivation Form											
MRF	Mortality Report Form											
UPR	Unanticipated Problem Report											
	Patient Completed											
CI	Contact Information	x	X	x	x	x	x	x	x	x	x	x
SWH	School and Work History	x	X		x		x					
BF	Behavior - Follow-up	x	X		x		x					
SF36	SF36 Health Survey	x	X		x		x					
BDI2	Beck Depression Inventory - II	x	X		x		x					
PETSF	Psychiatric and Emotional Test Survey - Follow-up	x	X		x		x					
IWQOL	Impact of Weight - Kids (IWQOL -Lite yrs 6&8)	x	X		x		x					
GSRS	Gastrointestinal Symptoms Rating Scale	x	X		x		x					
UIF	Urinary Incontinence - Follow-up	x	X		x		x					
BS	Berlin Sleep	x	X		x		x					
RHF	Reproductive Health - Follow-up	x	X		x	-	x					
MED	Medications	x	X		x		x					
IPAQ	International Physical Activity Questionnaire	x	X		x		x					

IPS	International Prevalence Study on Physical Activity	x	X		x		x					
FX	Fracture Survey	X	X		X		X					
ESS	Excess Skin Survey	x					x					
RHP	Reproductive Health Pregnancy Questionnaire	x	x		x		x					
UPPS-P	UPPS-P Behavior Scale						x					
SPSRQ	Sensitivity to Punishment and Sensitivity to Reward Questionnaire						x					
EM-CQ	Monetary-Choice Questionnaire						x					
DERS	Difficulties in Emotion Regulation Scale						x					
ATQ-EC	Adult Temperament Questionnaire-Effortful Control						x					
SBQ	LABS SBQ						X^					

**** In years 7, 9, and 11-15, cohort maintenance and minimal data collection by annual phone call will be performed***

^ Or after, if not collected at year 10

2.4 Coordinator Visit Checklist

VISIT CHECKLIST (EACH site should modify to fit process of site specific scheduling for in-person visits)
Enrollment Procedures
Study procedures for Adolescent Participants
Data Collection Flow
Visit Timepoints
Coordinator Visit Checklist
Blood Pressure Notification Letter for Participant

Physical Measures

Blood Pressure/Resting Heart Rate Welch Allyn Spot Vital Signs Blood pressure (BP) monitor provided by the study. If not possible to use the device, auscultate BP and hand count Heart rate. OFF Teleform will need to be completed each deviation if study Blood pressure machine not used.
Resting Heart Rate
Neck Circumference using the Gulick II Tape Measure (model 67020)
Waist Circumference using the Gulick II Tape Measure (model 67020)
Body Composition using the Tanita Scale
Sagittal using Holtain-Kahn Abdominal Caliper plus 20 cm extension bar

Specimen Collection

Central Laboratory
Local Laboratory
Repository

Corridor Walk – if in person visit and fit criteria. Done according to Timepoints table

Psychosocial Measures

Assurance of Informed Consent
Participant Behavioral Issues
Participant Psychosocial Issues completion of Safety **Action Plan as needed**
Cognitive testing per web based instructions done during the clinic/ research visit to promote completion of the instrument.

Correspondence with DCC
Teleform *the BDI-II and BDI-II Action plan* must be sent *WITHIN 24 hours.*

Procedures for conduct of retrospective chart abstractions for new SG cohort appear below.

2.5 Retrospective Chart Review for Vertical Sleeve Gastrectomy (SG) participation in Teen-LABS Study. (Conducted only at Cincinnati Children's & Nationwide)

We will enroll 38 additional SG participants who had surgery **between 3/1/2012 and 12/31/2015** to permit adequately powered comparisons of important outcomes between SG and RYGB participants. Our power analysis indicates that another 38 SG participants would be sufficient for these purposes. To maximize the long-term (5-10 year) SG follow-up visits in the 2016-2022 extension period, and to maintain uniformity with our consecutive enrollment methodology, we will sequentially recruit individuals meeting Teen-LABS inclusion criteria. We will screen the operative log at the two study sites (Nationwide and Cincinnati Children's) who performed SG in the 2012-2015 years to identify potential new SG participants. We will sort individuals in the screening list by date of SG surgery and consecutively recruit these individuals. Recruitment phone calls and letters will be used, as well as recruitment during routine clinic visits, as available.

Once consent is obtained, the DCC will assign a study ID number for the new participant and identify the relevant forms for completion. Chart abstraction will be conducted and prospective study visits will be scheduled for the anniversary of the surgical procedure. The visit year will be determine by the number of years out from surgical procedure. For example: if the date of surgery was 3/15/12, then visit 1 would be planned for 3/15/17 and would be considered 5 years out from surgery, and all data collected and reimbursement rate would be at the 5 year time point for the Teen-LABS study.

Medical Record Review and chart abstraction will be completed by a Teen-LABS certified staff or medically trained member using the below procedure and confirm data by **taking a screen shot from the chart or making a copy of the appropriate chart pages to use as a Source Document (SD).** **Do not infer any answers!!**

For data not available in Medical Records, mark (-1) on the Case Report Form Teleform (CRF). For missing data points on baseline LV form, the DCC prefers to document any baseline lab values that are out of window rather than document (-1) on the baseline LV.

TL VSG Retrospective data collected (rows) at visits (columns)		B	3	6	12	24	36	48	60
ANTH	Anthropometrics	x		x	x	x	x	x	x
PTP^	Prescribed Treatment Plan	x	x	x	x	x	x	x	x
CAF	Comorbidity Assessment - Follow-up			x	x	x	x	x	x
RCAF	Research Coordinator Assessment - Follow-up			x	x	x	x	x	x
LV	Lab Values	x		x	x	x	x	x	x
SMAF	Surgeon's Medical Assessment - Follow-up			x	x	x	x	x	x
HC	Healthcare Utilization Form		x	x	x	x	x	x	x
SHORT	Short Form								x
SQOP	Surgeon Questionnaire/Operative	x							
PO	Pre-Op	x							
POST	Post-Op		x						

GS	Gastric Sleeve	x							
CAB	Comorbidity Assessment – Baseline	x							
RCAB	Research Coordinator Assessment – Baseline	x							
SMAB	Surgeon's Medical Assessment – Baseline	x							
	As Needed								
AE	Adverse Events								
INF	Inactivation Form								
MRF	Mortality Report Form								
OFF*	Off Protocol								
UPR	Unanticipated Problem Report								

* The OFF form will only be needed to identify missed visit for the retrospective data capture
^ The PTP is done pre-op and at 30 days post-op or as close as possible if able to obtain

Newly enrolled VSG participants will complete the below listed Teleforms at study entry. Data will be captured using Teleforms for this initial enrollment visit then transition to REDCap for future visits.

EF	Enrollment Form
ANTH	Anthropometrics / Blood Pressure
MWE	400 Meter Walk Eligibility Form
MWF	400 Meter Walk Data Collection Form
CAF	Comorbidity Assessment - Follow-up
HC	Healthcare Utilization Form
CLAB FH	Central Lab – Fresh
CLAB_FZ	Central Lab – Frozen
NIH-DNA	NIDDK –shipment form
ICT	Informed Consent Tracking form
BDI2S	Beck Depression Inventory Scoring & Action Plan
SHORT	Short Form
AE	Adverse Events
INF	Inactivation Form
MRF	Mortality Report Form
UPR	Unanticipated Problem Report
	Patient Completed forms
CI	Contact Information
SWH	School and Work History
BF	Behavior - Follow-up
SF36	SF36 Health Survey
BDI2	Beck Depression Inventory – II
PETSF	Psychiatric and Emotional Test Survey - Follow-up
IWQOL	Impact of Weight - Kids (IWQOL -Lite yrs 6&8)
GSRS	Gastrointestinal Symptoms Rating Scale
UIF	Urinary Incontinence - Follow-up
BS	Berlin Sleep

RHF	Reproductive Health - Follow-up
MED	Medications
IPAQ	International Physical Activity Questionnaire
IPS	International Prevalence Study on Physical Activity
ESS	Excess Skin Survey
RHP	Reproductive Health Pregnancy Questionnaire

1. Enter study ID and date on each page.
2. Hospital code will begin with CIN15XX for Cincinnati and NCH55XX for Nationwide as assigned by coordinator.
3. All data not able to be referenced should be coded (-1) close to the answer box.
4. Date of surgery will be index date.
5. Confirm Informed Consent has been signed prior to chart abstraction and confirm dates on Informed Consent Tracking (ICT) form.
6. Obtain demographic information off of the: Admission / Demographic sheet and complete Enrollment form (EF) and Pre-op (PO) form.
7. Locate the vital sign sheet and obtain the Anthropometric data to complete the (ANTH) form. If weight and height not on that form locate these in the medical record and record accordingly. If the past history of weight is documented in the History and Physical section of medical record document pre-program weight on the Research Coordinator Assessment Baseline (RCAB) form.
8. Locate the pre-operative information and complete the data for past medical and surgical history and physical exam on the Pre-op (PO) form. If medical records indicates patient's functional status, document accordingly. Note medications prescribed obtaining this information from history and physical as well as physician and nurse's notes completing the Medication (MED) and Prescribed Treatment Plan (PTP) form.
9. Explain any other finding or information to show the status of the patient at time of surgery on the Pre-operative (PO) and the Surgeon's Medical Assessment Baseline (SMAB), the Co-morbidity Assessment Baseline (CAB) form and the Research Coordinator Assessment Baseline (RCAB) form. Record results of any tests (Diagnostic tests/ ECG/ EGD/ medical therapies prior to surgery).
    a. Make sure data SD has copy of where information was obtained i.e. Clinical Cardiac Exam or from Admission note or Discharge summary.
    b. Indicate any evaluations done by a specialist based on consultant notes in chart
    c. Note any other significant medical conditions such as Pseudotumor Cerebri tumor or Hypothalamic Obesity on (PO) form.
    d. Note any substance abuse or Alcohol use mentioned in chart (4 oz. wine= one drink / 12 oz. beer= one drink / 1 oz. hard liquor= one drink) and note any detection in blood or urine tests on the (PO) form in section 10 for other comorbid conditions that could affect clinical outcome following bariatric surgery.
    e. Record smoking history (20 cigarettes= 1 pack) on the Pre-OP form (PO).
    f. Note results of EKG, Diagnostic test results and Chest X-ray (question 1.14 "other" on the RCAB).
    g. Laboratory findings as noted in chart on the (LAB) form.
    h. Record time of surgery and pre and post op meds on the Surgeon's Questionnaire/ Operative Evaluation (SQOP), the Discharge Summary (DS) and the information regarding the Gastric Sleeve on the (GS) form.
    i. Record any interventions such as G tube or endoscopies done during hospitalization or any re-hospitalization or outpatient procedures done on the Post-operative Evaluation Form (POST) and select letter "e" Chart Review on page 1 of the form.

j. Complete the Health Care Utilization Form (HC) for any interval hospitalizations noted in the medical record.
k. Complete the Off Protocol Form (OFF) if indicated.

CRF completion by study time points:

Baseline Visit (Day of Surgery):

1. ANTH form
   Info obtained from pre-op note in EPIC, click on flowsheets:
   Click on "VITALS" flowsheet for pre-op V.S.
   Click on "NPO Weight HCG" flowsheet for HT/WT
   (Info not always available on pre-op notes and flowsheets. Some data points are captured from other flowsheets in EPIC.)
   For the Dexa scan click on chart review > procedures

2. PTP form
   Info obtained from Inpatient discharge summary form from surgical event. Chart review > encounter or notes.

3. LV form
   Info obtained from results review: Find the most recent results within past **180 days**
   Click on date and it will highlight that column then print.
   If results aren't all on one date will need to do more columns and prints.

4. RCAB form
   Info obtained from chart review > imaging and procedures and ECG
   Chart review > media button **** this is a great resource button for old records, Echo's and ECGs not found elsewhere.
   If you do not have something specifically stating that the test was not done the test should be marked unknown. (per Dr. Inge)
   Weight and Height are record the pre-program weight (prior 6 months to 1 year) at time of referral.

5. CAB form
   Info obtained from BAR MD VISIT FORM (INTIAL AND FOLLOW-UP) [382] under review flowsheet. (See end of MOP for codes to use to complete BAR form 382)

   For Nationwide it will be a review of medical history and if you do not have something specifically stating that they have a condition it should be marked -1.

6. SMAB form
   Info obtained from BAR MD VISIT FORM (INTIAL AND FOLLOW-UP) [382] under review flowsheet.
   Rosie I am not able to attach code correctly. Maybe you can??
   For Nationwide it will be a review of medical history and if you do not have something specifically stating that they have a condition it should be marked -1.

7. SQOP form
   Info should be on OP note and anesthesia records. Since questions are at time of surgery if OP note does not specify problem then it is a NO. If uncertain mark -1.
   Anesthesia record will provide details on start, stop…Lowest temp in OR is on record as T2(C).

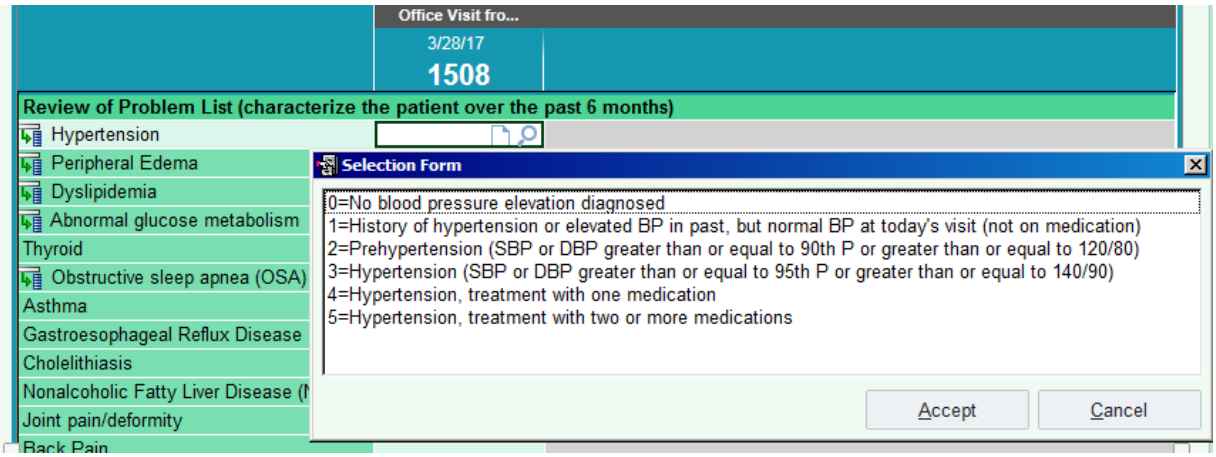
This can be found under media if before EPIC was in use in that department.

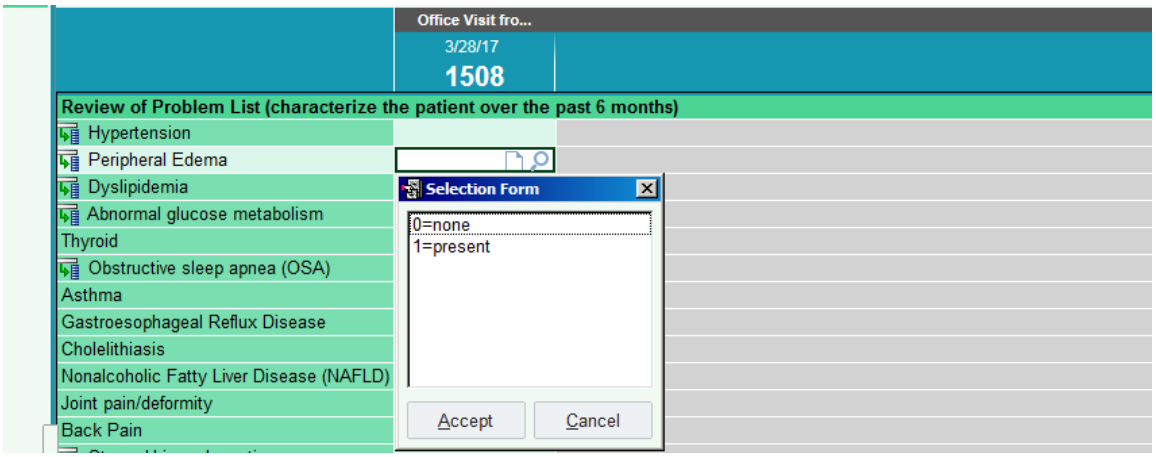
8. PO form
   Info should be on OP note and referral note.
   For prior surgery performed on the esophagus…. NOT for wt. loss.
   I did a (-1) since we are not assuming anything that is not on the OP note.
   Smoking status click on ht > social > substance and sexuality this will cover alcohol, drugs and sexual behavior.
   Question 10 other comorbidities: find in snapshot> problem list

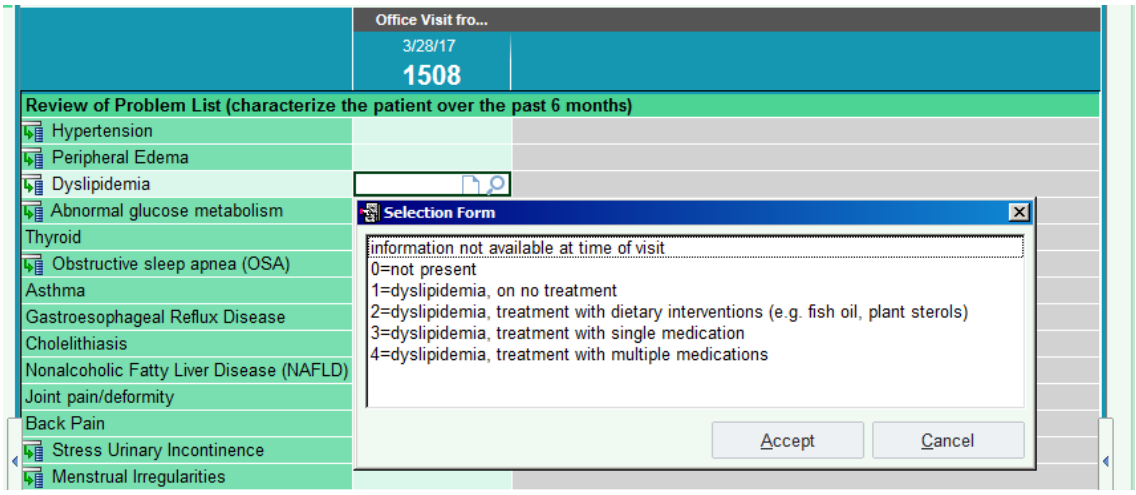
9. POST form
   Info should be on OP note
   Stage 2 diet = regular diet if not PO then is nasal tube feedings
   Found on discharge note. No TPN @ CCHMC for these kids.
   Date of extraction is the visit >/= 30 days after surgical date.

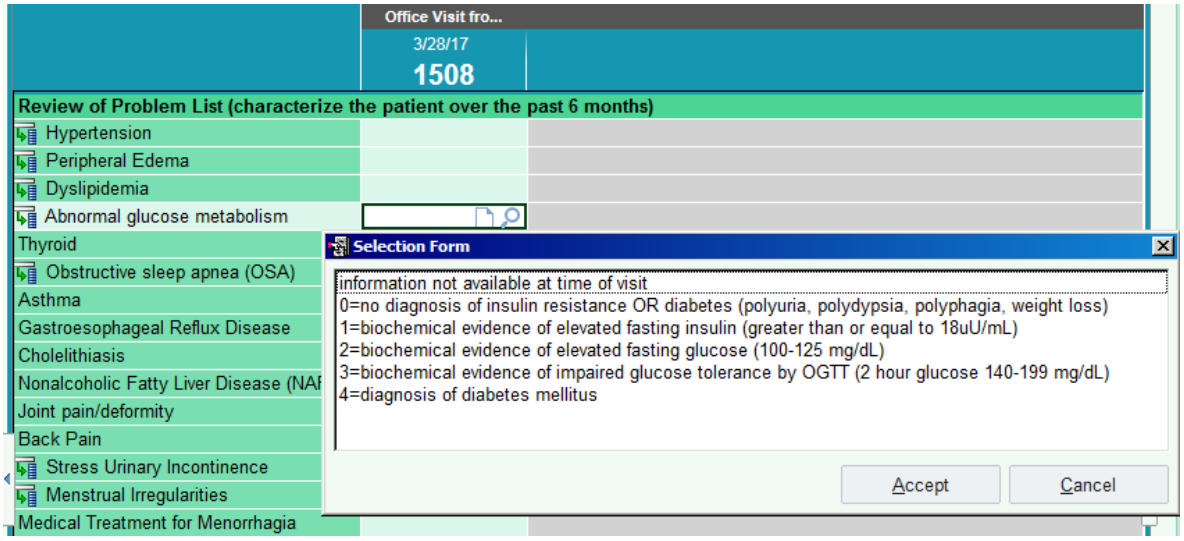
10. HC form
    Extract info as in original study

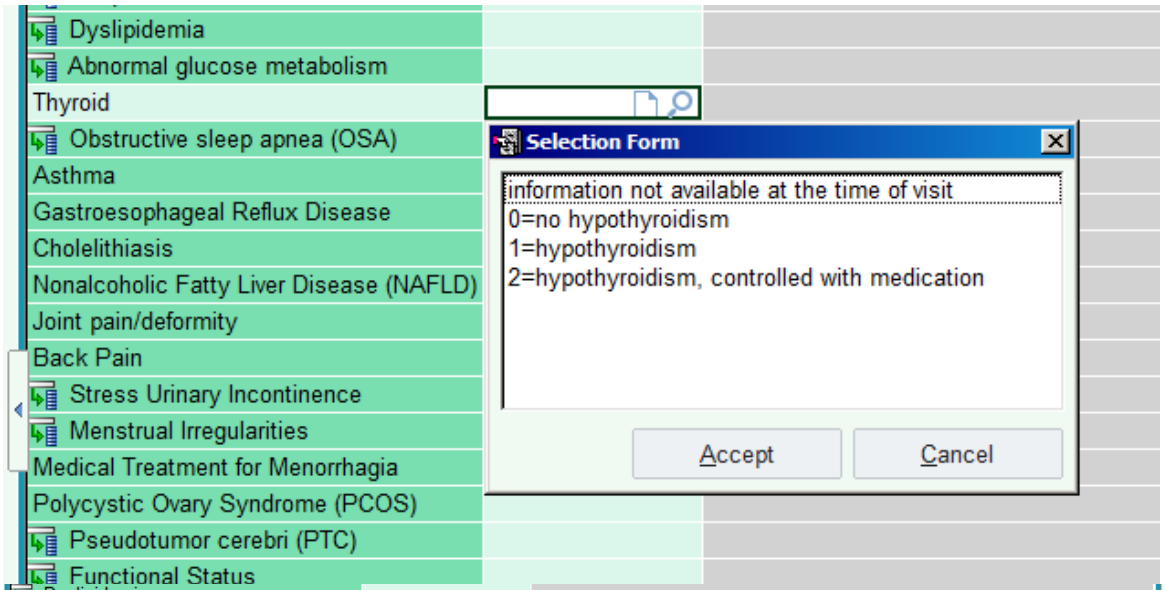
11. GS form
    Info should be on OP note
    Q2 always "divided"
    Q3 color of staple = ht.
    White =1.0
    Blue = 1.5
    Green -2.0
    Q4Ethicon stapler
    Q 7-9 no documentation = no

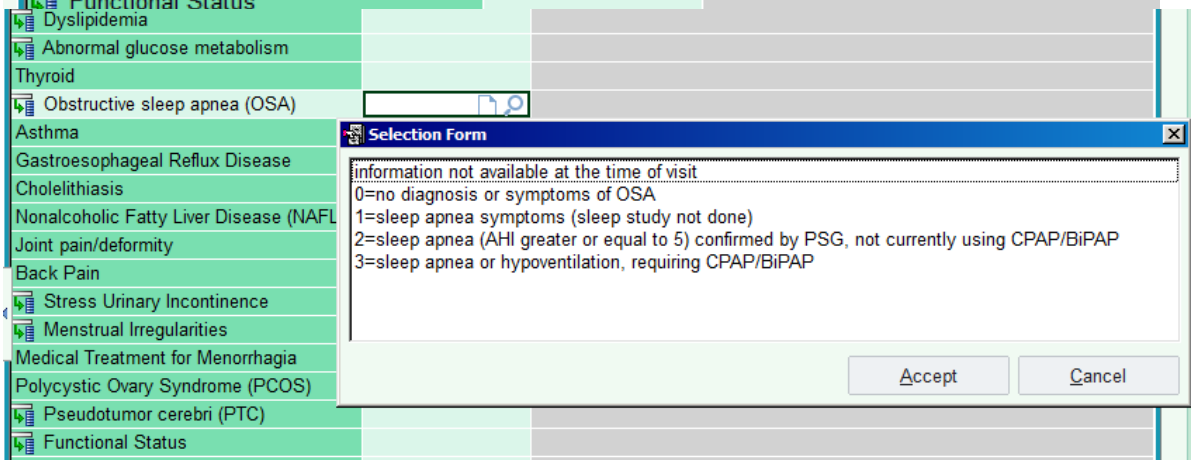


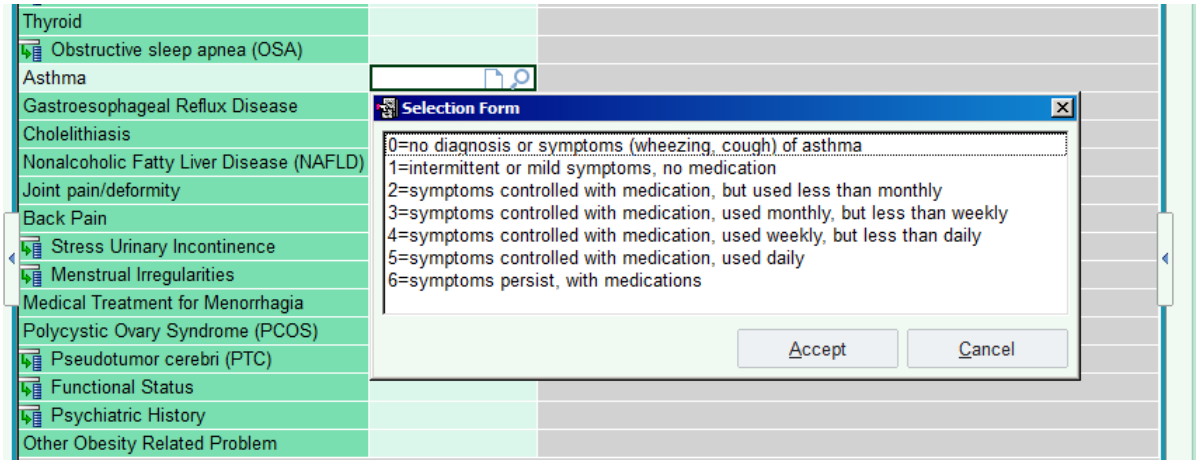

Office Visit fro...
3/28/17
1508
Review of Problem List (characterize the patient over the past 6 months)
Hypertension
Peripheral Edema
Dyslipidemia
Abnormal glucose metabolism
Thyroid
Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Selection Form
0=none
1=present
Accept
Cancel

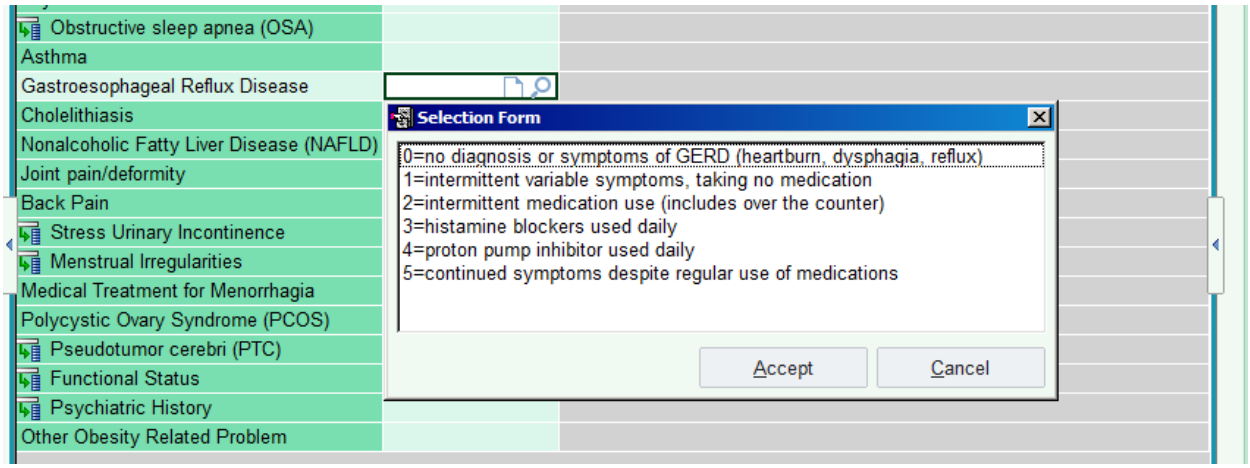

Office Visit fro...
3/28/17
1508
Review of Problem List (characterize the patient over the past 6 months)
Hypertension
Peripheral Edema
Dyslipidemia
Abnormal glucose metabolism
Thyroid
Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Selection Form
information not available at time of visit
0=not present
1=dyslipidemia, on no treatment
2=dyslipidemia, treatment with dietary interventions (e.g. fish oil, plant sterols)
3=dyslipidemia, treatment with single medication
4=dyslipidemia, treatment with multiple medications
Accept
Cancel

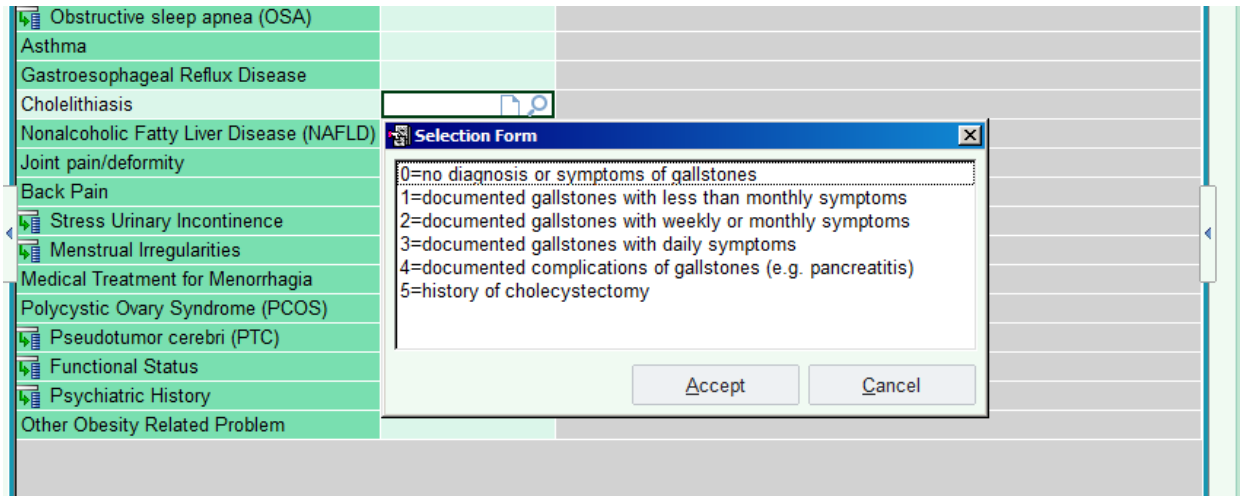

Office Visit fro...
3/28/17
1508
Review of Problem List (characterize the patient over the past 6 months)
Hypertension
Peripheral Edema
Dyslipidemia
Abnormal glucose metabolism
Thyroid
Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAF
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Selection Form
information not available at time of visit
0=no diagnosis of insulin resistance OR diabetes (polyuria, polydypsia, polyphagia, weight loss)
1=biochemical evidence of elevated fasting insulin (greater than or equal to 18uU/mL)
2=biochemical evidence of elevated fasting glucose (100-125 mg/dL)
3=biochemical evidence of impaired glucose tolerance by OGTT (2 hour glucose 140-199 mg/dL)
4=diagnosis of diabetes mellitus
Accept
Cancel

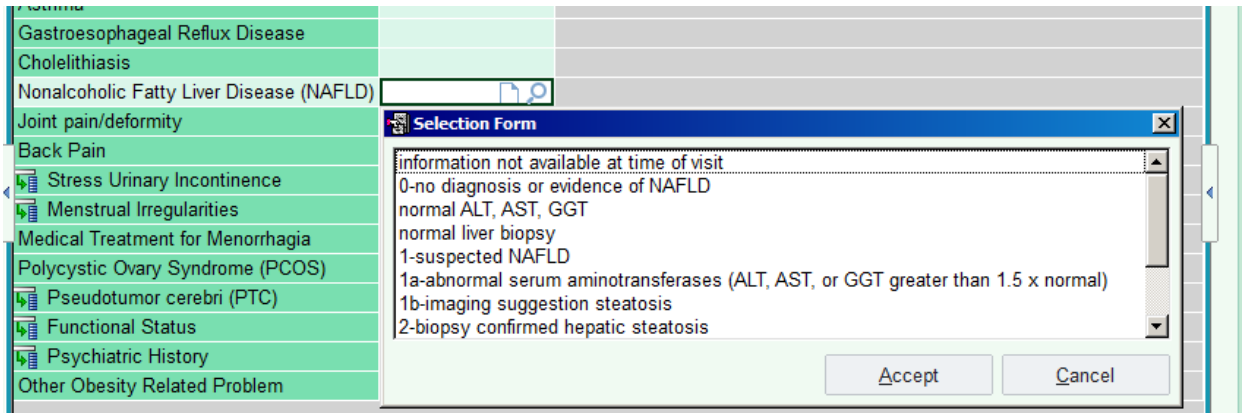

Dyslipidemia
Abnormal glucose metabolism
Thyroid
Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Selection Form
information not available at the time of visit
0=no hypothyroidism
1=hypothyroidism
2=hypothyroidism, controlled with medication
Accept
Cancel

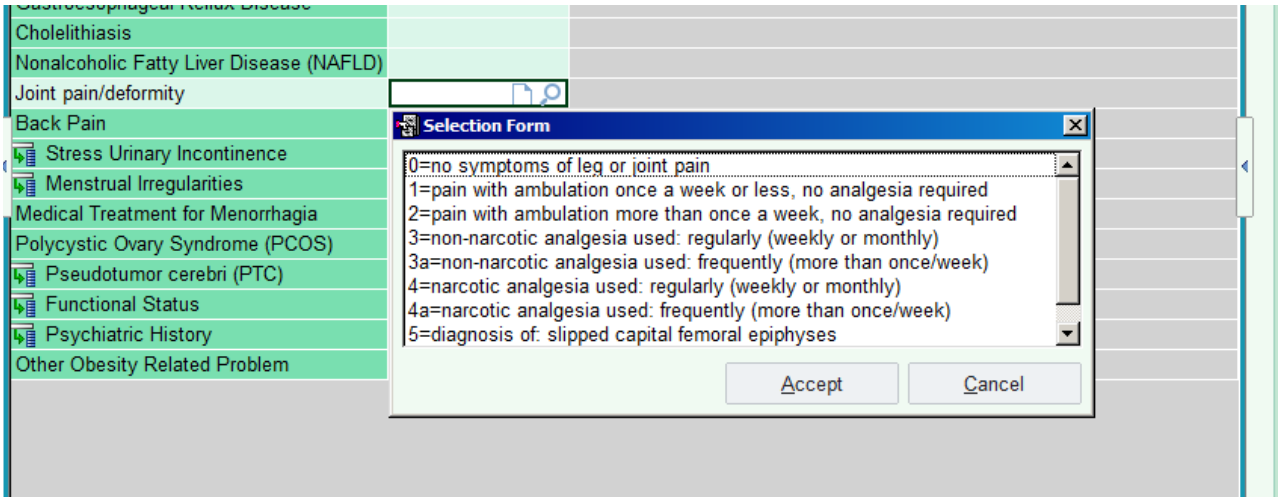

Dyslipidemia
Abnormal glucose metabolism
Thyroid
Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFL
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Selection Form
information not available at the time of visit
0=no diagnosis or symptoms of OSA
1=sleep apnea symptoms (sleep study not done)
2=sleep apnea (AHI greater or equal to 5) confirmed by PSG, not currently using CPAP/BiPAP
3=sleep apnea or hypoventilation, requiring CPAP/BiPAP
Accept
Cancel

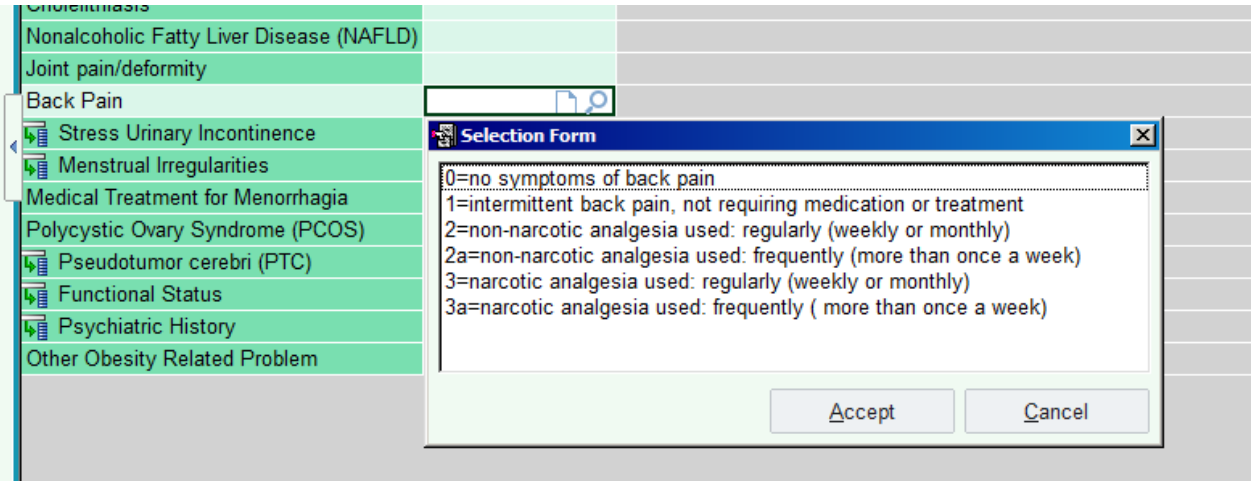

Thyroid
Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no diagnosis or symptoms (wheezing, cough) of asthma
1=intermittent or mild symptoms, no medication
2=symptoms controlled with medication, but used less than monthly
3=symptoms controlled with medication, used monthly, but less than weekly
4=symptoms controlled with medication, used weekly, but less than daily
5=symptoms controlled with medication, used daily
6=symptoms persist, with medications
Accept
Cancel

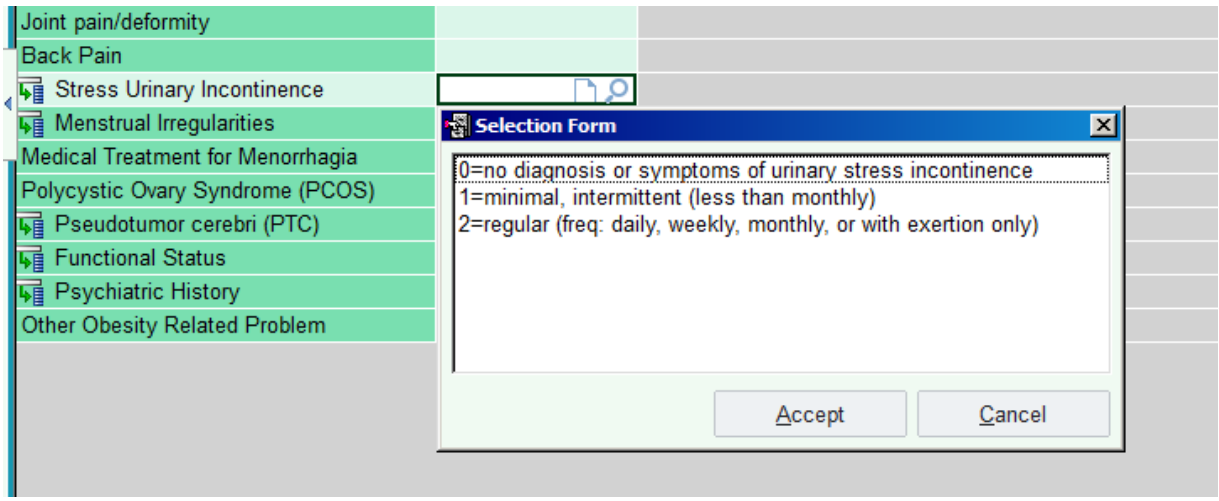

Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no diagnosis or symptoms of GERD (heartburn, dysphagia, reflux)
1=intermittent variable symptoms, taking no medication
2=intermittent medication use (includes over the counter)
3=histamine blockers used daily
4=proton pump inhibitor used daily
5=continued symptoms despite regular use of medications
Accept
Cancel

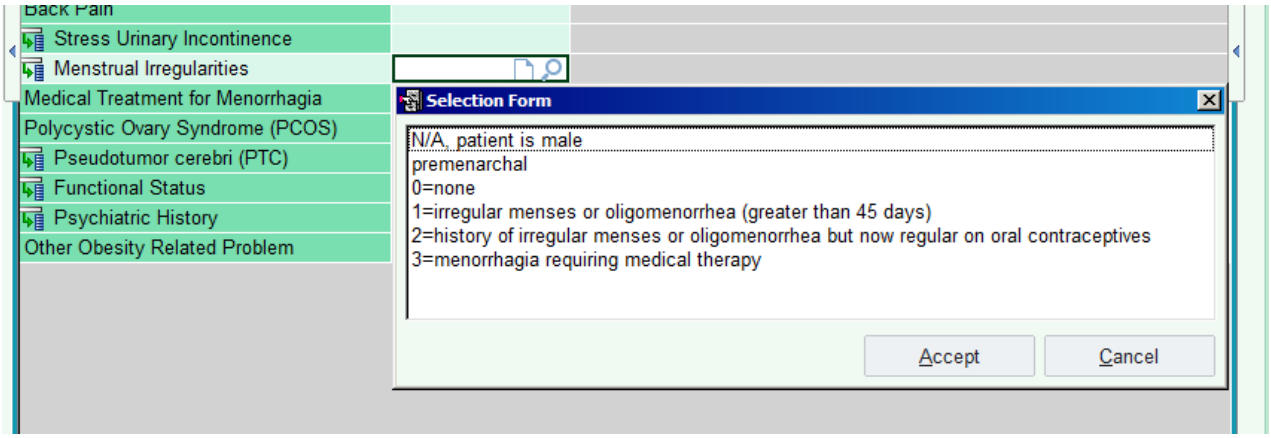

Obstructive sleep apnea (OSA)
Asthma
Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no diagnosis or symptoms of gallstones
1=documented gallstones with less than monthly symptoms
2=documented gallstones with weekly or monthly symptoms
3=documented gallstones with daily symptoms
4=documented complications of gallstones (e.g. pancreatitis)
5=history of cholecystectomy
Accept
Cancel

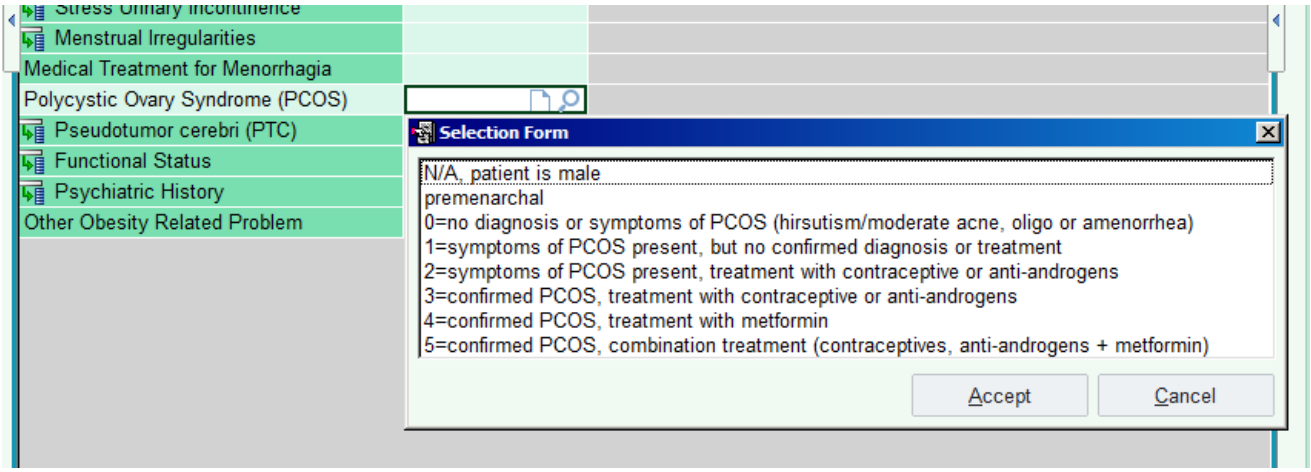

Gastroesophageal Reflux Disease
Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
information not available at time of visit
0-no diagnosis or evidence of NAFLD
normal ALT, AST, GGT
normal liver biopsy
1-suspected NAFLD
1a-abnormal serum aminotransferases (ALT, AST, or GGT greater than 1.5 x normal)
1b-imaging suggestion steatosis
2-biopsy confirmed hepatic steatosis
Accept
Cancel

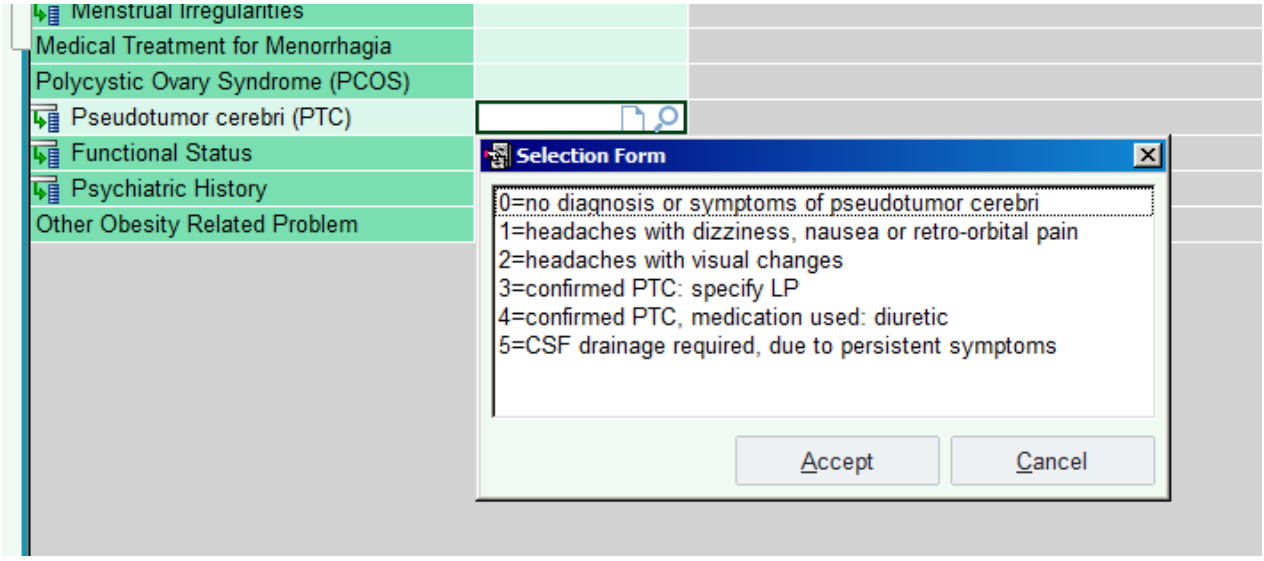

Cholelithiasis
Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no symptoms of leg or joint pain
1=pain with ambulation once a week or less, no analgesia required
2=pain with ambulation more than once a week, no analgesia required
3=non-narcotic analgesia used: regularly (weekly or monthly)
3a=non-narcotic analgesia used: frequently (more than once/week)
4=narcotic analgesia used: regularly (weekly or monthly)
4a=narcotic analgesia used: frequently (more than once/week)
5=diagnosis of: slipped capital femoral epiphyses
Accept
Cancel

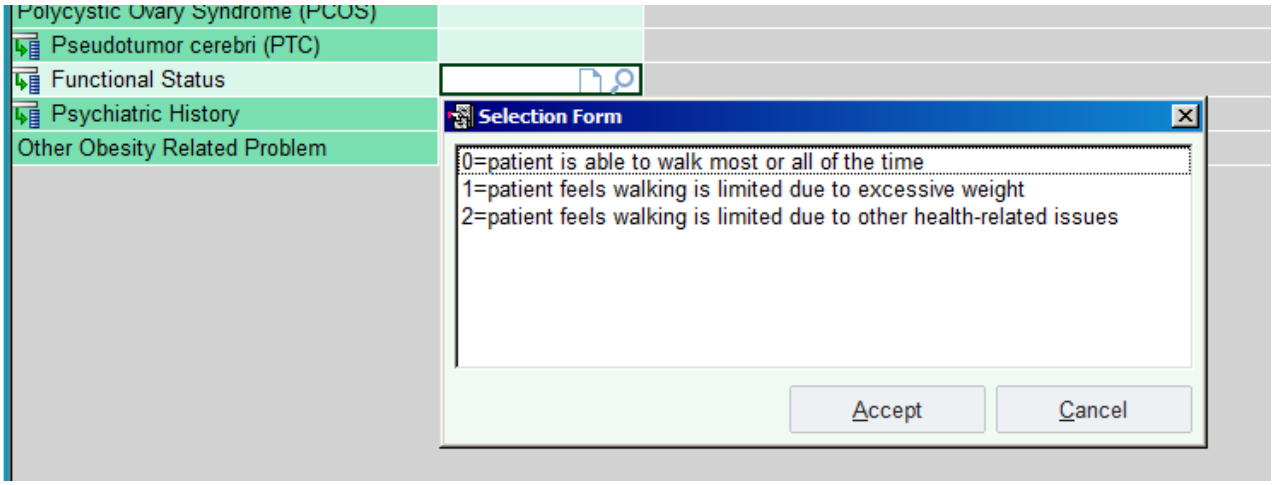

Nonalcoholic Fatty Liver Disease (NAFLD)
Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no symptoms of back pain
1=intermittent back pain, not requiring medication or treatment
2=non-narcotic analgesia used: regularly (weekly or monthly)
2a=non-narcotic analgesia used: frequently (more than once a week)
3=narcotic analgesia used: regularly (weekly or monthly)
3a=narcotic analgesia used: frequently (more than once a week)
Accept
Cancel

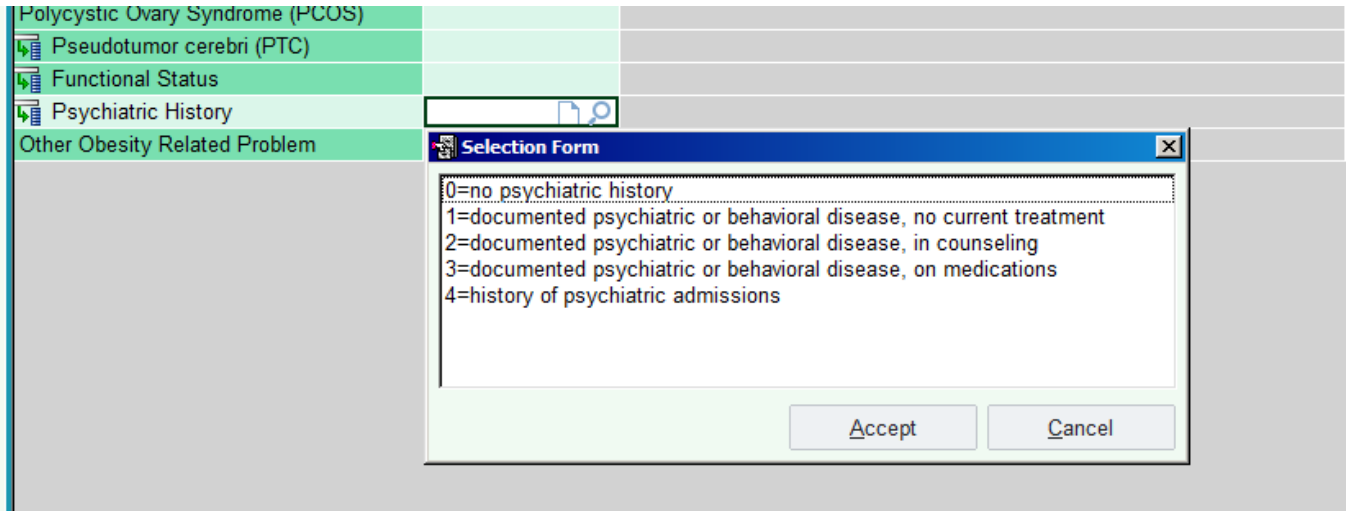

Joint pain/deformity
Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no diagnosis or symptoms of urinary stress incontinence
1=minimal, intermittent (less than monthly)
2=regular (freq: daily, weekly, monthly, or with exertion only)
Accept
Cancel


Back Pain
Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
N/A, patient is male
premenarchal
0=none
1=irregular menses or oligomenorrhea (greater than 45 days)
2=history of irregular menses or oligomenorrhea but now regular on oral contraceptives
3=menorrhagia requiring medical therapy
Accept
Cancel


Stress Urinary Incontinence
Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
N/A, patient is male
premenarchal
0=no diagnosis or symptoms of PCOS (hirsutism/moderate acne, oligo or amenorrhea)
1=symptoms of PCOS present, but no confirmed diagnosis or treatment
2=symptoms of PCOS present, treatment with contraceptive or anti-androgens
3=confirmed PCOS, treatment with contraceptive or anti-androgens
4=confirmed PCOS, treatment with metformin
5=confirmed PCOS, combination treatment (contraceptives, anti-androgens + metformin)
Accept
Cancel


Menstrual Irregularities
Medical Treatment for Menorrhagia
Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no diagnosis or symptoms of pseudotumor cerebri
1=headaches with dizziness, nausea or retro-orbital pain
2=headaches with visual changes
3=confirmed PTC: specify LP
4=confirmed PTC, medication used: diuretic
5=CSF drainage required, due to persistent symptoms
Accept
Cancel


Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=patient is able to walk most or all of the time
1=patient feels walking is limited due to excessive weight
2=patient feels walking is limited due to other health-related issues
Accept
Cancel


Polycystic Ovary Syndrome (PCOS)
Pseudotumor cerebri (PTC)
Functional Status
Psychiatric History
Other Obesity Related Problem
Selection Form
0=no psychiatric history
1=documented psychiatric or behavioral disease, no current treatment
2=documented psychiatric or behavioral disease, in counseling
3=documented psychiatric or behavioral disease, on medications
4=history of psychiatric admissions
Accept
Cancel

Section 3 – Protocols and Consents

Protocol, Informed Consents and Assents are in the regulatory binder and Teen-LABS Dropbox, accessible at https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QgOmBPyGpEzChIZla?dl=0 and should be updated accordingly. CRFs and QxQs are also in the Dropbox.

If utilizing e-REG binders please follow instructions from your institution to remain in compliance.

You may choose to list the various version numbers and approval dates here.

Section 4 – Quality Control

4.1 Quality Control Principles:
Overview. Study-wide quality control is the ultimate responsibility of the Clinical Sites and the Data Coordinating Center (DCC). The Teen-LABS Study Coordinator at each site must be trained and certified on the Teen-LABS study requirements and procedures. This section will address issues related to duplicate measures, equipment, issues related to quality control monitoring by the DCC and the Central laboratory, and site visits.

Quality Control Principles:
The purposes of quality control are:

- to ensure the quality of the Teen-LABS data;
- to provide constructive feedback to Teen-LABS staff performing data collection for quality performance in their data collection efforts; and
- to document the quality of the data for historical record.

4.2 Quality Control Procedures
The Teen-LABS DCC has primary responsibility for development and implementation of quality control measures including:

- training and certification of staff in standardized protocols prior to beginning data collection; maintenance of databases of completed certification;
- designing and implementing protocols and procedures for periodic site visits;
- developing quality control report forms and protocols for regular use by the clinical centers and the Teen-LABS affiliated laboratories;
- analyzing data collected with quality control protocols to: (i) ensure the quality of the performance of interviewers, technicians or other staff, (ii) ensure standardized data collection equipment, and (iii) ensure prompt notification of deviations from clinical centers;
- identifying problems in reporting or handling data from Teen-LABS affiliated laboratories and repository;
- reporting of pertinent information to the Data & Safety and Monitoring Board (DSMB), Executive & Steering Committee, as well as other pertinent groups when necessary;
- Maintaining current or historical data and documents to describe the quality and performance of the entire Teen-LABS study.

The role of the clinical centers in the Quality Assurance/Quality Control (QA/QC) plan for Teen-LABS is to implement quality control protocols, and to collaborate with and assist the DCC in the performance of its responsibilities by maintaining required records and logs and by notifying the DCC of any problems/issues that require assistance.

Recruitment and retention will be regularly monitored within the Coordinators Subcommittee. Investigators and Teen-LABS personnel are also expected to perform the following activities:

- Regular review of monthly reports generated by the DCC;
- Review of the specific quality control issues identified either by the sites, the Executive Committee or the DCC and the recommendations from the Steering Committee (SC) for resolution of such issues;
- Regular communication with the DCC and the SC regarding efficacy of quality control procedures and protocol.

4.2.1 Overall Procedure

Teen-LABS utilizes a series of certifications to assure that research study processes and procedures are being completed consistently and accurately within and across all sites. These certification processes have been developed in conjunction with LABS-1 and LABS-2. Anyone collecting or managing data for Teen-LABS (e.g., data managers, coordinators, surgeons) must be certified in the relevant portions of the protocol. Anyone collecting data for Teen-LABS must be trained. Anyone entering, managing, or accessing data must be certified in the data management system. Surgeons must be familiar with the Teen-LABS protocol and the Teen-LABS Operative forms. In addition, surgeons must meet the minimum Teen-LABS qualifications.

4.2.2 Individual Measures Certification

Coordinator Protocol Training:

1) Read the Teen-LABS Manual of Operations (MOP) completely. It can be accessed via the Teen-LABS Dropbox using the following link:
https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QgOmBPyGpEzChIZla?dl=0
Coordinators can contact the Central Study Coordinator for assistance accessing the Dropbox.

2) Review the **Teen-LABS Protocol available in the Teen-LABS Dropbox**
3) Review the Teen-LABS MOP with a Teen-LABS protocol-certified coordinator at the clinical site. This review should address the following items:

- study design (objectives, inclusion/exclusion criteria, recruitment and visit schedule);
- database enrollment procedures (recruitment, consent, patient confidentiality);
- Teen-LABS data collection flow chart;
- all forms (Self-assessment, Clinician Assessment) utilized by Teen-LABS and associated question by question (QxQ) form completion instructions;
- practice at least once, completing each of the study components (administering the self-assessment forms, taking physical measures, medication collection, chart review for prior clinical tests, 400-meter corridor walk, blood draw process, urine collection); and shipment to appropriate laboratories.

4) Observe a protocol-certified coordinator recruit and obtain patient consent.
5) Observe a protocol-certified coordinator collect pre-operative data from at least one patient.

Surgeon Protocol Training:

1) Read the Teen-LABS MOP completely. Particular attention should be paid to Section 1: Study Overview, Section 2: Scheduling and Visits, Section 3: Protocol & Consent and Section 10: Surgeons section can be accessed via the Teen-LABS Dropbox using the following link:
https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QgOmBPyGpEzChIZla?dl=0
Surgeons can contact the Central Study Coordinator for assistance accessing the Dropbox.

2) Review the **Teen-LABS Surgeon's Training**. This review should address the following items:

- Study design (objectives, criteria for Teen-LABS visit schedule, target composition of database population, inclusion/exclusion criteria)
- Teen-LABS bariatric surgeon qualifications
- Surgeon's requirements for participation in Teen-LABS
- Teen-LABS bariatric operation definitions (primary operations, second stage: conversions /revisions/reversals of bariatric operations, exclusions)
- Operative forms and related Question by Question (QxQ's) including a checklist for surgeon's dictation to ensure adequacy of operative note as source document
- Complete and send to DCC Surgeon Experience form and Duality of Interest
- Send signed and dated CV annually to DCC

Section 5 – Physical Measures

PHYSICAL MEASUREMENT PROTOCOLS
*It is essential that **ALL ASSESSORS FOLLOW THE PROTOCOL AS WRITTEN**, even a seemingly unimportant omission or variation in technique can make a significant difference in the measurements recorded.*

5.1 Blood Pressure (BP) & Resting Heart Rate
BP equipment must be inspected and validated on a weekly basis as detailed in the equipment's user manual. The operator needs to be trained and certified. All BP readings should be recorded on the right arm that has been bared from the shoulder. Long sleeves must be pushed up or removed to avoid interference with the cuff.
If for any reason (e.g., mastectomy, arterial-venous fistula, lymph dissection, or other reason) the patient's blood pressure cannot be measured using the right arm then take the measurement using the left arm. If blood pressure cannot be measured using either arm, record -5 (not done) for both diastolic and systolic values.

Materials Needed:
- Welch Allyn Spot Vital Signs Blood pressure (BP) monitor provided by the study. If not possible to use the device, auscultate BP and hand count heart rate. OFF Teleform will need to be completed each deviation if study blood pressure machine not used.
- Regular adult arm, large adult arm, and thigh blood pressure cuffs

Preparation:
The proper cuff size must be used to avoid under- or over-estimating BP when using indirect methods of measurement. To determine the proper cuff size, the operator must measure the arm circumference at the midpoint of the right arm. The midpoint of the arm is the point located halfway between the elbow and shoulder. With the patient standing and holding the arm bent at the elbow with hand resting lightly on their hip, fingers forward with thumb pointing to the rear, the arm length is measured from the acromion (or bony extremity of the shoulder girdle) to the olecranon (or the tip of the elbow), with a tape measure, allowing the tape to hang freely over the olecranon. The midpoint is marked on the dorsal surface. (A cosmetic pencil may be used to make this mark and can be easily removed later). The participant should then relax the arm along the side of the body. Pull an appropriate amount of tape out of the housing. Ensure that tape is in contact with but not indenting soft tissues. Align the tape at zero "zero line", alongside of the tape graduations. Place one end of the tape around the mark on participant's arm. Wrap the tape around the patient's arm. Care must be taken to keep the tape horizontal. Pull on the end of the tensioning mechanism until the calibration point can be seen. Calibration Point: When you pull slightly harder and harder on the tensioning device, two colored beads will be seen, separated by a silver disk separating the two beads. When you see one of the two, you are at the "calibration point". ***Four ounces is approximately equal to the force required to lift a stack of U.S. quarters. If the beads start to disappear into the end cap of the tensioning device, you are using too much force.***
Cuff size is then determined from the chart below. The sizes for cuffs overlap to provide flexibility in cuff-size selection. The first choice for cuff should always be for the larger size. Because it is often difficult to fit a cuff correctly on an obese person's upper arm, an incorrect fit can result in readings that are too high or too low. If a participant's upper arm circumference indicates use of the thigh cuff, but the arm is too short for the cuff, or the cuff does not remain secured when inflated, the long arm cuff or a conical (curved) thigh cuff should be used. ***NOTE: Cuff size must be determined at each visit***.
CUFF SIZE INDICATED BY MEASURED ARM CIRCUMFERENCE
CUFF SIZE (cm) ARM CIRCUMFERENCE (cm)

11 (Regular) 25.3-34.4cm
12 (Large) 32.1-43.4cm
13 (Thigh) 40.7-55.0

Measurement:
1. The measurement of heart rate and BP should be performed after the participant has been seated quietly, with feet flat on the floor, in an erect but comfortable posture for at least five minutes, and for at least thirty minutes since the participant has smoked or consumed caffeine-containing beverages. This procedure should be repeated 3 times using same protocol.
2. Place the blood pressure cuff, as determined in the arm measurement procedure, around the bare upper right (or left, if right cannot be used) arm so that the midpoint of the length of the bladder lies over the brachial artery and the mid-height of the cuff is at heart level. The lower edge of the cuff, with its tubing connections, should be placed about one inch above the natural crease across the inner aspect of the elbow. The cuff is wrapped snugly about the arm, with the palm of the participant's hand turned upward. The wrapped cuff should be secured firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.
3. Record the blood pressure on the data collection instrument.
4. Record the heart rate on the data collection instrument.
Note: Heart Rate is determined as an adjunct to the blood pressure measurement.
5. Remove the cuff, clean according to universal precautions, and store the equipment safely after the last reading.
6. Please make sure that you give a copy of blood pressure results to the participant, and document in REDCap (added to the ANTH form for surgical participants) that the letter was provided to the participant, or if one was not provided, the reason why. (See end of Section 5 for the current form.)

> ** Your blood pressure is ELEVATED (slightly above the acceptable range). Blood pressures can fluctuate from day to day and sometimes even from moment to moment. Therefore, it is important to have your blood pressure checked again when you see a doctor within the next six months. It is possible that it may be normal on the next reading. Present this form to the doctor.*
>
> *** Your blood pressure is HIGH. Blood pressures tend to fluctuate, and therefore it is important to have further checks of blood pressure. It is possible that it may read lower at the next reading. Please give this form to your doctor and get your blood pressure checked within the next 2 weeks.*
>
> **** Your blood pressure is VERY HIGH. Please see a doctor or go to a clinic or a hospital within the next few days to have the blood pressure re-checked. Present this form to the doctor.*

5.2 Heart Rate
VII. Measuring Heart Rate Manually:
If you are unable to measure heart rate using the pulse monitor, the resting heart rate may be measured indirectly by placing the fingertips on a pulse site. To determine the number of beats per minute, take the resting pulse rate for a full minute, or for 30 seconds and then multiply by two. One of the points at which the resting pulse can be accurately measured by palpation is at the radial pulse on the wrist, in line with the base of the thumb. Place the tips of your index and middle fingers (not the thumb, which has a pulse of its own) over the artery and lightly apply pressure.

5.3 Neck Circumference (at some sites, Bionutrition gathers these measurements)
Materials Needed:

- Gulick II Tape Measure (model 67020)

Preparation:
All participants are being asked to have this measurement taken over bare necks. Explain the procedure to the participant. Ask the participant to remove only the clothing necessary to complete the measurement, such as turtlenecks or other high collar shirts. Every measure should be taken to protect the participant's sense of dignity.

Measurement:
1. Verify that the participant is standing erect, weight split between feet, arms at side with feet together.
2. The measurer stands facing the right side of the participant. You will need to be able to view the participant's neck at eye level. If the participant is taller than you, you will need to use a stool in order to bring yourself to eye level.
3. Identify the laryngeal prominence (Adam's apple), and place the zero end of the tape just inferior to this prominence, on the participant's right side. *If you are unable to visually locate the laryngeal prominence, then take the measurement at the visual midpoint between the chin and the clavicle.*
4. Gently pull the tape around the neck in the horizontal plane. Ensure tape is snug, but not indenting soft tissues. Place this end of the tape just above the zero end.
5. Have the participant inhale and exhale normally. Pull gently on the end of the tensioning mechanism until just one colored bead in the tensioner can be seen. Warn the participant that they may experience slight discomfort from the slight pressure that you will add to get an accurate measurement.
6. When they exhale take the measurement by aligning the measuring end of the tape with the "0" mark.
7. Release the tape measure and repeat the above steps. If the two measures are within 2 cm of each other, the measurement is complete. Record both measurements on the
8. Three measurements should be taken and each recorded on the case report form.

5.4 Midpoint Waist Circumference
Materials Needed:

- Gulick II Tape Measure (Model 67020)
- Washable marker or cosmetic pencil
- 3 plastic clothespins

Preparation:
Explain the procedure to the participant. Ask the participant to remove only the clothing necessary to complete the measurement in non-restrictive garments (i.e., girdles, control top panty hose, etc.). The measurement should be taken against the skin. Use the clothespins to hold clothing (e.g. shirt) out of the way of the measurement, if necessary. Every measure should be taken to protect the participant's sense of dignity.

Measurement:
1. Have the participant stand erect with their feet together, abdomen relaxed, and their arms crossed over their chest, holding onto their shoulders.
2. First, you need to mark the points of measurement. The midpoint waist measurement will be taken around the abdomen horizontally at the midpoint between the highest point of the iliac crest (hip bone) and lowest part of the costal margin (ribs) in the mid-axillary line (directly under the armpit). On the participant's right side, identify the lowest part of the costal margin and the

highest point of the iliac crest. It may be helpful to have the participant identify these reference points. At this time, make a marking at the iliac crest using a washable marker or cosmetic pencil, for a measurement to be done later.
3. Place the zero end of the measuring tape at the costal margin and pull the tape down to the iliac crest. Note the total length and then make a mark at the midpoint of this measurement in the mid-axillary line (directly under the armpit). **See last page of Section 5 for a visual guide to these markings.**
4. Place the "zero" end of the tape at the marking on the right side. Have an assistant hold the tape in place. Slowly walk around the participant, pulling the tape in the horizontal plane (parallel to the ground) around participant's waist. Be sure that the tape remains in the horizontal plane all the way around.
5. When you return to the zero end of the tape, instruct the participant to exhale and relax the abdomen. Pull on the end of the tensioning mechanism until both colored beads can be seen. Note that this is more tension than what is used for the neck, which is measured using the calibration point on the tape measure.
6. When the tape is positioned in the horizontal plane at the correct height, align the measurement end of the tape directly above the zero end.
7. Read the measurement next to the tape's "zero line" and record the circumference to the nearest 0.1 centimeter.
8. Release the tape measure and repeat the above steps. If the two measures are not within 2cm of each other, a third measurement must be taken and recorded on the form.

5.5 Iliac Crest Waist Circumference
Materials Needed:

- Gulick II Tape Measure (model 67020)
- Washable marker or cosmetic pencil
- 3 plastic clothespins

Preparation:
This measurement is very similar to the previous measurement, but it is taken at a different location on the waist. Do this measurement immediately following the midpoint waist circumference so that the participant is appropriately dressed and markings are already made on the skin.

Measurement:
1. Have the participant stand erect with their feet together, abdomen relaxed, and their arms crossed over their chest with hands resting on our near the shoulders.
2. Place the zero end of the tape at the marking made at the iliac crest on the participant's right side.
3. Have an assistant hold the tape in place. Slowly walk around the participant, pulling the tape in the horizontal plane around participant's waist. Ensure that the tape remains in the horizontal plane regardless of body shape or skinfolds that might be present.
4. When you return to the zero end of the tape, do one more visual check to ensure that the tape is in the horizontal plane all the way around the participant. Instruct the participant to exhale and relax the abdomen. Pull on the end of the tensioning mechanism until both colored beads can be seen.
5. Align the measurement end of the tape directly above the zero end.
6. Read the measurement next to the tape's "zero line" and record the circumference to the nearest 0.1 centimeter.
7. At this time, before releasing the tape, you need to make a marking for a later measurement. Facing the participant, make a small marking at the center of the abdomen where the tape

crosses horizontally. This marking will be used later for the Sagittal Abdominal Diameter (SAD) measurement.
8. Release the tape measure and repeat the above steps 2 through 6. If the two measures are not within 2cm of each other, a third measurement must be taken and recorded on the form.
9. After you have completed all measurements using the Gulick II measuring tape, pull the tape *almost* all the way out and wipe with alcohol pads or appropriate disinfectant.

5.6 Body Composition is based on height and weight as described below.

Stadiometer (Height Measurement tool)

Instructions to obtain height measurement:

1. Use standard or study provided Stadiometer.
2. Ask participant to remove shoes.
3. Have participant stand up straight with foot inside the footprint mark.
4. Check that participant's back slightly touches ruler.
5. Record measurement on Anthropometric Teleform using centimeters.
6. Have participant move out from ruler and repeat steps 3, 4 and 5 a second and a 3rd time and record on the Anthropometric form.
7. After each use the stadiometer, especially the foot platform, should be cleaned with alcohol pads or appropriate disinfectant.

Materials needed to obtain weight:

- Tanita Scale
- Printer/Paper for printer

Preparation:

Because Tanita's body composition analyzers send a weak electrical current through the body, <u>participants who have a pacemaker or other internal electronic medical device are excluded from this measurement.</u> The weak electrical signal may cause such internal devices to malfunction. Participants are also excluded from the body composition measurement if they exceed 600 lbs. or if they refuse to remove shoes/wear hospital gown during the analysis.

Measurement:

1. The Tanita scale should always be used on a flat, stable surface.
2. Ask participant to remove shoes and socks/hose. Because the body composition analyzer uses a minor electric current to measure impedance, best results will be observed when measurement is taken in bare feet. Poor contact between the feet and electrodes may produce an error message. Also, the soles of the feet should be free of excess dirt, as this may act as a barrier to the electric current. ***Please note that if there are calluses on the soles of the feet, accurate measurement may still be possible. Place 0.5cc of saline or water in the center of each electrode. This will act as a conductive material and may allow the current to pass freely through a thin barrier.***
3. Press the [ON/OFF] key to turn on the Power. Adjust measurements by pressing [kg/lb] if needed, to record participant's weight in lbs.
4. You will then be prompted to enter participant's clothes weight. **For the purposes of Teen-LABS, the participant's clothes weight must be listed as 0 lbs.**
5. Select either standard male or standard female. *Teen-LABS will not be using the athletic male or athletic female settings from the four listed gender and body types.*
6. Enter participant's age.
7. After age is entered, the arrow will automatically advance to height. Using Centimeters (cm), measurement is made to the First Decimal Place by 0.5 cm increments, example 66 cm press the [6] [67] [.] [0] keys.

8. After entering the above data, the flashing arrow will appear next to STEP ON, after the LCD displays “8888”.
9. Participant should be asked to step slowly onto the weighing platform. If the participant’s inner thighs are touching (which is very likely), a towel should be placed between the thighs because touching legs may affect the measure. Heels should be placed directly on top of the posterior electrodes, while the front part of the foot needs to be in contact with the anterior electrodes.
10. After weight stabilizes, impedance measurement is taken. This is denoted by four “bubbles” which appear on the bottom half of the LCD. As the measurement is being taken, the bubbles will begin to disappear one by one. ***The participant must remain on the platform until the final bubble has disappeared and the display emits a short beep.***
11. Weight and percent body fat will be displayed on the LCD and detailed results will print out. It is suggested that you print this report three times; with one copy being given to the participant and the other two being kept in the participant’s research file for reference at later visits. The weight and percent body fat will remain on the screen for ten seconds before returning to gender and body type screen.
12. If all measurements are complete, press the [ON/OFF] key to turn off the power.
13. After each use, the weighing platform should be cleaned with alcohol pads or appropriate disinfectant. Follow directions for cleaning the platform as outlined in the instruction manual provided with your equipment.
14. Repeat the weight a second time and a third time.

After all the measures are complete mark the participant ID number and Date data obtained on the top of each Tanita print out.
Give one print out to the participant after recording the information on the Source Document (SD) Teleform and photocopy the other 2 Tanita printouts and attach to the back of the (SD).

5.7 Sagittal Abdominal Diameter (SAD)

Materials Needed:
- Holtain-Kahn Abdominal Caliper plus 20 cm extension bar
- Narrow tip felt marker
- Pillow – optional
- Small folded towel – if needed
- Form for recording measurement

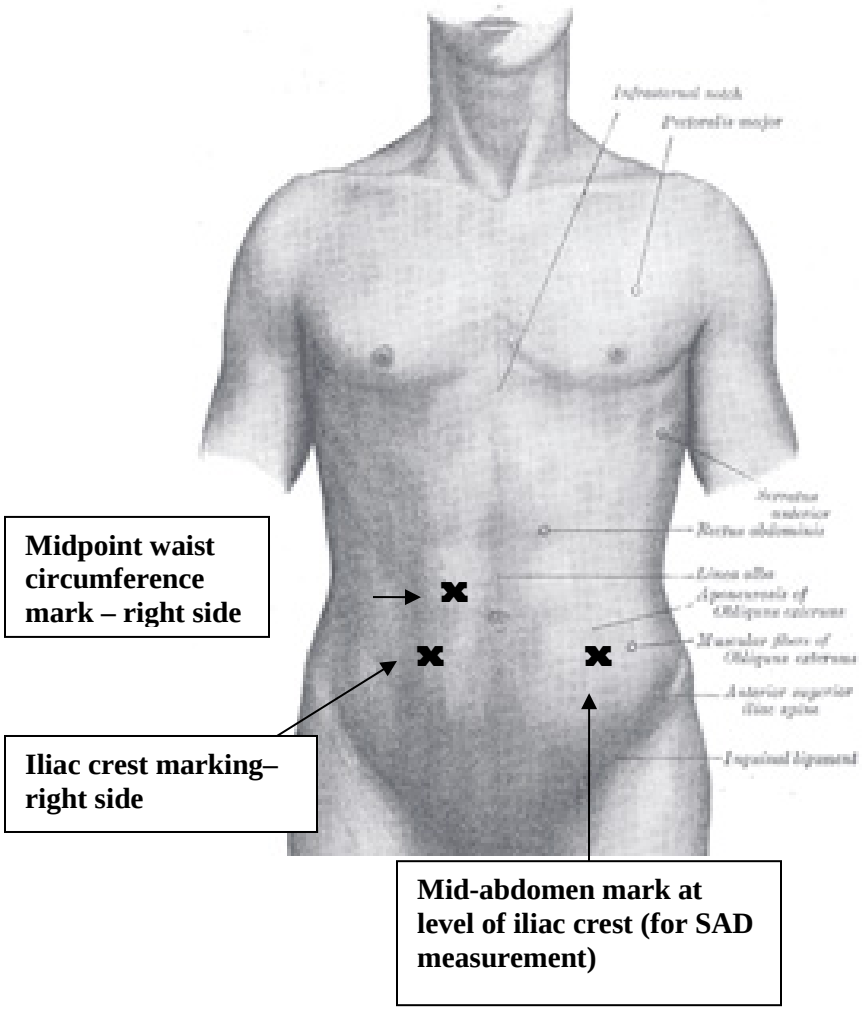
Preparation:
The sagittal abdominal diameter (SAD) measurement will be measured using a portable, sliding-beam, abdominal caliper while participants are in a supine position on the table. Prior to visit, the extension bar should be added to the calipers when the subject’s SAD is expected to be greater than 25 cm. If it is suspected that the SAD will be less than 25
cm then the extension bar should NOT be used and the reading taken as marked on the scale. The sagittal abdominal measurement, when possible, will be taken by two trained individuals: one examiner and one recorder. The examiner will take the measurements and call out the measurement result to the recorder. Recorder will check the participant’s position during the procedure and record measurements. The examiner will wait until the recorder verbally repeats and records the measurement before repeating a second time. A third measurement is taken only if the two measurements differ by more than 1.0 cm.

Measurement:

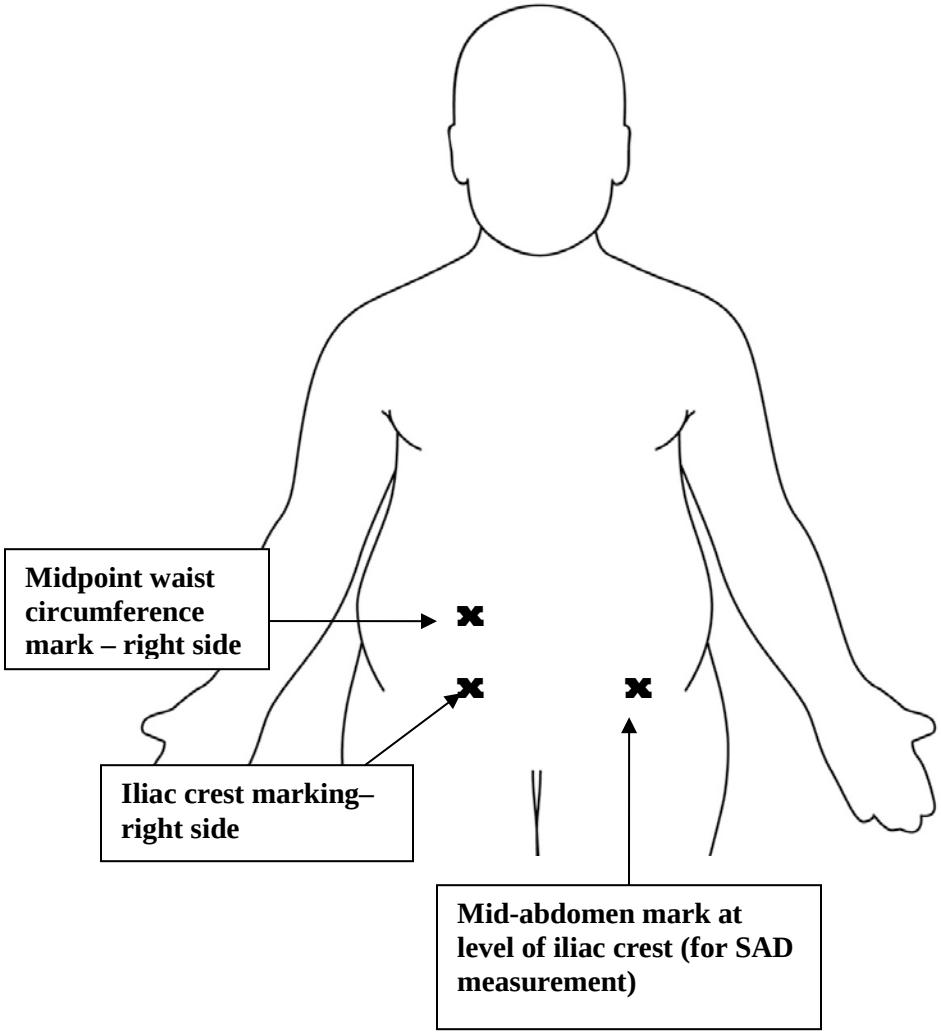
1. Participant will be measured wearing lightweight indoor clothing loose enough to be lifted up comfortably to access the abdominal area.
2. Lay participant supine on flat examination table and measure from the participant's right side. The head may be supported by a pillow. There should be no clothing around the middle of the back or abdomen.
3. Locate the marks on the center of the abdomen, made during the waist measurements.
4. Slide the caliper's upper arm to its fullest height.
5. Have the participant raise hips and lift back. Insert caliper's lower arm underneath the small of the back at the level of the mid-abdominal marking. If there is space between the table and the back, elevate the caliper's lower arm with a folded towel, just enough to make contact with the participant's back.
6. Adjust the caliper's location and slide its upper arm down until it is a half-inch directly over the mid-abdominal mark.
7. Adjust the calipers location until the bubble in the tip of the caliper is centered to be sure the shaft is vertical.
8. Have the participant inhale gently, exhale, and relax at rest.
9. Slide the upper arm of the caliper down so it is touching, but not compressing, the abdomen.
10. Check that the bubble in the spirit level confirms a vertical orientation and is in reading position.
11. Read the measurement at the top of the vertical shaft of the caliper's upper arm. An arrow points to the correct place to read the measurement on the centimeter scale. Remember to add 20 cm to the reading when the extension bar is used.
12. Examiner will record or call out to recording partner the diameter value and record to the nearest 0.5 cm. (Remember to add 20 cm to the reading when the extension bar is used). The recording partner will check the participant's position during the procedure.
13. Ask participant to relax.
14. Raise caliper's upper arm.
15. Repeat the procedure (steps 7 – 14) until three times and record measurements on form.
16. Clean calipers after each use with sanitizing wipe.

Visual of Markings Made for Teen-LABS Measurements (3 Markings Total)

Lean Individual (for reference)



Obese Individual



I.D. #: *PLACE IDENTIFICATION LABEL HERE*

Teen Longitudinal Assessment of Bariatric Surgery
www.Teen-LABS.org

Dear _____,

Thank you for participating in the Teen-LABS Study.

At your visit on _____ (date), we obtained your:

Systolic Blood Pressure: _____mmHg

Diastolic Blood Pressure: _____mmHg

Your **Systolic Blood Pressure** is†:	Your **Diastolic Blood Pressure** is†:
□ Normal (<120mmHg)	□ Normal (<80 mmHg)
□ Elevated (120-129)*	
□ Hypertension, stage 1(130-139)**	□ Hypertension, stage 1 (80-89)**
□ Hypertension, stage 2 (≥140)***	□ Hypertension, stage 2 (≥90) ***

* *Your blood pressure is ELEVATED (slightly above the acceptable range). Blood pressures can fluctuate from day to day and sometimes even from moment to moment. Therefore, it is important to have your blood pressure checked again when you see a doctor within the next six months. It is possible that it may be normal on the next reading. Present this form to the doctor.*

** *Your blood pressure is HIGH. Blood pressures tend to fluctuate, and therefore it is important to have further checks of blood pressure. It is possible that it may read lower at the next reading. Please give this form to your doctor and get your blood pressure checked within the next 2 weeks.*

*** *Your blood pressure is VERY HIGH. Please see a doctor or go to a clinic or a hospital within the next few days to have the blood pressure re-checked. Present this form to the doctor.*

Your blood pressure was measured by a trained lay examiner. These measurements were obtained as part of a research study and do not represent a medical diagnosis. Interpretation of these measurements must be made by your physician.

Sincerely,

<insert name and contact information of the surgical site PI>

† *According to Whelton, et. al. 2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults. J Am Coll Cardiol. 2018 May 15;71(19):2199-2269. Epub 2017 Nov 13. PMID: 29146533*

Section 6 – Specimen Collection

6.1 Preparing for the Research Laboratory Sample Collection

- When possible, Teen-LABS ("TL") research blood should be drawn on a different day than blood draws for clinical purposes. However, if local clinical specimens must be drawn at the same time as research blood is obtained, priority must be given to the clinical specimens.
- Research blood samples will be collected and divided into four categories seen below. These are listed in order of priority, for situations where the blood volume being drawn is nearing the maximum allowable limits:
    1. Samples to be shipped to the Northwest Lipid Metabolism and Diabetes Research Laboratories (NWRL) Teen-LABS "Central Laboratory" at each visit (most important)
    2. Samples to be sent to the NIDDK Biospecimen repository (NIDDK-R) to be shipped to the NIDDK at regular intervals (next most important)
    3. A sample to be shipped to the NIDDK DNA Sample Bank (NIDDK-DNA) at baseline (next most important)
    4. Local site repository if applicable (next most important)
    5. The minimum amount of blood should be ordered and drawn based on the permission given per Informed Consent.
    6. Once minimum requirement met for each sample as outlined in the simplified collection scheme table, aliquot remaining serum and plasma for biospecimen repository as to not waste any of the processed samples.

6.1.1 Supplies needed for Teen-LABS sample collection (does not include venipuncture kit)

1. Teen-LABS tubes for Sample Collection
    a) 1 - 8.5 mL Tiger top vacutainer
    b) 2 - 6 mL Red top vacutainer
    c) 1- 3 mL purple top vacutainer (Vitamin B1)
    d) 1- 2 mL purple top vacutainer (HbA1c)
    e) 1- GLASS 10 mL purple top vacutainer (NIDDK-DNA)
    e) 1- GLASS 10 mL purple top vacutainer (NIDDK-R, plasma)
    f) 2 – 6 ml red top vacutainers (NIDDK-R, serum) OR 1 –10 mL serum separator tube (tiger top) OR 2-3 5 ml serum separator tubes (gold top).
    g) 1- Urine Cup – (TL urine albumin; NIDDK-R urine)

2. Teen-LABS Tubes for Sample Processing
    a) CL - 5- Clear 2 mL tubes with blue caps (CRP, Insulin, Ferritin, PTH, and Vitamin D)
    b) CL - 1- Amber 2 mL tube (Vitamin A)
    c) CL - 2- 3.5 mL tubes with blue caps (Urine Albumin, Lipid Profile)
    d) NIDDK-R - 30- Cryovials (10 for TL plasma [purple top], 10 for TL serum [red tops], and 10 for TL urine)

3. Teen-LABS tube for DNA (one 10mL purple top provided as described below in section 6.1.3

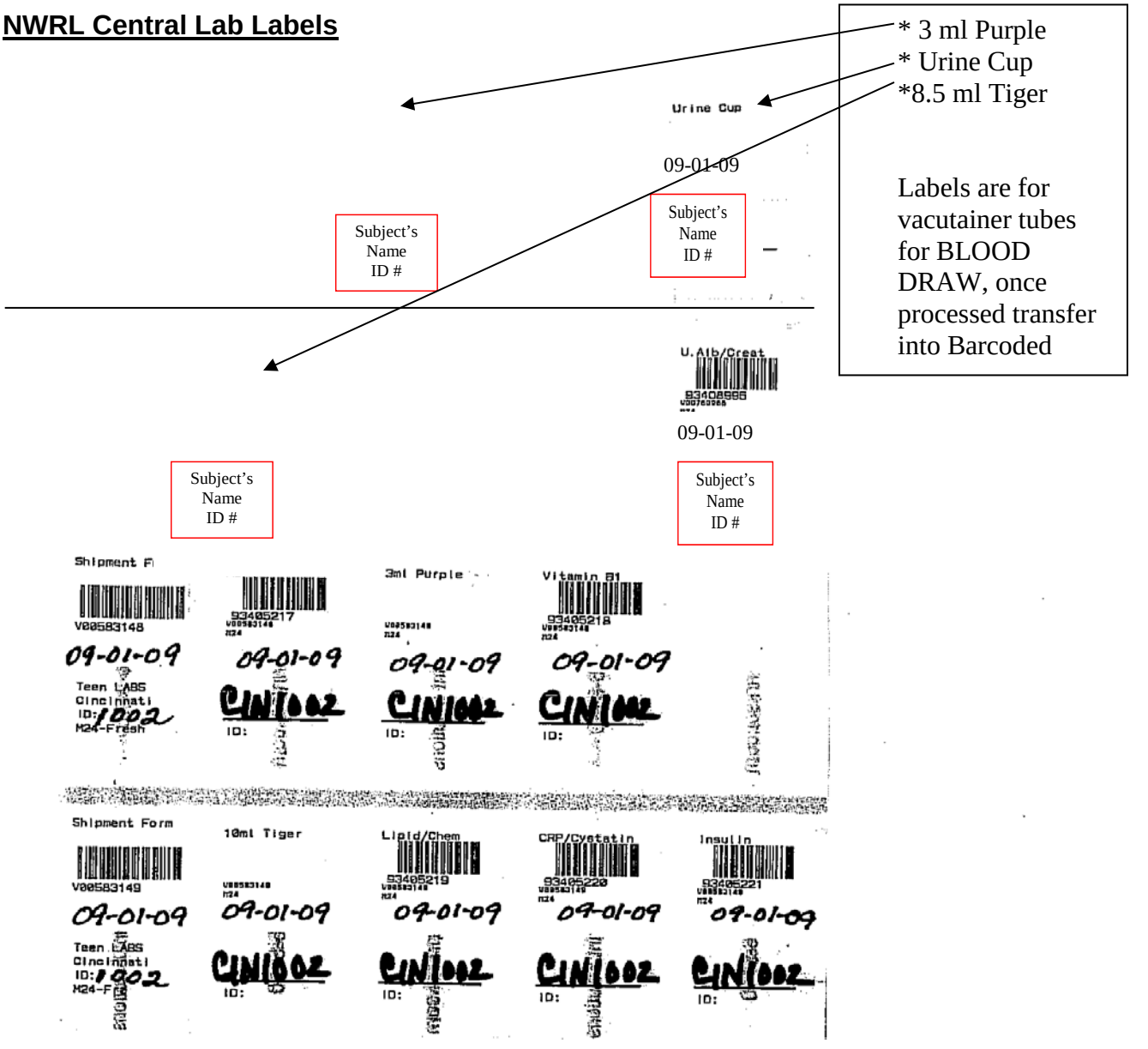
6.1.2 Labels for the Teen-LABS Samples (see next page)

1. The TL labels for the **Central Laboratory** are organized by visit type (i.e. Baseline, M6, M12, M24 and annual) with one set of labels per sheet - be sure to use the labels for the correct visit and do NOT mix bar codes attached to sheet which lists visit types. Complete the label for each participant and visit, adding the correct Teen-LABS ID number on the white portion of the label using thin point black Sharpie pen.
2. For the **NIDDK DNA sample**, separate labels are provided to affix to the GLASS purple top tube to be sent to the NIDDK-DNA bank. This label includes the study site abbreviation, NIDDK site number, TL number, gender and month/year of birth of the participant, and the date the sample was collected.
3. Labels for **NIDDK Biospecimen Repository storage** cryovials, come on a larger, separate sheet, pre-printed with the TL number and visit code distinctly different than the Central Lab labels. The sheets of labels are for the 10 cryovials for "Plasma", 10 cryovials for “Serum” labels, and 10 cryovials with "Urine". Make sure that the TL number is visible and barcode area able to be scanned prior to attaching to cryovial.
4. If also banking specimens locally using a separate protocol and consent, labels for local sample banking should be prepared per local protocol.

Sample Labels

Once the labels are completely filled out using your sharpie marker make a copy of the label sheet to use as source documentation and mark any samples not obtained per protocol or not sent to study laboratory, and keep this copy with participants' information. Make sure an "off protocol" form is completed with reason why sample not obtained or not sent.

NWRL Central Lab Labels



DNA Rutgers Label

632 CIN 1000
Sex F
Date 03-15-07

Biospecimen Repository Labels

** Sample T0000034 not sent – crossed out and “Off Protocol” completed and sent to DCC.

6.1.3 DNA Laboratory instructions for obtaining, labeling and shipping samples to NIDDK Repository at Rutgers Cell and DNA Laboratory.

- Sample kits are provided by NIDDK Rutgers repository which contains the 10 mL purple top tube for collection, along with the FedEx shipping label.

  A. Confirm permission to draw and send DNA to the NIDDK Repository:
     - Coordinators: <u>review the current IRB approved Teen-LABS Informed Consent Form</u> and verify permission to draw and store DNA at the NIDDK repository.
  B. Separate labels are provided for DNA sample: affix to the 10 mL purple top glass tube to be sent to the NIDDK-DNA Repository.
  C. This label includes the 3 digit specific study site abbreviation along with the participants’ Teen-LABS study ID number, gender of the participant, and the date the sample was collected.
  D. Ideally the DNA sample should be drawn at the Baseline visit however if not able to obtain and permission is given to collect may be drawn during a different visit.
  E. DNA should only be sent one time to the NIDDK Repository unless notified by NIDDK and DCC that an insufficient quantity was obtained and instructed to send another sample. Informed consent permission to send DNA must be reviewed prior to redrawing and sending the specimen.
  F. Complete NIDDK Genetics Phlebotomy form and send per instructions on form to Rutgers and DCC.

6.2 Central Laboratory (NWRL) samples

Clinical sites will be drawing and sending serum, plasma, and urine specimens to the NWRL ("Central Lab") for every participant pre-operatively (baseline), 6 and 12-month, and annually thereafter. The Central Lab has provided a detailed Manual of Operations for drawing, freezing and shipping the specimens. That manual should be used in conjunction with this document.

The following samples will be sent to the Central Lab: **(See simplified Collection Scheme)**

HbA1c Vitamin B1
Lipid Profile/Chemistries C-Reactive Protein (CRP)/Cystatin C Insulin
Ferritin Vitamin A Parathyroid hormone (PTH) 25-OH Vitamin-D Urine Collection (urine albumin, urine creatinine)
Transferrin Vitamin B12/Folate Glucose

To facilitate this process, the Data Coordinating Center ("DCC") provides teleform shipment and tracking forms

6.2.1 Specimen Log and Sample Tracking

Personnel responsible for drawing blood should be provided with the appropriate order sets, labels, tubes and a copy of the teleform Shipment Form for each scheduled blood draw. Blood should be drawn in the established priority order. The teleform Shipment Form should be completed at the time of the blood draw to accurately reflect the status of the specimen collection. The information regarding the blood draw (date, time, volume) should be recorded.

6.2.2 Central Laboratory Shipment Form

The Central Lab requires that a Shipment Form be completed for the samples for each participant and included when the specimens are shipped to the Central Lab. **Complete the form accurately and completely. Be sure to check the box next to each of the sample tubes collected to ensure that all sample tubes are tracked appropriately. This Shipment Form should be faxed to the Central Lab and included in the shipment box and keep a copy in participants' files. Remember to track any samples not obtained and sent via the copy of the label sheet and submit "off protocol" form with reason not obtained and sent.

6.2.3 Reporting Abnormal Laboratory Critical Results to the PI and Site Reporting Abnormal Laboratory Results to PI's

Regarding abnormal results in laboratory data collected for research purposes and processed in a central laboratory:
The lab tests are run by the Northwest Research Laboratory (NWRL) as the specimens are received.

The NWRL reports all the abnormal values to the DCC and as soon as they are available. The DCC data manager will send the abnormal lab reports to the respective site PI where the participant was enrolled within one business day of receipt from the Central Laboratory and request a receipt notification from each PI are tracked in the DCC's internal tracking database. The confirmation acknowledgement from the site that the report has been received is saved in the

Central Study Files to assure the abnormal results are acted on per clinical protocol at each institution and are tracked in the DCC's internal tracking database. The DCC does not obtain any follow-up information regarding any intervention on the part of the site to address the results. Per the DSMB, the DCC will track incoming NWRL abnormal reports within a separate internal tracking database. The DCC will enter the date report was received from NWRL, the date sent to the site, and the date the site acknowledged receipt from the DCC.

At a minimum, the following research tests warrant notification of the local clinical investigators:
i. Parathyroid hormone
ii. Folate
iii. Vitamin B12
iv. Vitamin B1
v. Vitamin D
vi. Glucose

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Teen Longitudinal Assessment of Bariatric Surgery

FROZEN

The Teen-LABS Central Laboratory
Adolescent Specimen Shipment Form

This form is used to accompany specimens drawn for a single subject and shipped to the NWRL for analysis. A copy of this form should be retained at the clinic. Place the original into a ziploc bag; put the ziploc bag on top of the polyfoam shipping container; close the outer cardboard box and tape shut.

Please PRINT NEATLY and complete this form in blue or black INK. Mark response boxes like this: ☒

1. Visit: ☐☐ (1=Baseline; 6=6 Month; 12, 24, 36, 48, etc. = annual visits in months)
2. Place Participant's **Shipment Form Label** in box to the right:
3. Participant ID: Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐
4. Date specimens collected: ☐☐ / ☐☐ / 2 0 ☐☐ *(mm/dd/yyyy)*
5. Date specimens sent: ☐☐ / ☐☐ / 2 0 ☐☐ *(mm/dd/yyyy)*
6. Clinical site: _____

Contact Person: _____ Phone: (☐☐☐) ☐☐☐ - ☐☐☐☐

Mark all items included in shipment and record barcode:
***Note:** If the participant is non-fasting, please indicate in the comments section below. If you have a specific unscheduled test, please indicate in comments section.*

	Barcode
☐ Lipid Profile/Chem - 2.5mL cryovial (S. Creat/Calcium, S. Alb, Glucose)	☐☐☐☐☐☐☐☐
☐ CRP/Cystatin C - 2mL cryovial	☐☐☐☐☐☐☐☐
☐ Insulin - 2mL cryovial	☐☐☐☐☐☐☐☐
☐ Ferritin - 2mL cryovial	☐☐☐☐☐☐☐☐
☐ Vitamin A - 0.5mL **amber** cryovial	☐☐☐☐☐☐☐☐
☐ PTH - 0.5mL cryovial	☐☐☐☐☐☐☐☐
☐ Vitamin D - 0.5mL cryovial	☐☐☐☐☐☐☐☐
☐ Urine Alb/Creat. - 2.5mL cryovial	☐☐☐☐☐☐☐☐

This section to be completed by NWRL.

Date shipment received:
☐☐ / ☐☐ / ☐☐☐☐ *(mm/dd/yyyy)*

Mark all items received in shipment.

- ☐ Lipid Profile/Chem - 2.5mL cryovial
- ☐ CRP/Cystatin C - 2mL cryovial
- ☐ Insulin - 2mL cryovial
- ☐ Ferritin - 2mL cryovial
- ☐ Vitamin A - 0.5mL **amber** cryovial
- ☐ PTH - 0.5mL cryovial
- ☐ Vitamin D - 0.5mL cryovial
- ☐ Urine Alb/Creat. - 2.5mL cryovial

Please email to: CEBdata@cchmc.org or
fax to: (513) 636-0277
Cincinnati Children's Hospital, Division of Biostatistics and Epidemiology, Data Management Center.

Comments:

_____

_____

_____

☐ *Difficult blood draw; will attempt to collect at participant's next visit.*

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Teen Longitudinal Assessment of Bariatric Surgery

FRESH

The Teen-LABS Central Laboratory
Adolescent Specimen Shipment Form

This form is used to accompany specimens drawn for a single subject and shipped to the NWRL for analysis. A copy of this form should be retained at the clinic. Place the original into a ziploc bag; put the ziploc bag on top of the polyfoam shipping container; close the outer cardboard box and tape shut.

Please PRINT NEATLY and complete this form in blue or black INK. Mark response boxes like this: ☒

1. Visit: ☐☐ (1=Baseline; 6=6 Month; 12, 24, 36, 48, etc. = annual visits in months)

2. Place Participant's **Shipment Form Label** in box to the right:

3. Participant ID: Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

4. Date specimens collected: ☐☐ / ☐☐ / 2 0 ☐☐ *(mm/dd/yyyy)*

5. Date specimens sent: ☐☐ / ☐☐ / 2 0 ☐☐ *(mm/dd/yyyy)*

6. Clinical site: _____

Contact Person: _____ Phone: (☐☐☐) ☐☐☐ - ☐☐☐☐

Mark all items included in shipment and record barcode:

Note: If the participant is non-fasting, please indicate in the comments section below.

	Barcode
☐ HbA1c 2mL Purple-top	☐☐☐☐☐☐☐☐
☐ Vitamin B-1 3mL Purple-top	☐☐☐☐☐☐☐☐

This section to be completed by NWRL.

Date shipment received:
☐☐ / ☐☐ / ☐☐☐☐ *(mm/dd/yyyy)*

Mark all items received in shipment.

☐ HbA1c
2mL Purple-top

☐ Vitamin B-1
3mL Purple-top

Please fax to: (513) 636-0277
Cincinnati Children's Hospital, Division of Biostatistics and Epidemiology, Data Management Center.
Email: CEBdata@cchmc.org

Comments:

_____

_____

_____

_____

☐ *Difficult blood draw; will attempt to collect at participant's next visit.*

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Teen
[redacted] **Longitudinal**
[redacted] **Assessment of**
[redacted] **Bariatric**
[redacted] **Surgery**
[redacted]

FAX

Northwest Lipid Metabolism & Diabetes Research Laboratories
University of Washington

TO: **Specimen Processing**
FAX: **(206) 685-6880**
Phone: (206) 616-6474

FROM: _____

Phone: _____

FAX: _____

PLEASE BE ADVISED OF THE FOLLOWING SHIPMENT ARRIVAL:

Clinical Site: _____ Number of boxes shipped: _____

Date specimens shipped: _____

Fresh Shipment Tracking # : _____

_____

_____

Frozen Shipment Tracking #: _____

_____

_____

Remarks:

6.2.4 Shipment to the Central Laboratory

The Central Lab will initially provide 2 polyfoam shipping containers complete with cardboard outer box and enough supplies in bulk to be used for approximately 20 participants. Each site needs venipuncture supplies such as needles, gloves, vacutainers, transfer tubes, labels, etc. An order form to request additional supplies is included in this document.

Central Laboratory Shipment Forms for fresh as well as frozen should accompany the specimens and be shipped the day obtained. The Fresh samples (HbA1c and Vitamin B1) are sent in Styrofoam container packed with ice packs supplied by NWRL. These fresh samples need to be sent within 24 hours of draw unless special arrangements are made with NWRL. Specimens that will be sent on Friday need to have approval by staff at NWRL so that someone will be available to receive and process shipment. The frozen samples may be batched and shipped within 10 days of visit. Specimens will be shipped overnight to the Central Lab with dry ice. Appropriate Teleform tracking and Shipment Form should be faxed to both the NWRL and DCC prior to enclosing in shipment boxes. NWRL will return the used shipping containers to the site for future use and to repeat this process. Specimens should be prepared for shipment as detailed in the Central Lab Manual of Operations.

6.3 NIDDK Repository Samples

Coordinators please **review the Teen-LABS most current signed Informed Consent Form** (DNA has separate selection option) and verify permission to store blood, and urine for the bio-specimen repository. **(See also completing the Bio-specimen Shipping Log)**

6.3.1 NIDDK Biospecimens

Obtain the following specimens to be shipped to the NIDDK Repository.

1. Obtain 10ml of blood into an EDTA (Purple top) tube for plasma isolation for NIH biospecimens repository. Invert tube 8-10 times immediately after collecting. Centrifuge sample at 3000 rpms for 15 minutes at 4°C. Aliquot 0.5mL of plasma into as many 1 mL cryovials as needed to use all of the plasma. Place provided bar coded labels vertically and store vials at -80°C freezer until later time when study Coordinator will pack and ship by batches to NIH repository.

2. Obtain 10ml of blood into a Serum Separated Tube SST (red top, “tiger top”, red+ black top, or gold top; this tube has no anticoagulant and therefore a clot forms in the tube) tube for serum isolation for NIH biospecimens repository. Invert tube 5 times and allow sample to clot at room temperature for 20-30 minutes. Centrifuge sample at 3000 rpms for 15 minutes at 4°C. Aliquot 0.5mL of serum into as many 1 mL cryovials as needed to use all of the serum. Place provided bar coded labels vertically and store vials at -80°C freezer until a later time when study Coordinator will pack and ship by batches to NIH repository.

3. URINE for bio-specimens repository: Obtain at least 15 ml of **Urine** in urine container provided. Use clean catch technique for urine collection (having females wipe from front to back three times using antiseptic towelettes, discarding towelette after each wipe): Prepare 10 aliquots of 0.5mL of urine into 1 mL cryovials. Place provided bar coded labels vertically and store vials at -80°C freezer. Coordinator will pack and ship by batches to NIH repository.

6.3.2 Tracking, Storing, and Shipping the Biospecimens for the NIDDK Repository

Once collected, the samples of plasma, serum, and urine should be placed in separate 9”x9” cardboard boxes provided by the NIDDK. The boxes should be labeled with the NIDDK site abbreviation and number and the type of sample contained in the box. Samples should be shipped on Monday-Wednesday each quarter or when one or more boxes are full. Each sample should be documented by tracking the sample into an Excel file as follows:

1. Scan or enter the barcode on the vial into the “Barcode” column for each specimen.
2. Enter the Teen-LABS Sample ID in the “Sample ID” column for each specimen. The Sample ID is a combination of each participating site’s 3-digit NIDDK Site ID followed by a hyphen and the subject ID – for example, 635-BCM4001.
3. Enter the date the specimen was drawn from the subject in the “Date Collected” column. Use the following format: mm/dd/yyyy
4. Enter code for visit date specimen drawn (Baseline = 1, 6, 12, 24)
5. Enter the first letter of the specimen type in the “Sample Type” column (in caps).
    a. S = serum
    b. P = plasma
    c. U = urine
6. Enter the volume of the aliquot in each vial in the “Volume” column. The volume should be in milliliters and include two decimal places – for example, 0.50 or 0.25.
7. Enter “ml” in the “UOM” column (i.e., unit of measure).
8. Save the file as an Excel or .csv file with the following file name format:
    a. Teen-LABS_Specimen_Shipping_Log_SiteXXX_mmddyyyy
    b. (XXX is the 3-digit Site ID)
9. Email the file to the repository at niddk.mailbox@precisionformedicine.com
    a. With subject line Teen-LABS_Specimen_Shipping_Log_SiteXXX_mmddyyyy
    b. Make sure you copy the DCC on your email to the repository or send the file as a separate notice to:
    CEBData@cchmc.org
10. Print a copy of the file and include it in your shipment to the repository.

Barcode	Sample ID	Date Collected	Visit Code	Sample Type	Volume	UOM	Box Name	Position
				P	0.25	ML	Plasma	A01
				P	0.25	ML	Plasma	A02
				S	0.25	ML	Serum	A03
				U	0.25	ML	Urine	A04

6.3.3 PHYSICAL DETAILS OF SHIPPING: boxes are provided by NIDDK Repository (Assembling the STP 320 Repository Shipper)

1. Upon receipt of the empty shipping kit from the repository, remove the “EMPTY PACKAGING” cover from the outer box.
2. Place the specimen box and the absorbent strip inside the plastic bag. Seal the bag.
3. Place the plastic bag inside the white Tyvek envelope. Seal the envelope.
4. Place the Tyvek envelope in the cardboard inner box. If only one or two specimen boxes are being shipped; fill the rest of the space inside the cardboard inner box with packing material (e.g., bubble wrap) or an empty specimen box to prevent movement during shipment. Tape the box and place it in the middle of the cooler.

5. Fill the remainder of the space between the inner cardboard box and the inner walls of the cooler with dry ice.
6. Place the lid on the cooler. Place the “EMPTY PACKAGING” cover and shipping form on top of the cooler lid.

Place the Excel file of specimens on top of cooler lid.

7. Close and tape the outer cardboard box.
8. Place a checkmark in the block on the outer cardboard box next to “BIOLOGICAL SUBSTANCE, CATEGORY B”. Do not cover this marking with labels.
9. Affix a label with your name and return address to the side of the box in the “Shipper:” block.
10. Affix the repository address label to the side of the box in the “Consignee:” block.
11. Affix the dry ice label below the repository address label. Enter the weight of dry ice on the label in kilograms.
12. Affix the “UN3373 BIOLOGICAL SUBSTANCE, CATEGORY B” label to the right of the dry ice label.
13. Use the pre-printed Fed Ex air bill to ship specimens to the NIDDK Repository:
    a. Section 1: Fill in your name, return address, phone number and the date. Leave “Sender’s FedEx Account Number” blank.
    b. Section 6, Special Handling: Check “Yes, Shippers Declaration not required”. Check the “Dry Ice” block; enter “1” and the weight of dry ice in kg.
    c. Section 7: Enter “1” under “Total Packages” and the total weight of the package.
    d. Follow the peel-and-stick instructions on the back of the air bill. As shown, affix the air bill to a side of the box adjacent to the labeled side.
14. Call Federal Express, 1-800-GO-FEDEX (1-800-463-3339). Give them the account number (in Section 7, Payment) on the preprinted FedEx air bill and your pickup address. FedEx will dispatch a courier to pick up the package. Please schedule shipments Monday through Wednesday to avoid weekend shipment delays. **Do not ship frozen packages on Friday; the repository is closed on weekends.**
15. Send a shipment notification to the repository via email at
    niddk.mailbox@precisionformedicine.com and CEBData@cchmc.org
    on the day the package is picked up by FedEx. Include the 12-digit FedEx tracking number in the notification,
16. Contact the NIDDK Repository via email or call Eduard Chani at 240-415-6052 (office) or 301-318-8218 (mobile) regarding questions about packaging and shipping.

NIDDK Repository
https://repository.niddk.nih.gov

niddk.mailbox@precisionformedicine.com

Precision for Medicine
8425 Precision Way, Suite M
Frederick, MD 21701
niddk.mailbox@precisionformedicine.com

Eduard Chani, PhD
Senior Project Manager
eduard.chani@precisionformedicine.com

240-415-6052 office
301-318-8218 mobile
301 668 3416 fax

NIDDK Repository Contacts
Sharon Lawlor - sharon.lawlor@nih.gov Phone 301-480-2153
Jeff Weiner – jweiner@nih.gov Phone 301-496-5765
Beena Akolkar – beena.akolkar@nih.gov Phone 240-593-1733

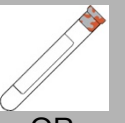
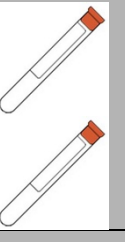
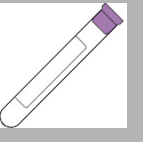
6.4 Teen-LABS-Teen Collection Scheme: for NWRL samples (see white sections) and for NIDDK samples (see gray sections) of this schematic

Teen-LABS Blood and Urine Processing Scheme

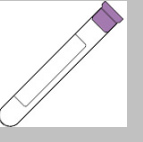
Visits: Baseline, 6 Month, 12 Month, 24 Month and Annual

Analyses	Fasting Condition	Blood Collection Tube	Visual Reference	Transfer Plasma/Serum to Labeled Tubes and Freeze
Lipid Profile Glucose Chemistries C-Reactive Protein Cystatin C Insulin	Fasting	8.5 mL Tiger-top SST		Centrifuge and freeze samples: • 2.0 mL into a 3.5 mL **blue** top tube. Label: **Lipid Profile/Chem**. • 0.5 mL into a 2.0 mL **blue** top tube. Label: **CRP/Cystatin**. • 0.5 mL into a 2.0 mL **blue** top tube. Label: **Insulin**.
Ferritin Transferrin Vitamin B12/Folate Vitamin A	Fasting	6ml Red-Top		Centrifuge and freeze samples: • 1.5 mL into a 2.0 mL **blue** top tube. Label: **Ferritin** • .5 mL into a 2.0 mL **amber** cryovial. Label: **Vitamin A**
PTH 25-OH Vitamin-D	Fasting	6mL Red-Top		Centrifuge and **freeze immediately** samples: • 0.5 mL into a 2.0 mL **blue** top tube. Label: **PTH** • 0.5 mL into a 2.0 mL **blue** top tube. Label: **Vit. D**
HbA1c	Fasting	2.0 mL Purple-top		Do NOT centrifuge or freeze. • Do not centrifuge. • Label: **HbA1c**. • Store in refrigerator.

Vitamin B1	Fasting	3ml Purple-Top		Do NOT centrifuge or freeze. • Do not centrifuge. • Label: **Vit B1**. • Store in refrigerator.

Urine Collection (urine albumin, urine creatinine)	Non-Fasting Acceptable	Collection Cup & 3.5 mL transfer cryovial		• Transfer 3.0 mL of urine from the collection cup to the 3.5 mL cryovial. Label: **Albumin/Creatinine** • Aliquot remaining urine equally into 10-2.0 mL cryovials. Label: **Urine Teen-LABS** (* process according to directions in 6.3.1)
Serum collection for NIDDK repository	**Option of tubes to use**	2- 6 mL red tops **or** gold tops **or** SST tiger top	 OR 	Draw (one) 10 mL "Tiger top" SST tube or two (6mL redtops or gold tops) for biospecimen collection (* process according to directions in 6.3.1)
Plasma collection for NIDDK repository		10 mL purple top EDTA tube		Plasma isolation for biorepository (* process according to directions in 6.3.1)

*** Confirm DNA selection per the most recent Informed Consent prior to Doctor's ordering sample and drawing Blood**

****BASELINE ONLY** NIDDK DNA		10 mL GLASS Purple-Top		Do NOT centrifuge or freeze. Label: **Teen-LABS site+ ID/Sex/Date** Store in refrigerator Ship in boxes supplied from Rutgers DNA Cell laboratory

** Or, ONE time blood draw if NOT ABLE to obtain at Baseline, if agreed to DNA Collection it may be drawn at a different visit. (Remember to confirm permission to draw DNA per most recent Informed Consent)

Make sure that the Informed Consent has been signed by participant or legal representative of the adolescent prior to obtaining samples for blood and urine. When the participant turns 18, a new consent is given to them to make the choice for themselves regarding obtaining and sending samples to the NIDDK CENTRAL REPOSITORY.
Wording on the Informed Consent, which needs to be verified prior to drawing blood or obtaining urine, is something to the nature of "With your permission, samples of your blood, urine, and DNA will be submitted to the NIDDK Central Repository. All of these samples only contain a code without any of your personal information on them. The NIDDK Central Repository is a research resource supported by the National Institutes of Health. The Repository collects, stores, and distributes biological samples and associated data from people with many kinds of disorders, from unaffected family members, and from other healthy people. The purpose of this collection is to make samples available for use in research for the study of obesity and other diseases, after the current study is completed. Sending samples to the Repository may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases."

Initial your choice below:
I agree to allowing samples of blood and urine to the repository
_____ YES _____ NO

PERMISSION TO USE SAMPLE OF BLOOD, DNA (GENETIC MATERIAL)
DNA is a genetic material which carries information about who you are. These samples will be stored at the NIDDK.
_____ YES _____ NO

PERMISSION TO BE CONTACTED FOR FUTURE RESEARCH STUDIES
_____ YES _____ NO

6.4.1 Holiday Schedule for Shipping Specimens
If you have any questions or concerns with the holiday schedule please see the annually updated schedule that is sent from Central Lab and Repository.
CBL is officially closed on all US federal holidays and, more importantly, **FedEx will NOT deliver on these days.** Therefore, avoid shipping on any day *preceding* a US federal holiday (see calendar below).

When a holiday falls on a Monday or Tuesday, the last day to ship samples is the Thursday of the preceding week. The samples are expected to be delivered on Friday, but if there is a FedEx delay we will have personnel in the laboratory to receive the samples on Saturday. **PLEASE NOTE:** The week before Christmas is an especially busy week for FedEx, and delays are expected. Therefore, we strongly recommend that the last day to ship samples is 2 days before the holidays.

When a holiday falls on a Friday, the last day to ship samples is the Tuesday of that week. The samples are expected to be delivered on Wednesday, but this allows for receipt on Thursday if there are FedEx delays.

Due to the length of the **Thanksgiving holiday**, the only day to ship samples is the Monday of Thanksgiving week. The samples are expected to be delivered on Tuesday, but if there is a FedEx delay we will have personnel in the laboratory to receive the samples on Wednesday. **Remember, FedEx will NOT deliver on Thanksgiving.**

Section 7 – Bone Density

7.1 Overview

Bone health data to be collected at a single study visit corresponding to an annual visit between 6-10 years after bariatric surgery.

- Cross-sectional design comparing bone density of RYGB and SG participants to a BMI-similar, non-surgical control group
- TL participants at study sites with a Hologic DXA machine (CCHMC, Nationwide, and Baylor) will be invited to undergo bone density measurement by DXA at one study visit between 2016-2021.
- Control participants (n=100) who have a BMI similar to the postoperative BMI of the surgical group, and who are demographically similar will be recruited from the community at each site in proportion to number of surgical participants at that site.
- Individuals on medications or with medical conditions known to have strong effects on BMD will be excluded (see exclusion criteria below).
- Control participant ID numbers - Hospital code will begin with CIN12XX for Cincinnati, NCH52XX for Nationwide, and BCM42XX for Baylor as assigned by coordinator.
- Visit time points for these data should be obtained as close to the visits 72, 96 and 120 months so that corresponding ANTH, FX and IPAQ data are included.

7.2 Eligibility

7.2.1 Inclusion criteria

<u>Bariatric Surgery Cases</u>

Individuals who meet inclusion criteria will be identified through the bariatric surgery database.

Sites: CCHMC in Cincinnati, Baylor in Houston, and Nationwide in Columbus
Sex: males and females
Race: all racial and ethnic groups
Age at surgery: 19.99 years of age or less at time of surgery
Time since surgery: 4-10 years since surgery.

<u>Non-surgical Controls</u>

Control participants will be recruited such that the mean age, sex, race and BMI are similar to the current age and BMI of case participants. Based on data from the last measurement (obtained in 2017), we will recruit participants with the following characteristics:

Sex: 75% females, 25% males
Age: 20-30 years
BMI: 25-60 kg/m^2
Race: 68% white, 32% non-white

We will 100 recruit control participants into one of 4 groups: white females (n=51), white males (n=17), black females (n=24) and black males (n=8). The distribution of participants by sex and race is approximate, and the final number will be adjusted per the characteristics of the surgical participants recruited. The DCC will examine the age and BMI distributions mid-way through recruitment to ensure that the mean age and BMI distributions are similar to surgery patients, and adjust recruitment if necessary to achieve this goal.

<u>As a starting point, we calculated recruitment goals based on the existing Teen-LABS participants.</u> Each center has specific recruitment goals for females and males for a specific BMI category. Race/ethnicity goals are provided by sex but not by BMI category as the number of racial/ethnic

minorities is small making it difficult to recruit into a specific category. Thus, the racial/ethnic minorities can be in any BMI category. Participants should be selected based on the recruitment needs of each site, and specific to sex and race. Please refer to the recruitment grids shown below.

CCHMC	All	By Sex			By Race (18% black)	
BMI group		*Female*	*Male*		*Non-black*	*black*
All	50	39	11	All	41	9
25-35	14	10	4	Female	34	7
35-45	21	16	5	male	9	2
45-55	12	10	2			
55-65	3	3	0	0% Hispanic		
BCM	All	By Sex			By Race (37% black)	
BMI group		*Female*	*Male*		*Non-black*	*black*
All	30	23	7	All	19	11
25-35	8	6	2	Female	14	9
35-45	13	10	3	Male	5	2
45-55	7	6	1			
55-65	2	2	0	8 Hispanic females, either race		

NCH	All	By Sex			By Race (24% black)	
BMI group		*Female*	*Male*		*Non-Black*	*black*
All	20	16	4	All	15	5
25-35	6	5	1	Female	12	4
35-45	8	6	2	male	3	1
45-55	5	4	1			
55-65	1	1	0	0 Hispanic		

Example: CCHMC will recruit 50 participants in total. Of these, 39 will be female. 10 females should have a BMI between 25-35, 16 females with a BMI between 35-45, 10 females with a BMI between 45-55 BMI, and 3 females with a BMI between 55-65. Of the 39 female participants, 34 should be non-black, and the remaining 7 should be black. None of the control participants at CCHMC should be Hispanic.

7.2.2 Exclusion criteria

- Non-ambulatory, wheelchair bound
- Medical conditions:
  - Cushing syndrome
  - hypogonadotropic hypogonadism
  - lymphoma
  - panhypopituitarism
  - primary hyperparathyroidism
  - hyperthyroidism
  - leukemia
  - osteogenesis imperfecta
  - primary ovarian failure
  - syndromic and genetic forms of obesity
- Medications:
  - o bisphosphonate medications - current or historical use
  - o systemic prednisone of >5 mg/day or equivalent for >3 months in the last year
  - o anti-epileptic medication such as phenytoin or carbamazepine in the last year
  - o heparin therapy for >3 months in the last year
- History of chemotherapy or radiation treatment

- Pregnant currently or within last 3 months. A urine pregnancy test will be obtained at the start of the study visit to confirm that participants are not pregnant.
- Lactating currently or within last 6 months
- Depo-Provera contraceptive use in the last three years, or prior use greater than 24 months in total
- Exceeds 400 lb
- Orthopedic hardware:
    - Controls: any indwelling hardware that cannot be removed
    - Surgery cases: indwelling hardware that cannot be removed in **all** of the following locations: lumbar spine, both hips and both forearms. If hardware is present, then DXA scans of that region will not be performed, but all other scans will be performed.

Individuals who self-report receipt of radiographic contrast material (barium) in the past 7 days or nuclear medicine studies in past 3 days should be rescheduled for a later date.

Study staff should email naila.merchant@cchmc.org at CIN or lauren.volz@nationwidechildrens.org at NCH or dlallen@texaschildrens.org at BCM regarding questions about eligibility of specific medications and medical conditions.

7.2.3 Recruitment Strategies for Surgery and Control participants

Bariatric surgery cases
We will only contact those individuals who have agreed to be contacted for research studies and new VSG cases. The DCC statisticians will identify the optimal study visit (post-op year 6, 8 or 10) for bone measurements and communicate this to the sites. The study coordinators are then responsible for assessing eligibilty.

Non-surgical controls
Recruitment of non-surgical participants will occur within this funding cycle (cycle 3), beginning in the first year of the cycle. Multiple strategies will be used to recruit non-surgical controls using IRB-approved materials. Strategies may include: print advertising; e-mail blasts, social and digital media; news/broadcasts; face-to-face marketing; and flyers at Cincinnati Children's, UC Health, Nationwide Children's Hospital, Baylor College of Medicine and in the community. Advertisements will provide phone and/or email contact information so potential participants can reach out to the study team with questions and get more information. Contact information includes phone number and email:

513-516-0947 or Naila.Merchant@cchmc.org for CIN
614-722-4712 or lauren.volz@nationwidechildrens.org for NCH
832-822-0677 or dlallen@texaschildrens.org for BCM

Potential participants that learn about the research protocol through e-mail or advertisement may also have the option of completing an electronic eligibility screener. Individuals who are not eligible will be notified after completion of the screener. Individuals who are potentially eligible to participate can choose to provide their contact information so that research staff can contact them about participation.

7.2.4 Screening

7.2.4.1 Surgery cases

Study staff will tell surgery cases about the new bone component when they are scheduling a follow-up Teen-LABS visit. Based on directions from the DCC, the study coordinators will assess eligibility of surgery participants when scheduling either their 6-year, 8-year or 10-year study visits. Some of the information on the DXA screening form (available at the end of Section 7) may be available from the medical record or other Teen-LABS form, but some questions must be asked over the phone to rule out any exclusion criteria. Individuals who are eligible will be scheduled for DXA scans at their upcoming study visit.

Some surgery cases may be ineligible at the time of screening, but their eligibility status could change during the course of the study. Possible reasons for a change in eligibility are weight loss, no longer pregnant, and medication use. These criteria are noted on the DXA screening form. Eligibility of surgery cases should be reassessed at their next Teen-LABS study visit.

Surgery Screen Fails: Enter reason for ineligibility on the DXA eligibility form once final ineligibility has been determined.

7.2.4.2 Control participants

A screening interview will take place over the phone to rule out any exclusion criteria using the DXA screening form. The screening interview will be conducted by study staff, and information will be documented on the DXA Screen Form. Potential participants will first give verbal consent to pre-visit screening. They will be given the opportunity to ask questions regarding the study. If desired, interested individuals can be sent a copy of the informed consent document either through email or postal mail to review prior to agreeing to be in the study.

Individuals who meet eligibility criteria over the phone and agree to participate in the study will be scheduled for a study visit.

The results of telephone screening of control participants will be done at each clinical site. Each center should set up a Control Participant screening log in Excel using the format in the example below. The ineligibility reason code is the question number from the DXA screening form. The screening logs will be saved with the participant's source documents.

Sequential number	Study site	Screening date	Eligible	Ineligible reason
1	CIN	30 Aug 2017	No	Q3 pregnancy
2	CIN	30 Aug 2017	Yes	
3	CIN	4 Sept 2017	No	Q17 hyperthyroidism
...				

7.3 Enrollment and Study Visit

Participants will arrive at the specified location on the day of their scheduled study visit. A study representative will meet the subject. The study will be described to the participant, and they will be given the opportunity to ask questions regarding the study. Consent document will be provided to the control participant for signing. The consent document will contain the participants study ID number and MRN.

Confirmation of Eligibility after Informed Consent – Surgery cases and controls

Once consent is signed, the study coordinator will review eligibility criteria with the participant.

Weight must be verified to be < 400 lb (182 kg). Individuals whose weight exceeds this are not eligible for the bone study.

Female participants will provide a urine sample for a pregnancy test.

- If pregnancy test negative, proceed with study protocol.
- If pregnancy test positive, the subject is no longer eligible for the bone study.

Individuals who do not meet eligibility criteria are considered a screen fail. Surgery cases may continue with the non-bone components of their study visit. For controls, the visit is closed.

Controls: For controls who shows up for a DXA visit and sign the consent form, the EF "Enrollment Form" and "DXA Visit Info Form" should be completed. If the person is determined to be ineligible for DXA at the study visit, the DXAELIG should be completed.

Surgery cases: The "DXA Visit Info Form" will be completed if the DXA visit is performed or if the participant has reached last possible time point to screen for DXA and is ineligible. If ineligible for DXA, DXAELIG "DXA Eligibility Form" will be completed.

Anthropometric Measurements (ANTH)
Height, weight, circumferences and Tanita measurements of surgery cases and controls will be obtained by Teen-LABS certified research staff as described previously and recorded on the ANTH form.

Control Participant Medical and Reproductive History (MH)
Information on medical and reproductive history of control participants will be obtained on the Control Participant Medical and Reproductive History form. Medical and reproductive histories of surgery participants are obtained on other Teen Labs forms.

IPAQ
Surgery cases and controls will complete the IPAQ physical activity assessment form.

Calcium and Vitamin D Intake
Surgery cases and controls will complete the Calcium & Vitamin D food frequency questionnaire.

While in clinic:

- Form must be completed in soft-lead pencil (No. 2); responses filled out in ink are treated by the electronic scanner as though they are "missing."
- Have the participant fill in their Teen-Labs number with the 4 numbers only, excluding site location (for example, 1000 for CIN1000).
- Make sure the participant completes all fields, including age, sex and, for females, if they are pregnant or breastfeeding.
- For all questions, make sure the participant notes how often they usually eat/drink each of the foods listed, including at breakfast, lunch, dinner, snacks, and eating out, and how much on those days for the questions that ask for that information.
- Make sure all questions are answered to the best of their knowledge.
- If a question is not relevant, it can be left blank.
- The coordinators should also make sure that the circles are completely filled in to ensure proper scanning.

After clinic:

- Once the questionnaire is complete, scan or photocopy it and save as a source document. The original questionnaires should be kept together in a separate file.
- Every 3 months, send the original completed questionnaires by FedEx to:
  Heidi Kalkwarf, PhD
  240 Albert Sabin Way, MLC 2010
  Cincinnati Children's Hospital Medical Center
  Division of Gastroenterology, Hepatology & Nutrition
  Cincinnati, Ohio 45229-3039
  Phone: 513-636-3808
- Dr. Heidi Kalkwarf will provide a DXA result letter to the coordinators for each participant. The coordinators will fill in the necessary PHI, keep a copy of the letter, send the original letter to the participant, and document in REDCap (under the DXA form for both surgical & control participants) that the letter was sent. A copy of the letter should be saved with the participant's source documents. A blank copy is included at the end of section 7.

- Prior to shipping, email FedEx tracking number to Heidi.Kalkwarf@cchmc.org and copy cebdata@cchmc.org.

Once a sufficient number of questionnaires have accumulated at CCHMC, they will be sent to Nutrition Quest for processing and calculation of calcium and Vitamin D intakes. A list of ID numbers associated with each questionnaire will be included in the package mailed to Nutrition Quest. Once processed, Nutrition Quest will send an electronic data file to the DCC (cebdata@cchmc.org) for merging with the rest of the Teen-LABS data.

Nutrition Quest (Formerly Block Dietary Data Systems)
15 Shattuck Square, Suite 288, Berkeley, CA 94704-1151
Phone 510-704-8514/ Fax 510-704-8996

Fracture History form (FX)
Surgery cases and controls should complete the Fracture History form.

DXA Performance form (DX)
Details of DXA measurements and completion of the DXA performance form are described in Section 7.4.

Summary of forms to be completed in conjunction with the one-time DXA Scan obtained only at CIN, NCH and BCM centers. Data will be captured with paper and pencil and entered into REDCap by coordinator at each center within a week of completion of the DXA study.		
	Surgery cases	Controls
DXA screening	X	X
Informed Consent		X
EF: Enrollment form		X
DXA eligibility form	X	
Control DXA eligibility form (if ineligible at study visit)		X
ANTH	X	X
MH: Control participant medical & reproductive history		X

Calcium & vitamin D intake questionnaire	X	X
FX: Fracture history questionnaire	X	X
IPAQ	X	X
DP: DXA performance	X	X
PQCT: pQCT performance *(Cincinnati only)*	X	X

Completion of Study Visit
Ensure that study visit checklist is completed by the end of the study visit.
Retain completed study visit checklist in participant's research file.

Compensation
Participants will receive $100 as compensation for participating in the bone study.

7.4 DXA Measurements

7.4.1 Introduction
The participant's bone mineral density will be measured by Dual X-Ray Absorptiometry (DXA). The anatomic sites of measurement include: AP lumbar spine, forearm, hip and whole body. If a participant has indwelling hardware that cannot be removed, the DXA scans of that region should not be performed as it will not be valid. Scans of the other regions should be performed as specified below.

Materials Needed:
- Hologic 4500A or newer model (Delphi, Discovery or Horizon) DXA machine
- Hospital gown, 'scrubs', or similar clothing without snaps, zippers, rivets, buttons, metallic paint or other adornments
- Measuring tape or ruler
- Spine positioning block
- Chair/stool is also used for one scan

The participant should be dressed in a hospital gown or scrubs, and, if necessary, thin socks. A thin sheet may be placed over the subject for warmth. Under wire bras and other undergarments with buttons or snaps should be removed.

7.4.2 Subject Registration in DXA Machine
Please follow instructions in **Error! Reference source not found.** TABLE 1 on the next page for creating the participant's "biography". An example is shown in Figure 1. The entry for last name should be the study ID number (no leading zeroes) followed by the subject's first and last initials. The initials should be in capital letters without spaces.

TABLE 1. FIELDS TO ENTER IN THE ***PATIENT BIOGRAPHY*** PAGE

Field	Comment	Entry	Example
Last name	Full study ID	Exactly as on CRF*	CIN1000
First name	*Leave blank*		
Middle initial	*Leave blank*		
ID	*Leave blank*		
Identifier 2	*Leave blank*		
Sex		As usual	Female
DOB		As usual	January 16, 1990
Menopause age	*Leave blank*		

Weight	*Leave blank*		
Height	*Leave blank*		
Ethnicity		Select Black or white	white
Referring Physician	Used to identify the study	Short study name	TeenLabs3
Patient comment	*Leave blank*		

Always get the subject's initials and ID number from the Study Coordinator to ensure consistency. Be sure to use zeroes (Ø) and not the letter "O" when entering the Subject ID into the Pat ID field.

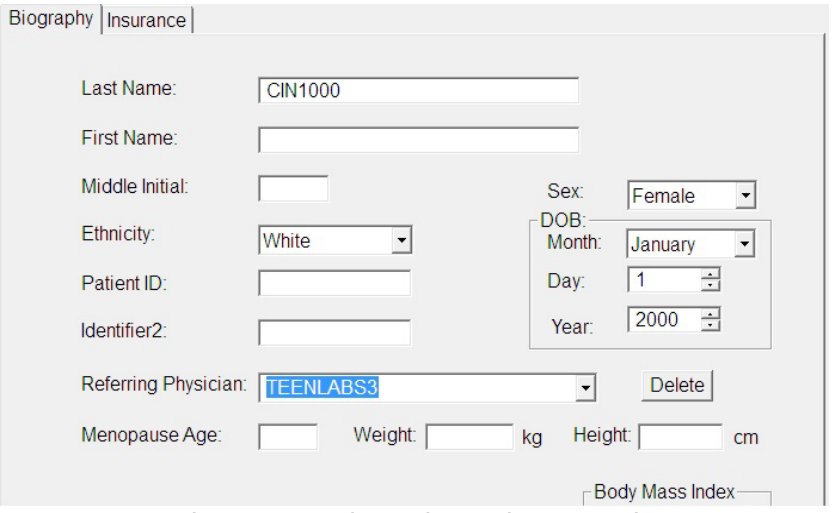


Figure 1. Patient Biography example

Use instructions in TABLE 2 to complete the ***Scan Properties*** page (Figure 2).

TABLE 2. FIELDS TO ENTER IN THE ***SCAN PROPERTIES*** PAGE

Field	Entry	Example
Operator	Operators initials	GAU
Height	*Leave blank*	
Weight	*Leave blank*	
Scan Comment	*Leave blank*	

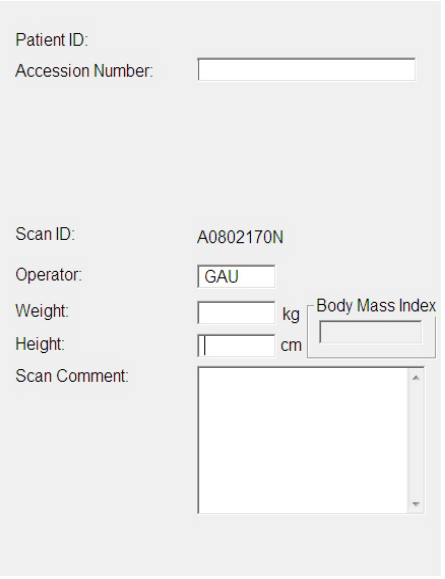


Figure 2. Scan properties page.

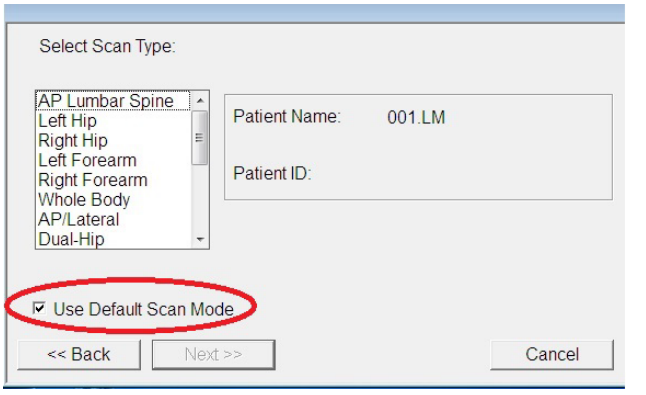
7.4.3 DXA Scan Acquisition

In order to get the most consistent subject results it is important to follow consistent procedures in acquiring all scans. These include the following:

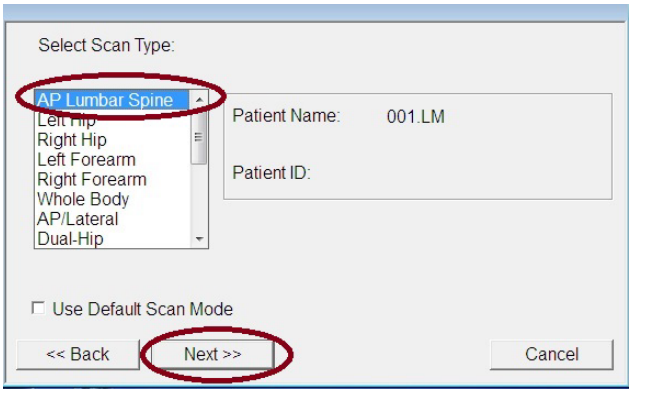
- **Review the Hologic Manual for acquiring the whole body, spine, hip and forearm scans, including illustrations on correct positioning**.
- Use the same scan mode for each type of scan throughout the study.
- Remove all radiopaque objects from the scan areas.
- If the participant has indwelling hardware in the region to be scanned, do not perform that specific scan.
- Ensure correct positioning of the participants.
- Ensure that no movement occurs during scanning.
- Monitor the scan during acquisition. If positioning is not correct, or the participant has moved, abort the scan, reposition the participant if necessary and restart the scan.
- Scans can be repeated up to 2 times (3 scans total) per skeletal site.
- A copy of each scan should be printed so that the study coordinator can verify that the correct ID number, birth date, sex and race have been entered into the DXA biography fields.
- NOTE: When scanning a participant, it is important to keep in mind that it is much less time consuming to rescan the participant immediately if a problem is detected, rather than having to recall them for a repeat of the scan on another day.

7.4.4 AP Spine Scan

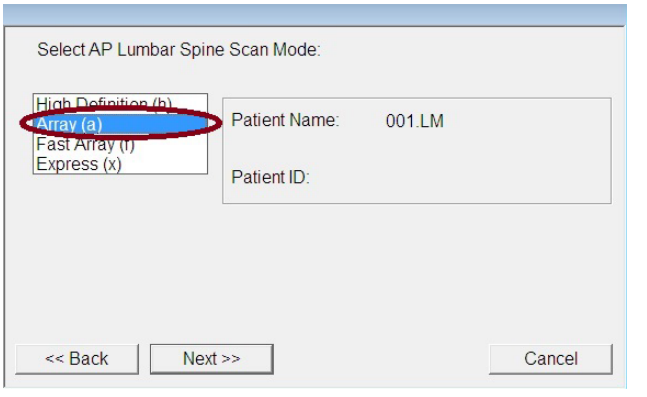
- Do not perform a spine scan if there are orthopedic rods.
- Have participants remove umbilical adornments/piercings.
- Select **Array** scan mode *(not default*). To do so, *unselect* “Use Default Scan Mode” by clicking on the box so that there is no check mark.



- Select AP Lumbar spine scan and press next.



- Select Array (a) and then next.

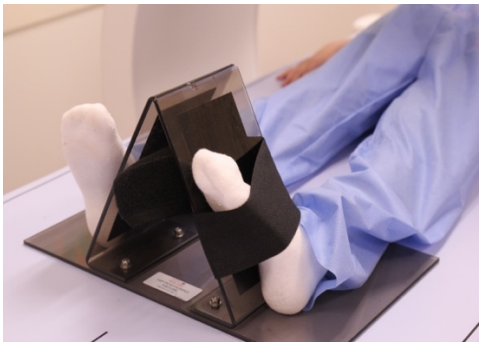


- Keep the scan width and length set to the default settings.
- Make sure that the participant is centered on the table top. To assist in positioning the spine correctly, use positioning block placed underneath the knees to keep the participant's back and pelvis flat against the tabletop.
- Scan the Lumbar spine to include L1 through L4. Make sure that the AP spine scan includes both iliac crests at the bottom of the image and at least one vertebra with ribs at the top.
- Inspect the image as it is being acquired. Hit Stop Scan when T12 is visible.

- Repeat scan in the event of movement or poor positioning. Do not make more than 3 attempts to acquire a satisfactory scan.

7.4.5 Hip Scan

- Scan the left hip. If there is an orthopedic pin in the left hip, then scan the right hip.
- Select **Array** scan mode *(not default)* following the same directions as for the spine.
- Keep the scan width and length set to the default settings.
- Use the hip scan positioning fixture.
- Ensure the left femur is positioned parallel to the long axis of the table. To do this, slightly move the hip scan positioning fixture towards the center or away from the center of the table. Recheck the position of the knee to ensure the hip is still in position as outlined above.
- Make sure the left leg is properly rotated and abducted using the hip scan positioning fixture. Always position the participant's leg by apply rotating force above the knee. This will ensure that the hip itself is rotated, not just the lower leg. Proper rotation and abduction will alleviate many analysis problems. With optimal positioning the lesser trochanter will be barely visible.

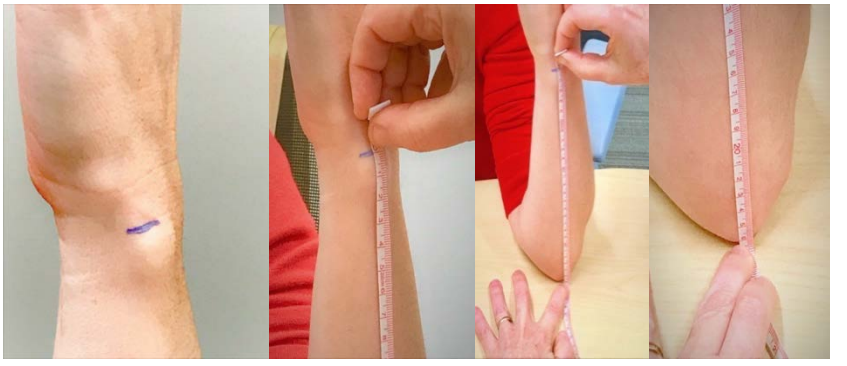


- Repeat scan in the event of movement or poor positioning. Do not make more than 3 attempts to acquire a satisfactory scan.

7.4.6 Forearm Scan

Scan the LEFT forearm. If the participant has orthopedic hardware in the left forearm or a cast or recently (within 4 months) had a cast removed from the left forearm, the right forearm should be scanned. Rings on the fingers do not need to be removed as they will not interfere with the regions of interest in the scan image.

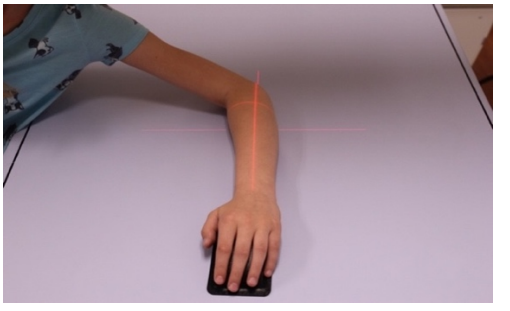
Measure forearm length from the top of the ulnar styloid ("bump" on the pinky side of the wrist) to the tip of the olecranon process (elbow) using a non-stretchable tape measure. The elbow should be placed on a flat, firm surface with the forearm extended vertically. The zero mark on the tape measure should be placed at the top of the ulnar styloid.



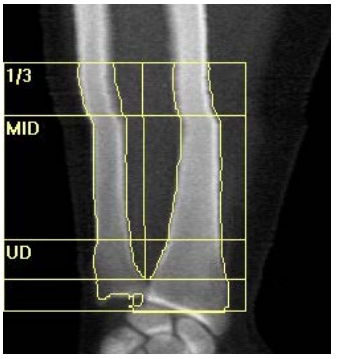
The tape measure is extended along the length of the forearm and read at the tip of the olecranon, which is on the flat surface. The forearm length should be documented on the DXA performance form. The measurements should be made in triplicate. This information is ***required*** for analysis of the forearm scan.

Keep the scan width and length set to default settings. When prompted, enter the measured length of forearm. The software will automatically set scan analysis settings based on this length.

- The participant should be seated on a chair next to the table and their arm resting on the table.
- Align the long bones of the forearm with the long axis of the laser.
- Ensure that no obstruction is within 1 cm (0.4 inch) on either side of the forearm.

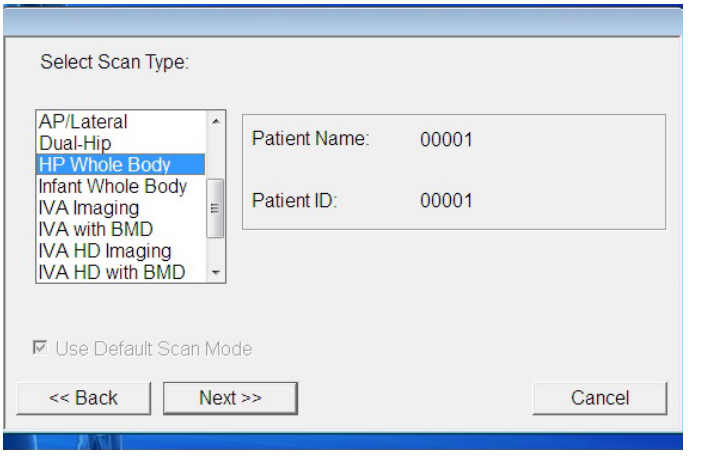


- Inspect the image as it is being acquired. Abort the scan if positioning is incorrect or movement is detected. In a good forearm scan, the arm is centered, the forearm bones are parallel to the long axis, there is no movement in the regions of interest
- Repeat scans in the event of movement or poor positioning. Do not make more than 3 attempts to acquire a satisfactory scan.
- Below is a right forearm scan with movement in the 1/3 region of interest.

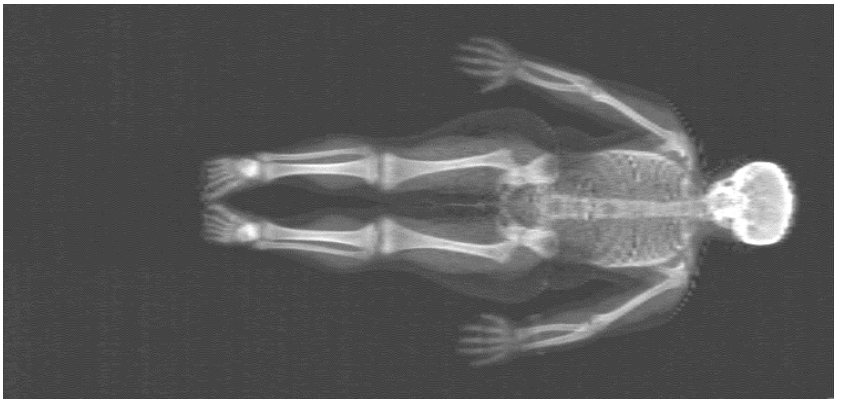


7.4.7 Whole Body Scan

- The whole-body scan should not be performed if there is major orthopedic hardware. Piercings should be removed before scanning if at all possible. Small metal piercings are acceptable.
- Choose the high precision whole-body scan mode (HP whole body).

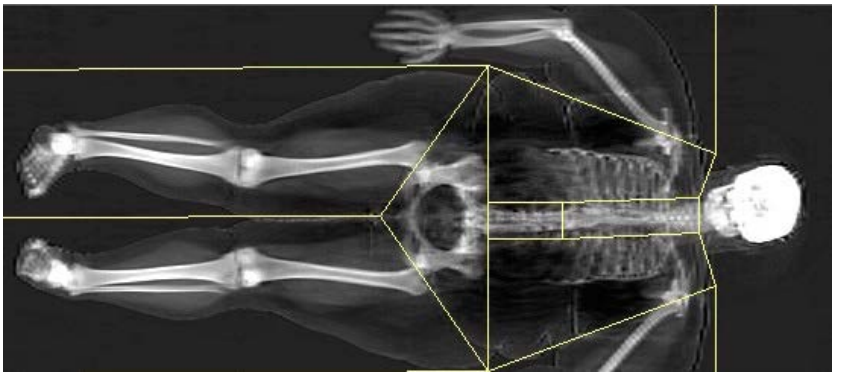


- Before placing participant on the table, manually move the detector to the upper right-hand corner of the table closest to the starting point of the scan.
- Position the subject with the head near the “head end” of table and the body centered in the width (shorter axis) of table and aligned with the long axis of the table. The subject’s head should face straight up, not turned to the left or right. If required for subject comfort, use only radiolucent pillows.
- The legs and feet must be positioned together with a Velcro strap around the feet to help avoid movement. Please keep the feet relaxed with the toes pointed upwards.
- Position hands with palms flat against the scan table. Please maintain space between the arms and the torso when possible. If necessary, with larger or heavier participants, the hands may be placed next to the hips. **Do not** tuck the hands under the hips to keep them in the scan field. If necessary, tape the subject’s hands to the scan table.



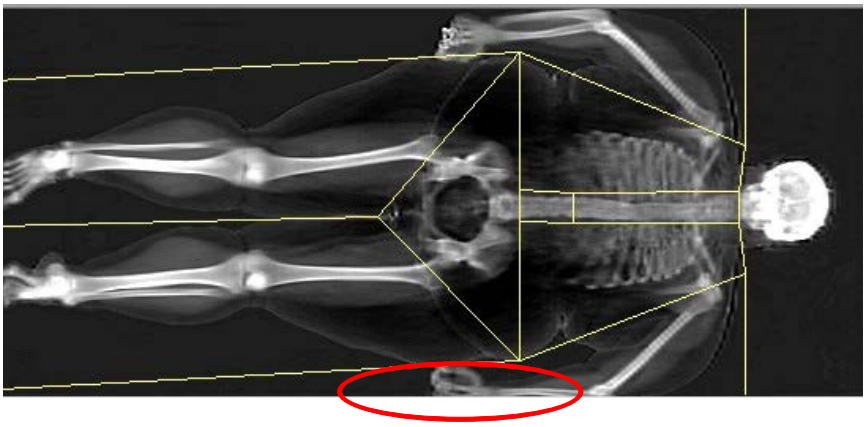
CORRECTLY POSITIONED WHOLE BODY SCAN – LEAN PARTICIPANT
Correct alignment: head straight, feet together, palms flat on table.

- Special positioning is needed for those participants whose arms exceed the table width. For these individuals, shift the body to the left so that their Right arm is completely on the table top and their Left arm is hanging off the table. When this is done, the DXA software automatically uses information from the Right arm to impute the Left arm. This is called reflection positioning. It is helpful if the technician holds the left arm that is off the table so that it does not drag when the table moves. Please check the positioning of the arms carefully before beginning the scan. If the arms are not clearly within the inner lines on the table top, use the reflection positioning. When in doubt, use reflection positioning to avoid having to repeat the scan.



CORRECT REFLECTION POSITIONING FOR WHOLE BODY SCAN OF OBESE PARTICIPANT
Body is shifted to the left, right arm is completely on the table, left arm is off the table.

- Monitor the scan during acquisition for patient movement so the scan may be stopped and restarted. Do not engage the patient in conversation because it may cause motion, but give them encouragement and updates on the scan's progress.
- Examine the scan image after the scan is acquired to be sure that either both arms are completely in the scan image or that reflection positioning was used. The software will not automatically 'fix' a scan when only a small part of the arm is cut-off. The figure below shows a scan where the left arm was not completing in the scan region and was cut-off. Reflection positioning should have been used.



- Repeat scan in the event of movement or if part of the arm is cut-off. Do not make more than 3 attempts to acquire a satisfactory scan.

7.5 CRF Completion and Quality Control

A DXA technician will fill out the CRF for DXA performance immediately after scans have been completed. The following steps must occur before leaving the DXA room with the participant.

- A DXA technician will print off all scans for the participant's visit, regardless of whether they are considered good or bad scan.
- The study coordinator will double check all scan biographies and ensure the number of scans printed is accurately captured in the CRF. Any errors in DXA biographies and/or CRF documentation must be rectified the day of the study visit.

7.6 Radiation Exposure

The estimated radiation exposure (effective dose) associated with the DXA scans performed as described above is given below. Estimates are from Blake, Bone 2006;38:935–942 and Thomas, J Clin Densitometry 2005;8:415–422. The largest values are provided.

Scan type	Effective Dose (micro Sieverts)
Whole body	4.2
AP lumbar spine (array mode)	14.8
Hip (array mode)	10.2
Forearm	0.03
Total	29.2

Note: When repeat scans (2 repeats for 3 total) are specified in the event of movement, the maximal total radiation exposure for DXA scans is increased to 87.7 micro Sieverts. This is comparable to approximately 11 days of back ground radiation.

7.7 Data Security

The Archive function in Hologic scanners is used to store scan files to a predefined folder or on to a CD. For data security, all scan files should be archived soon after scanning in case of a computer failure. Archive scan files on a regular (at least weekly) basis.

7.8 Transferring Scan Images to CCHMC for Analysis

Scans should be copied to a CD and sent via FedEx to the DXA laboratory at CCHMC within 1 month after the scan is obtained. Prior to shipping, send FedEx tracking number to:

Suzanne.Summer@cchmc.org and copy cebdata@cchmc.org. All scan analysis will be performed at CCHMC.

Send all Images to:
Cincinnati Children's Hospital Medical Center
Suzanne Summer, T2.417
240 Albert Sabin Way
Cincinnati, Ohio 45229-3039
Phone: (513) 636-0456

7.9 Peripheral QCT Scans

At the Cincinnati center only, surgery participants and controls will have bone measurements by peripheral QCT (pQCT) as well as by DXA. We will obtain pQCT scans to better characterize effects of bariatric surgery on bone mineral density and cross-sectional dimensions. PQCT scans will be obtained on the tibia and radius at the distal 4% and 30% sites. These measurement sites were chosen to maximize the types of information to be obtained. The 4% sites of the tibia and radius are within the distal metaphysis and are composed primarily of trabecular bone. The 30% sites are in the diaphysis and are predominantly cortical bone. PQCT scans will be acquired using the Stratec XCT 2000 scanner with a voxel size of 0.4 mm and a speed of 25 mm/sec. The calibration stability of the pQCT is assessed daily by scanning a phantom and evaluating the vBMD results. Radiation exposure associated with the pQCT scans <10 micro Sieverts.

DXA SCREENING	
Subject's Name:	**If enrolled,** **Study ID:** |_|_|_|_|_|_|_|_|
Address:	**Email:**
Contact Number: **Availability:**	**Date:** |_|_|-|_|_|_|-|_|_|_|_| D D - M O N - Y Y Y Y

Parts of this form may be completed by review of the Teen-LABS records for surgery cases.

How did you hear about the study? _____

If currently INELIGIBLE, ask the following question:

Presently, you do not meet eligibility for this study. May we call you back in the future to see if we have an opportunity for you to participate? ☐ ***No*** ☐ ***Yes***

Exclusion reason	Descriptive Information	
	Have you had bariatric surgery?	☐ No ☐ Yes
	What is your date of birth?	|_|_|-|_|_|_|-|_|_|_|_| D D - M O N - Y Y Y Y
	How old are you now?	___ ___ . ___ years
	What is your height?	___ feet ___ . ___ inches
	Calculate height in meters	total inches ___ ___ ___ x 0.0254 = ___ . ___ ___ meters
	What is your most recent weight?	___ ___ ___ lb x 2.2 = ___ ___ ___. ___ kg
1. weight	Is weight > 400 pounds?	☐ No ☐ **Yes,** *exclude for now. May be re-screened at another time*
	Calculate BMI	___ ___ . ___ kg/m^2
	What do you consider your race? You can choose more than one category.	☐ American Indian or Alaskan Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Refused
	Do you consider yourself to be Hispanic or Latino?	☐ No ☐ Yes
	What is your sex?	☐ Male ☐ Female

2. recruitment needs	**Exclude** based on recruitment needs? ☐ No ☐ **Yes,** *but may be re-screened at another time*

If respondent is male, skip to question 6

Questions for females			**Exclude**
3. pregnancy	Are you currently pregnant or have you been pregnant in the last 3 months? ***If ineligible for this reason, may re-screen at another time*	☐ No	☐ Yes
4. lactating	Are you currently breastfeeding or have been breastfeeding in the last 6 months? ***If ineligible for this reason, may re-screen at another time*	☐ No	☐ Yes
5. Depo	Have you taken Depo-Provera in the last 3 years or have you taken it for more than 24 months in total? ***If ineligible for this reason, may re-screen at another time*	☐ No	☐ Yes

Resume questions for males and females			**Exclude**
6. wheelchair	Do you require a wheelchair to get around?		
7. chemotherapy	Have you had chemotherapy? *If yes, then go to question 7a. If no, go to question 8.*	☐ No	☐ Yes*
7a.	Have you received chemotherapy in the last year?	☐ No	☐ Yes
7b.	Did you ever take methotrexate?	☐ No	☐ Yes
	If responded YES to 7, but NO to 7a and 7b, patient is eligible for the study. *Ask patient to bring any information regarding history of chemotherapy to the study visit, as we do not know all the long-term effects of chemotherapy*		
8. radiation	Have you received radiation therapy?	☐ No	☐ Yes

9. metal hardware	**Controls:** Do you have orthopedic hardware, like rods, pins or plates, that cannot be removed anywhere in your body? ☐ No ☐ Yes *if yes, then ineligible* **Surgery cases:** Do you have orthopedic hardware, like rods, pins or plates, that cannot be removed in your: spine ☐ No ☐ Yes both hips ☐ No ☐ Yes both wrists ☐ No ☐ Yes *If yes to **all** (spine, both hips & both wrists), then ineligible*	☐ No	☐ Yes
MEDICATIONS "Have you ever been prescribed the following medications"			**Exclude**
10. bisphosphonates	Bisphosphonates (Fosamax, Actonel), Pamidronate (Aredia), or Zoledronic acid (Zometa) - - used to treat osteoporosis	☐ No	☐ **Yes**
11. anti-epileptics	Anti-epileptic drugs such as Phenytoin (Dilantin) or Carbamazepine (Tegretol) - for seizures. Acceptable medications include Zonisamide	☐ No	☐ **Yes**
12. Prednisone	Oral prednisone with a dose of ≥ 5mg/day for > 3 months in the last year? *(or equivalent)* Prednisone may be used long term for a variety of inflammatory conditions, such as arthritis, inflammatory bowel disease, lupus…… One or 2 dose packs for poison ivy does not exclude you from participating. ***If ineligible for this reason, may re-screen at another time*	☐ No	☐ **Yes**
13. Heparin	Heparin for >3 months in the last year - for blood clots ***If ineligible for this reason, may re-screen at another time*	☐ No	☐ **Yes**

MEDICAL CONDITIONS "Have you ever been diagnosed with the following:"		**Exclude**
14. Osteogenesis Imperfecta/Brittle Bone Disease	☐ No	☐ **Yes**
15. Hypogonadotropic hypogonadism	☐ No	☐ **Yes**
16. Pan hypopituitarism	☐ No	☐ **Yes**

17. Primary hyperparathyroidism	☐ No	☐ **Yes**
18. Primary ovarian failure	☐ No	☐ **Yes**
19. Hyperthyroidism	☐ No	☐ **Yes**
20. Cushing Syndrome	☐ No	☐ **Yes**
21. Syndromic Obesity (e.g., Prader-Willi Syndrome, Cohen Syndrome, Bardet-Biedl Syndrome, POM-C mutations, MC4R mutations)	☐ No	☐ **Yes**
22. Leukemia or lymphoma	☐ No	☐ **Yes**

For eligibility questions regarding specific medications or medical conditions, please email Halley.Wasserman@cchmc.org.

Is the individual eligible to participate in the bone study? ☐ No ☐ **Yes**

If no, what was the first exclusion number and reason? _____

If yes, does she/he want to participate? ☐ No ☐ **Yes**

DXA scans are not valid if you have recently had contrast material, such as barium, for radiographic imaging. Please schedule DXA visit at least 7 days after any radiographic procedure involving contrast material.

Comments for scheduling: _____

Teen Longitudinal Assessment of Bariatric Surgery
www.Teen-LABS.org

Weight: _____Pounds

Age: _____Years

Dear _____,

At your visit on _____, we performed a bone mineral density test using a dual energy x-ray absorptiometry (DXA) machine. As part of this test, we obtained bone density measurements of your spine and hip.

A bone mineral density test measures the amount of mineral — namely calcium — in your bones. This test helps assess the health of your bones and is an important test for osteoporosis, the most common type of bone disease. Osteoporosis occurs when the bone tissue becomes thin and frail and can lead to fractures (breaks in the bone). Consuming enough calcium and vitamin D is one important way to maintain healthy bones. Regular physical activity, such as moderately vigorous walking, is also very important for bone health.

This table provides the results of your bone mineral density test.

Your bone mineral density tests results (Hologic DXA machine)			Compared to young adult reference ranges, your bone density is considered:	
	g/cm^2	Z-score	Within the expected range for your age	Below the expected range for your age
Lumbar spine			☐	☐
Total hip			☐	☐
Femoral neck			☐	☐

The Z-scores show how your bone density at each location compares to other people of the same age, sex, and race. For young adults, ages 20 to 30 years, a Z-score of < -2.0 is considered below the expected range for your age, and indicates that you may be at increased risk for osteoporosis. Because your bone mineral density was measured as part of a research study and not a test your personal doctor ordered, these results are not a diagnosis. We recommend you share this form with your doctor so he or she can evaluate and follow-up on your bone health. If your bone density score was below the expected range for your age, your doctor may need to do more tests and discuss treatments or ways to help prevent bone loss or strengthen weak bones.

Thank you for participating in this important bone health study. For further questions related to this test or to Teen-LABS, you may call or write to us at:

Dr. [insert site investigator name and email]

[insert local site coordinator name and email]

Section 8 – Corridor Walk

8.1 Background and Rationale
Limitation in ability to walk is an important outcome of morbid obesity. Walking ability and endurance can be directly assessed by performance testing. The 400-meter walk test has been shown to be related to VO2 max (the maximum volume of oxygen consumed by the body each minute during exercise, while breathing air at sea level); thus the walk not only tests ability to walk but also physical fitness. This test is a modification of a long distance corridor walk administered in the Health ABC study, a study of body changes in the elderly and how these changes affect cognitive and physical function. This modified test, instructs patients to **walk at their usual pace** (as opposed to walking at the fastest pace they can maintain).

8.2 Materials Needed
- White cloth tape or marker and colored tape
- Digital stopwatch

8.2.1 Stopwatch
The stopwatch will be used to measure the time it takes to complete the walk. Press the middle (mode) button to make sure you are in stopwatch mode. The display should read **0:0000**. To time the task, just press the right-hand button (labeled STA/STP) at the top of the stopwatch to begin, and press again when the task is completed. The time is digitally displayed on the stopwatch. To get the display to read **0:0000** again, press the left (lap) button. Time is displayed as minutes: seconds, hundredths of a second.

8.3 Preparation
8.3.1 Course Preparation: 20 Meters
For consistency between centers, the walking course length will be 20 meters and should be laid out in advance of patient's test in an unobstructed, dedicated corridor.
Cloth tape or marker should be used to indicate the beginning and the end of the 20 meter length. Place a 10 cm length of tape marking every 5 meters between the start and stop of the course. In addition place a 10 cm length of colored tape marking 1 and 19 meters on the course.
Label each piece of tape. Participants are to walk in a clockwise direction going around the 1 and 19 meter marks (which allow for a 1 meter turn at each end). Sites that are unable to dedicate a 20 meter length of corridor for the 400 meter walk are permitted to dedicate 10 meters of a corridor, however, it is preferred that sites follow the 20 meter protocol.

8.3.2 Participant Preparation
To eliminate the effect of different footwear on test performance, this test should be performed in tennis shoes or comfortable walking shoes with minimal or no heels. The participant should be instructed prior to the visit that they should wear or bring appropriate shoes to the clinic. Patients wearing footwear that impedes their walking should be excluded from the test.

8.4 Eligibility Assessment Form
Use the Corridor Walk Eligibility Assessment Form to determine whether a patient should be excluded from the 400 Meter Walk. The exclusion criteria are explained below. If it is unclear to the examiner whether or not the patient's safety would be compromised to complete the walk, the patient should be excluded and the reason for exclusion appropriately noted on the Corridor Walk Eligibility Assessment Form.
Note, it is important to complete questions 1-5 on the Corridor Walk Eligibility

Assessment Form even if a patient is found to be ineligible before you complete question 5 so that we know all of the reasons a patient is ineligible. Since the Teen-LABS subject may have answered yes to one of the questions in #5 and want to participate in the 400 meter walk test, consult your PI or Co-investigator at site for approval to allow the walk test, and complete "off protocol form" with rationale.

8.4.1 Use of Walking Aid

If participant uses a walker they are excluded from the 400 m walk. If the participant uses a straight cane for joint relief but is otherwise stable, or if the participant is blind but is not walking disabled they may attempt the corridor walk. For walking aid use see question 4.1 on the medical form. Examiners should pay close attention to the participant's stability throughout the walk to ensure that the patient is kept safe.

8.4.2 Blood Pressure

Refer to the blood pressure data collected as part of patient's clinical visit. The exclusion criteria are:

- SBP >180 mmHg
- DBP > 100 mmHg

8.4.3 Heart Rate

Refer to the heart rate data collected as part of patient's clinical visit. The exclusion criteria are:

- <40 bpm
- >130 bpm,

8.4.4 ECG

Prior to the completion of the 400-meter eligibility form and the patient's clinical visit, check the patient's chart to see if there were any abnormal ECG hard copy references in the last 12 months. The exclusion criteria are:

- Atrial fibrillation or atrial flutter (new onset)
- Wolff-Parkinson-White (WPW) or ventricular pre-excitation
- Idioventricular rhythm
- Ventricular tachycardia
- Third degree or complete A-V block
- Any statement including reference to acute injury or acute ischemia, or marked T
- wave abnormality
- Abnormal ECG test result reported on the Teen-LABS Research Coordinators
- Assessment Baseline (RCAB) form (baseline only).

Note: This exclusion criterion only applies to patients who have an ECG. If the patient has not had an ECG, please refer to other exclusion criteria in this §4.

8.4.5 Additional Exclusion Criteria – Past 3 months

The Corridor Walk Eligibility Assessment Form lists several additional exclusion criteria related to events that may have occurred in the past 3 months:

The next test assesses your walking ability by having you walk about 1/4 mile. To determine if you should try the test, I need to ask you a few questions.

- In the past 3 months, were you hospitalized for myocardial infarction or heart attack
- In the past 3 months, have you had angioplasty or heart surgery?
- In the past 3 months, have you seen a health professional or thought about seeing a health professional for new or worsening symptoms of chest pain?
- In the past 3 months, have you had angina?

- In the past 3 months, did you have major thoracic (chest), abdominal or joint surgery?
- In the past 3 months, were you hospitalized for 3 or more days?
- If the answer is “Yes” to any of the above questions do not test until screened and approved by PI or Co-PI at site and complete “off protocol form’ with rational for decision or if applicable you do not need to ask questions 6 and 7 on the eligibility form. Do not administer the 400-meter walking test or complete the 400-meter walk data collection form

8.4.6 ADDITIONAL EXCLUSION CRITERIA

If the answer is “No” to all of the above questions, continue to question 6 on the eligibility form: Do you feel it would be unsafe for you to try to walk up and down this hallway?
If the patient answers “Yes” you do not need to ask question 7 on the eligibility form. Do not administer the 400-meter walking test or complete the 400-meter walk data collection form. If the answer is “No” ask the last question: Are you wearing shoes that make it difficult for you to walk? If the answer is “Yes” do not administer the 400-meter walking test or complete the 400- meter walk data collection form. However, if patient has comfortable shoes to change into ask participant to change shoes and mark no.

8.5 ADMINISTERING THE TEST

8.5.1 EXPLAIN THE TEST

Accompany the participant to the starting line.
We would like you to attempt to walk 400 meters (about ¼ mile). Please walk at your usual pace. During this test, I will ask you to rate how hard you feel you are working while you continue walking. When I ask you to rate how hard you are working during the walk, I want you to think about the total feeling of exertion in your overall body, including your breathing and muscles.
If, at any time during the test, you feel any chest pain, tightness or pressure in your chest, you become short of breath or if you feel faint, lightheaded or dizzy, or you feel knee, hip, calf, or back pain please tell me. If you feel any of these symptoms, you may slow down, rest and then continue, or stop.
Before we begin the test I will measure your heart rate. After you complete the test, I will tell you to stop, and measure your heart rate immediately and again after a 2-minute rest. Do you have any questions?

8.5.2 TEST

Measure the participant’s heart rate right before you start the test and record this value.
When I say ‘GO,’ start walking at your usual pace. “Ready, GO."
Start timing with the first footfall over the starting line (participant’s foot touches the floor on the first step). For every lap, offer standard encouragement, and call out the number of laps completed and the number remaining. Record each lap on the form. Encourage participant each lap (or every other lap if the 20 meter course is used): Keep up the good work. You are doing well. Good job. Etc. Also tell the participant, You have completed __ laps and have __ to go.

When the participant completes 4 laps, their effort should be recorded. Please tell me how hard you feel you are working right now. Is it “light”, “somewhat hard”, “hard”, or “very hard”? If the participant reports “hard” or “very hard”, remind the participant to walk their “usual pace without overexerting yourself” and ask the question again after 8 laps if answer is hard or very hard. I would like to remind you to walk at your usual pace. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest. If the participant feels they need to stop and rest, they may stand in one place and rest. Also, if the participant appears to be in obvious distress (excessive sweating, unusually pale, labored breathing, unsteady/wavering gait, appears confused,

or unresponsive to questions) or pain, you may recommend that he/she stand in place and rest for a moment. After 30 seconds, ask them if they can continue walking. If they can, continue the walk and record the rest on the form. If they need to rest longer, have them continue to stand. After another 30 seconds, ask them if they can continue walking. If they can, continue the walk and record the rest stop on the form.
If they cannot continue after a 60-second rest or if they need to sit down, stop the test. There is no limit to the number of rest stops as long as they can complete the walk without sitting and within 15 minutes. When the participant completes 400-meters (10 laps, first footfall on or over the finish line), stop the stop watch. Record time and heart rate as well as average heart rate for walk. Restart the stopwatch to time the 2-minute recovery time. Do not have the participant sit down yet. At 2 minutes, while the participant remains standing, record heart rate again. Ask the participant if they would like to sit down. Complete the remainder of the 400-meter walk form with the patient present.

8.6 STOPPING

If possible, the test should not be stopped cold. The participant should be told to slow down, and the examiner should quickly approach and meet the participant to check their pulse, and record the heart rate, time, and distance. If necessary, bring a chair to the participant. Always indicate on the 400 M Corridor Walk Data Collection forms why the participant did not complete the walk.

8.6.1 EXAMINER INITIATED STOP

The examiner may initiate a stop if the patient's heart rate exceeds 135 and remains above 135 for more than 5 minutes. The patient's heart rate monitor will emit a short beep to alert you and the patient that the heart rate is out of range. If a participant appears short of breath (has difficulty talking while walking) or complains of dizziness, he/she should be asked if they feel able to continue to walk. If so, a staff member should walk by the participant at a close distance to prevent falling for the rest of the walk and the patient should be asked about their symptoms every two minutes for the rest of the walk. Participants may stop the walk at any time, but should not be allowed to lean against any wall or other surface (desk, counter etc.). Staff may stop the walk for evidence of inability to talk while walking, unstable gait, or any other staff concern about the immediate safety of the participant. All participants who exhibit the above symptoms should be escorted to a chair upon stopping the walk and should be guarded when first getting up again.

8.6.2 PARTICIPANT INITIATED STOP

Participant reports a significant degree of any of the following symptoms:

- chest pain, tightness, or pressure
- trouble breathing or shortness of breath
- feeling faint, lightheaded or dizzy
- leg pain
- need to sit down
- OR participant requests or needs their cane or assistive device to complete the test

As noted above, if the test is stopped, record heart rate, distance covered, and time.
Also, complete the 2 minute recovery heart rate. Record the reason on the 400-meter Walk data collection form. At any point of concern, contact the clinic supervisor to come and assess the participant. This may include measuring the participant's blood pressure or other assessments to be determined by the clinic supervisor.

8.6.3 TIME LIMITS

The protocol allows for rest stops, but the total test time should not exceed 15 minutes. If the total elapsed time reaches 15 minutes, stop the test and record the distance covered.

8.7 CHEST PAIN/OTHER SYMTOMS FROM TEST

If the participant develops chest pain or other symptoms listed below, the clinic supervisor should be notified immediately.

If a participant requires medical attention due to an injury, fall or as a result of the below symptoms during or upon completion of the 400 M walk, an Adverse Event report is to be completed, and the PI and DCC immediately notified of the event.

1. Chest pain, pressure and/or other "anginal symptoms".
2. Severe shortness of breath defined as greater than anticipated for the level of physical exertion during the 400-meter walk.
3. Loss of consciousness or an acute or new-onset bout of "dizziness" and/or "lightheadedness" that does not resolve with termination of the test and/or quiet sitting.
4. Persistent severe lower extremity pain that does not resolve with termination of the test.
5. Wheezing/dyspnea

Section 9 – Psychosocial Measures

There are several important specific tasks to address regarding psychosocial issues for each study visit. To ensure that participants receive important information regarding the use of alcohol, tobacco and drugs and to ensure that he or she completes all the study related psychological measures due at the visit time point, coordinators will:

1) Provide an informational flyer regarding alcohol use after bariatric surgery.
2) Review forms to ensure participant completes the entire data collection forms per instructions.
3) Manage suicidal ideation on the participant's part using approved interventions outlined in the manual of procedures in 9.2.2 and 9.3 below.

9.1 Alcohol and Bariatric Surgery

FLYER TEXT START (this flyer text will be used at each site using their institutional branding):

Alcohol and Bariatric Surgery

Life is full of exciting choices and the older you get, the more there will be! You are making choices about everything; like what to do this weekend and what to eat for dinner. You also are making choices about things that can be risky or harmful to you. A good example – the choices you make about drinking alcohol.

Even young adults who can drink legally can have problems with drinking. You likely know of instances when drinking too much leads to bad outcomes like alcohol-related car crashes, poisoning, or even death. There is a lot of information out there to help people your age make smart and safe choices around drinking alcohol to avoid these possible problems.

Because you had weight loss surgery, drinking alcohol is a lot more dangerous for you than for other people your age. Just as your body now processes food differently, your body processes alcohol in a different way – so differently that you are at risk of harming yourself or someone else even if you drink a lot LESS than the people you know or who are with you if your drink.

New research is showing that:

• After weight loss surgery, your blood alcohol level will likely be over the legal limit to drive - even after only ONE drink and the alcohol will be in your system longer than someone who did not have weight loss surgery.

• Because your body is now more sensitive to alcohol, your risks are greater for harming yourself, like alcohol poisoning or drinking-related injuries (i.e., risk of death) even when you drink less than those around you.

• You may even be at greater risk for becoming addicted to alcohol.

The bottom line – if you choose to drink alcohol, ALWAYS DRINK SMARTER remembering that you respond differently than other people.

• If you choose to drink, even one drink is a lot for your body to handle.

• Binge drinking (4-5 or more drinks) on a night out is dangerous for anyone, but especially dangerous for you.

• Do not drive after drinking alcohol. This also means do NOT be the “designated driver” just because you had fewer drinks than your friends.

If you feel that drinking alcohol may be an issue for you after surgery, please contact your primary care physician or your bariatric team (INSERT SITE INFO) to discuss this further. They will be able to help you find resources to deal with any alcohol-related issues in your local area.

You can also go to this link, which can help you find places to get help.
http://www.niaaa.nih.gov/alcohol-health/support-treatment

FLYER TEXT END

All participants were sent a newsletter in 2015 with the following information based on the flyer above and this text is included in the MOP as it may be used again in future communications with participants:

You are making choices about everything; like what to do this weekend and what to eat for dinner, and whether or not you choose to drink alcohol. Even young adults who can drink legally can have problems with drinking. You likely know of instances when drinking too much leads to bad outcomes like alcohol-related car crashes, poisoning, or even death.
Because you had weight loss surgery, drinking alcohol is a lot more dangerous for you than for other people your age. Just as your body now processes food differently, your body processes alcohol in a different way – so differently that you are at risk of harming yourself or someone else even if you drink a lot LESS than the people you know or who are with you if you drink. If you choose to drink alcohol, always drink smarter remembering your body responds differently than other people.
If you feel that drinking alcohol may be an issue for you after surgery, please contact your primary care physician or your bariatric team to discuss this further. You can also go to this link, which can help you find places to get help. http://www.niaaa.nih.gov/alcohol-health/support-treatment

9.2 Beck Depression Inventory

All Teen-LABS patients must complete the Beck Depression Inventory (BDI-II) in clinic at the scheduled Teen-LABS appointment. (Form needs to be faxed to DCC on the day administered.)

Teen-LABS personnel (Study Coordinator) must be present to administer the BDI-II questionnaire.

Once the questionnaire is completed by the subject and returned to the Coordinator and BEFORE THE PARTICIPANT LEAVES THE CLINIC or proceeds to the next step in the Teen-LABS schedule, the Coordinator should immediately

- check the completeness of the instrument,
- score the BDI,
- look specifically at the response to Question 9.

9.2.1 Beck Depression Inventory (BDI) and the Suicide Behavior Questionnaire (SBQ) Intervention Plan and Intervention Protocol

Includes Scoring Instructions for the BDI-II and SBQ and Instructions on Reporting the BDI-II and SBQ Scoring and Action plan to Data Coordinating Center (DCC).

All situations below require further action.

If any item is skipped, redirect the participant to the instructions at the top of the form. If after reviewing instructions, the subject refuses to answer Question 9 implement the BDI Scoring and Action Plan. If the subject refuses to answer any other question mark -4 ("Refused" and initial and date as indicator that instructions were reviewed with subject and participant chose NOT to answer specified item.) Total the score using the highest possible score for the missing value of the question the participant refused to answer, and if greater than or equal to twenty, implement the BDI Action Plan. If scoring does not reach that threshold, no further action indicated.

Complete the BDI Scoring and Action Plan for any of the below:

- If **participant refuses to answer** Question 9: Review the instructions at the top of the BDI-II Form with the participant; mark -4 "Refused to answer" along with your initials and date, to show that you had reviewed the instructions for completion of the form, but participant declined to answer this specified question.
- If on the BDI-II Question 9 the adolescent endorsed the 3rd or 4th response choice (score 2 - "I would like to kill myself" or score 3 - "I would kill myself if I had the chance"). ALSO INITIATE BDI LETHALITY PLAN.
    - If the adolescent endorsed the 1st or 2nd, response; choice 1 – "I don't have thoughts of killing myself" or choice 2 - "I have thoughts of killing myself but I would not do it", no further action is needed.
- BDI-II Score greater than or equal to 20: Complete the BDI-II Scoring by adding the values selected by the subject to get a total score for the BDI-II. If an adolescent's total score on the BDI-II indicates significant depressive symptomatology (raw score $\geq$ 20), the Study Coordinator will contact the site mental health professional within 24 hours of the BDI-II administration. The Study Coordinator will document this contact has been made on the BDI-II Scoring and Action Plan form or site specific forms, per institution.

This mental health professional must, within one week, speak with the adolescent and his/her primary caregiver to provide a clinical referral for psychological services in their local

area. If score requires follow-up, be sure you complete the BDI-II Scoring and Action Plan making sure you list appropriate contact made for follow-up.

THE BDI-II and IF INDICATED, the BDI Scoring and Action Plan, needs to be Faxed to the DCC at 513-636-0277 the SAME DAY that the form is completed!

9.2.2 BDI LETHALITY PLAN (if dictated by scoring of Question 9 on BDI-II):
Say to the adolescent participant…

"Now that you are done filling out all of the measures I just need to follow-up on a few things. I noticed that you had marked on this questionnaire that you are thinking about harming or killing yourself." ASK NO FURTHER QUESTIONS AND SAY "Remember when you first agreed to be in the Teen-LABS study we told you in the consent form that if for any reason we were worried that you were in danger in any way that we would make sure that we did everything we could to keep you safe and get you the help you need? Based on your response, I am concerned about your safety."

IF THE PARTICIPANT IS A MINOR (AGE <18):
"What I am going to do next is ask your caregiver to come in so I can let them know what is happening. Then what we will do together is get in touch with a mental health professional who is part of the Teen-LABS staff so that he/she can talk with you more about this and we can make a plan together about what to do next."

GET CAREGIVER (showing no alarm, remaining calm and "matter of fact")

SAY TO CAREGIVER, IN FRONT OF THE ADOLESCENT:
"Remember when you were read the consent when you started in the Teen-LABS study you were told that if for any reason we felt [subject's first name] was in danger in any way that we would make sure that we did everything we could to keep him/her safe and get them the help they need? Based on [subject's first name]'s answers to some questions on Teen-LABS forms I am concerned about his/her safety. What I am going to do next is get in touch with one of the doctors who is part of the Teen-LABS staff so that he/she can talk with both you and [subject's first name] more about this and we can make a plan together about what to do next. I am going to page them now."

HOPEFULLY THIS CAN BE DONE IN THE ROOM WITH THE FAMILY PRESENT SO THEY HEAR WHAT YOU ARE SAYING. DO NOT LEAVE THE TEEN ALONE AND PLAN ON BEING WITH THIS FAMILY UNTIL A SAFETY PLAN IS IN PLACE.

Page the mental health professional on call for Teen-LABS Study. If no response from the site mental health professional, page the PI. Be sure to inform the PI at an appropriate time of this action. (See contact information sheet for phone/page numbers.)

IF THE PARTICIPANT IS AGE 18 OR OLDER:
YOU NEED THEIR PERMISSION TO INFORM THE CAREGIVER OF WHAT IS HAPPENING. IF THEY DECLINE – YOU NEED TO RESPECT THAT AND MOVE FORWARD WITH PAGING THE MENTAL HEALTH PROFESSIONAL.

PAGE TEEN-LABS MENTAL HEALTH PROFESSIONAL.

When reached say “Hello Dr. (name). This is (your name) from the Teen-LABS study. I am here with a participant, his/her name is [subject’s name] and I have concerns for his/her safety. When filling out the Beck Depression Inventory, he/she endorsed suicidal ideation.”

THE TEEN-LABS MENTAL HEALTH PROFESSIONAL WILL DIRECT YOU FROM THERE. IT WILL BE BEST IF HE/SHE CAN COME TO THE CLINIC AND DO THEIR FOLLOW-UP IN PERSON. REGARDLESS, THE SITUATION IS NOW PLACED IN THE HANDS/RESPONSIBILITY OF A LICENSED CLINICIAN.

IF THE TEEN-LABS MENTAL HEALTH PROFESSIONAL IS UNAVAILABLE, PAGE THE SITE PI TO ALERT THEM OF THE SITUATION. Proceed with the Clinical site policy/ procedure for emergent situations. In the event neither the mental health professional nor PI are available or if the PI does not respond, or cannot handle the problem, use whatever emergency response system you would use within your institution, including if necessary, escorting your subject and family to Emergency Room for emergent care, and document outcome. The intent here is treat these study participants clinically at this point, just as any other patient who is at risk of self-harm would be evaluated and treated.

COORDINATOR MUST COMPLETE THE BDI-II Scoring and Action Plan and any other site specific protocol form (that is on file with the DCC) AND BE SURE MENTAL HEALTH PROFESSIONAL’S FOLLOW-UP ACTIONS ARE ALSO COMPLETED.

9.3 Suicide Behavior Questionnaire Intervention Plan
All Teen-LABS participants must complete the Suicide Behavior Follow-up Questionnaire (SBQ) in clinic at the YEAR 10 scheduled Teen-LABS VISIT. The Suicide Behavior Questionnaire (SBQ) is given once at the YEAR 10 visit and will require that the Intervention Plan and Intervention Protocol is completed as described below.

Clinic administration:
The Teen-LABS Coordinator must be present to administer the SBQ questionnaire. Once the questionnaire is completed by the participant (and before the participant leaves the clinic or proceeds to the next step in the schedule), the Coordinator must immediately check the completeness of the instrument and assess the participant’s response to the questions as indicated below.

Assessment of responses:
Determine if the participant selected one of the underlined responses below to SBQ questions 2, 4 or 5.

Question 2- Since having bariatric surgery have you ever thought about or attempted to kill yourself?
Never
It was just a brief passing thought
I have had a plan at least once to kill myself but did not try to do it
I have had a plan at least once to kill myself and really wanted to die
I have attempted to kill myself, but did not want to die
I have attempted to kill myself, and really hoped to die

Question 4- Since having bariatric surgery have you **ever** told someone that you were going to commit suicide, or that you might do it?

No
Yes, at one time, but did not really want to die
Yes, at one time, and really wanted to die
Yes, more than once, but did not want to do it
Yes, more than once, and really wanted to do it

Question 5- How likely is it that you **will** attempt suicide someday?
No chance at all
Rather unlikely
Unlikely
Likely
Rather Likely
Very Likely

IMPORTANT: If any of the UNDERLINED responses to **questions 2 or 4** on the SBQ are selected, the Coordinator must ask the question AGAIN BUT NOW USING reference to the **past 4 weeks**. (e.g., Have you thought about or attempted to kill yourself **in the past 4 weeks**?). If yes, follow the "high-risk protocol" below.

IMPORTANT: If an underlined response to **question 5** on the SBQ is selected, the Coordinator must follow the "high-risk protocol" below.

High Risk Protocol
The Coordinator should immediately notify (call mobile phone or page) the study PI or designated mental health professional or other designated bariatric on-call clinician at the site.
The Coordinator should wait with the participant (in person at the clinic) until the PI or designated clinician arrives to assess the case.
The PI or designated clinician should assess the subject for risk of imminent harm to self and contact emergency services if needed just as any other patient who is at risk of self-harm would be evaluated and treated.

If the PI or designated clinician is not immediately available, proceed with the Clinical site policy/ procedure for emergent situations. In the event neither the mental health professional nor PI are available or if the PI does not respond, or cannot handle the problem, use whatever emergency response system you would use within your institution, including if necessary, escorting your subject and family to Emergency Room for emergent care, and document outcome. The intent here is treat these study participants clinically at this point, just as any other patient who is at risk of self-harm would be evaluated and treated.

If the participant reports a history of suicidal thoughts/attempts/telling someone about plan, but reports nothing like that **in the past 4 weeks** the following protocol should be followed:

Suicidal thoughts/attempts/telling someone about plans, **but not in the past 4 weeks**:

The Coordinator should notify the study PI or designated Clinical Personnel at the site with-in 3 days of the completion of the SBQ.

The PI should contact the participant within 7 days of the completion of the SBQ. At least 3 attempts should be made within this time frame.

The PI or designated clinician should assess the subject for risk of imminent harm to self and contact emergency services if needed (please see example phone script).
If contact cannot be made within 7 days, a certified letter should be mailed to the participant (please see example letter).

All activity must be noted in the participant's research file and the SBQ Action plan CRF completed and sent the day of administration of the questionnaire to the DCC.

Phone script:

> "Hello this is Dr.____from the Teen-LABS study. Do you have a minute to chat privately? The reason I am calling you is that your answers on a self-report form you completed during your last research visit suggested that you have *(SELECT APPROPRIATE CHOICE BASED ON SUICIDE FORM RESPONSE)* 1) had a plan for suicide in the last year but did not attempt suicide and/or 2) thought it was likely you might attempt suicide in the future. We are concerned and would like to know if you got help or would like to get help.

If participant indicates an ongoing problem and is not in treatment:

- "Could I offer you some information about possible resources in this area that might be helpful for you?" (Provide over the phone but offer to mail information as well.)

Additional points to consider making:

- "My calling doesn't necessarily suggest that you are currently having a problem; I only wished to discuss this with you briefly to see if you might want some help."
- "We appreciate your answering these questions honestly."
- "Thanks much for discussing this with me and for your participation in the Teen-LABS project. We very much appreciate your ongoing participation and your willingness to answer these questions."
- If participants notes that they thought their information was confidential/de-identified and is upset that they were called, please gently remind them that their informed consent document stated that researchers can take steps to prevent serious harm (for more details, exact language from informed consent document is below).

Informed consent language:
** **EXCEPTIONS TO CONFIDENTIALITY**
Even with the Certificate of Confidentiality, the investigators continue to have ethical and legal obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person. For example, if the study staff learns of possible suicidal tendencies or other risk of harm to yourself or others, we are required to notify the proper medical providers or legal authorities. However, the information you provide to the research staff for this study may, but does not necessarily go into the medical record that your surgeon and clinic staff use to monitor your health. Accordingly, you should be sure to report any health problems or concerns to your surgeon or nursing staff at your clinic visit. Otherwise they may not learn of any health problems that you report only to the study staff.

9.4 Computerized Cognitive Testing

These data collection measures can be administered remotely, using a home computer and provided link, in approximately an hour of time. Coordinators are welcome to complete the measures themselves once before administering to study participants, so that the coordinator knows more about the experience that the study participant will have and will thus be able to field questions that may arise. Please note- they can NOT be completed on a tablet or a smartphone. There are two testing sessions that participants will have to complete, one is through a system called WebNeuro and the second is through a system called Millisecond/Inquisit. Both systems and their instructions are described below:

9.4.1 WebNeuro Test Description

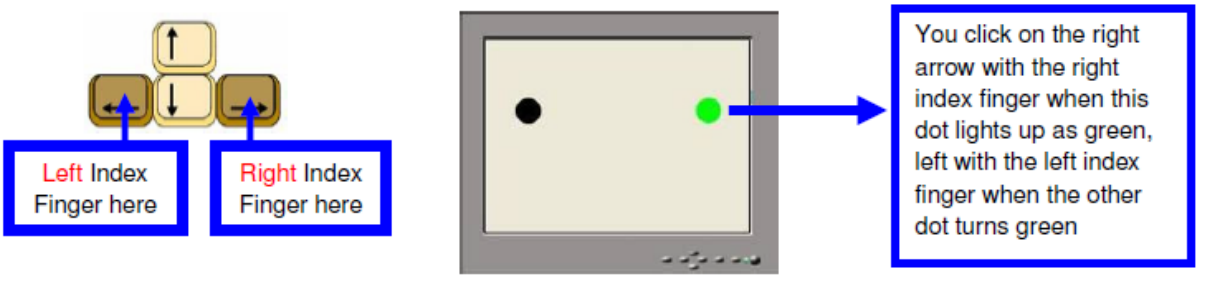
WebNeuro is comprised of 12 reliable and valid subtests. After reading the instructions and completing practice items to ensure comprehension, participants are then asked to complete the subtest. Data is automatically stored after completion of each subtest. Much of the below information about the tests has been abstracted from the manual and appears on the next pages:

1. Finger Tapping

Testing procedure: Using the dominant hand only the participant is required to tap the space bar on the keyboard with only the tip of the index *(pointing)* finger as quickly as possible for 60 seconds as counted down by a clock icon on the screen. Both the number of taps, as well as the variability of time taken from each strike of the finger to the next, are measured and reported on.

The other fingers remain inert on the table surface, palm down. The dependent variable is total number of taps with the index finger on the dominant hand only. The wrist should not be used in a flapping motion, just the forefinger should rapidly move up and down. The test is tiring, it is meant to be, and draws on large areas of the brain for its rapid movement.

2. Choice Reaction Time

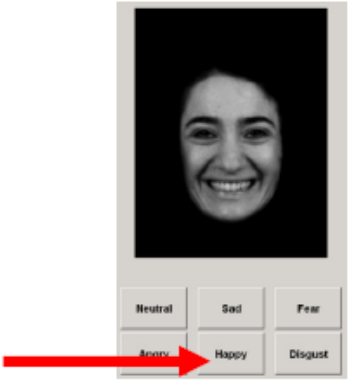


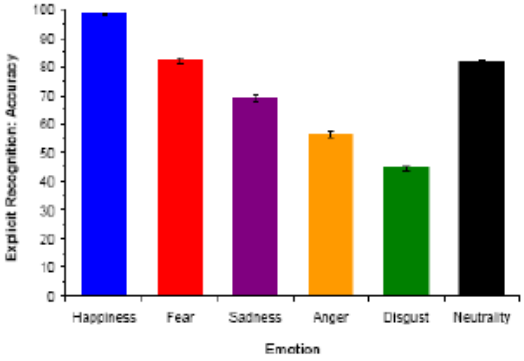
Test procedure: The participant will be required to attend to the computer screen as one of two black target circles, on either the right or left side of the screen, is illuminated in green in pseudo random sequence over a series of trials. For each trial, using the left index finger on the left arrow, and the right index finger on the right arrow, the participant is required to click either the corresponding right or left arrow (in tan color above) on the keyboard as quickly as possible. Twenty trials are administered with a random delay between trials of 2-4 seconds. Speed is greater when the participant sits centrally in front of the screen, both hands relaxed on the desk and keyboard. The participant will have to mouse click on the “START” symbol and then rapidly move both forefingers to the keyboard to begin the subtest actions.

<u>3. Memory Recognition - Verbal List-learning, immediate forced choice recall, and delayed forced choice recall:</u>

Test Procedure: The participant is presented with a list of 20 words, each presented on the screen individually, which the participant is asked at first to attend to, memorize and later recognize. The list contains 20 concrete words from the English language. The list is presented 3 times. After each trial, the screen then presents three words each time: one is the correct word the participant has just learned and the other two are distracter words, i.e. foils. The participant is required to recognize as many of the previously seen words as possible by quickly left-clicking on the correct word in each of 20 trials, in a forced choice procedure (see above). A delayed memory recognition trial is completed approximately 10 minutes later (trial number 4) after a number of intervening tasks (see the other subtests below).

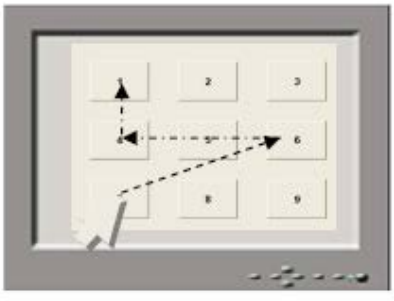
<u>4. Emotion Recognition (Explicit recognition)</u>





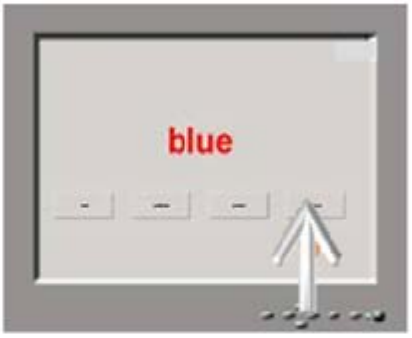
Test Procedure: The participant is presented with a series of faces with different emotional expressions (fear, anger, disgust, sadness, happiness, and neutral) as on the left above. The participant is required to use the mouse to click and identify the correct emotional valence presented by the face by clicking on the correct identifier tab at the bottom of the screen, such as Sad, Happy, Neutral and so on. Though this subtest assesses speed and accuracy of response to facial emotions, its primary purpose in the current study is to provide stimuli for an implicit memory test. Specifically, participants will be asked to recognize faces presented during this subtest later in the assessment (see below).

5. Forward Digit Span



Test Procedure: The participant is presented with a series of digits flashed on the computer screen, separated by a one second interval. The participant is asked to remember what they saw and then enter the digits on a touch pad in the same order as presented, using the mouse to click on the screen *touch pad* that appears *NOT THE KEYBOARD*. The participant is required to recall the digits in same order as they were given. The number of digits in each sequence is gradually increased from 3 to 7, with two trials of the same number of digits at each level. The test will terminate if two consecutive errors are made on a single string of digits.

6. Verbal Interference

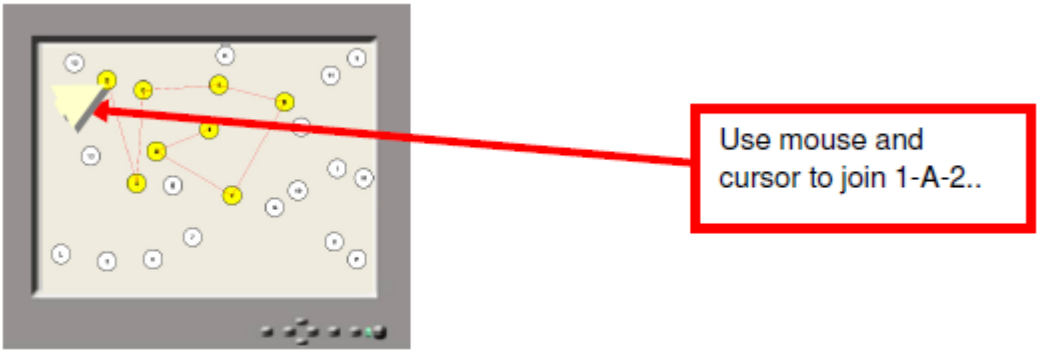


Test Procedure: The participant is presented with four colored words, one at a time. Each word is drawn from the following set of four colors: red, yellow, green and blue. Below each colored word is a response pad with the four possible names of the colors displayed in black and in fixed format. In part 1, the participant is required to read the name of each word, and as quickly as possible left-click on the appropriate matching tab. So if the word is “blue”, as above, the participant clicks on the key that is labeled “blue”.

In **part two**, the participant is required to name the contrasting color of the ink in which the word is printed, as quickly as possible and click on the appropriate tab. So if the participant sees the word ‘green’, written in red ink, they click on the tab for RED as that is the color of the ink on the screen, NOT green, as they did before.

Each of the two parts of this subtest lasts for 1 minute. Responses are made on the screen by clicking on the appropriate word on the bottom screen tab.

7. Switching of attention

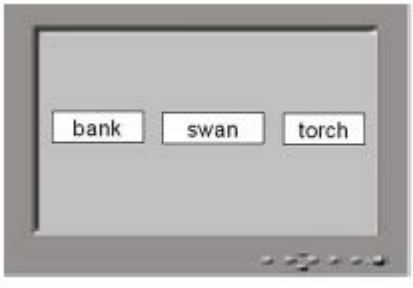


Test Procedure: On this version of this commonly used test, there is only one part. The participant is presented with a pattern of 13 numbers (1-13) and 12 letters (A-L) on the screen. The participant is required to use the mouse to click on each number and then each letter in a number-letter-number sequence until complete. The computer draws a fine line to connect each number or letter to the preceding number or letter in the sequence. This allows the participant to visualize the path that they have clicked on. An erroneous attempt to join, say, 1-B-2 instead of 1-A-2-B, is met with a "wrong" signal appearing briefly on the screen.

8. Go/No-Go

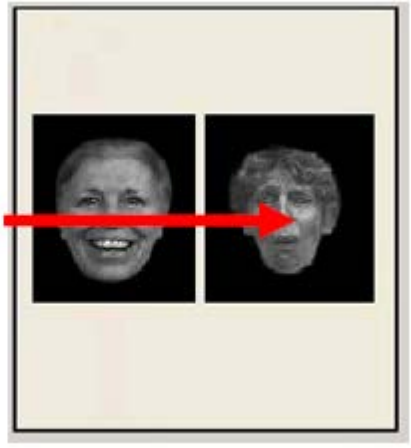
Test Procedure: The color of the word 'PRESS' is frequently presented in green (Go) and infrequently in red (No Go). The object of the test is to press the SPACE BAR once each time the word PRESS appears. The participant is required to inhibit button-press responses when PRESS appears.

9. Delayed Memory Recognition Task



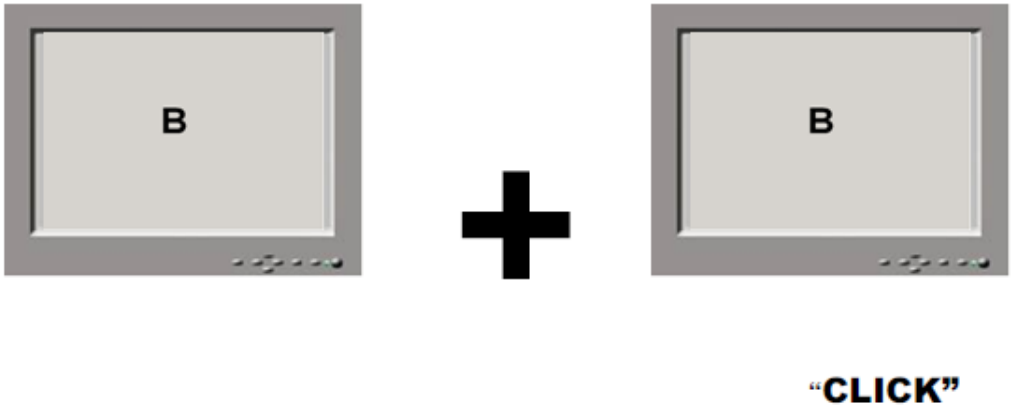
Test Procedure: The participant is required to remember the words presented to the participant 10-15 minutes earlier on the Recognition Memory trials, choosing as before, between one target and two foils, matched to make the task more difficult.

10. Emotion Recognition Test: Delayed Recall (Implicit recognition)



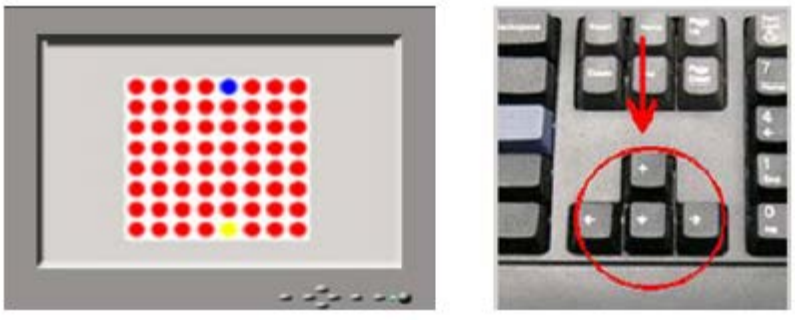
Above is an example of the delayed recall task which asks the participant to click on whichever face they have seen before, in this case, the one on the right. Both speed and accuracy is measured.

11. Sustained Attention (1-back task)



Test Procedure: To tap sustained attention on this task, a series of similar looking letters (B, C, D or G) is presented to the participant on the computer screen (for 200milliseconds), separated by an interval of 2.5 seconds. If the same letter appears twice in a row, consecutively, the participant is required to press the space bar just once. Speed and accuracy of response is equally stressed in the task instructions. There are 125 stimuli presented in total, 85 being non-target letters and 20 being target letters (i.e. repetitions of the previous letter).

12. Executive Maze



Test Procedure: In this version of an electronic maze, the participant is presented with a grid (8x8 matrix) of circles on the computer screen. The object of the task is to identify the fixed, hidden path through the grid, from the beginning point at the bottom of the grid in Yellow, to the end point at the top in Blue. The participant is able to navigate around the grid by using the arrow keys on the keyboard. A total of 24 consecutive correct moves are required to complete the maze. The participant is presented with an **X** if they make an incorrect move, and a _if they make a correct move. The task measures how quickly the participant learns the route through the maze and their ability to remember that route. Only one maze is presented no matter how long the participant works for. The test ends when the participant completes the maze twice without error or after 5 minutes have elapsed, when the test automatically times out. The maze pathway winds its way back and forward, up and down, and the participant can only move at right angles, not diagonally.

WebNeuro Test Administration

Participants will be asked to complete WebNeuro testing at a time and place convenient to them, as close to the time of the study visit as possible (within a 30 day time frame before or after the

study visit). Completion requires a computer with internet connection, keyboard, and mouse. Internet connection is only required for test download and upload of results – not task completion. This minimizes risk for data loss in the event of internet disruption during completion.

Login Code and Password:
The participant will be given a login code and a password from the professional service provider. The login code will look like this or something similar: OH00230-00015 meaning this is the 15th person to do WebNeuro for a company or provider labelled OH00230 for instance. The password will look something like this:

JOKEFULL

namely two four-letter words put together.

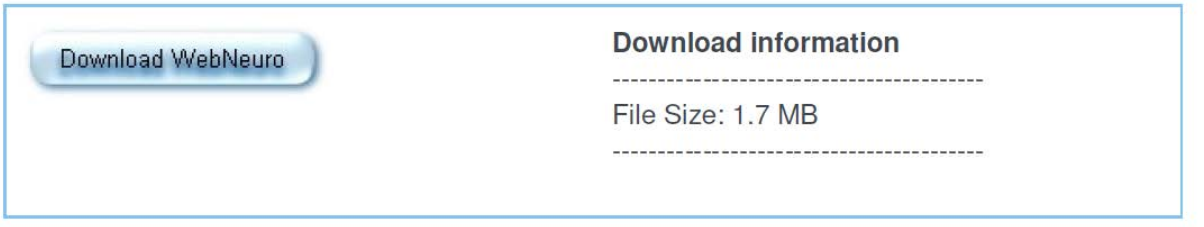
Why do they need this?

- In order to protect their privacy, the name or other study ID number does not appear on the report and no one gets to see the report, or know who did the report, apart from the person who gave the participant the Login Code and the Password.
- The participant will need both Login Code and Password to enter the website to begin using the Assessment to measure their brain functions

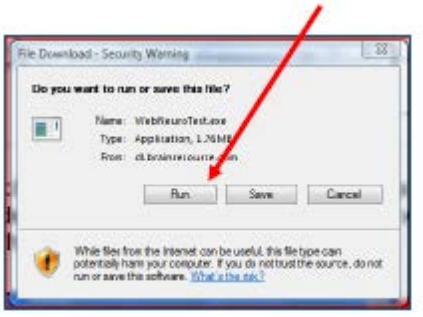
How is the test engine started, and the codes used ?
Log on to the internet and paste this into the web browser:
http://dl.brainresource.com/download/webneuro.html

This will produce a screen with the following Download WebNeuro button:

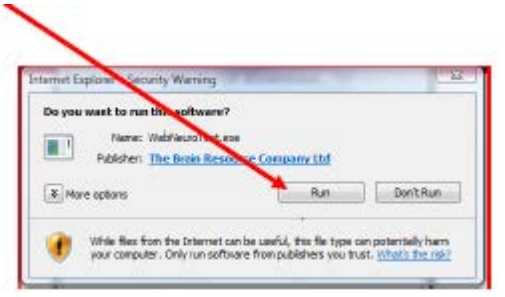
Download information



Clicking on "**Download WebNeuro"** will allow the test engine to run in the browser, or be downloaded to the desktop: this is completely safe. This will prompt the participant to click on **"Run"** as below, which the participant should do as below (or alternatively save the engine to the desktop):

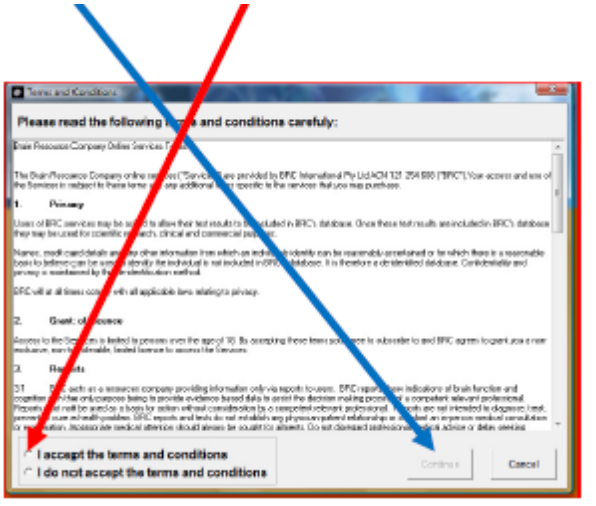


This will leave the participant with an icon to click on, which will run the assessment for them, as below, click on **Run**:

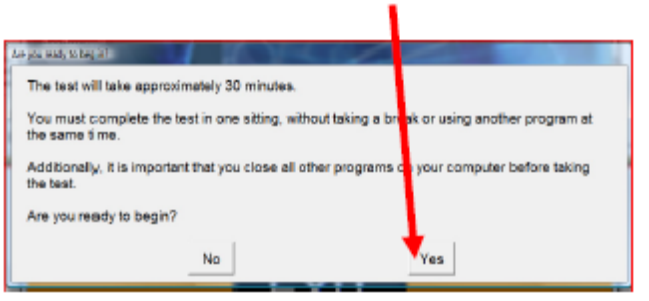


This will never harm the computer. WebNeuro can now be started:

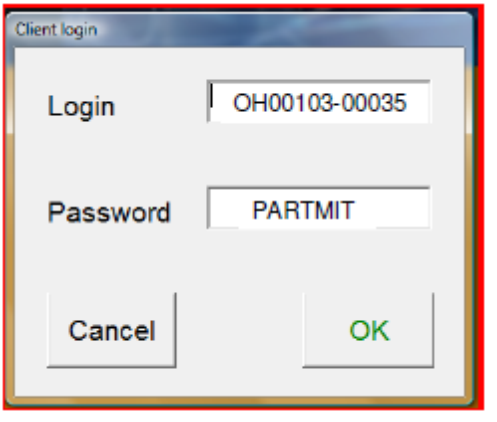
The above icon will wait until the participant clicks on “Start” to load the terms and conditions page: the participant will need to highlight **“I accept the terms and conditions”** to proceed and then click on “Continue”



The computer will then warn the participant of an average 30 minutes that should be set aside. Click on “Yes” when the participant is ready to begin.

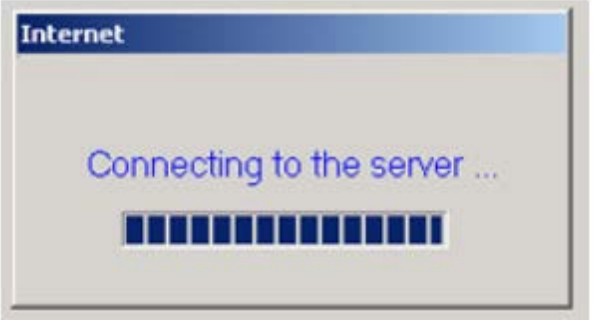


The computer will now ask for the unique login code and password issued to the participant in order to choose the right test, and the right destination for the report: click on OK when the participant is ready for the first parts of the test.



What to do when finished:

The *assessment will terminate* automatically, with a screen like this, and attempt to upload the data to Brain Resource server for scoring and report generation, which will take a few minutes, and appears as below:



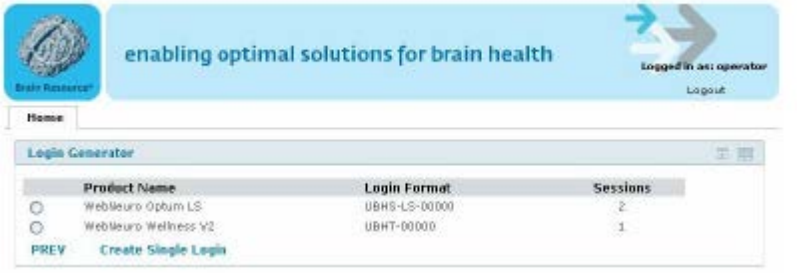
The participant can then click on the EXIT button to leave the system. The test results will be mailed to the study team member who issued the login code and password.

9.4.2 WebNeuro Study Administrator Activities

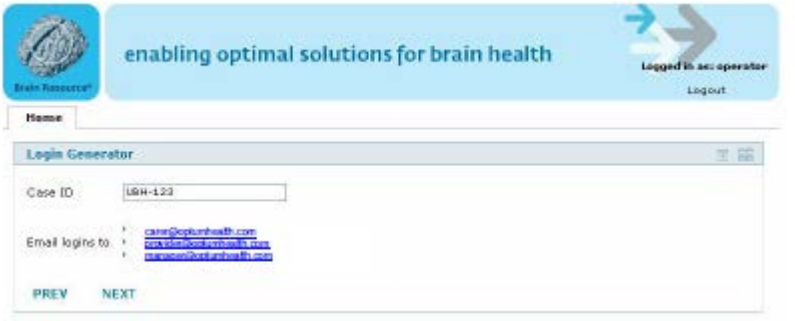
Generating a Login Code:
The licensed operator (Site PI or Coordinator) will have an Administrative Name and Password issued to them and will login through the Brain Resource Portal which is accessed from the URL https://secure2.brainresource.com/portal/

This will open a login generator screen as below, with a dropdown menu to allow for operators to select their organization.

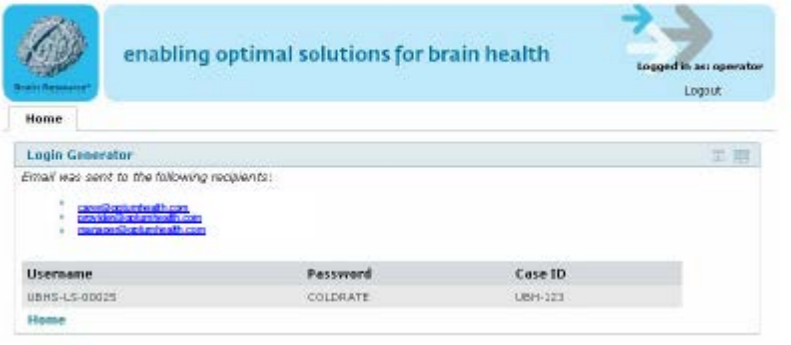
The screen that appears next will allow for the choice of test formats:



After the choice of assessment is made, the screen that follows asks for a Case Identity Number to be inserted, to track the participant from the Teen-LABS side and includes the operator's email addresses to which the reports will be sent:



The following screen confirms that the Login Code and Password that is shown on the screen has been sent to the persons mentioned in the screen above and below:



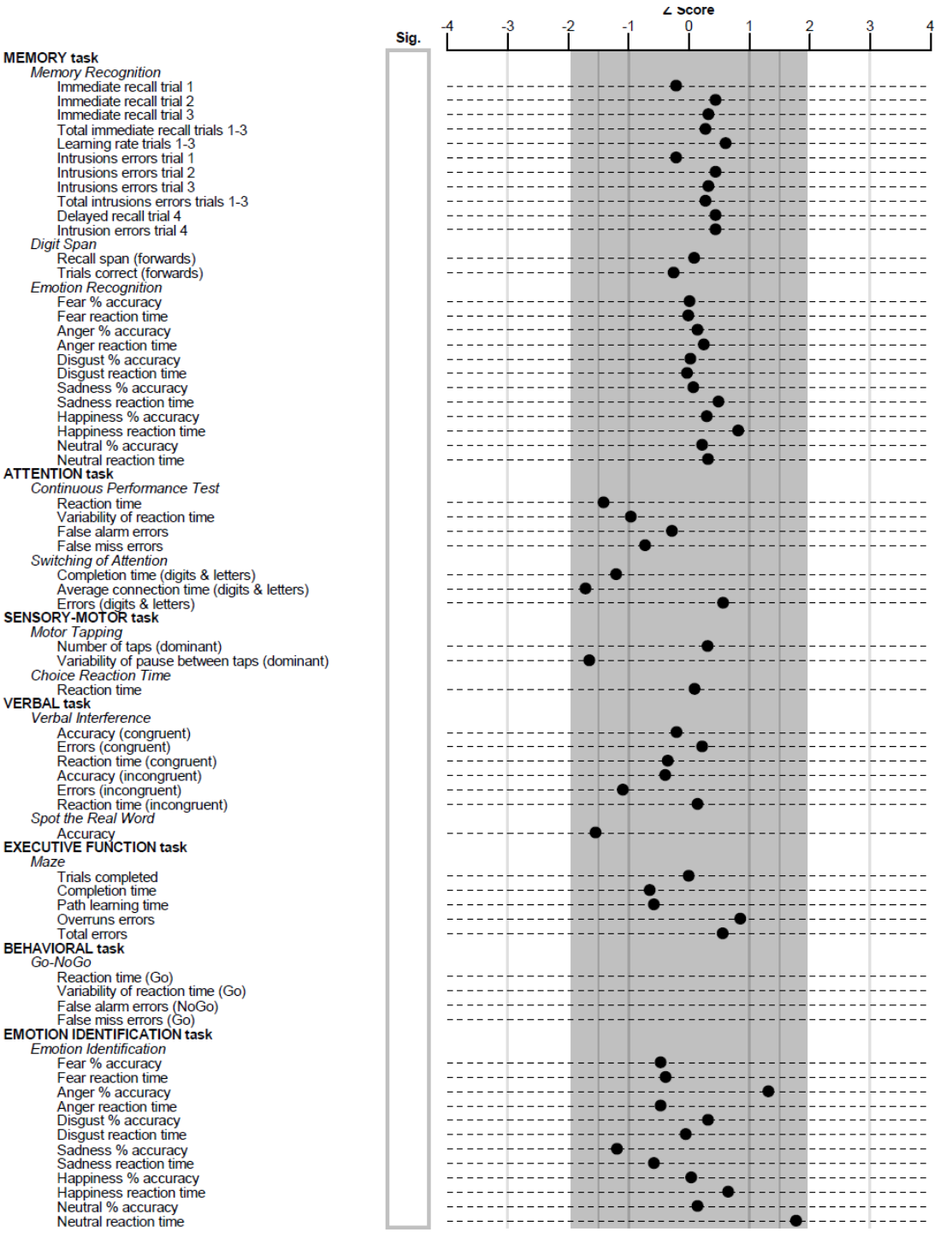
9.4.3 WebNeuro Safety Procedures

Identification of severe cognitive dysfunction

Within a few minutes of finishing the test, the report will be sent to the operator (the study team member that issued the Login Code and Password). Below is a sample guide to understanding what the test results may reveal. Results are presented in 2 formats – summary and detailed.

Test	Level	Function Measured	Functional Significance
Cognition			
Memory	Average	Working memory recall and recognition	Ability to attend to, learn, remember, store, retrieve and manipulate new information. It includes long and short term memory
Attention, Behavioral	Borderline	Sustained attention Focussed attention Impulsivity Cognitive flexibility	Ability to selectively concentrate during cognitive tasks, detect and respond to change in the environment, sustain attention over time and control impulses
Sensory-Motor/Spatial	Average	Hand/eye coordination Accuracy of selecting an appropriate response	Ability to perform motor skills and respond to information in a timely fashion. It includes reaction time
Verbal	Average	Word comprehension Verbal memory	Ability to recognize words, access words and remember what has been heard
Executive Function	Average	Planning Abstraction Error correction	Ability to plan, strategize, execute complex tasks, abstract thinking, rule acquisition, inhibiting inappropriate actions and ignoring irrelevant sensory information
Emotion Identification	Average	Emotional expressions	Ability to recognize interpersonal emotions through facial expression

Deficit	$\leq$-2 standard deviation	Average	>-1 and <1 standard deviation
Borderline	>-2 and $\leq$-1 standard deviation	Superior	$\geq$1 standard deviation



All test results will be sent to and reviewed by Dr. John Gunstad, a licensed clinical neuropsychologist, for the possible presence of severe cognitive dysfunction. This will be done on a biweekly basis. Site Coordinators will submit the participant completion for their sites to Dr. Gunstad. Once Dr. Gunstad reviews the information he will provide reports back to the Site Coordinators. Study participants will be identified as having severe cognitive dysfunction if they meet either of the following criteria:

- Average test performance >2 SD below mean of normative data for two or more cognitive domains
- Diagnostic criteria for dementia based on ICD-10 criteria

Participants will then receive feedback regarding their test performance, based on the reports given by Dr. Gunstad to the Site Coordinators. Specifically, participants will receive one of two emails/letters that: 1) categorizes their level of test performance (i.e. within expected ranges or poorer than expected); 2) reminds them of the limited nature of the testing and that no clinical diagnoses can be generated; 3) encourages them to talk to their care providers if they have concerns regarding their cognitive function in everyday life; and 4) provides contact information for local neurological evaluation.

It is important to note that no clinical diagnoses will be made on the basis of this brief assessment. In clinical settings, identification of cognitive impairment or psychological disorders is based on patient interview, review of appropriate records, testing, and other sources of data (e.g. collateral report, etc.). By only including a subset of these activities, the proposed study does not meet the established definition of a clinical evaluation and thus cannot provide the same level of care.

Our research team has utilized these approaches in past studies with good success. In addition, the combined inclusion/exclusion criteria of the Teen-LABS project suggest that very few individuals will have severe cognitive impairment that require clinical intervention.

Data Safety

The confidentiality and validity of cognitive test data will be protected through several steps. As noted above, cognitive testing will provide a unique identification number for each study participant. This number is distinct from any identifying information collected as part of Teen-LABS and will ensure confidentiality. Similarly, all cognitive test data will undergo centralized processing in a de-identified manner and can only be matched to Teen-LABS data through an additional step by study investigators.

Data validity is promoted through the automated scoring of cognitive tests, which is automatically entered and verified. This data is then available for study investigators through a secure, online portal that is automatically backed up on a daily basis.

9.4.4 Millisecond Computer Tasks for Psychopathology Dimensions:

Testing will include the following measures:

1.) **Difficulties in Emotion Regulation Scale (DERS)**
2.) **Impulsive Behavioral Scale (UPPS-P)**
3.) **Effortful Control Subscale of the Adult Temperament Questionnaire (ATQ-ECS)**
4.) **Sensitivity to Punishment/Sensitivity to Reward Questionnaire (SPSRQ)**
5.) **Delayed Discounting Task**

These measures, described in detail below, should be completed by the participants as close to the study visit as possible (within a 30 day time frame, before or after the study visit). Completion requires a computer with internet connection, keyboard, and mouse. The computer tasks will be administered via the web using software from Millisecond Software using the Inquisit 4 program.

- Difficulties in Emotion Regulation Scale (DERS; As described by Gratz & Roemer in 2004). The DERS is a 36-item self-report questionnaire that assesses six domains of emotion

dysregulation (i.e., non-acceptance of negative emotions, inability to engage in goal-directed behavior when distressed, difficulties controlling impulsive behavior when distressed, limited access to effective emotion regulation strategies, lack of emotional awareness, lack of emotional clarity) and has been found to have acceptable internal consistency as well as adequate test-retest reliability and construct validity (Gratz & Roemer, 2004).

- UPPS-P Impulsive Behavior Scale (UPPS-P; Cyders & Smith, 2007). This is a 59-item self-report measure assessing five dimensions of impulsivity. Only the negative urgency and positive urgency subscales will be administered. The measure has demonstrated good internal consistency and validity (Cyders & Smith, 2007).
- Effortful Control Scale of the Adult Temperament Questionnaire (ATQ-ECS; Evans & Rothbart, 2007). This 19-item self-report measure assesses several components of dispositional effortful control, including attentional control (i.e., ability to voluntarily focus or shift attention), inhibitory control (i.e., ability to inhibit behavior), and activation control (i.e., ability to activate behavior as needed). The measure has evidenced good reliability and validity (Evans & Rothbart, 2007).
- Sensitivity to Punishment and Sensitivity to Reward Questionnaire (SPSRQ; Torrubia et al., 2001). This is a 44-item self-report measure that is based on Gray's behavioral inhibition and activation motivational systems conceptualization, and assesses sensitivity to punishment and reward. The measure has demonstrated adequate internal consistency, test-retest reliability, and construct validity. Only the Sensitivity to Reward subscale of the measure will be administered.
- Delay Discounting Task (Kirby et al., 2000; Kishhinevsky et al., 2012). Delay discounting tasks require participants to choose between receiving a larger amount of money after a delay versus receiving a smaller amount immediately. The size of the smaller immediate reward is adjusted based on previous responses, narrowing the range of choices until an indifference point (i.e., amount at which the smaller more immediate reinforcer and larger delayed reinforcer are judged as being of equal value) is determined for each delay interval.

Login Website and Password:

http://research.millisecond.com/dgreen/teenlabs.web

Teen-LABS participants will be given the Millisecond website information and will use their unique Teen-LABS ID # (ex: CIN1000) to log in. Once the participant enters their unique password, they will immediately be prompted to begin the tasks. Once the participant completes all tasks, there will be an end screen that indicates they are finished.

Completion logs will be checked within the Millisecond site by the Research Administrator at the Neuropsychiatric Research Institute (NRI). This information will be sent to the Teen-LABS DCC for communication to the Teen-LABS site Coordinators. All data files will also be uploaded to the Teen-LABS DCC by the Research Administrator at NRI.

9.4.5 Information to provide to study participants

Text for the email that comes from Teen-LABS

Thank you for taking part in Teen-LABS!

For this next part of the project, you'll be asked to play computer games that will test your memory and concentration. There are 2 separate tests that you will need to complete.

1. WebNeuro: http://dl.brainresource.com/download/webneuro.html
    - Login: (Coordinator to obtain unique Login & Password from Central Study Coordinator)
    - Password:

2. Millisecond/Inquisit: http://research.millisecond.com/dgreen/teenlabs.web
    - Login: (Teen-LABS ID #)

Testing will take about 30 minutes and we'd like for you to complete it without taking a break or working on other things. So, please choose a quiet time when you won't be interrupted and turn off your phone/social media to avoid distractions.

To complete testing, you'll need a computer with an internet connection, keyboard, and mouse.

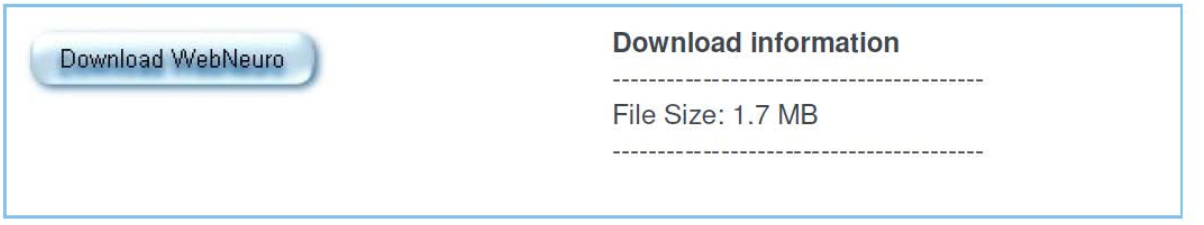
Just in case you run into any troubles (or like knowing all the details in advance), attached is a set of instructions for setting up and running the computerized tests.

WebNeuro attachment to send with the above email

Getting Started

The email from Teen-LABS will give you a link to download the computerized test or you can download it from the following address:
http://dl.brainresource.com/download/webneuro.html

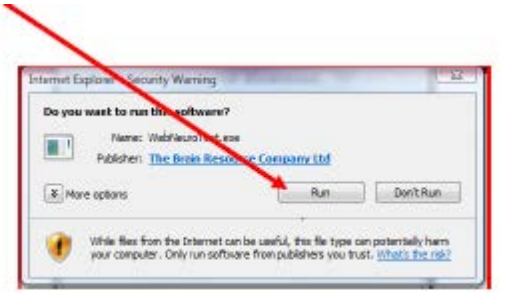
This will produce a screen with a Download WebNeuro button that looks like this:



Clicking on "**Download WebNeuro"** will allow the test engine to run in the browser, or be downloaded to the desktop.

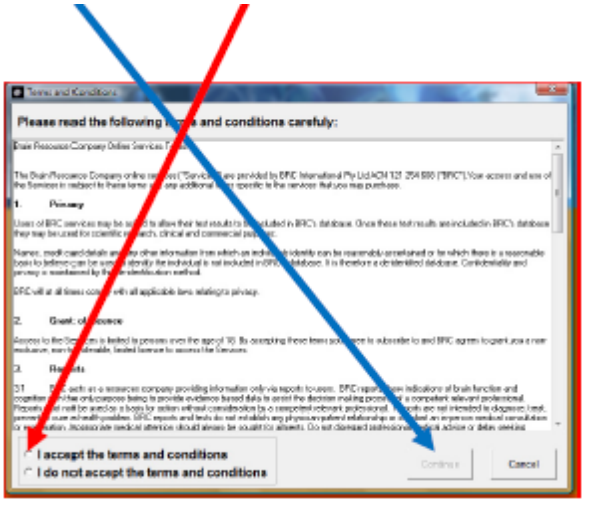
This will ask you to press "**"Run"** as pictured below – this is the fastest way to get started (or you can alternatively save the engine to the desktop):

This will give you another icon to click on to run the software - click on **Run**:

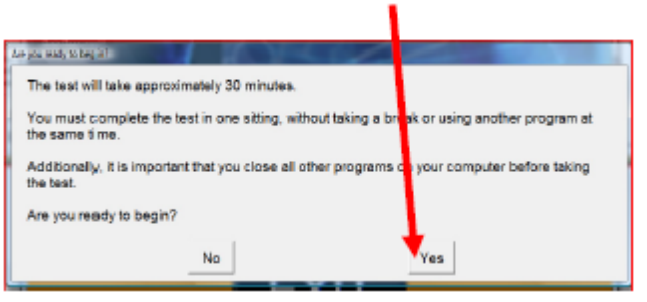


WebNeuro can now be started:

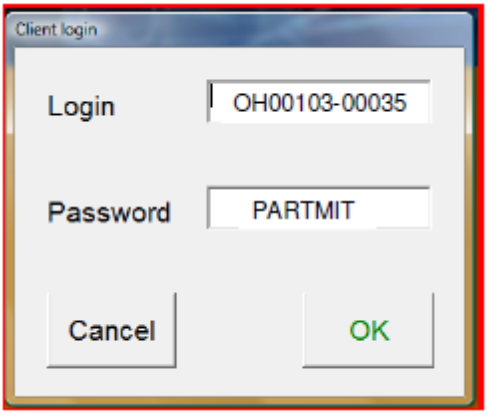
The above icon will wait until you press “Start” to load the terms and conditions page. You’ll need to highlight **“I accept the terms and conditions”** to proceed and then click on “Continue” to advance



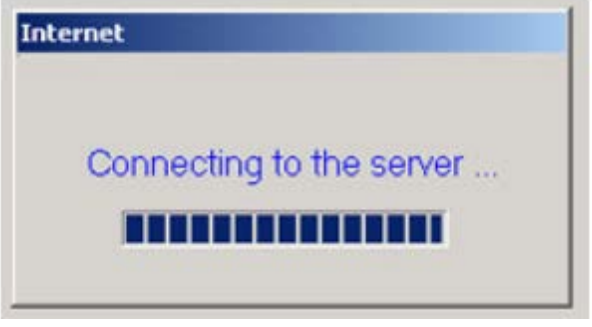
The computer will then remind you that an average 30 minutes that should be set aside. Click on “Yes” when you are ready to begin.



The computer will now ask for the unique login code and password given to you by Teen-LABS. Enter this information to the spaces provided.



When the test is complete, it will automatically save your data and upload it for processing. The screen will look like the following and sometimes takes a minute or so:



You can then then click on the EXIT button – Congratulations! Testing is complete!

Millisecond/Inquisit information to send with email and WebNeuro instructions:

Teen-LABS Inquisit Tasks

The email you have received from Teen-LABS will provide you with a link to a page that will launch the Inquisit software that we are using to administer a set of questionnaires. There will be a total of five assessments that you are being asked to complete. Please answer each question to the best of your ability. That email will also contain an ID number specific to you - if you have lost your ID number, please contact your Teen-LABS coordinator to retrieve it.

You can use the link provided in the email or the link below to access the questionnaires.
You will need to be using either a PC/Mac desktop or laptop, or an Apple mobile device such as an iPhone or iPad. The instructions for both types of devices are provided below.

http://research.millisecond.com/dgreen/teenlabs.web

Using a PC or Mac
Click the link provided to get started. You should see the page below - start by clicking the "Download the player installer" link. This will prompt your computer to download a file called "IQWebPlayerSetup". Save that file in a location you can get to again, such as your "Downloads" folder or your Desktop.

After choosing the folder to save in, your file will be downloaded and accessible right from the browser – simply click on the file or the "run" option, depending on what internet browser you are using. However, if this is not the case, you can navigate to the folder it was saved in and double click it to run it.

Then, you can click the big, green "Start" button to begin the assessments. Make sure you have your 7-character ID number available - as soon as you click the Start button, you will be prompted to enter it. Your number will be something like "NRI 1234" and will be unique to you. Input the number exactly, double checking to make sure you have put it in precisely as it was sent to you, and then click "OK". You will now begin testing, and can follow the instructions on each page until all 5 assessments have been completed.

After you have completed testing, the program will automatically end and you can close your web browser. Thanks so much!

Using an Apple Mobile Device

Start by opening the link sent to you - or the link below - on your mobile device. Make sure you have your 7-character ID number written down or easily accessible. When the page open's in your device s browser, click the "Download the free player" link OR the "Download on the App Store" link to open up the Inquisit app on the app store.

Inquisit Player
Millisecond Software. LLC

This study requires the free Inquisit Web Player:

1. Download the free player from the App Store.
2. After the player is downloaded, click the Start button.

On the App Store's download page, click the blue "GET" button, then the "INSTALL" button that appears in its place. Once it has been installed, **return to the page from the link you had opened in your browser (Safari).** You do not need to "OPEN" the app you just downloaded to continue.

On the original linked page, you can now click the big, green "Start" button to begin the assessments. Make sure you have your 7-character ID number available - as soon as you click the Start button, you will be prompted to enter it. Your number will be something like "NRI1234" and will be unique to you. Input the number exactly, double checking to make sure you have put it in precisely as it was sent to you, and then click "OK". You will now begin testing, and can follow the instructions on each page until all 5 assessments have been completed.

After you have completed testing, the program will automatically end and you can close your web browser. Thanks so much!

Section 10 – Surgeon Section

10.1 Certification process for surgeons

1) Read the Teen-LABS Manual of Operations (MOP) completely. It can be accessed via the Teen-LABS Dropbox at:
https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QqOmBPyGpEzChIZla?dl=0

2) Commit to follow the Teen-LABS protocol
3) Complete Surgeon's Experience Form
4) Complete Duality of Interest Form (annually)
5) Provide signed and dated CV (annually)
6) Provide proof of human subject training (annually)
7) Review annually the Duality of Interest Policy and complete the form that will be provided annually

Section 11 – Data Collection and Management

11.1 Overview

Data management personnel within the Teen-LABS Data Coordinating Center (DCC) for this project will be located at Cincinnati Children's Hospital Medical Center Division of Biostatistics & Epidemiology. The primary responsibilities of the DCC are to ensure the completeness and accuracy of the collected data while maintaining subject confidentiality, and to provide the operational infrastructure to facilitate cooperation and communication among the clinical sites. The DCC will provide a centralized information management system for collecting, editing, storing, and analyzing data. This includes development of data collection forms for the adolescent data, a manual of operations, quality control procedures, security and confidentiality of data, and long-term data storage.

Prior to the start of the study, the Principal Investigators and Site Coordinators at each adolescent clinical site will be trained and certified on design, collection of the variables, and other aspects of the study. Each Site Coordinator will be responsible for data collection and transport of the data to the DCC via email or secure Fax.

11.2 Identifying Source Data

Each TL study site is required to keep accurate records to ensure that the conduct of the study is fully documented. A template will be developed such that all relevant intraoperative data is captured in the surgeon's dictated operative note which will become the source document for operative data. The results of all clinical and clinical laboratory evaluations will be maintained in the participant's medical and research records and the data will be transferred to the DCC via facsimile or email on TeleForms®. Safety data will be recorded on forms specifically designed for this purpose. All the SAEs will be reported on an SAE report form as well as on individual data collection forms. All data will be reviewed periodically by the DSMB and IRB. The DSMB and/or the IRB have the authority to withdraw any participants and/or terminate the study because of safety findings.

11.3 Permitting Access to Source Data

The investigational site participating in this study will maintain the highest degree of confidentiality and security permitted for the clinical and research information obtained from Teen-LABS participants. Medical and research records should be maintained at each site in the strictest confidence. However, as a part of the quality assurance and legal responsibilities of an investigation, the investigational site must permit authorized representatives of the sponsor(s) and health authorities to examine (and when required by applicable law, to copy) clinical records for the purpose of quality assurance reviews, audits, and evaluations of the study safety and progress.

11.4 Data Forms and Database

The data collection forms have been created using TeleForm®. TeleForm® is a software application that automates data capture. Teleforms will be sent electronically to each clinical site in PDF format for printing and completion. The Site Coordinator will be responsible for completing all necessary forms for each subject at each visit and returning completed forms to the DCC in a timely fashion. Completed forms will be sent back to the DCC via fax or email (to be scanned into the system). Upon receipt the forms, there will be a log that is recorded, stamped with the date received and processed. Once forms are in the system, the software evaluates the form images and runs data quality checks to detect answers that may be out of range, missing or

inconsistent with skip-pattern logic. Questionable data is flagged and sent to a human verifier to be reviewed. For the psychological instruments under copyright for which there is no TeleForm® version, permission is granted before a TeleForm® version can be constructed.

Use of TeleForm allows scanned information to be entered directly into a database. The database will be created in Microsoft Access given its ease in exporting into SAS for data cleaning and statistical analysis. Once all the data has been verified, it will be exported to a SAS database for additional data quality checks. SAS programs were developed to generate data error reports. At the beginning of the study, data checks will be done weekly in order to identify any problem with collection methods. After six months, the DCC and the Steering Committee will discuss going to a biweekly process. The schedule will depend upon the amount of data coming to DCC on a weekly basis. These data error reports will be sent to the site for clarification and resolution. Resolution will be indicated on the report form and signed and dated by the Site Coordinator at each site and returned to the DCC. This will provide documentation of problems incurred and the solution. This method is currently used for many other studies managed by staff under the supervision of Director of the DCC. After all the data cleaning, a master file will be created.

Annually, the Central Study Coordinator will travel to each site and randomly select 10% of the charts to review for data completion and accuracy. A greater than 5% error rate will result in further review of the source documents for the clinical site. If this error rate for the site does not decrease, a conference call between the appropriate study personnel will be made to discuss the issue and devise a solution.

The DCC will meet each month to ensure that communication across sites about all aspects of data collection and abstraction are progressing without problems. The study steering committee will have monthly phone calls with the PI's at each clinical site. Executive committee calls will be planned weekly for study monitoring purposes.

An important component of the DCC and the sites' collaboration is communication. The DCC will seek and welcome ongoing input from the sites on any of the operating procedures that may not work. This input is imperative because these individuals are the most familiar with the capabilities and limitations in the data collection efforts at each site. The DCC will also place calls on a frequent and routine basis to facilitate communications. For example, a problem may occur at a site that the site believes they can resolve. The Central Study Coordinator will further facilitate communications by serving as a point contact for the Site Coordinators to answer procedural questions as they arise involving the DCC as necessary.

11.5 Data Storage

All paper forms will be stored under lock and key in file cabinets kept in the DCC offices. Only study personnel will have access to the offices and file cabinets.

Electronic data will be stored on a network server that is backed up nightly. Access to the stored electronic data will be limited to study personnel and password protected. The server is maintained and all backups are conducted by the Informatics Division of Cincinnati Children's Hospital. The Informatics Division is responsible for numerous servers used by the different investigators within the Children's Hospital Medical Center complex.

11.6 Final Audit

At the end of the study, the Central Coordinator will visit each site for a final check of the source documents.

The Teen-LABS Data Base Management System is divided into two systems: 1) a local tracking application on the site's PC, and 2) a centralized database at the DCC.

11.7 Patient/Participant Initialization

The Teen-LABS participant ID is used on all data collection instruments and labels for identifying items associated with individual study participants such as laboratory specimens, supporting documentation, etc. A place is provided on each form to write a patient's ID using the following format:

Site ID	Subject ID

All study reports that refer to individual patients use this ID as the only means of identification. On reports and study printouts, the patient ID number is printed without separating dashes or spaces (for example, a valid study ID that appears on a report will be of the form "30000042"). Following is a description of the convention used for generating Teen-LABS patient IDs:

ID Element	**Description**	**Valid Values**
Site number	A three-character code for the clinical site where the participant is enrolled.	CIN, BHM, PIT, BCM , NCH

ID Element Description Valid Values

Sequential ID number	A seven-digit sequential number that uniquely identifies (within the Teen-LABS clinical site) each participant registered.	Integer values with leading zeros, ranging from "0000001" to "9999999".

Other identifying numbers found on any potential data sources (e.g., hospital or clinic chart numbers, social security numbers, insurance identification numbers, etc.) ***should not be used as the Teen-LABS study ID***.

11.8 Data Monitoring, Processing, Management and Verification

To ensure the highest possible quality of data collected, the DCC will establish standard operating procedures -. The essential features in having high quality data for analyses are excellent documentation, control over data flow, communication, and training. The process of standardization will be achieved through the Manual of Operations and the site visits prior to the start of the study. The Manual of Operations includes a copy of the protocol and addresses each data form item on a question-by-question basis. This discussion will include a clinical interpretation of the intent of the question, an explanation of how it should be answered, and the coding of the response. The purpose of this manual is to be a valuable resource to personnel at each clinical site. - All drafts of the Manual will be dated and cataloged in the study library so that material development is documented. The Central Study Coordinator will also be responsible for retraining Site Coordinators during the annual visit to each site.

All form questions are pre-assigned missing values, e.g., null, for the purpose of data entry. Data entry screens require a set degree of completeness before a form can be accepted as ‘final.’ For incomplete forms, the missing value is entered into the database. Validation checks will be applied during the data entry process.

A related issue is data out of "expected" and "valid" ranges. You may encounter valid values outside the expected range, e.g., bmi > 510 rather than 5.1. In such cases the system will notify the DCC personnel that the data entered is out of *expected* range but entry **is** allowed. A query list will be sent asking the Site Coordinator to verify data values outside the expected range, if possible. Once data has been validated/verified, the query will be satisfied and removed from the form’s query list.

11.9 Edit Checks

Computerized data validation routines will be used to enhance data quality, including,: a) initial screening of data, using logic and range checks built into data entry screens; b) cross-form functional and consistency checks; and c) edits assessing the serial integrity of data, particularly in longitudinal studies.

11.10 Reporting

Monitoring study data will occur at both the Coordinating Center and the site in order to achieve and maintain a high level of quality. Some of the monitoring and quality control reports will be transmitted to the sites for immediate action and attention; other quality control and monitoring reports will be generated for the Steering Committee.

11.11 Data Conversion and Extraction

SAS analysis files can be extracted from the database using SAS/Access. Programmers continually develop routines to create other specialized analysis files from the Access database or the SAS database. Prior to merging or extracting any data into or from the

database, merge/extraction routines are being developed and will be thoroughly tested. Since data arrives from differing locations, verification includes consistency checks across all platforms as well as any other routine checks. All routines are properly documented and changes and updates to the code noted.

11.12 Database Closure and Documentation

Upon study completion, after all clinic and laboratory data have been collected and filtered through various quality control routines, the resulting database will be converted to SAS. The final data sets will be certified and issued version numbers to synchronize analytic efforts and will be distributed in Teen-LABS in compliance with Steering Committee and institutional policy. The choice of media on which to copy and distribute copies of the database to the investigators will depend upon the systems and the media available at that point in time.

Documentation will be prepared that contains a brief overview of the project, the goals, and the type of data collected. This will be followed by a list of variable names, their positions, and short descriptions of each variable contained on the media.

11.13 Security

Security measures will be established to prevent the ability of any unauthorized personnel to access the data for any patient enrolled into the trial. Confidentiality of data maintained by the DCC is of the utmost priority. As part of the standard operating procedures of the Division of Biostatistics and Epidemiology (DBE) at Children's Hospital, personnel in the unit routinely adhere to security procedures. The DBE has a set of Standard Operating Procedures that is given to each new employee. Upon employment, every person is made aware of confidentiality of all information and signs a pledge to maintain this confidentiality. None of the information on a patient is discussed with unauthorized personnel.

11.14 Disaster Recovery

All data, programs, code, documents, etc. associated with the Teen-LABS project will be backed up nightly at the Coordinating Center to a tape library. These tapes are kept indefinitely and are located in a fireproof cabinet that remains locked at all times. Periodically, copies of tapes are moved to an off-site location for storage. In the event that there is any loss of data, the information can be restored from tape in a matter of hours. The entire computer facility is provided with conditioned power.

Section 12 – Recruitment and Retention

Teen-LABS RECRUITMENT AND RETENTION ACTIVITIES

12.1 GENERAL INFORMATION

Essential aspects of maximizing participation and promoting retention are:
1) Careful screening and assessment of potential barriers to adherence and retention prior to randomization
2) Careful monitoring of adherence problems (which often predict retention problems), identifying these problems early before participants refuse further study contact
3) Applying specific strategies to address problems. General retention strategies and those to be applied in special situations are described in the following sections. However, since the methods most likely to maximize retention may vary by individual and by clinic, each Teen-LABS site must design an appropriate retention plan for their participants.

12.2 GENERAL RETENTION STRATEGIES

Teen-LABS retention will be enhanced by strategies such as: facilitating access to the clinic, maximizing staff availability, providing participants tangible and intangible support, and providing appropriate information to participants.

12.2.1 Facilitate Access to the Clinic

A. Maps and Signs:

The study site should be easy to find. Maps and good signage are essential.

- Maps often are available from sources within the institution or can be developed by Teen-LABS staff. Detailed information such as elevator location, floor and room numbers is needed to guide participants to the specific area. Signage may be harder to acquire than maps because it often requires organizational sanction.

B. Physical Setting:

The clinic should be a convenient and attractive area containing, as appropriate, a waiting area with receptionist/secretary, rooms that provide privacy for data collection or counseling, and offices for the staff.

- Participants should be escorted by staff and introduced to personnel in each area used for study activities. Escorting should continue until the participant volunteers to travel from one area to another independently.
- Bulletin boards, posters, and other materials may be used to provide information on Teen-LABS and promote participants' allegiance to the study.
- Bariatric chairs, weight and width appropriate, should be available in waiting and interview areas to ensure the comfort and safety of the participants. Bariatric wheelchairs should also be available for participants with mobility limitations.

C. Transportation:

Convenience and cost of transportation are two factors that may affect study retention particularly among lower-income participants and those who reside or work in areas where public transportation is not well developed.

1. Convenience:

Appointment keeping and study retention may be affected by the location and cost of parking garages or lots, distance from bus stops, perceptions of safety in gaining access

to the building, as well as any other inconveniences associated with travel. To decrease travel concerns, we recommend the following:

- Include information about public transportation stops and parking garages on location maps discussed above
- Address safety concerns. Do no assume that participants know what is risky versus safe behavior related to parking and walking in the area around the study site. If necessary, provide escort services to parking or transportation areas.
- Discuss traffic and driving concerns to guide when visits are scheduled.

2. Cost:
Develop a site-specific reimbursement policy for transportation expenses incurred by participants. Centers may elect to pay parking charges, etc., for all participants or to reimburse on an "as needed" basis. Mechanisms for reimbursement vary depending upon institutional policies and local resources and may include any of the following:

- Stamps to validate tickets or charge cards
- Tokens for public transportation purchased in bulk and given to participants at each visit
- Charge accounts from taxicab and van services
- Volunteer transportation services, such as services provided for senior citizens, which can be utilized at low or no cost to the study
- Contact the institutional marketing and social services departments for further information and resources on transportation issues.

12.2.2 Maximize Availability of Staff

Appointment Hours:
Study participants are "customers". As volunteers, they cannot be expected to alter their schedules or to miss work as they would to utilize other health care services.

- Accommodate participants schedules by keeping the hours that staff is available for Teen-LABS visits as flexible as possible.
- Become familiar with other participant obligations and schedule accordingly. For example, participants enrolled in school may need to schedule visits during summer or holiday breaks.

Availability Outside Of Business Hours:
Participants may be need to be seen for Teen-LABS visits outside of normal business hours (i.e., early morning for fasting blood draws or evenings to complete questionnaires). When appropriate, staff should be available for appointments outside normal clinic hours to maximize retention.

Staff Willingness to Spend Time with Participants:
Another way to enhance retention, is the participant's perception of the staff's willingness to accommodate their individual needs. The amount and quality of time staff give participants may be just as important as flexible schedules and access during non-business hours. For instance, a participant from another study told the study coordinator, "I like coming here because you listen to my stories." It is important for participants to feel they are important and valued by the staff. This begins at the front door with friendly reception by staff and continues through the actions of staff over the duration of volunteers' participation in Teen-LABS. Pleasant, kind, helpful, and attentive staff will facilitate bonding and maximize study retention.

Facilitating Appointments:
There are a number of ways to help participants keep their appointments, such as any of the following:

- Provide participants with wallet-sized appointment cards, which include the clinic phone number and "check-off" statements (fasting vs. non-fasting appointment, bring completed forms, bring medications, etc.) to help them prepare for the next visit.
- Mail written reminders or place phone calls to the participants a week before the appointment. Since such calls will facilitate familiarity between staff and participants, study staff should take turns placing such calls.
- Remind participants by phone the day before their appointment.

12.2.3 Assurance of Informed Consent
The Teen-LABS consent form alone is complex. Therefore, the consent process must be streamlined as much as possible. In addition to Teen-LABS many participants may also be approached for participation in other substudies or ancillary studies. To retain participants over the length of such studies, they must have a clear understanding of what is expected of them for EACH study. Clinical centers may enhance the consent process by any, or all, of the following ideas:

- Distribute a professional looking handout for each study that summarizes (in bulleted form) what will be expected of the patient while enrolled in that specific protocol.
- Create a PowerPoint presentation for use in conjunction with the consent process. Such a presentation gives the patient a visual explanation of the consent form in addition to reading the consent document. Visual aids may include a map of Teen-LABS clinical centers, projected enrollment rates, bulleted points explaining what is expected of the patient while enrolled, a study timeline, etc.
- The Step Watch Activity Monitor should be available to show to patients during the consent process, giving them a better understanding of this portion of the protocol.
- Give the patient a welcome packet or participant handbook to take home with them.

12.2.4 Provide Tangible Support
Tangible support includes those items that enhance voluntary participation in Teen-LABS and minimize potential barriers to retention, fulfilling endpoint goals.
These items include:

- Reimbursement for parking and/or mileage
- Gift cards (Target, local grocery stores, book stores, coffee shops, etc. "for major life events such as graduation from college, wedding, new baby")
- Snacks for consumption following completion of fasting blood draw
- Greeting cards, such as "thank you", or "welcome to Teen-LABS," a "get well" card following surgery, anniversary cards at annual follow-up, and "thank you" cards planned to send at end of their participation. Coordinators are encouraged to send birthday cards to each participant.

12.2.5 Provide Intangible Support
Intangible support includes items that enhance participation in Teen-LABS and minimize potential barriers to retention, but are more subtle in nature than the tangible support items. Intangible support may include:

- A letter of endorsement from the surgeons explaining the Teen-LABS research project

- A meeting with potential participants during a visit with their surgeon to strengthen the surgeon-to-research connection
- Quarterly phone calls to participants
- Body composition readings
- Staff visibility at support groups and/or other patient activities, including a walk/run group for bariatric surgery patients
- Pre-visit reminder calls
- Well-organized and timely visits and possibly some outside-of-normal business hours as needed.

12.2.6 Provide Emotional Support

Participants feel supported when they perceive the study staff as caring and when they perceive themselves as full partners in the research process. The following actions may increase participant perceptions of support:

- Maintain a safe and comfortable study environment
- Create a relationship in which goals are jointly established
- Express interest in important aspects of a participant's personal life
- Ask about the participant's personal reaction to aspects of Teen-LABS
- Acknowledge what the participant has reported
- Be creative. When possible, conduct study procedures in a manner that best meets the specific needs of the participants and family members

12.2.7 Continue Using Motivational Enhancement Methods

Use motivational techniques when interacting with participants. Examples include:

- Maintain your enthusiasm for their participation in your body language. Your voice, eye contact and facial expressions should let each participant know how valuable they are to the study
- Praise the patient for showing up at and keeping appointments
- Vocalize your appreciation for their time and efforts
- Help each participant become excited by their successes. Encourage them to celebrate their milestones following surgery (30 days, 6 months, 1 year, etc.) in their own way (e.g., going out for a special activity, etc)
- Encourage participants to surround themselves with people who have a positive attitude to their successes.

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In addition to the work done by the coordinator, all members of the medical team should be encouraged to fully support each participant and their weight loss and healthy lifestyle effort

12.3 The Teen-LABS Participant Handbook

The Teen-LABS Participant Folder has been designed for study participants to save important materials, such as consent forms, lab results, fact sheets, booklets and other information they receive about the study. The Folder should be presented to the participant when they agree to participate and should include:

1. Welcome letter to participants from Mary Horlick, MD (NIH) printed on letterhead and provided to the clinics from the coordinating center
2. Welcome letter from the site Principal Investigator, signed by all Teen-LABS surgeons at medical center. Sites will tailor their binders to include additional information specific to their participants. Some suggestions on what the sites can include in the handbook are:

1. Appointment reminder (with day, time & location of next appt) and a list of materials to bring to next clinic visit
2. Map of Teen-LABS clinical sites
3. Closest parking – cost of garage parking/availability of vouchers
4. Directions to medical center
5. Map of campus and medical center
6. Public transportation – location of closest bus stops, and commuter train stations
7. Disabled shuttle information
8. What to do if the weather is severe and volunteers cannot get to the hospital/clinic for an appointment, how volunteers are informed if the clinic is closed or if there is a program cancellation/change (due to severe weather), i.e.; radio, phone call
10. Teen-LABS web site address and information
11. Information regarding investigators, coordinators and research staff with contact information.

Participants will receive monetary incentives to cover the time burden of participating in the study. In consideration of the importance of excellent retention for achieving study goals, and of the increasing competing demands on the participants' time as they age and become young adults with additional life responsibilities (e.g., work related demands, relationships, family, and/or college) we have realized a need for reasonable annual increases in reimbursement for participants' time. To cover participants increasing time demands all annual visit incentives have been increased $100.00, except for study year 7 and 9 visits which are partial, phone call visits. Also, to accommodate participants who are unable to participate 100% and complete a full annual study visit, participant reimbursement has been prorated (except for partial visit study years 7 and 9). Participants will be reimbursed based on what elements of their scheduled study visit they complete. Depending on which visit they are completing and what elements of the study visit they complete, participants will be paid up to a maximum of $300.00 for the costs, inconvenience, and time associated with participation in this research study. If a participant is unable to complete a full visit, the reimbursement amount will be prorated. The table on the next page outlines the prorated reimbursement schedule for participants continuing in the study for each study visit:

Study Visit	For completion of Self-Assessment Questionnaires	For completion of Physical Measurements	For completion of Blood Draw & Urine Collection	For completion of Phone Interview	Total Maximum Participant Amount Possible (for full study visit)
5 year full visit	$50.00	$120.00	$90.00	n/a	$260.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
6 year full visit	$50.00	$130.00	$100.00	n/a	$280.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
7 year phone call	$25.00	n/a	n/a	$25.00	$50.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
8 year full visit	$50.00	$140.00	$110.00	n/a	$300.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
9 year phone call	$25.00	n/a	n/a	$25.00	$50.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
10 year full visit	$50.00 $50.00 psych measures	$150.00	$120.00	n/a	$370.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
11 year phone call	$30.00	n/a	n/a	$30.00	$60.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
12 year phone call	$35.00	n/a	n/a	$35.00	$70.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
13 year phone call	$40.00	n/a	n/a	$40.00	$80.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
14 year phone call	$45.00	n/a	n/a	$45.00	$90.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
15 year phone call	$50.00	n/a	n/a	$50.00	$100.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00

Prorated reimbursement schedule for new SG cohort being recruited 2017-2019:

Study Visit	For completion of Self-Assessment Questionnaires	For completion of Physical Measurements	For completion of Blood Draw & Urine Collection	For completion of Phone Interview	Total Maximum Participant Amount Possible (for full study visit)
3 year full visit	$50.00	$100.00	$70.00	n/a	**$**220.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
4 year full visit	$50.00	$110.00	$80.00	n/a	**$**240.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00
5 year full visit	$50.00	$120.00	$90.00	n/a	$260.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
6 year full	$50.00	$130.00	$100.00	n/a	$280.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
7 year phone call	$25.00	n/a	n/a	$25.00	$50.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
8 year full visit	$50.00	$140.00	$110.00	n/a	$300.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
9 year phone call	$25.00	n/a	n/a	$25.00	$50.00
Midyear phone call	n/a	n/a	n/a	$10.00	$10.00
10 year full visit	$50.00 $50.00 psych measures	$150.00	$120.00	n/a	**$**370.00
Midyear phone call	n/a	n/a	n/a	$10.00	**$**10.00

In addition, compensation for travel to the study site may be provided for all participants continuing in the study for the full annual study visits (years 3-5, 6, 8, and 10) that occur after June 2009 and for new 2017-2018 SG cohort for full annual study visits. The

compensation will be based on the federally allowable reimbursement for automobile use, based on round trip distance from the participant's home to the clinical center. The compensation schedule is below:

- Round trip travel from home to center up to 125 miles: $25 compensation
- Round trip travel from home to center 126-250 miles: $100 compensation
- Round trip travel from home to center 251-375 miles: $150 compensation
- Round trip travel from home to center 376-500 miles: $200 compensation
- Round trip travel from home to center over >500 miles: $250 compensation

Participants continuing in the study who live >250 miles round trip from the center may also be reimbursed for reasonable lodging costs up to $150.00 per visit for full study visits in years 3-5, 6, 8, and 10. SG cohort who live >250 miles round trip from the center may also be reimbursed for reasonable lodging costs up to $150.00 per visit for full study visits (visits 1, 2, and 4).

If a DXA is done, participants will receive a one-time reimbursement of $100.00.

The non-surgical cohort for DXA comparison will be reimbursed $100.00 for their one-time visit.

Since our study participants are maturing and having many "life changing events" such as marriages, births, graduations etc. they will be provided with congratulation baskets (total value not to exceed $25.00) to celebrate these milestones and acknowledge these important changes.

12.4 IDENTIFYING AND RESOLVING RETENTION PROBLEMS

In spite of the best efforts, retention problems may still arise. Regardless of the stage participants have reached in Teen-LABS or the level of difficulties they are experiencing, study staff should remain proactive.

Keys to successfully identifying & resolving retention problems include:

- Remain sensitive to signs of problems, to identify them at the earliest possible moment, when intervention is easiest and most effective
- Carefully document problems, to allow for timely and complete communication among staff and with the participant to address the problem
- Design interventions to effectively resolve problems. For example, maintain positive communication with participants who are having difficulty committing to follow-up visits. Efforts to address possible adherence and retention problems should be initiated during screening. Prior to enrollment, emphasize the following points to potential participants:

There is a critical need for follow-up visits regardless of success following bariatric surgery. Staff should stress the following:

- "We really, really want you to stay in touch. We know there may be times when your research appointments may be an inconvenience to you or times when you feel that the surgery has been less successful than you anticipated. However, we hope that you understand the importance of staying in contact with us over the course of time. This is the best way for us to learn more about the effectiveness of bariatric surgery."
- The study staff will make every effort (consistent with good sense and respect for the participant's privacy) to maintain contact during the length of the study. If the point is made early that we will try to maintain contact no matter what challenges are encountered, it will be easier to do, should it become necessary. Potential

participants should be told that Teen-LABS staff will do all they can to maintain contact, including calling, writing, and trying to reach an identified contact person. Discuss with potential participants the specific strategies they would most like you to enlist if contact dwindles at any time during the study. Enlist the participant's involvement in deciding the types and extent of contact strategies to be used should retention become an issue (e.g., contact at work, contact spouse, and enlist PCP in reinforcing importance of study). Participant involvement in the early stages may be a powerful factor in their response to and acceptance of these efforts should they be utilized. In addition to the tangible & intangible means of support outlined in section 12.2 other strategies to optimize retention during the course of the study may include:

- Occasional phone contact between research appointments by surgeon and/or research coordinator
- Choosing an alternate team member with strong participant rapport to contact the participant
- Optimize use of retention materials as response to a missed visit by mailing an incentive package (e.g., send a greeting card or other tangible incentive)
- In making contact with participant who has a missed visit, remind them that their spouse or a friend is always invited to attend with them

12.4.1 Specific Retention Problems

Signs of potential difficulty are identified below as "red flags" and should be taken seriously and fully discussed with potential participants as well as research staff. The results of the behavioral run-in itself should be carefully evaluated for signs of difficulty. In addition to general strategies appropriate to all potential retention problems, Teen-LABS staff should be aware of specific retention problems and ways to address them. These are discussed below. In the participant research file, carefully document specific "red flags" as well as interventions used to curb them.

A. Protocol Adherence Red Flags

Clinic staff and investigators must be vigilant in order to identify early problems with adherence. Indicators of potential adherence problems include the emergence of the following red flags:

- Problems scheduling initial research visit
- Difficulty reaching participants by phone or failure to return calls
- Participant reservations about study burden
- Complaints about clinic procedures
- Showing up significantly late to visit
- Missed visits
- Forms not returned
- Step Watch Activity Monitor not returned
- Rescheduling twice or more for a visit

B. Interventions for Protocol Adherence Problems

If research staff identify that a participant is having problems adhering to the protocol, the first step should be to "validate" the participant's feelings. A conversation starter to open the communication may be as follows: "Teen-LABS asks a lot from people. What part of this study is hardest for you right now? Perhaps I can help make it a little easier". When participants consistently need more attention or a repetition of information, contact the P.I. or surgeon.

Other interventions to be considered in addressing identified red flags include:

- Provide opportunity to meet in any reasonable location or at any reasonable time which is convenient to participants
- Emphasize the positive; praise all successes (i.e., coming to last appt, turning in all forms, etc)
- Re-emphasize benefits from participation and follow-up (ability to help other patients in future, knowledge gained on factors related to obesity and weight-control surgery)
- Encourage the Principal Investigator and other investigators to hold regular sessions designed to help participants see the “big picture” (i.e.; news about obesity and bariatric surgery) if allowed
- Encourage Principal Investigator to call participant to offer encouragement if allowed
- Maintain contact through newsletters and scheduled calls, mailed notes when indicated
- Offer extras, if acceptable to local IRBs, including birthday cards and incentives at follow-up visits. These incentives should be used to underscore the bonding between staff and participants, not to replace that basic social connection
- Address all concerns about the study; involve the Principal Investigator, if appropriate and allowed
- Be prepared to explain how some questionnaires help us reach the objectives set forth in Teen-LABS
- Encourage family participation in coming to appointments

12.4.2 Participant Behavioral Issues

Staff should be alert for things that participants say or do that indicate they are dissatisfied or discouraged with certain aspects of their Teen-LABS experience. Such issues should be addressed as quickly and effectively as possible.

A. Participant Behavior Red Flags

Participant behaviors which suggest emerging adherence problems and are considered red flags include:

- Complaints about research visits
- Impatience during research visits
- “Distance” during research visits
- Lack of concern about non-adherence to protocol
- Complaints about burden of study (time required, questionnaires, blood draws, etc.)

B. Interventions to Address Participant Behavioral Problems

For participants who feel ignored or taken for granted, the PI *may* be the best person to contact the participant if allowed by local IRB. If the Principal Investigator does initiate contact, he/she should focus on emphasizing the importance of Teen-LABS and of the participant to Teen-LABS. Other interventions include:

- Communicate caring and respect for participant in all actions
- Acknowledge and discuss any concerns the participant communicates and address as appropriate
- If a participant expresses concerns, follow-up with a phone call to discuss more fully or tell participant about what's being done to address the concern
- Be open to discussing issues the participant wants to talk about even when unrelated to Teen-LABS

12.4.3 Participant Psychosocial Issues

During the length of the study, Teen-LABS participants may experience psychosocial challenges that are independent of or possibly related to their life after surgery (such as family problems or transitions, major job changes, and other events). These events may produce major problems for retention, especially among participants whose coping resources are limited.

A. Participant Psychosocial Red Flags

- Specific complaints concerning lack of family support
- Active efforts by family members to sabotage participants' participation in Teen-LABS
- Major family crisis, illness, or transition
- Major job transition
- Major psychosocial problems

B. Interventions to Address Participant Psychosocial Problems

- Take an open, inquiring attitude to find out what is going on for the participant *Maintain appropriate professional boundaries. The Study Coordinator, no matter how skillful, is not a clinician and should not provide ant counseling or advice
- Encourage family support for participation in Teen-LABS
- The Study Coordinator should contact the site-specific psychologist and together collaborate with the participant to generate a plan for appropriate action. All such referrals should be documented.

Some participants might have psychosocial problems severe enough to interfere with active participation in the study. In this case Teen-LABS staff should help the participant find help or treatment for the problems outside of the study. Participants who have psychological disorders (e.g., major depressive disorder, anxiety disorders, and substance abuse disorders) need treatment. The P.I. or other qualified staff should refer participants who may be suffering from such disorders for appropriate treatment. All such referrals should be documented.

12.5 Retention Monitoring and Assistance/Drop-Out Recovery

Despite the staff's best efforts some participants will not complete annual outcome visits and will be considered inactive. Each site should develop a dropout recovery process. The fundamental goal of drop-out recovery is to reactivate participants and to keep them from formally withdrawing from the study. Drop-out recovery plans should try to re-establish contact and communication first, and then address adherence and active participation. Engaging participants in topics unrelated to Teen-LABS may help. Maintaining even minimal contact with participants during periods when motivation to be active in Teen-LABS is low makes it easier to reengage them in the study. Efforts to contact inactive participants should be initiated by the staff member who has the best rapport with the individual participant.

Each clinic should involve the PI and research coordinators in devising a stepwise approach for drop-out recovery. Specifically, sites should devise a hierarchical list of efforts to reactivate participants. Strategies should be implemented sequentially at intervals of 1-2 weeks.

- Telephone contact efforts x 2-3 by research coordinator. If telephone contact is not made, pursue the following:

1) Letter of concern from clinic with statements indicating "sorry we've missed you, hope you are well, want to help however possible to assist you in getting back into our study of weight-control surgery, please contact us at your earliest convenience"

2) Telephone contact effort by PI
3) Final letter from clinic indicating desire to continue to follow participant for health monitoring. This letter may express encouragement to re-contact at any time, support for their efforts, a message of gratitude for their participation thus far, and a message as to how important they are to helping us understand effects of weight control surgery, etc.

Cohort retention plan with remote/home visit plan and outpatient testing.
Retention of participants will be insured by first collecting detailed contact information for the participants, the parents or guardians if applicable, and two close relatives not living with the patient to aid in tracking participants in the event of missed visits. We will plan to obtain the patient's social security number, land phone and cell phone numbers, social networking site, e-mail addresses and the physical address of their residence at each study visit. In addition, we will obtain similar information from each parent/guardian, and the close relatives at each annual visit. Consent will be obtained to have personally identifiable information and contact information stored centrally at the Data Coordinating Center. The information will be stored in a central database for retention purposes and will not be shared with anyone outside the study team. In addition, permission will be obtained from the patient to obtain health and anthropometric information from their personal physician(s) in the event that information needs to be gathered from an office visit to their personal physician(s). By consenting to the study, participants agree to be contacted by investigators for participation in any additional research studies approved by the ancillary study committee.

To assure cohort retention, a "SHORT form" teleform will be utilized to capture current contact information and important health related issues at the time of scheduling each milestone visit.

1. To maximize our contact efforts various communication means (i.e. email, mailings, phone calls, social networks, and text messaging, etc.) will be utilized to update contact information, maintain contact, schedule appointments, remind participants of appointments, and for general study correspondence. A Teen-LABS study cell phone will be used for text messaging by study staff members. Considerable efforts will be made to continually build rapport, stress the confidentiality of the data, and explain the importance of the research and how it could have a positive impact on other adolescents.

2. A Study Newsletter will be created and used to maintain contact with participants and maintain enthusiasm for the study. The Study Newsletter will be distributed to study participants and their parents/guardians several times per year. Various methods may be utilized to distribute the Study Newsletter (i.e. mail, email, Facebook, etc.). The proposed newsletter would include the following content: information on general study progress, important study and clinic phone numbers, support group meeting dates and topics, patient stories, nutritional information, health and fitness information, general research articles of interest, and financial services information. This content will be used as a resource to keep in touch with study participants and their families and to build stronger relationships in an effort to increase retention rates. A mock-up of the newsletter template will be provided to the IRB under separate cover.

3. At each timepoint, detailed information will be ascertained from the family regarding the names, addresses, and phone numbers of people who might

know where the family is living in case they lose contact with the study. Obtaining identifying information of significant individuals (i.e. relatives and friends) has been useful in tracking study participants in previous longitudinal studies with adolescents.

4. During study visits, participants will be provided with coordinators' business cards with reminders to call the toll-free number if they move or change phone numbers.

5. Given that the length of time from the 12-month to 24-month and annual assessments is longer than previous timepoints (6 months), participants will be notified that they will be contacted by phone at approximately 18 months. For the renewal period, due to visits being on an annual basis following the 12 month visit, participants will be notified that they will be contacted by phone mid-year between all annual visits. To increase the likelihood that phone calls will be returned or that participants will take our calls, compensation of $10 will be awarded (mailed) when the mid-year contact is made. The content of this mid-year phone call will consist of demographic updates (changes in addresses, phone numbers, custody, schools, etc.), and reminders of the upcoming annual study assessment.

6. Frequent communications, including birthday cards, holiday cards, and quarterly newsletters, will be employed to facilitate the maintenance of the central database and maintain contact with participants.

7. Compensation for travel to the study site can be provided for all participants for the 12 month and annual study visits that occur after September 2009. The reimbursement schedule set out in section 6.D.10 will be followed.

8. Participants may also be reimbursed for reasonable lodging costs as specified in section 6.D.10.

9. A study logo will be created depicting "Teen-LABS" that will establish trust, rapport and pride in participation.

10. Study refrigerator magnets and other materials will be issued that contain reminders to call the toll-free number if they move or change phone numbers.

11. To maintain contact with study participants various methods will be utilized should a participant become lost to follow-up.

    Because this is a long-term study, with extended periods of time between research-related interactions, maintaining the cohort will be a challenging element of completing the research. In order to facilitate the retention of the cohort, specific information will be obtained during the first research encounter (and updated at all subsequent encounters). Although critically important to the successful completion of the research, if a participant expresses concern and or refuses to provide this information they will not be excluded from the research. The following specific information will be collected and used for this purpose:

    - *Social security number of the participant*

- *Contact information (i.e. address, phone number, email) of the participant/parents*
- *Contact information (i.e. address, phone number, email) of one more contacts (close friends or family) not living with the participant.*

Once collected, this contact information will be stored in a separate secure database separate from the participant's research-related information and will not be shared with additional participating sites, external research coordinating centers or as a part of the main study database.

In the event that a research participant becomes lost to follow-up and traditional re-contact methods (i.e. telephone, email, traditional mail, etc.) are unsuccessful, the use of a nationwide electronic search strategy will be employed. This will include general use of public web-based search functionality, and as a last resort, the use of a 3rd party service (such as WhitePages Premium, Accurint, etc.). The use of 3rd party services to identify current contact information for a lost to follow-up research participant will be administered through a centralized standard process managed by the Central Study Coordinator. Only the demographic/contact information identified above will be utilized for the purpose of facilitating the search function. Specific individual request will be submitted to the Central Study Coordinator that will perform the search. The Central Study Coordinator will provide a report back to the research team that includes the most current available contact information for the requested research participant(s). Records of each search will be maintained and be available for IRB review if needed.

The research team will attempt to re-contact the lost to follow-up participant. Once contact is re-established, the participants will be reminded of the research study and that they voluntarily agreed to participate, interest in continued participation will be verbally confirmed and documented and the participant will return to active study participation as appropriate based on their status/time point in the research.

Along with 3rd party search services, study staff will also search publically available resources including White Pages ®, directories (high school, college, alumni, etc.), search engines (Yahoo, Google, etc.), credit bureau (Equifax, Experian), and social media websites to assist in ascertaining new contact information (address, phone number) for participants whose phone numbers and addresses have become obsolete. Name, social security number, date of birth, last known address, and other demographic information provided by the participant at the time of study enrollment will be used in an effort to locate participants who are lost to follow-up. Use of this retention contingency will be kept to a minimum and only used when all other methods of contact have failed.

Executing searches on online social networking sites to look for individual adolescents and/or caregivers would aid our efforts in keeping in contact with these eligible and willing families. Searches on online social networking sites are only to recruit/retain individual adolescents, not to send out blanket recruitment messages on the web. Nor are they performed to harass or trouble adolescents that are not interested in participating.

Accurate records, which reflect the frequency of use of these various strategies, will be kept and can be reported to the IRB on an annual basis, upon request. Once reached, participants will be reminded that they are voluntarily participating and can chose to not participate if they wish.

When searching online for a participant, we will be using the study-specific Facebook (or other social networking profile) page. We will ask participants to "friend" our study page. We will use state of the art confidentiality and privacy settings when "friending" occurs by setting our profile preferences commensurate with keeping all names and identities of all other "friends" hidden. Those who have friended the study page will not be allowed to view the names or profiles of others in the study. The use of social networking with aid us in maintaining communication with participants once enrolled.

There are two broad categories of communication. First, we will send out study updates and general communication (i.e. Facebook posts) to participants who have "friended" the study page. For example,

Have you moved in the past 6 months or gotten new phone numbers? Please call Teen-LABS (xxx-xxxx) or message us your new information!

It is possible that these communications will appear in participants' "news feeds", but the communications will be benign in nature. They are simply designed to stay in contact with adolescents and remind them that they can contact us at any time. PHI will not be communicated in these general communications unless prior authorization for use and/or disclosure of limited protected health information have been obtained from the participant. For example, our study newsletter often features study participant(s) and their name (typically only first name) and/or picture in the newsletter. We will post a link to the newsletter on the Social Network site, but the participant's information will not be directly in the post, just the link to the newsletter. Again, prior to using participant names and photos, the required authorization to use the information and for what purpose will be obtained from the participant.

Second, since social networking is one of the most common ways adolescents use to communicate we will use social networking to communicate directly with participants about scheduling their study visits. These individual communications (i.e. Facebook messages) will be sent securely though individual private messaging through social networking sites and will not be visible to anyone outside the study team. Hence, these communications will NOT appear in "news feeds" and are akin to email communications like those that are routinely used in studies of this kind. For example,

> *Your annual study visit is now overdue. If you would like to participate with us in Teen-LABS this year please call Teen-LABS (xxx-xxxx) or message us.*

Adolescents and caregivers will be told that, since this is a longitudinal study, we will obtain information that will help us find them in case they move. This

information includes several demographic details such as their address, various phone numbers, social security numbers, social networking screen names (if different than their name), and the names and addresses of close relatives or friends who will know of their whereabouts. Participants will be informed that we will use this information to locate them and that their information will be secured and will not be shared with anyone outside the study team. However, we will also inform them that social networking sites occasionally use personal information for targeted advertising and we do not have control over this.

Approval of the Teen-LABS Facebook account has been obtained from Marketing & Communications and staff members will read and follow CCHMC's Social Media Policy.

12. If all opportunities to coordinate an on-site visit have failed, the study will utilize Examination Management Services, Inc. Health Services Division (EMSI) to conduct remote/home visits.
    A. EMSI Service Overview: EMSI will partner with the study's research coordinators at each site to gather study data at participants' homes if the participant is unable to return to the clinical center for a study visit in person.
        1. Study coordinators will mail self-report forms to participants and will assist them with completion by phone.
        2. EMSI staff will drive to the participant's home, collect these self-report forms, perform anthropometric measurements using Tanita scale and stadiometer, and perform mobile phlebotomy, blood/urine specimen processing, packaging, and shipment of biosamples to our central laboratory.
        3. The corridor walk (400m walk test) will not be done due to safety and cost implications.
        4. All EMSI personnel performing services for this study will have completed the required Human Subject Certification course, the Teen-LABS study protocol training, and training for the handling of dry ice shipments before any scheduled home visit.
    B. Authorization to Release PHI to EMSI: A business service agreement will be in place between each study site and EMSI to allow demographic/contact information to be given to EMSI to arrange the home visit.
    C. Scheduling Procedures: Once the DCC confirms the need for this home visit with the local site coordinator and the participant and family agrees to allow EMSI to come to their home, the home visit protocol will be activated and EMSI National Service Center (NSC) staff will contact the appropriate EMSI branch office and provide the subject contact information, location, date, and time of services.
        1. Kits will be shipped from EMSI NSC Dallas, Texas to the local branch office.

2. Blood will be collected, processed, and shipped according to Teen-LABS protocol to the NWRL (our study Central laboratory and storage of bio-specimens for the NIDDK Repository).
3. Anthropometric measurements will be done.
4. Teleforms will be completed for laboratory and anthropometric measures.
5. All forms (including completed self-report data forms) will be packaged and sent FedEx back to local site coordinator.

D. Supplies for the remote/home visit: The following supplies will be provided directly to the branch office or local examiner per appointment, and will be shipped back to EMSI NSC when visit completed.
   1. Blood supply kits-OSHA compliant Bio Hazard standards will be followed for disposal of used supplies
   2. Tanita Scale
   3. Stadiometer

E. Incident Reporting
   1. In the event of an adverse event or unexpected problem during the home visit, the EMSI examiner must report it to EMSI NSC immediately by phone
   2. EMSI NSC will notify the site coordinator and DCC central study coordinator immediately.

F. The BDI-II form will be completed only in person at study visits, NOT over the phone.

G. The DCC will be responsible for tracking and reporting of EMSI visit for future DSMB reports.

H. The DCC will be responsible for prompt reporting of any adverse events or unexpected problems per Teen- LABS data and safety monitoring plan.

13. In the event that a participant is not willing or able to have an EMSI home visit nor come back to the clinical site, they may go to an outpatient setting to have their anthropometric measurements, blood pressure, pulse and when possible, blood work and urine sample collected for the study. The results from this testing will be given to the Teen-LABS study as well as a copy to the participant to share with their local health care provider. Quest Diagnostics Health & Wellness is one of the outpatient settings that provides services for the Teen-LABS cohort. For this process, please refer to the Quest protocol and registration and scheduling instructions, available by accessing the Teen-LABS Dropbox at: https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QqOmBPyGpEzChIZla?dl=0

14. Since our study participants are maturing and having many “life changing events” such as marriages, births, graduations etc. we will provide congratulation baskets (total value not to exceed $25.00) to celebrate these milestones and acknowledge these important changes.

Additional retention measures
In addition to the cohort retention plan outlined above, the following strategies will be implemented in order to optimize participant retention.

1. Considerable efforts will be made using the means outlined above to locate a participant should they become lost to follow-up. In the event that all resources have been utilized and the participant cannot be reached, study staff members may make a visit to the participant's home, particularly to those who lack telephone service. This visit will be performed in order to confirm that the family continues to reside at the presumed residence. This plan is not to harass or trouble families that are not interested in participating in Teen-LABS project. The plan is only in place to contact families who are interested in participating.

   Execution of a Home Visit recruitment plan will allow the research team to contact families willing to participate who are otherwise unreachable. Our plan is outlined as follows:
   A. As we have already implemented, letters to schedule are sent to the address on file.
   B. All phone numbers are attempted, including phone numbers of the alternate contacts given to us by the participant or family member.
   C. A certified letter is sent to the home.
   D. If we receive confirmation from the certified letter stating the family lives at the residence AND IF the family has not contacted us to "opt-out" of the study (called the study line or written us to express disinterest), study investigators may exercise an option to visit the participant's home to re-assess desire to continue to participate.
   E. A trained dyad of one research assistant and one senior level researcher travels to the home to deliver invitation or IRB approved retention materials. For the protection and safety of the home visit research team, the team will alert a designated CCHMC study staff person that they are going to make a home visit. The team will notify the designated person upon arrival to the participant's home and upon leaving the home.
   F. If the family is not home, study materials are left.
   G. If the family is home, the dyad is trained to follow the same IRB approved scheduling dialogue that would occur over the phone in a face-to-face fashion. This conversation occurs so the family may answer any questions they may have and for the research team to provide additional information about the study.

2. Participants will also be asked to provide a picture to be stored in the central database registry. This will provide us with an updated picture to the one taken prior to surgery and also serve as an additional means to confirm a participant's identity and is invaluable when searching for them on social network sites (i.e. Facebook).

3. The Central Study Coordinator oversees retention at all sites and has been added to the other participating sites' IRB protocols, so that they may assist the other sites with retention efforts.

4. A sub-committee, entitled the Retention Oversight Committee (ROC) was previously established to monitor the implementation of the retention plan, evaluate the effectiveness of retention strategies, and lead efforts in any revision of the retention plan in response to study progress.

5. Up to 25 study participants, age 18 years or older were recruited to record an audio and / or video messages to share with all study participants. All messages were submitted to the IRB for approval prior to recording. Participants agreeing to record the message(s) signed a letter acknowledging their participation in the study and that they would like to extend their involvement in the project.

PROCESS FOR SENDING PACKETS HOME FOR COMPLETION FOR STUDY VISIT (NO LONGER NECESSARY SINCE REDCAP IS NOW BEING USED FOR FORM COMPLETION)

To prepare the study packet of Teleforms for completion prior to research visit:

1. Check informed consent for re-consenting issues:
    a. Is the most up to date consent form signed?
    b. Did the participant turn 18 years of age?
2. Prepare the ID printed Teleforms with the following considerations:
    a. Is the participant male? If so, the reproductive health TL_RHF teleform should NOT be included in packet
    b. Is the participant female and 18 years of age? If so, send all pages of the reproductive health teleform TL_RHF
    c. If the participant female and is less than 18 include only pages one and two of the reproductive health form TL_RHF
3. Send only the “self-administered forms” home. Do not send the BDI and BDIS2 Teleforms to the participant. (See Table 1 for specific issues to consider when sending packet.)
4. Include instructions to the participant in the cover letter outlining a schedule for the day with reminders of what to do while completing forms at home.
5. Send the packet to arrive at the participants home two weeks prior to the planned study visit based on the following criteria:
    a. If not yet 18 years of age send to parent / legal guardian for completion
    b. If 18 years send to participant at confirmed address

Table 1.	**Packets**
SWH	School and Work History
BF	Behavior – Follow-up
SF36	SF36 Health Survey
PETSF	Psychiatric and Emotional Test Survey – Follow-up
IWQOL	Impact of Weight – Kids
GSRS	Gastrointestinal Symptoms Rating Scale
UIF	Urinary Incontinence – Follow-up
BS	Berlin Sleep
RHF	Reproductive Health – Follow-up (Only if female. If <18 years old, only send pages 1&2).
MED	Medications

MAF	Medical Assessment Follow-up
IPAQ	International Physical Activity Questionnaire
IPS	International Prevalence Study on Physical Activity

Section 13 – Operations Memos
List all updates

All Operations Memos will be numbered and should be kept for future reference. Please insert memos as received:

Section 14 – Publications and Presentations

Teen Longitudinal Assessment of Adolescent Bariatric Surgery (Teen-LABS) publications information available per website
http://www.ucdenver.edu/academics/colleges/medicalschool/departments/surgery/Research/Teen-LABS/Pages/Teen-LABS-Publications.aspx

Consortium Publication and Presentation Subcommittee Mission Statement:
Propose to the Steering Committee a formal policy for presenting and publishing Teen-LABS data including preparing manuscripts, assigning tasks in analysis and writing, writing group membership, authorship, internal review, and other issues related to abstracts, presentations and publications. This policy covers full manuscripts, abstracts, and other publications and presentations. The process has been developed to ensure that the study results are disseminated in a timely, accurate and clear manner.

Ancillary Study Overview and Guidelines available per website
http://www.ucdenver.edu/academics/colleges/medicalschool/departments/surgery/Research/Teen-LABS/Pages/Ancillary-Study-Overview.aspx

Section 15 – Site Visit Guide

Plan for Teen-LABS Site Visit and Data Review

The Data Coordinating Center will arrange for the central study coordinator to conduct an annual site visit to each center to promote communication, answer questions, and ensure that study procedures are understood and correctly carried out. The annual site visit will insure the effective and standardized delivery of recruitment efforts and the collection of appropriate and valid data within each of the Teen-LABS study clinic sites. Members of the site visit team will be selected by the Data Coordinating Center and will include the Central Coordinator from the Coordinating Center and may include other personnel from the DCC, the NIDDK, along with one or more personnel from selected centers. Site visits may also be performed if consistent departures from the Protocol and Manual of Procedures are detected. Retraining may be done as needed during these visits, depending on the availability of staff.

The Investigator and coordinator at the Clinical Site to be visited will be given a minimum of 15 business days notice of the visit to prepare for the site visit. The DCC will be responsible for selecting a random sample of 10% of all enrolled participants at each site (or a minimum of 15 charts). In addition, the charts for any subject that has had a serious study related adverse event either anticipated or unanticipated will be audited. All charts which have required adjudication by the TL steering committee will also be audited.

The Central Study Coordinator will review the site records and the data reported to DCC to verify accuracy.

This site visit will include a review of part or all information submitted to the DCC regarding the specified subject along with the full source documents (SD) to assure integrity of data. This could include medical records from all hospital admissions both inpatient and outpatient, physician clinic chart or shadow chart as well as all signed Informed Consent/Assent statements and other items that may be kept in the subject's source document.

The DCC will ensure that all data clarification notes have been properly documented. Site coordinators are responsible for coding/correcting the paper forms based on the notes sent by the DCC. All coded/corrected data should be done in red (or differently colored) ink and MUST be initialed and dated next to the item number. Where appropriate the incorrect item should be crossed out with single line and initialed and dated. If additional data is added this too should be initialed and dated. The paper forms MUST match the data in the database.

Specific items of interest:

Clinical Information

To ensure BMI is accurate, what was reported to the DCC will be compared to what is in the source documents.

The hospital charts and outpatients clinic notes will be reviewed and used for a comparison to the clinical data reported to the DCC. This review will be based on, but not limited to, the use of the attestation sheet, preoperative initial consultation and

management by the bariatric team, history and physical examination at the time of admission for bariatric procedure, discharge summaries, operative reports and reports of any other procedures performed, daily progress notes, nursing medication administration records, laboratory values, radiographic testing, and reports of any other consultations. The review of the data will thus be able to verify demographics (age of participants, race/ethnicity), anthropometrics, major co morbid conditions, and medical/surgical complications, and readmissions to that facility.

Beck Depression Inventory (BDI-II) & Suicide Behavioral Questionnaire (SBQ)
Adolescents may become distressed when asked about their psychosocial status. The Beck Depression Inventory 2 and the Suicide Behavioral Questionnaire (SBQ) is used to determine significant depression and/or suicidality within patients. If a subject is deemed suicidal or clinically depressed, based on the score of the BDI 2 or SBQ, an Action Plan is set into place to document that proper psychological assessment and/or referrals were made. If the subject had a BDI-II ACTION or a SBQ Plan reported to the DCC subsequent to the BDI-II/ SBQ administration, the source document and clinic chart will be reviewed to insure that the disposition was consistent with the Action Plan. Since Teen-LABS is an observational study we are not able to mandate this clinical care beyond notification of the qualified clinician at the site. However, if the BDI-II / SBQ Action Plan is not completed properly, the Central Coordinator will work with the Site PI on implementing a plan that ensures all participants are seen by an appropriate clinician (e.g., psychologist or psychiatrist).

Teen-LABS Data Review Checklist

The Data Coordinating Center (DCC) will provide each Clinical Center a list of case report forms (CRFs) for each subject that is to be reviewed at the time of the Site Visit and should be kept with this report

Site IRB # _____
Date reviewed: _____
Reviewed by: _____
Role in Study_____

Protocol / Protocol Amendment(s) / CRF(s)	**Present**	**Absent**	**N / A**
• A copy of the original protocol & a copy of the corresponding protocol signature sheet	☐	☐	☐
• A copy of each protocol amendment & a copy of the corresponding protocol signature sheet	☐	☐	☐
• A copy of the IRB Approved Data Collection Forms	☐	☐	☐

IRB Approval / IRB Correspondence (including but not limited to)**:**	**Present**	**Absent**	**N / A**
• Protocol, Protocol Amendment(s), descriptions of any protocol deviation(s)	☐	☐	☐
• IRB correspondence on CRFs and amendment(s) to CRFs	☐	☐	☐
• IRB approval of the Informed Consent Form (ICF) or Assent form (AF)	☐	☐	☐
• IRB approval of any other written information to be provided to the research participants	☐	☐	☐
• IRB approval of Advertisements for subject recruitment (if used)	☐	☐	☐
• IRB comment on Subject compensation (if any)	☐	☐	☐
• IRB notification and response to Adverse Events	☐	☐	☐
• Interim or Annual Reports (continuing IRB review)	☐	☐	☐
• IRB copy of the Final Study Report	☐	☐	☐
Any other documents submitted to and approved by the IRB for use in the study.			
Other correspondence with IRB			

Information Given to Research Participants (if applicable)	**Present**	**Absent**	**N / A**
• The original Informed Consent Form (ICF) and Assent Form (AF) approved by the IRB	☐	☐	☐
• All revised ICF(s) +AF approved by the IRB and all correspondences related to ICF/AF changes. *The old versions of the ICF/AF must be clearly labeled in order to avoid using outdated versions*	☐	☐	☐

Data Safety Monitoring	**Present**	**Absent**	**N / A**
• A copy of the Data Safety Monitoring Plan (DSMP) if not included in the protocol	☐	☐	☐
• A copy of the Data Safety Monitoring Board (DSMB) roster and charter and all documentation relating to the DSMB is filed	☐	☐	☐
The original signature log documenting the signatures and initials of all persons authorized to make entries and /or corrections on data collection forms. The signature log must include the following information:			
• Name of each investigator(s) and study personnel participating or conducting the research	☐	☐	☐
• Signature and date of signature of investigator(s) and study personnel participating or conducting the research	☐	☐	☐
• The initials of investigator(s) and study personnel participating or conducting the research	☐	☐	☐
• The role and responsibilities of each individual listed as a delegate by the PI. (see check-list)	☐	☐	☐

Correspondence and Required Reports	**Present**	**Absent**	**N /A**
Correspondence between the Data Coordinating Center (DCC) and the investigator, site and coordinator. May include, but not limited to the following:	☐	☐	☐
• Reminders	☐	☐	☐
• Progress reports	☐	☐	☐
• Final reports	☐	☐	☐
• Monitoring reports	☐	☐	☐
• Safety notifications from DCC or DSMB to investigator	☐	☐	☐
• Steering Committee call minutes	☐	☐	☐
• Coordinator call minutes	☐	☐	☐
• Telephone notes	☐	☐	☐

Laboratory Certification	Present	Absent	N /A
• A current copy of the laboratory certification	☐	☐	☐
• A current copy of the laboratory accreditation	☐	☐	☐
• A copy of any established quality controls and/or external quality assessments	☐	☐	☐
Laboratory References Ranges	**Present**	**Absent**	**N /A**
• A copy of the laboratory reference range(s) for medical/laboratory/technical procedure4(s) and/or test(s) included in the protocol. Some unusual lab test may not have a reference range	☐	☐	☐
• A copy of any change in value(s) and range(s)	☐	☐	☐

Record of Retained Body Fluids and Tissue Samples	Present	Absent	N / A
• Documentation of the location and identification of repository samples	☐	☐	☐
• Shipment documentation of all samples for Teen-LABS (excluding any patient identifiers)	☐	☐	☐
• Any Correspondence with central repository related to specimens	☐	☐	☐
• All information in common files needs to be de-identified	☐	☐	☐
• All documentation of specimen shipping/handling should be kept (Shipment forms and tracking numbers)	☐	☐	☐

Source Documents (SD) (Research Medical Record)	Present	Absent	N / A
• A Research Medical Record must exist for each subject entered into Teen-LABS to document the existence of the research subject and proper informed consent	☐	☐	☐
• Documentation that all Adverse Events (Expected and Unexpected) have been fully disclosed and reported	☐	☐	☐
• Documentation that all items sent to DCC are accurate and all data queries have been satisfactorily tracked	☐	☐	☐
• Documentation that all Unanticipated Problems have been reported to IRB and DCC	☐	☐	☐
• Evidence that source documents (SD) (Private Health Information [PHI]) are kept separate from (CRF's) data identified by study ID	☐	☐	☐
• Location and proof of Enrollment Log linking PHI and de-identified Teen-LABS ID for all participants	☐	☐	☐

at the site. Enrollment Log must be up to date and secured in a locked file separate from all other identifiable research medical records			
• Telephone call log (in attempt to follow up with a subject) will be kept in Source Documents with identified study materials	☐	☐	☐

Investigator's Curriculum Vitae (CV) / Credentials	**Present**	**Absent**	**N / A**
(This information will be needed on an annual basis for the annual progress reports and should be shared with your grants manager or staff).			
• A current copy (*within the past 12 months*) of the curriculum vitae or other statement of qualifications for each of the Principal Investigators, Co-investigator/Sub-investigators	☐	☐	☐
• A current copy (*within the past 12 months*) of a curriculum vitae or other statement of qualifications of all Study Coordinators involved	☐	☐	☐
• A copy of the current medical licensure/credentials for the PI, issued in the state where the research study will be conducted for all Investigators	☐	☐	☐
• A signed copy of the Significant Financial Conflict of Interest form for the Principal Investigator, co-investigator, sub-investigators and all research staff involved in the conduct of Teen-LABS	☐	☐	☐
• A signed copy of the educational requirements regarding human subject research certificate for the Principal Investigator, co-investigator, sub-investigators and all research staff involved in the conduct of the study	☐	☐	☐

Records Retention	Present	Absent	N /A
The investigator documents knowledge of the requirement to maintain all of the records in the Research Binder as follows:			
• The records must be maintained for a period of two (2) years following the end of the study	☐	☐	☐
• All data with personal identifiers (PHI protected by HIPAA) will be kept totally separate and NOT LINKED to Teen-LABS ID number	☐	☐	☐
• List of participants /Enrollment Log	☐	☐	☐

Financial	Present	Absent	N /A
All correspondence and agreements relating to the financial aspects of the study, including budgets and payment schedules, should be filed in a separate binder and not filed in the “Research Study Binder”	☐	☐	☐

Section 16 – Study Directory

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Section 17 – Training

Principal Investigator and Coordinators

The consents for Teen-LABS are as follows:

- The current Teen-LABS Participant Adult re-consent, enrolled in Teen-LABS and are all greater than age 18 and will continue to participate.
- The Adult Consent for the SG cohort and Caregiver and Assent if applicable
- The Adult Consent for the Control cohort.

The consent process should take place after the eligibility criteria has been established. For the Cincinnati site, the process of recruiting and consenting usually takes place after a patient's clinical appointments, so to not put a burden on clinic's flow.

Read the consent verbatim! This is not only for your protection, but the patient's as well. Just like when we administer the Teen-LAB's measures, the consent process also needs to be standardized. Reading the consent verbatim ensures the staff, the institution, and the patient that all of the information has been properly represented. When administering the consent form, it may be helpful to take a pause at the end of each page, summarizing what has been read. This is to make sure the patient fully understands what is being asked of them. This is also a good opportunity to stop and ask questions, so to clarify any matters that maybe confusing or difficult to understand.

It is also the person administering the Informed consents' responsibility to make sure that the patient understands the distinction between the clinical work that is being done, and the research we are asking them to participate in.

Rapport Building: Rapport building begins at the point of recruiting and consenting! Reading over the consent form in a standardized practice and summarizing the main topics will help set the tone for successful recruitment! The recruiter needs to be able to know the details of the study. This is so that the patient can fully understand the purpose and importance of Teen-LABS. This practice will aid at putting the participants mind at ease, by helping them not to feel overwhelmed with what you have to say. Whenever consenting a family, look at it from their perspective. How would I as a parent want to be approached with this information, and how are they going to take care of my child?

Also, when recruiting and consenting do not be shy – let people see your conviction! Let them know why you believe Teen-LABS is important, and how their contributions will make a difference!

Say something like **"**As you know, by having bariatric surgery you are in a unique group of adolescents. We are asking that you participate in this project, so that we can learn more about folks like you who are having this type of surgery. Research is very different the clinical work that you are used to seeing. Research enables you to tell us your story, whether it be though blood-draws, walk-tests, or interview questions. And by telling us your story, you are informing us on things like what it is like to be a person your age seeking bariatric surgery. Also, research is another tool we use to better inform the team, so that we may provide the best care to our patients.

Optimal Methods "Subject Completed"
"Optimal Methods Subject Completed," which focuses on Standardizing Participant's Measures. These are the measures that are completed by the patient. In other words, they are the participant's self-report. As an aid to the administrator, on these measures a notation has been placed at the bottom of each self-repot form. Please note, that in the Teen-LABS study none of the forms are completed by and interview format.

A roster of the self-reported measures, which are administered by a research coordinator and at what timepoints, can be located in SECTION 2, TABLE 2 of the MOP.

It is important that when administering the self-report measures that the directions are read verbatim, so that the patient knows exactly how to complete the self-assessments. Each of the measures has their own standardized format.

Validating data: Standardizing helps to keep our data reliable and valid!
The psychology measures scaled scores are set. Meaning, calculating the raw data will give you a total score of how the patient is feeling. Therefore, tampering with measure's instructions will hinder its design.

Check measures for completeness: It is also important to check each measure for completeness immediately following after a participate fills out the form. So to not make anyone feel uncomfortable, like we are reading over their answers, state something like, "after you are done I am going to go through & make sure each question was filled out correctly, or not double marked. I just wanted you to know that I am not judging your answers, just making sure everything has been filled out correctly.

When doing this it is also important that you look at the content, making sure the responses make sense. At this moment you are managing the integrity of our data! Again you are not reading the answers, just making sure mistakes were not made. For example; on date of birth - they did not put 2007 as the year they were born. Or circling male, when a female is the one participating.

Reviewing scoring of key items (BDI # 9 and the SBQ): The BDI & SBQ is a self-assessment, which looks at depression. Question number 9 assesses suicide. (See Section 9 for specifics on BDI.)

Reporting adverse events: If a participant endorses number 9 on the BDI, or SBQ, check with your local institution whether or not an Adverse Event needs to be submitted to your local IRB.

Reimbursing Participants: Make sure you have your participant complete a W-9 tax form as it is required for ClinCard reimbursement.

Follow site specific instructions

Receipt: Do not place subject ID number on receipt, for this is another way we de-identify our participants. The receipt's design is fairly simple, but first it is important to check to see if your institution has specific requirements. What we list is the name of the study, the PI name, your name, the child's name, and the parent's name. For your protection, and auditing purposes, make sure all of your receipts are logged into a

secured database. And also make sure that a copy of the receipt is kept in a secured cabinet.

Continue to build rapport, **Thank the family for their time and efforts!** Let the family know that their participation is truly valued!

Section 18 – Data Collection Forms

For Cycle 3: Teen-LABS Data collection Forms and Q X Q (Teen-LABS forms and Question by Question) is currently under construction based on review and approval of protocol by NIH, DSMB and IRB.

Forms will be available via Teen-LABS Dropbox at:
https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwht8QqOmBPyGpEzChIZla?dl=0

Section 19 – Old Sections

Archive all outdated sections of MOP once you receive an updated section and more current version of Teen-LABS MOP