

Teen-LABS MOP TABLE OF CONTENTS

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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 and 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 and up through 15 year) outcomes of adolescent

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 March 2022.

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/AABEwht8QqOmBPYGpEzChlZla?dl=0>

Data Safety Monitoring Charter (DSMC)

Data Safety Monitoring Plan (DSMP)

Section 2 – Enrollment, Consenting & Incentives (ClinCard)

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, the study enrolled 38 additional SG participants at selected sites in the third cycle of funding to permit adequately powered comparisons of important outcomes between SG and RYGB participants. Power analysis indicated that an 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 sequentially recruited individuals meeting inclusion criteria. We screened 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 sorted potential participants in the screening list by date of SG surgery and consecutively recruit these individuals. Recruitment phone calls and letters were 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) were abstracted from medical records up to their enrollment date. Major healthcare utilization self-reported events (operations, other procedures, or hospitalizations) during or following bariatric surgery were also abstracted so that potential complications of surgery or of underlying medical conditions could be analyzed. On site as well as Quest research visits have and will continue to be conducted to collect a complete annual visit research dataset. In this manner, all 38 new enrollees were 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 Baylor College of Medicine 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, in part, due to weight loss. There is concern that bariatric surgery in adolescence may adversely affect bone health long-term. Even small annual declines in BMD are

MOP Updated 05/05/2022

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 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.

The informed consent document for surgical Teen-LABS participants has been and will continue to be revised whenever important new safety information is available, whenever the protocol is amended, and/or whenever any new information becomes available that may affect participation in the study. We are revising the paper informed consents (for surgical Teen-LABS participants only) to an electronic consent (eConsent) which will be submitted and approved by the IRB prior to initiation. All participants will be re-consented with eConsent (see Section 3 for guidelines to request eConsent for your participant). If eConsent is not approved or unable to be utilized, a copy of the consent, additional signature page (for them to sign and return) and a return envelope with postage will be mailed to the participant.

A Teen-LABS investigator or study coordinator will review the consent and answer questions by phone, prior to any further research being conducted. The coordinator will document this process with a note, to coincide with the electronic signature provided on the electronic consent by the participant. The participant will be reminded that participation in the study is voluntary and that he or she may withdraw from the study at any time, for any reason.

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 Control cohort.

Read the consent verbatim! This is not only for your protection, but the patient’s as well. 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 begins at the point of recruiting and consenting! Reading over the consent form is a standardized practice and summarizing the main topics will help set the tone for successful follow up! The coordinator 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 participants, look at it from their perspective. How would I want to be approached with this information, and how are they going to take care of me?

Also, when 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 patients. 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 through blood-draws, questionnaires, 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.

Follow site specific instructions and continue to build rapport by **thanking them for their time and efforts!** Let them know that their participation is truly valued!

Please see Section 3 for additional information regarding Consent forms.

2.2 Reimbursing Participants.

Make sure you have your participant complete a W-9 tax form as it is required for reimbursement. The form should be updated when participants change addresses and if there is a name change.

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 for full study visit (excluding mileage)
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 full visit	\$50.00	\$30.00	\$120.00	n/a	\$200.00
Midyear phone call	n/a	n/a	n/a	\$10.00	\$10.00

In addition, participants receive compensation for travel to a Quest Diagnostics Patient Service Center (PSC) location to complete a full annual study visit (years 5, 6, 8, 10 and 15). 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 PSC. 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

If a DXA scan is done, participants (years 6, 8, 10, and a second scan around year 15)) will receive a one-time reimbursement of \$100.00 for their visit and surgical patients are eligible to receive compensation for travel to a clinic site to complete a DXA scan. The compensation schedule is based on round trip distance from the participant's home to the clinic site:

- 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

CLINCARD INFORMATION AND REQUESTS:

Checklist for Teen-LABS ClinCard Payments

Issuing or Loading Money to ClinCard for Quest Visit

1) When preparing for Quest visit, plan to send these items to the participant:

- ☐ New ClinCard (if needed)
- ☐ ClinCard Tips Sheet
- ☐ Personalize & print ClinCard Letter
- ☐ Blank W-9 form for participant to complete if address and/or name has changed since previous form was obtained or if participant does not have completed form on file

2) Contact participant, and during phone call:

- ☐ Confirm that the Quest visit took place (and obtain Quest location address for mileage), samples collected, and data completed

- ☐ Confirm address matches participant's ID in case they want to cash out their ClinCard
- ☐ Obtain/confirm Social Security #
- ☐ Ask participant if they wish to be notified by ClinCard via text or email when card has been loaded with visit payment; fill in cell # and/or email address

3) After confirming the visit and information with the participant:

- ☐ MapQuest/Google Maps mileage from site to home for reimbursement
- ☐ Electronically sign Teen-LABS ClinCard Payment Request, confirming payment amount and verifying

that the visit occurred

- ☐ Save Teen-LABS ClinCard Payment Request as: Subject ID visit # ClinCard Payment date
(ex: CIN1234 v84 ClinCard Payment 04-01-2022)
 - Each site determines where to save electronic copy
- ☐ Save original Teen-LABS ClinCard Payment Request in participant's electronic folder
- ☐ Send secure email to Jenn Black & Jenny Knox with subject line: Subject ID Payment Request
(ex: CIN1234 Teen-LABS Payment Request) & attach Teen-LABS ClinCard Payment Request
- ☐ After visit is complete, complete REDCap forms

Issuing or Loading Money to ClinCard for Phone Call

1) Prior to phone call:

- ☐ Electronically fill out PDF Teen-LABS ClinCard Payment Request form
- ☐ Determine whether participant already has a ClinCard or if one needs to be issued. If one needs to be issued, place name/# label from ClinCard envelope onto Teen-LABS ClinCard Payment Request form.

2) During phone call:

- ☐ Complete forms specific to visit
- ☐ If ClinCard has already been issued or sent, confirm # matches their ClinCard
- ☐ Confirm address on participant's ID in case they want to cash out their ClinCard
- ☐ Obtain/confirm Social Security #
- ☐ Ask participant if they wish to be notified by ClinCard via text or email when card has been loaded with visit payment; fill in cell # and/or email address

3) After phone call:

If participant does not already have a ClinCard, mail the following items:

- ☐ ClinCard envelope
- ☐ Personalize and print ClinCard Thank You Letter
- ☐ ClinCard Tips Sheet
- ☐ Electronically sign Teen-LABS ClinCard Payment Request, confirming payment amount and verifying

that the visit occurred and indicate that at a minimum the Short Form was sent to CEBDATA

- ☐ Save Teen-LABS ClinCard Payment Request as: Subject ID visit # ClinCard Payment Request date
(ex: CIN1234 v84 ClinCard Payment Request 04-01-2022)
 - Each site determines where to save electronic copy
- ☐ Save original Teen-LABS ClinCard Payment Request in participant's electronic folder
- ☐ Send secure email to Jenn Black & Jenny Knox with subject line: Subject ID Payment Request
(ex: CIN1234 Teen-LABS Payment Request) and attach Teen-LABS ClinCard Payment Request

Issuing or Loading Money to ClinCard at DXA Clinic In-Person Visit

- When scheduling, remind participant to bring ClinCard to their visit if they already have one
- Include draft request form and MapQuest/Google Maps mileage from site to home for reimbursement

1) Prepare for participant's visit:

- ☐ MapQuest/Google Maps mileage from site to home for reimbursement
- ☐ Obtain participant's ClinCard envelope (if it has not already been issued)
- ☐ ClinCard Tips Sheet
- ☐ Teen-LABS ClinCard Payment Request
- ☐ Blank W-9 form for participant to complete during visit if address and/or has changed since previous form was obtained or if participant does not have completed form on file

2) At visit, when participant has completed the visit:

- ☐ Ask participant to fill out W-9 form if address and/or name has changed since previous form was obtained or if participant does not have a completed form on file
- ☐ Fill out Teen-LABS ClinCard Payment Request and enter # from ClinCard envelope onto form (8 digit token number in window of envelope); if ClinCard has already been issued, confirm # matches their ClinCard
- ☐ Confirm address on form matches participant's ID in case they want to cash out their ClinCard
- ☐ Obtain/confirm Social Security #
- ☐ Ask participant if they wish to be notified by ClinCard via text or email when card has been loaded with visit payment; fill in cell # and/or email address
- ☐ Give participant ClinCard & ClinCard Tips Sheet
- ☐ Obtain completed W-9 form from participant

3) After visit

- ☐ Complete Teen-LABS ClinCard Payment Request confirming payment amount
- ☐ Save Teen-LABS ClinCard Payment Request as: *Subject ID visit # Teen-LABS ClinCard Payment date* (ex: CIN1234 v84 Teen-LABS ClinCard Payment 04-01-2022)
 - Each site determines where to save electronic copy
- ☐ File original Teen-LABS ClinCard Payment Request in participant's folder
- ☐ Send secure email to Jenn Black & Jenny Knox with subject line: *Subject ID* Payment Request (ex: CIN1234 Teen-LABS Payment Request)
 - * *Files can be combined into 1 PDF or kept as separate files*
 1. Teen-LABS ClinCard Payment Request
 2. MapQuest/Google Maps mileage from site to home for reimbursement
 3. Completed W-9 form if applicable

If participant forgets to bring ClinCard to DXA Clinic Visit:

- ☐ Ask participant to contact you with card #
- ☐ Confirm card # is correct & proceed with after visit steps (#3 above)

Issuing Replacement Card (if participant loses ClinCard)

If their original card had a balance remaining it will be transferred to the new card.

- ☐ Mail the replacement card to the participant with the replacement card letter
- ☐ Once participant confirms card has been received, follow the process for requesting payment

2.3 Study Procedures for Participants.

Annual Post-operative Outcome Elements.

These data will be collected around the annual surgery anniversary, with 6 months minimum between annual study visits and 12 months preferred between annual visit completion. Please see Timepoints table later in this section for forms to be completed at annual visits.

- Updated contact information
- Anthropometrics (Anthropometrics Form)
- Most recent vital signs, laboratory values, medications prescribed
- Psychosocial self-assessment forms
- Smoking status, Other conditions possibly affecting outcomes
- Healthcare utilization
- Supplement adherence

Teen-LABS Participants with Learning Disabilities

Teen-LABS Participants with Learning Disabilities who need caregivers to complete forms should only exclude the SF36 and IWQOL but all others should be completed.

Due to the small number of remaining follow-up visits for the University of Alabama, Birmingham (UAB)/Children's of Alabama site, the coordination of ongoing visits will be centrally managed from Cincinnati Children's Hospital Medical Center (CCHMC) as of protocol revision #9, April 2020. For any remaining full study visits (years 10 and 15), participants will be offered the option of going to a local Quest Diagnostics PSC location. The participant will complete research assessments via REDCap survey link provided by the CCHMC central coordinator. For study visits in years 11-14, these will be completed as outlined below for all sites. Contact information for UAB participants will be obtained from the site's files and central retention office via secure electronic communications and will be stored securely as outlined in section 8.

In years 7, 9, and 11-14 full study visits will not be conducted and the data collection points at these times are referred to as phone visits. For those participants who pass through these time-points during the 3rd cycle, contact will be maintained and a brief health interview will be done by telephone. However, in years 10 and 15 (full study visits), participants will complete a Quest visit and REDCap questionnaires online; at 10yr only participants will also complete WebNeuro & Inquisit measures online. Participants need to complete a new Contact Information form (mailed/emailed or completed by coordinator during the phone interview) for every phone visit and full study visit. Requests to complete "as needed" forms will be mailed to the participant for every phone visit and full study visit, which include: W-9 form and Consent, as well as if they need a new ClinCard. Coordinators will complete pg.1 of the Short form and REDCap Short form for every phone visit and full study visit. If a new consent is completed, Coordinators will also complete the ICF in REDCap. Since each phone visit has 2 parts, the phone portion and the "self-assessment" forms, if the participant does not complete and return the forms needed, they will not be paid for that part of the visit.

During our 3rd funding cycle, we experienced the pandemic COVID. Adjustments and accommodations had to be made due to closures of facilities and quarantining, including allowing the 10yr full visit/V120 to be completed into the 11yr/V132 phone call visit timeframe and is referred to as "10yr backup/V120backup." Since these two visit years overlap the same timeframe, there should be a minimum of 6 months between visit documentation/completion for V120 backup and V132; the preferred timeframe between visits is 12 months.

Interim contact referred to as midyear calls as specified in retention plan between annual time-points will ensure cohort maintenance, collect change of address, and health status updates. Coordinators will complete pg.1 of the Short form and REDCap Short form for every mid-year contact.

Files to send via secure email to the Central Study Coordinators

- Consent
- Contact Information
- Short Form pg. 1
- W-9 form (if applicable; a new form needs to be completed for an address and/or name change)
- Payment requests (and mileage documentation if applicable)

File naming

When sending files please use the following naming convention:

ID_Visit#_Document Type_mm.dd.yy

(ie: BCM4004_Visit72_Consent_07.10.2022)

* The date in the file name should be the date that you as the Coordinator reviewed/completed the "Review date" within the document.

2.4 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
	<i>Surgeon/Coordinator Completed</i>											
ANTH	Anthropometrics	x	X		X		x					x
ANTH	Blood Pressure	x	x		X		x					x
HC**	Healthcare Utilization Form	x	X	x	X	x	x	x	x	x	x	x
ICT**	Informed Consent Tracking form	x	X	x	X	x	x	x	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											
CI*	Contact Information	x	X	x	x	x	x	x	x	x	x	X
	<i>Patient Completed</i>											
CI*	Contact Information (Can be completed by CRC)	x	X	x	x	x	x	x	x	x	x	X
SWH	School and Work History	x	X		x		x					X
BF**	Behavior - Follow-up	x	X		x		x					X
SF36	SF36 Health Survey	x	X		x		x					X
PETSF	Psychiatric and Emotional Test Survey - Follow-up	x	X		x		x					X
IWQOL	Impact of Weight - Kids (IWQOL -Lite yrs 6&8)	x	X		x		x					X
GSRS	Gastrointestinal Symptoms Rating Scale	x	X		x		x					X
UIF	Urinary Incontinence - Follow-up	x	X		x		x					X
BS	Berlin Sleep	x	X		x		x					X
RHF	Reproductive Health - Follow-up	x	X		x		x					X

MED	Medications	x	X		x		x					X
IPAQ	International Physical Activity Questionnaire	x	X		x		x					X
IPS	International Prevalence Study on Physical Activity	x	X		x		x					X
FX	Fracture Survey	X	X		X		X					X
ESS	Excess Skin Survey	x					x					X
RHP**	Reproductive Health Pregnancy Questionnaire	x	x		x		x					X
UPPS-P ⁺	UPPS-P Behavior Scale						x					
SPSRQ ⁺	Sensitivity to Punishment and Sensitivity to Reward Questionnaire						x					
M-CQ ⁺	Monetary-Choice Questionnaire						x					
DERS ⁺	Difficulties in Emotion Regulation Scale						x					
ATQ-EC ⁺	Adult Temperament Questionnaire-Effortful Control						x					
BRIEF	BRIEF Health Literacy Screening Tool											x
CES-D	Center for Epidemiologic Studies Depression Scale, NIMH											x
QEW-5	Questionnaire on Eating and Weight Patterns-5											x
FSSM	U.S. Adult Food Security Survey Module											x

* *In years 7, 9 and 11-14, cohort maintenance and minimal data collection by annual phone call will be performed*


** The AE, INF, MRF, RHP, ICT, HC and UPR forms are completed as needed

* These 5 tests are part of the WebNeuro and Inquisit measures

** Modified BF for year 15

2.5 Coordinator Visit Checklists

EACH site should modify to fit site-specific scheduling for Quest Diagnostics PSC visits; please see example copy below:

		
Teen-LABS STUDY		
Dr. Helmrath IRB# 2016-9583	Quest VISIT CHECKLIST	ParticipantID: _____ Visit Number: _____ Date of Visit: _____

Checklist began on ____/____/____ Coordinator: _____ Participant: _____

SCHEDULING/ STUDY VISIT PREPARATION:

- ☐ Send REDCap link for questionnaires to participant; they should let you know when completed
- ☐ Confirm ClinCard number/expiration date: _____ Needs new ClinCard? Y/N
- ☐ Confirm mailing address, license address, SS#, phone and email information (SHORT form info)
- ☐ Let Jenn know participant is going to Quest; she will create lab orders and email them to you
- ☐ Forward lab orders to participant; CAN THEY PRINT THEM and take to Quest? Y/N
- ☐ Participant to locate closest Quest PSC location: <https://appointment.questdiagnostics.com/patient/confirmation>
- ☐ Create Google Map directions from participant's home address to closest Quest PSC once location is decided
- ☐ Day/time chosen to go? _____ Walk in only; wait times will vary by location/time of day
- ☐ Reminders: Fast for 8 hours before blood draw; do not provide any PHI to Quest, only participant ID and year of birth
- ☐ V120 NEURO TESTS ONLY: Request WebNeuro login/password from Jenn; Inquisit login is participant's ID (ex: CIN1000)
- ☐ Send instructions for neuro tests with passwords to participant, they should let you know when completed
- ☐ Prep packet -> Informed Consent, ClinCard FAQs, replacement ClinCard (if needed), Quest lab orders (if participant can't print them), CI, W-9 form
- ☐ Mail packet to participant
- ☐ Review REDCap questionnaires/forms for completeness; follow up about missing questions; certify each form

DAY OF QUEST VISIT:

- ☐ Follow up with participant or have them let you know they are finished
- ☐ Complete all interview forms if not done before
- ☐ Send ClinCard Payment Request with Google Maps directions to Jenn/Rosie/Kerri
- ☐ Enter study payment amount in Teen-LABS tracking database

When Forms/Consents returned:

- ☐ Review questionnaires/forms for completeness
- ☐ Review the signed Informed Consent w/ participant, complete ICF, and process note
- ☐ Sign/copy w/ MRN in right corner and send to HIM (Ped Surg. Pick up); original to study chart
- ☐ Send the following via secure email to Jenn:
☐ ICF ☐ CI form ☐ W-9 ☐ SHORT Page1

To Complete Study Chart:

- ☐ Save lab results of abnormal Clinical Lab Reports from CEBDATA in participant's electronic Source Document; reply to CEBDATA/Jenn B that you RECEIVED email) -> Forward name of participant to Dr. Helmrath/Linda Kollar, cc: Jenn
- ☐ Request CAF form be completed at time of lab abnormal contact from clinical staff to participant
- ☐ File lab abnormal acknowledgment "Got it" email from medical staff of team
- ☐ Use lab results to complete a blood pressure letter and REDCap ANTH form; file copy of blood pressure letter in electronic Source Document
- ☐ Email or mail a copy of the lab results and the completed blood pressure letter to the participant

Any PROCEDURES NOT OBTAINED:

- ☐ Anthropometrics NOT obtained -REASON: _____
- ☐ Lab samples NOT drawn -REASON: _____
- ☐ Self-assessment forms NOT completed -REASON: _____
- ☐ Other Off Protocol Event -REASON: _____

All elements above completed except for _____

On Date: _____ By: _____

Final signoff that ALL elements for visit were completed:

Coordinator Signature

Date _____

Phone Visit Checklist

Began on ____/____/____ Coordinator: _____ Participant: _____

STUDY VISIT PREPARATION

- ☐ Are they scheduled in EPIC? Reminder of this year's PHONE visit-no mileage compensation.
 - ☐ Possible study visit dates _____ 2) _____ 3) _____
 - ☐ Save INITIAL Teen-LABS ClinCard Payment Request
 - ☐ Start Redcap visit info; Complete SHORT form
 - ☐ Confirm SS#, address on ID, phone number, email, and ClinCard#
 - ☐ Mail consent/W9/CI to subject; ClinCard mailed? ☐ Yes ☐ No Card #: _____
 - ☐ Obtain re-consent/consent process note
 - ☐ Review questionnaires/forms for completeness
 - ☐ Sign/Send Payment Request to Rosie & Jenn. Partial payments? _____
 - ☐ Copy of ICF to HIM w/ MRN on front (Ped. Surg pick up)
 - ☐ Scan & email:
 - ☐ ICF
 - ☐ W-9
 - ☐ CI form
 - ☐ Short Form p.1
 - ☐ Enter study payment amount in database
- To Complete Study Chart:**
- ☐ Complete all documentation
 - CRFs, source documents, checklists, study-related AEs to IRB, etc.
 - ☐ Update Teen-LABS database

Any PROCEDURES NOT OBTAINED & WHY

- ☐ Forms NOT completed—

REASON: _____

- ☐ Other Off Protocol Event—REASON: _____

Document any additional off protocol issues or notes about the visit to consider for next time point.

Final signoff that ALL elements were completed

Coordinator Signature

Date _____

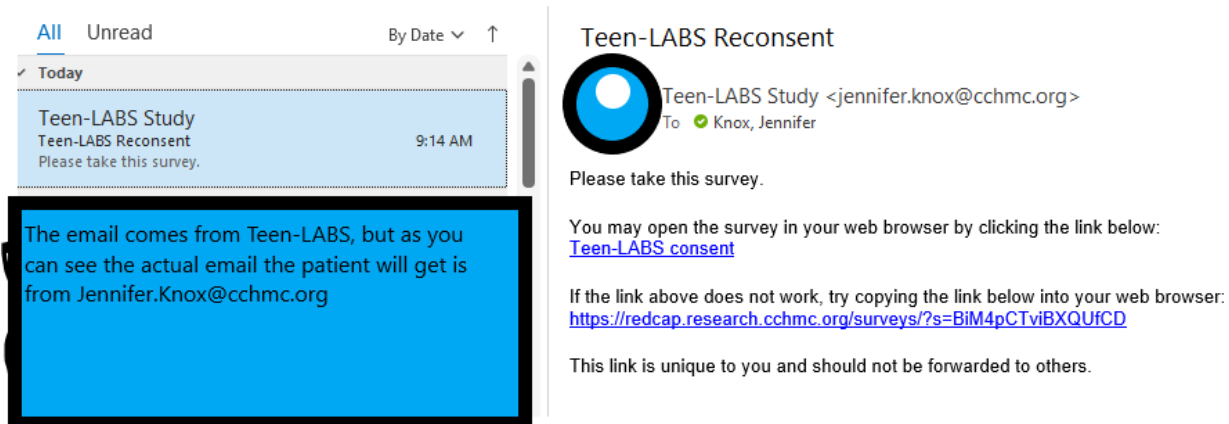
Section 3 – Protocols and Consents




Protocol and Informed Consents are in the regulatory binder and Teen-LABS Dropbox, accessible at <https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwh8QqOmBPYgPzEzChlZla?dl=0> and should be updated accordingly.

Procedure for requesting eConsent for your participant:

1. Send the Study ID and email of participant to Jennifer Knox.
2. The eConsent email will be sent from Teen-LABS Study/Jennifer.Knox@cchmc.org to the participant for them to open and complete, they will need to:
 - a. Select yes or no to consent
 - b. Enter their first name, last name
 - c. Sign their name
 - d. Click the 'Now' button to timestamp their signature
 - e. Once completed and certified, they have the ability to download their signed consent for their records.
3. Once the consent is completed by the participant, an automated email is sent to Jennifer Knox.
4. A REDCap link/survey will be sent to you to complete.
 - a. This survey will be signed/dated after you have reviewed the consent by phone with the participant. A few other questions will be addressed as well.
5. Once completed, the PDF version of the signed consent and your process note will be sent to you and Jenn Black for study records.
6. Complete an ICT (Informed Consent Tracking) form within REDCap.

Below are some screenshots of what the participant or you will see:



1) Do you consent to the study? <small>* must provide value</small>	Yes, I consent to participate in the study ▾
2) First Name: <small>* must provide value</small>	Participant Firstname
3) Last Name: <small>* must provide value</small>	Participant Lastname
4) Participant's Signature By signing this consent form I, _____, certify that I agree to participate in this study. <small>* must provide value</small>	
<div> Add signature</div>	
5) Participant Consent Date <small>* must provide value</small>	<div><input type="text"/> <input type="button" value="Now"/> D-M-Y H:M</div>
<div>Next Page >></div>	

The participant will click the 'Add signature' icon and sign their name on their device, then click the 'Now' button which will timestamp the date/time for their signature, then click 'Next page.'
If the patient does not complete this all at once, the signature and timestamp will not be recorded, and they will be prompted to enter it again.

Teen-LABS consent

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

1 / 8 | 58% | [Icons]

Teen-LABS consent Page 1

The following is an electronic consent for the Teen-LABS research study.

Once we have completed our phone call to review this consent, you can 'sign' and save it for your records.

Thank you!

STUDY TITLE: Adolescent bariatrics: assessing health benefits and risks (Teen-LABS)

STUDY NUMBER: 2016-9583

FUNDING ORGANIZATION: National Institutes of Health - NIDDK

OVERALL Teen-LABS STUDY PRINCIPAL INVESTIGATOR: Thomas H. Inge, MD, PhD

CONTACT PHONE NUMBER: 312-227-4334

VERSION NUMBER: 2.28.2022

INTRODUCTION:

We appreciate your willingness to continue to participate in the Teen-LABS study. As always, your participation is entirely voluntary and if you change your mind and decide not to continue with the study, you will just need to notify us in writing. Ask us any questions you have now or any time in the future.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about what happens following weight loss surgery performed in adolescence.

You have previously participated in Teen-LABS in prior years. We are asking you to continue to participate in the research study to 1) document the long-term safety of weight loss surgery when performed during adolescence, 2) document the effect weight loss surgery has on your weight status as well as physical and psychosocial health over

☒ I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

[<< Previous Page](#) [Submit](#)

The participant has to click the empty box (which becomes a checkmark-shown above) to certify the information, then click Submit.

The next screen the patient will go to, will have the option for the participant to save their signed consent.

Below are screenshots of the survey for the coordinator to complete once the consent has been reviewed by phone. Click on the 'Individual Obtaining Consent' link.

Teen-LABS Signature Page



Teen-LABS Study <jennifer.knox@cchmc.org>

To ● Knox, Jennifer

Please take this survey.

You may open the survey in your web browser by clicking the link below:

[Individual Obtaining Consent](#)

If the link above does not work, try copying the link below into your web browser:

<https://redcap.research.cchmc.org/surveys/?s=A3476fPBBzkZ66RC>

This link is unique to you and should not be forwarded to others.

You will enter your first and last name, click 'Add signature' button to sign on your device, then click the 'Now' button or calendar/clock icons to timestamp your signature. **This signature is to verify you have reviewed the consent by phone, so the date/time should reflect that date/time.**

Individual Obtaining Consent

Resize font: [Survey Queue](#)

1) Username of individual obtaining consent

2) Full name of the individual obtaining consent

3) Signature of individual obtaining consent

[Add signature](#)

4) Timestamp for individual obtaining consent

M-D-Y H:M

Below is the next screen that has multiple questions about your conversation with the participant and reviewing the consent. Once you answer all the questions, you can make a note to include if dates are different, etc in the comment section. You also have the option of uploading the signed consent form and your signature page. However, we will send you the entire file including the signed consent and process note.

Informed Consent Process Note



[Survey Queue](#)

Please complete the survey below.

Thank you!

NOTE: The following PDF of consent is a copy that can be used for alerts and notifications module to email copies of documents. Find the official document in the File Repository. You can tell the difference in documents by looking at the footer. The officially signed document has the signature hash added into the footer. A copy will not have this additional information.

If you want the document to auto-complete into this field, ask the administrators to turn on the Save Survey to PDF external module. Once enabled, configure the completed consent to save in this field location.

1) PDF of Signed Informed Consent

[TeenLABSConsent_2022-03-2... 1120.pdf \(0.1 MB\)](#)

[Upload new version](#) or [Remove file](#)

2) PDF of Signed Individual Obtaining Informed Consent

[IndividualObtainingConsen... 1125.pdf \(0.03 MB\)](#)

[Upload new version](#) or [Remove file](#)

Participant's Name: _____

Date of Birth: _____

MRN: _____

Study ID: STUDY1234

Consent Process Review

3) Reviewed Screener with the participant and verified eligibility prior to consenting?

☐ Yes

☐ No

[reset](#)

4) The participant/LAR was given the opportunity to read the consent document, or the consent document was read to them, explaining details of the research study.

☐ Yes

☐ No

[reset](#)

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

The consents for Teen-LABS are as follows:

- Teen-LABS Participant Adult Consent (all who were former adolescents when enrolled have now aged into adulthood).
- Adult Consent for the Control cohort.

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

Section 4 – Quality Control, Data Collection and Management

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.

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;
- 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:

- 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;
- Regular review of monthly reports generated by the DCC:
 - Central Study Coordinator will send priority report and retention reports to study sites to utilize for identifying participant visits that are due; coordinators will provide

an update in the column “CRC Comments” to note status of the visit and efforts that have been made to contact the participant (phone call, voicemail, email, text, letter sent, etc.) including dates of attempted and completed contacts.

- DCC also requests coordinators to provide completed visits on a monthly basis, including participant ID, date visit completed, and visit timepoint.

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 trained and certified in the relevant portions of the protocol. 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 of 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/AABEwht8QqOmBPYgPEzChIZla?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;

4) Observe a protocol-certified coordinator recruit and obtain patient consent or re-consent a patient.

4.3 Data Collection and Management

4.3.1 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 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, sending the data to the DCC via secure email or secure Fax, and addressing data queries.

4.3.2 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. 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.

4.3.3 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.

4.3.4 Data Forms and Database

The data collection forms initially were created using TeleForm[®]. TeleForm[®] is a software application that automates data capture. Teleforms were sent electronically to each clinical site in PDF format for printing and completion. Data collection forms that were originally created in TeleForm have been recreated in REDCap for electronic collection of the same data. The Site Coordinator will be responsible for completing all necessary forms for each subject at each visit and entering data into REDCap database in a timely fashion.

The REDCap system has a data quality module which allows for real time edit checks within the database using range validations, missing data, etc. Queries will be issued as needed and forwarded to the site coordinators accordingly directly from the DCC or REDCap. The Data Quality Plan also allows for SAS program checks outside of the system for data outliers and other discrepant data. These discrepancies will also be queried via REDCap or directly from the DCC to site coordinators.

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 calls with the PI's at each clinical site. Executive committee calls will be planned bi-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.

REDCap Data Entry Guidelines document is available via Teen-LABS Dropbox at:
<https://www.dropbox.com/sh/5z5z4ljuypgtapp/AABEwh8QqOmBPYgPEzChIZla?dl=0>

4.3.5 Data Storage

All paper forms were previously stored under lock and key in file cabinets kept in the DCC offices. Only study personnel had 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. PHI data (social security number, phone numbers, social networking site contacts, e-mail addresses, home address) will be stored in protected databases at Lurie and CCHMC which are on network servers that are backed up nightly.

4.3.6 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.

4.3.7 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, UAB, 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.***

4.3.8 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 as needed.

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.

4.3.9 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.

4.3.10 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.

4.3.11 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.

4.3.12 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.

4.3.13 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.

4.3.14 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 5 – Specimen Collection

5.1 Instructions for sending participants to complete a visit at a Quest Patient Service Center (PSC) location:

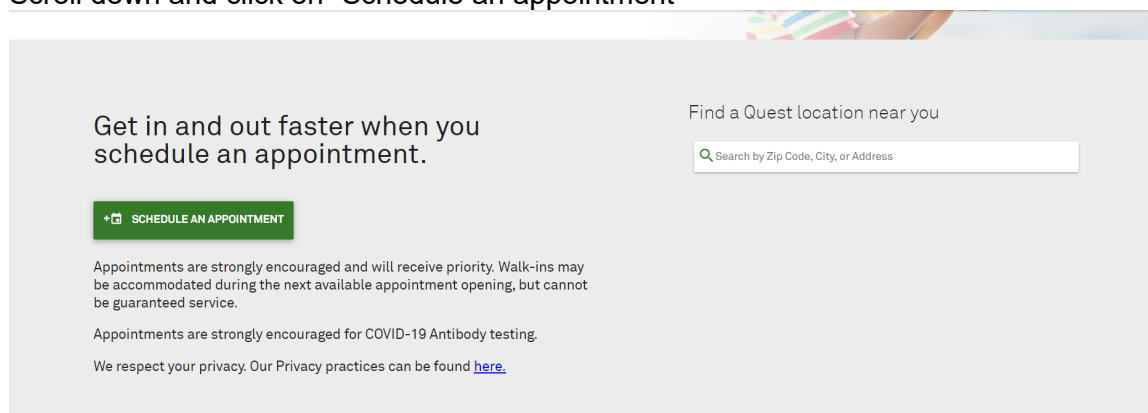
1. Request lab orders from Central Study Coordinator or Deputy Central Study Coordinator (example copy provided at the end of this section)
2. Save Lab Order Confirmation Letter as a PDF document to email or mail to participant
3. Participant will need to bring a printed paper copy of the PDF Lab Order Confirmation Letter to complete their lab work at a PSC.
4. Participant will need to check in with their name and date of birth that was used for scheduling the appointment online. For their lab work, they will use the de-identified information provided on the 2nd page of the lab orders:
 - a. De-identified first name will be Teen-LABS ID with numbers only (ex: 1000)
 - b. De-identified last name will be Teen-LABS ID with numbers only (ex: 1000)
 - c. DOB will be 1/1/participant's year of birth (ex: 1/1/1980)
 - d. Patient ID will be participant's full Teen-LABS ID (ex: CIN1000)

Please advise participants to not provide any PHI (name, DOB, phone number) even if the PSC asks for it; participants can inform the PSC that they are participating in a research study and Quest is not permitted to have their actual name, DOB or phone number (PHI) and only the information that is on the order set can be used and is linked to the barcode.

Participants can schedule an appointment online for a Quest PSC, however, they will need to enter their personal information only for scheduling purposes. They will use the printed lab orders with de-identified information for their appointment upon checking in at the PSC. Please see information below on how to schedule a Quest appointment online.

Coordinators will use the participant's lab results to complete the ANTH form in REDCap and use Quest's certification number 3333 for the form since the anthropometrics were collected by Quest. Coordinators will also complete a blood pressure notification letter (template included at the end of this section) based on the participant's lab results and mail/email a copy of the letter and the participant's FINAL lab results to each participant. REDCap will need to be updated that the blood pressure letter was mailed.

To find the closest Quest PSC location, view the days and hours that the location is open and schedule an appointment, go to: www.QuestDiagnostics.com/psc
Scroll down and click on "Schedule an appointment"



The screenshot shows the Quest website's appointment scheduling page. On the left, there is a green button labeled "SCHEDULE AN APPOINTMENT" with a calendar icon. Below it, text states: "Appointments are strongly encouraged and will receive priority. Walk-ins may be accommodated during the next available appointment opening, but cannot be guaranteed service." and "Appointments are strongly encouraged for COVID-19 Antibody testing." At the bottom, it says "We respect your privacy. Our Privacy practices can be found [here](#)." On the right, there is a section titled "Find a Quest location near you" with a search bar labeled "Search by Zip Code, City, or Address".

Click on “All Other Tests” for the question “To get started, please selection your reason for visiting.”

←

To get started, please select your reason for visiting.

COVID-19 Test ⓘ COVID-19 Antibody Test ⓘ

Employer Drug and Alcohol ⓘ Employer Health and Wellness ⓘ

Glucose ⓘ Purchased a Test From QuestDirect ⓘ

T-SPOT.*TB* test (tuberculosis) ⓘ **All Other Tests** ⓘ

Specimen Pickup/Dropoff ⓘ

Appointment details

- 1 Reason for visiting
All Other Tests
- 2 Location, date, and time
- 3 Who's visiting
- 4 Insurance information

Continue

[Previous](#)

Enter zip code, city or address to search for closest location (if a location cannot be found, try searching using the closest large city; contact the Central Study Coordinators if there are any issues finding a location nearby):

← → ↻ appointment.questdiagnostics.com/patient/appointment

Quest Diagnostics NEED HELP? ~ CREATE ACCOUNT

Schedule Appointment

✓ REASON FOR VISIT TESTING LOCATION SCHEDULE

TESTING LOCATION

🔍 Search by Zip Code, City, or Address

Show Map ▾

Select where you'd like to go for your testing

Choose the preferred location from the list of options (can also click on “Show Map” to see locations). Other lab names will possibly appear in the results-only choose a designated ‘Quest Diagnostics’ location to ensure proper execution of appointment and our study needs:

✓ REASON FOR VISIT

TESTING LOCATION

SCHEDULE

TESTING LOCATION

Q Avondale, OH 45229, USA

Show Map

Select where you'd like to go for your testing

2.3 mi

1. Quest Diagnostics - Steger Drive
6700 Steger Dr First Floor, Cincinnati, OH 45237

Open: 8:00 AM-1:00 PM,
2:00 PM-3:30 PM

0 minute wait for walk-in patients

9.5 mi

2. Quest Diagnostics - Inside Walmart on Colerain
10240 Colerain Ave, Cincinnati, OH 45251

Open: 7:30 AM-4:00 PM

0 minute wait for walk-in patients

Once a location has been selected, note the days and hours the location is open and choose a date from available options, then choose a time from the dropdown options on the date:
Schedule Appointment

✓ REASON FOR VISIT

✓ TESTING LOCATION

SCHEDULE

< September 2021 >

Sun	Mon	Tue	Wed	Thu	Fri	Sat
29	30	31	1	2	3	4
5	6	7 1 Available	8 17 Available	9 19 Available	10 15 Available	11
12	13 23 Available	14 28 Available	15 27 Available	16 26 Available	17 19 Available	18
19	20 28 Available	21 24 Available	22 28 Available	23 26 Available	24 25 Available	25

Participant will enter their personal information to schedule an appointment:

Who is coming in for this testing?

First Name*

Last Name*

Date of Birth

Month*

Day*

Year*

Phone Number*

Type*

Mobile

Landline

Email Address*

How would you like to receive notifications about your appointment? *

Email

Text

By choosing text, you agree to receive texts/calls, including by autodialed or prerecorded means, regarding this and future appointments, your account or Quest Diagnostics services at the number you provide. Consent is not a condition of purchasing any goods/services. Normal charges may apply.

SCHEDULE APPOINTMENT

Participant’s personal information is only for scheduling purposes; they will use the lab orders with de-identified information for their appointment upon checking in at the PSC.

Example copy of lab orders (2 pages):



STL-73916921-0000050

Lab Order Confirmation



The Teen-LABS Study Principal Investigator has electronically sent an order for your lab tests to Quest Diagnostics. Please take these pages to a Quest Diagnostics Patient Service Center to have your lab work collected.

To locate a Patient Service Center, visit our website at www.QuestDiagnostics.com/psc

Please remember to:

- ✓ Wear sleeves that roll up easily (optional).
- ✓ Fast from everything except water for 8 hours prior to lab work if possible.

Instructions for Quest Diagnostics Patient Service Center Staff:

- These are de-identified patients.
- Please use the Patient ID on the requisition and not the patient names.
- Please do not enter any patient demographics.
- Account is client bill.
- Diagnosis codes are not needed.
- If there are any questions, please consult with your manager or contact the study coordinators at 513.516.0947 or 513.498.0989

Order Confirmation Information

Patient: 1000, 1000
DOB: 01/01/1980
Patient ID: CIN1000
Physician/UPIN: Inge, Thomas H (1619946407 H22286)
Client: Univ Of Co-Teen Labs Study (73916921)
Date: 01/01/2021
Requisition #: 0000035

Test Codes: 7600 Lipid Panel, Standard
6517 Albumin, Random Urine With Creatinine
10231 Comprehensive Metabolic Panel
6399 Cbc (Includes Differential And Platelets)
482 Gamma Glutamyl Transferase (Ggt)
5616 Iron, TIBC And Ferritin Panel
457 Ferritin
927 Vitamin B12 (Cobalamin)
466 Folate, Serum
17306 Vitamin D, 25-Hydroxy, Total, Immunoassay
496 Hemoglobin A1C
10124 Hs-Crp
921 Vitamin A (Retinol)
35202 Pth, Intact Without Calcium
561 Insulin
94588 Cystatin C With Glomerular Filtration Rate, Estimated (Egfr)
891 Transferrin
5042 Vitamin B1 (Thiamine), Blood, Lc/Ms/Ms
19690 Weight
19689 Height
19691 Blood Pressure

Diagnosis Codes:

Example information that sites can modify and submit to IRB for approval to send to participants with the Quest lab orders:

March 15, 2024

Dear participant,

Thank you for your participation in the Teen-LABS Study! We are so glad you decided to complete your visit at a Quest Diagnostics Laboratory location.

Below are some helpful hints to make your visit with them quick and simple:

- **Fast from everything except water for 8 hours prior to your lab work if possible.**
- Locate your nearest Quest Patient Service Center:
<https://appointment.questdiagnostics.com/patient/confirmation>
- Let your coordinator know what day/time you plan to go to Quest and the address of the location so that we may assist if any problems arise.
- You can schedule an appointment online using your name. This will also be used at check in at the site on a kiosk.
- Your coordinator will email you lab orders to **print and take with you.**
- Quest will only use your participant ID and year of birth as identifiers to your specimen.
- Let your coordinator know when your visit is finished.

Sincerely,

Clinical Research Coordinator

Phone, email, address

Example Quest Visit Checklist:

Checklist began on ____/____/____ Coordinator: _____ Participant: _____

SCHEDULING/ STUDY VISIT PREPARATION:

- ☐ Send REDCap link for questionnaires to participant; they should let you know when completed
- ☐ Confirm ClinCard number/expiration date: _____ Needs new ClinCard? Y/N
- ☐ Confirm mailing address, license address, SS#, phone and email information (SHORT form info)
- ☐ Let Jenn know participant is going to Quest; she will create lab orders and email them to you
- ☐ Forward lab orders to participant; CAN THEY PRINT THEM and take to Quest? Y/N
- ☐ Participant to locate closest Quest PSC location:
<https://appointment.questdiagnostics.com/patient/confirmation> and recommend to schedule an appointment online
- ☐ Create Google Map directions from participant's home address to closest Quest PSC once location is decided
- ☐ Day/time chosen to go? _____
- ☐ Reminders: Fast for 8 hours before blood draw; do not provide any PHI to Quest, only participant ID and year of birth
- ☐ V120 NEURO TESTS ONLY: Request WebNeuro login/password from Jenn; Inquisit login is participant's ID (ex: CIN1000)
- ☐ Send instructions for neuro tests with passwords to participant, they should let you know when completed
- ☐ Prep packet -> Informed Consent, ClinCard FAQs, replacement ClinCard (if needed), Quest lab orders (if participant can't print them), CI, W-9 form
- ☐ Mail packet to participant
- ☐ Review REDCap questionnaires/forms for completeness; follow up about missing questions; certify each form

DAY OF QUEST VISIT:

- ☐ [Follow up with participant or have them let you know they are finished](#)
- ☐ Complete all interview forms if not done before
- ☐ Send ClinCard Payment Request with Google Maps directions to Jenn/Rosie/Kerri
- ☐ Enter study payment amount in Teen-LABS tracking database

When Forms/Consents returned:

- ☐ Review questionnaires/forms for completeness
- ☐ Review the signed Inform Consent w/ participant, complete ICF, and process note
- ☐ Sign/copy w/ MRN in right corner and send to HIM (Ped Surg. Pick up); original to study chart
- ☐ Send the following via secure email to Jenn:
☐ ICF ☐ CI form ☐ W-9 ☐ SHORT Page1

To Complete Study Chart:

- ☐ Save lab results of abnormal Clinical Lab Reports from CEBDATA in participant's electronic Source Document; reply to CEBDATA/Jenn B that you RECEIVED email)→ Forward name of participant to Dr. Helmrath/Linda Kollar, cc: Jenn
- ☐ Request CAF form be completed at time of lab abnormal contact from clinical staff to participant
- ☐ File lab abnormal acknowledgment "Got it" email from medical staff of team
- ☐ Use lab results to complete a blood pressure letter and REDCap ANTH form; file copy of blood pressure letter in electronic Source Document
- ☐ Email or mail a copy of the lab results and the completed blood pressure letter to the participant

Any **PROCEDURES NOT OBTAINED:**

☐ **Anthropometrics NOT obtained –REASON: -**

☐ **Lab samples NOT drawn—REASON:**

☐ **Self-assessment forms NOT completed—REASON:**

☐ **Other Off Protocol Event—REASON:**

All elements above completed except for _____

On Date: _____ By: _____

Final signoff that ALL elements for visit were completed:

Coordinator Signature

Date _____

Blood pressure notification letter template:

Teen



I.D. #:

PLACE IDENTIFICATION LABEL HERE

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[†]:

- ☐ Normal (<120mmHg)
- ☐ Elevated (120-129)*
- ☐ Hypertension, stage 1(130-139)**
- ☐ Hypertension, stage 2 (≥140)***

Your **Diastolic Blood Pressure** is[†]:

- ☐ Normal (<80 mmHg)
- ☐ Hypertension, stage 1 (80-89)**
- ☐ 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

MOP Updated 05/05/2022

Quest test codes and test descriptions:

Test Code	Test Description
7600	Lipid Panel
6517	Microalbumin (Urine) w/ Creatinine
10231	Comprehensive Metabolic Panel
6399	CBC with Diff/Plt
482	GGT
5616	Iron, TIBC, Ferritin Panel
457	Ferritin
927	Vitamin B12
466	Serum Folate
17306	Vitamin D, 25-OH, Total
496	Hemoglobin A1c
10124	hs - CRP
921	Vitamin A
35202	Parathyroid hormone (PTH)
561	Insulin
94588	Cystatin C
891	Transferrin
5042	Vitamin B1 (Thiamine), Blood, LC/MS/<S
19690	Weight
19689	Height
19691	Blood Pressure

5.2 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 Quest as the specimens are received. Quest reports all laboratory values as soon as they are available. The DCC data manager will regularly send abnormal lab reports to the respective site PI where the participant was enrolled within one business day of receipt from the Quest Central Laboratory and request a receipt notification from each PI. The confirmation acknowledgement from the site coordinator that the report has been received is saved in the DCC study files and tracked in REDCap to assure the abnormal results are acted on per clinical protocol at each institution.

Coordinators will complete a blood pressure notification letter (template previously included above) based on the participant's lab results and mail/email a copy of the letter and the participant's FINAL lab results to each participant. REDCap will need to be updated that the blood pressure letter was mailed.

The DCC does not obtain any follow-up information regarding any intervention on the part of the site to address the results.

Section 6 – Bone Density

6.1 Overview

Teen-LABS participants at study sites with a Hologic DXA machine (CCHMC, Nationwide, and Baylor) will be invited to undergo bone health assessment by DXA at 2 study visits.

- The first DXA visit:
 - ❖ Optimally, this DXA visit should be as close as possible to the 72, 96, and 120-month visits so that corresponding ANTH, FX and IPAQ data are included.
 - ❖ DXA visits can be completed during 84, 108, 120 backup and 132-month visits if necessary
 - ❖ The first DXA visits will occur through August 31, 2022.
- The second DXA visit:
 - ❖ Optimally, data collection should occur as close as possible to the 180-month visit.
 - ❖ DXA visits can be completed during visits 156, 168, 180 and 192 months as long as there is a minimum of 4 years between the first and second DXA visits.

Control participants (n=100) will be recruited from the community at the CCHMC, Nationwide and Baylor sites in proportion to number of surgical participants at that site.

- Control participant visits will occur through August 31, 2022.
- Control participant ID numbers - Hospital code will begin with CIN12XX for Cincinnati, NCH52XX for Nationwide, and BCM42XX for Baylor as assigned by coordinator.
- Individuals on medications or with medical conditions known to have strong effects on BMD will be excluded (see exclusion criteria below).

6.2 Eligibility

6.2.1 Inclusion criteria

Bariatric Surgery Cases

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: 6-11.5 for first DXA visit, and 13-16 years since surgery for second DXA visit with a minimum of 4 years between DXA scans. Participants who did not have a DXA visit between 6-11.5 years post-surgery are still eligible to have a DXA visit at 13-16 years post-surgery.

Non-surgical Controls

Control participants will be recruited such that the mean age, sex, race and BMI are similar to the age and BMI of case participants at the first DXA visit. Based on data from 2017, we will recruit participants with the following characteristics:

Sex: 75% females, 25% males

Age: 20-30 years

BMI: 25-60 kg/m²

Race: 68% white, 32% non-white

We will recruit 100 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 numbers will be adjusted per the characteristics of the surgical

participants recruited. The DCC will examine the age and BMI distributions periodically through recruitment to ensure that the mean age and BMI distributions are like surgery patients and adjust recruitment targets to achieve this goal.

We calculated recruitment goals based on the existing Teen-LABS participants and controls recruited to date. Each center has specific recruitment goals for females and males for a specific BMI category and race. 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.

Final Control participants needed by clinical center, age, sex, race, and BMI as of March 8, 2022

BCM 10 total		
Age: 25-33 years		
BMI	White*	black
females		
20-29	1	0
30-39	1	1
40-49	2	2
50-65	1	1
total	5	4
males		
20-29	0	0
30-39	1	0
40-49	0	0
50-65	0	0
total	1	0

NCH 7 total		
Age: 23-31 years		
BMI	White*	black
females		
20-29	0	0
30-39	3	0
40-49	2	0
50-65	0	0
total	5	0
males		
20-29	1	0
30-39	0	0
40-49	0	0
50-65	1	0
total	2	0

CCHMC 6 total		
Age: 22-28 years		
BMI	White*	black
females		
20-29	0	0
30-39	2	0
40-49	0	1
50-65	2	1
total	4	2

* 'White*' should include all NIH race categories except black and black/non-black mixed race.

6.2.2 Exclusion criteria

- Non-ambulatory, wheelchair bound
- Medical conditions:

Cushing syndrome	hyperthyroidism
hypogonadotropic hypogonadism	leukemia
lymphoma	osteogenesis imperfecta
panhypopituitarism	primary ovarian failure
primary hyperparathyroidism	syndromic and genetic forms of obesity
- Medications:
 - bisphosphonate medications - current or historical use
 - systemic prednisone of >5 mg/day or equivalent for >3 months in the last year
 - anti-epileptic medication such as phenytoin or carbamazepine in the last year
 - 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 3 years, or prior use > 24 months in total
- Exceeds DXA table weight limits (i.e., 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 in one region, then it will not be scanned, but all other regions will be scanned.

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 Heidi Kalkwarf Heidi.kalkwarf@cchmc.org and Halley Wasserman Halley.wasserman@cchmc.org regarding questions about eligibility of specific medications and medical conditions.

6.2.3 Recruitment Strategies for Surgery and Control participants

Bariatric surgery cases

The DCC statisticians have identified the optimal study visits for bone measurements and communicated this to the sites. Please see section 6.1 above for specific details. The study coordinators are then responsible for assessing eligibility.

Non-surgical controls

Recruitment of non-surgical participants will occur within funding cycle 3 ending August 31, 2022. 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 jennifer.knox@cchmc.org for CIN

614-722-4712 or lauren.pavlechko@nationwidechildrens.org for NCH

832-506-4436 or citrine.elatrash@bcm.edu 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.

6.2.4 Screening

6.2.4.1 Surgery cases

Study staff will tell surgery cases about the new bone component when they are coordinating a follow-up Teen-LABS visit. Based on directions from the DCC, the study coordinators will assess eligibility of surgery participants when coordinating their study visits. Some of the information on

the DXA screening form (available at the end of this chapter) 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.

Some surgery cases may be ineligible at the time of screening, but their eligibility status could change during 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 a midyear timepoint or annually depending on what their reason for ineligibility was.

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

6.2.4.2 Control participants

A pre-visit screening interview will take place via REDCap and/or over the phone to rule out any exclusion criteria using the DXA screening form. The pre-visit 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. 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 pre-visit screening of control participants will be collected 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 study'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

6.3 Enrollment and Study Visit

Participants will arrive at the specified location on the day of their scheduled study visit. The coordinator will meet the subject and describe the study to the participant, and they will be given the opportunity to ask questions regarding the study. The 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 confirm eligibility criteria from the pre-visit screening 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 at the scheduled study visit are considered a screen fail. For controls, the visit is closed.

Controls: For controls who show up for a DXA visit and sign the consent form, the EF “Enrollment Form” and “DXA Visit Info Form” should be completed within REDcap. 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. These are located within REDcap.

Anthropometric Measurements (ANTH)

Height, circumferences, and Tanita measurements of surgery cases and controls will be obtained (3x)_by Teen-LABS certified research staff as described previously and recorded on the ANTH form.

Participant Medical and Reproductive History (MH)

Information on medical and reproductive history of control participants will be obtained on the Medical and Reproductive History form specific to Control participants. 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 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

- 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

- Dr. Heidi Kalkwarf will provide a DXA result letter (at least every 3 months or sooner) to the coordinators for each participant after the scans have been sent to CCHMC and analyzed (see section 6.8 below). The coordinators will fill in the necessary PHI, keep a copy of the letter, send the original letter to the participant with site PI signature, 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 this section.

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 6.4.

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 on paper and/or within REDCap surveys. Data will be 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 (<i>Cincinnati at first DXA visit only; will not be done at any second DXA (15 year) visits</i>)	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 (surgical and non-surgical controls) will receive \$100 as compensation for participating in the bone study.

Surgical participants are also eligible to receive compensation for travel to a clinic site to complete a DXA scan. The compensation will be based on round trip distance from the participant's home to the clinic site. 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

6.4 DXA Measurements

6.4.1 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.

6.4.2 Subject Registration in DXA Machine

Please follow instructions 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	<i>Leave blank</i>		
Middle initial	<i>Leave blank</i>		
ID	<i>Leave blank</i>		
Identifier 2	<i>Leave blank</i>		

Sex		As usual	Female
DOB		As usual	January 16, 1990
Menopause age	<i>Leave blank</i>		
Weight	<i>Leave blank</i>		
Height	<i>Leave blank</i>		
Ethnicity		Select Black or white	white
Referring Physician	Used to identify the study	Short study name	TeenLabs3
Patient comment	<i>Leave blank</i>		

Always get the subject's initials and ID number from the Study Coordinator to ensure consistency. Be sure to use zeroes (0) 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	<i>Leave blank</i>	
Weight	<i>Leave blank</i>	
Scan Comment	<i>Leave blank</i>	

Patient ID:
 Accession Number:

 Scan ID: A0802170N
 Operator:
 Weight: kg
 Height: cm
 Body Mass Index:
 Scan Comment:

Figure 2. Scan properties page.

6.4.3 DXA Scan Acquisition

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.**
- 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.

6.4.4 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 Scan Type:

AP Lumbar Spine
Left Hip
Right Hip
Left Forearm
Right Forearm
Whole Body
AP/Lateral
Dual-Hip

Patient Name: 001.LM
Patient ID:

☒ Use Default Scan Mode

<< Back Next >> Cancel

- Select AP Lumbar spine scan and press next.

Select Scan Type:

AP Lumbar Spine
Left Hip
Right Hip
Left Forearm
Right Forearm
Whole Body
AP/Lateral
Dual-Hip

Patient Name: 001.LM
Patient ID:

☐ Use Default Scan Mode

<< Back Next >> Cancel

- Select Array (a) and then next.

Select AP Lumbar Spine Scan Mode:

High Definition (h)
Array (a)
Fast Array (f)
Express (x)

Patient Name: 001.LM
Patient ID:

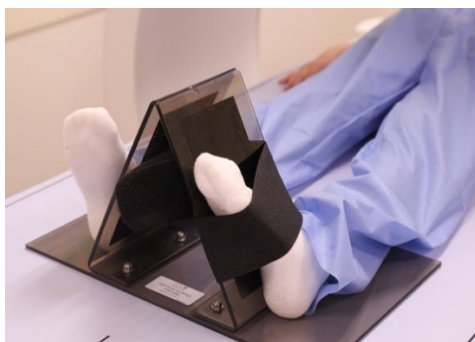
<< Back Next >> Cancel

- Keep the scan width and length set to the default settings.
- Make sure that the participant is centered on the tabletop. 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.

6.4.5 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.

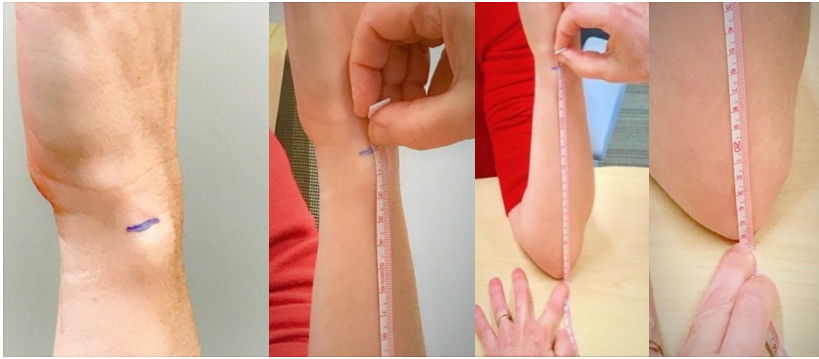


- If the participant has a fat pannus, have them hold it back toward the abdomen so that it does not lie over the hip region. Overlapping fat tissue alters the DXA results making them invalid.
- Repeat scan in the event of movement or poor positioning. Do not make more than 3 attempts to acquire a satisfactory scan.

6.4.6 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.

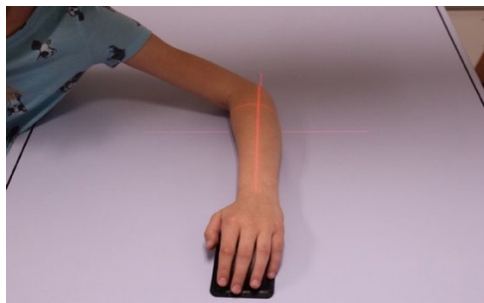
Measure forearm length from the top of the ulnar styloid (“bump” on the pinky side of the wrist) to the tip of the olecranon process (elbow) using a non-stretchable tape measure. The elbow should be placed on a flat, firm surface with the forearm extended vertically. The zero mark on the tape measure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



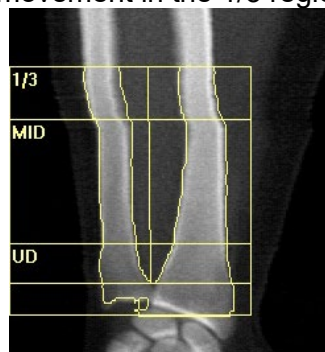
The tape measure is extended along the length of the forearm and read at the tip of the olecranon, which is on the flat surface. The forearm length should be documented on the DXA performance form. The measurements should be made in triplicate. This information is **required** for analysis of the forearm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

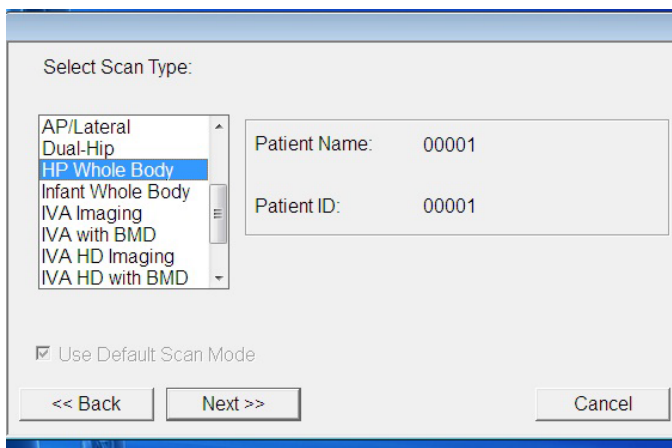


- Inspect the image as it is being acquired. Abort the scan if positioning is incorrect or movement is detected. In a good forearm scan, the arm is centered, the forearm bones are parallel to the long axis, there is no movement in the regions of interest
- Repeat scans in the event of movement or poor 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.



6.4.7 Whole Body Scan

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



Select Scan Type:

AP/Lateral
Dual-Hip
HP Whole Body
Infant Whole Body
IVA Imaging
IVA with BMD
IVA HD Imaging
IVA HD with BMD

Patient Name: 00001
Patient ID: 00001

☒ Use Default Scan Mode

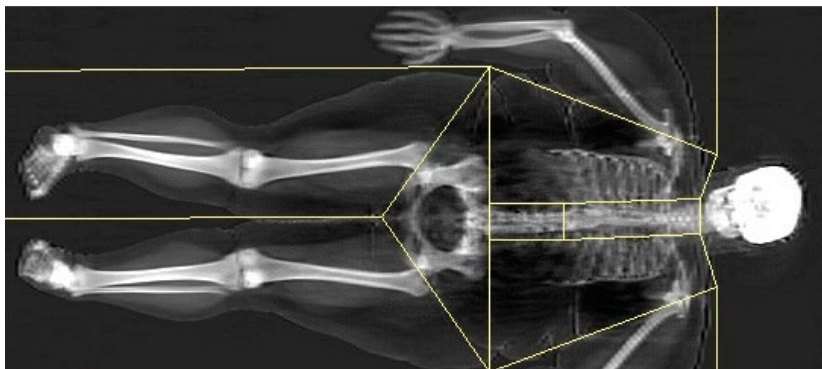
<< Back Next >> Cancel

- 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.



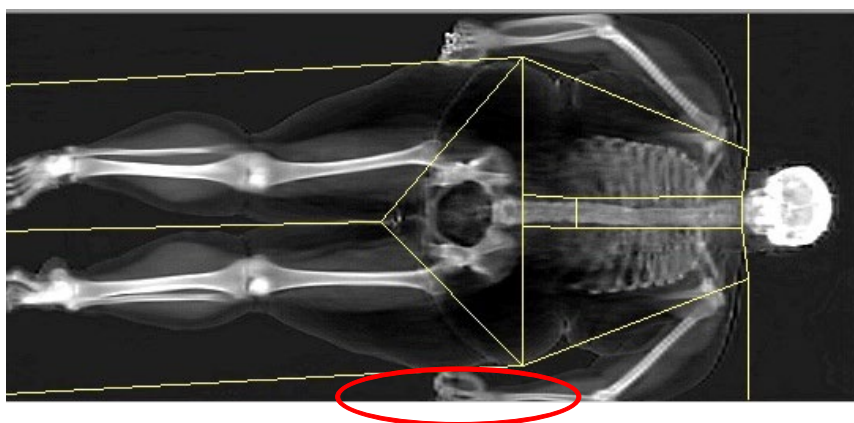
CORRECTLY POSITIONED WHOLE BODY SCAN – LEAN PARTICIPANT
Correct alignment: head straight, feet together, palms flat on table.

- 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.

6.5 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.

6.6 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 a set of DXA scans is 87.7 micro-Sieverts. This is comparable to approximately 11 days of background radiation. TL participants who have 2 DXA visits will have a maximum of approximately 22 days of background radiation across both visits.

6.7 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.

6.8 Transferring Scan Images to CCHMC for Analysis

Raw scan images should be copied to a CD (or sent electronically via secure email/portal as designated by Dr. Heidi Kalkwarf) and sent with a paper copy of the completed DXA Performance Form (include forearm length on the form) via FedEx to the DXA laboratory at CCHMC within 1 month after the scan is obtained. Prior to shipping, send FedEx tracking number via email to: Suzanne.Summer@cchmc.org and copy cebddata@cchmc.org. All scan analysis will be performed at CCHMC.

Send all Images to:

Cincinnati Children's Hospital Medical Center
Suzanne Summer, T2.245
240 Albert Sabin Way
Cincinnati, Ohio 45229-3039
Phone: (513) 636-0456

6.9 Peripheral QCT Scans (this will not be done for any 15 year DXA 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: <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u>
Address:	Email:
Contact Number:	Date: <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> <u> </u>
Availability:	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?	<input type="checkbox"/> No <input type="checkbox"/> Yes
	What is your date of birth?	<u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> <u> </u> 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?	<input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Refused
	Do you consider yourself to be Hispanic or Latino?	<input type="checkbox"/> No <input type="checkbox"/> Yes
	What is your sex?	<input type="checkbox"/> Male <input type="checkbox"/> Female

2. recruitment needs	Exclude based on recruitment needs? <input type="checkbox"/> No <input type="checkbox"/> Yes , but may be re-screened at another time
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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? <i>**If ineligible for this reason, may re-screen at another time</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes
4. lactating	Are you currently breastfeeding or have been breastfeeding in the last 6 months? <i>**If ineligible for this reason, may re-screen at another time</i>	<input type="checkbox"/> No	<input type="checkbox"/> 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? <i>**If ineligible for this reason, may re-screen at another time</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes

Resume questions for males and females			Exclude
6. wheelchair	Do you require a wheelchair to get around?		
7. chemotherapy	Have you had chemotherapy? <i>If yes, then go to question 7a. If no, go to question 8.</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes*
7a.	Have you received chemotherapy in the last year?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
7b.	Did you ever take methotrexate?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
	<i>If responded YES to 7, but NO to 7a and 7b, patient is eligible for the study.</i> <i>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</i>		
8. radiation	Have you received radiation therapy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes

9. metal hardware	<p>Controls: Do you have orthopedic hardware, like rods, pins or plates, that cannot be removed anywhere in your body? <input type="checkbox"/> No <input type="checkbox"/> Yes <i>if yes, then ineligible</i></p> <p>Surgery cases: Do you have orthopedic hardware, like rods, pins or plates, that cannot be removed in your:</p> <p>spine <input type="checkbox"/> No <input type="checkbox"/> Yes both hips <input type="checkbox"/> No <input type="checkbox"/> Yes both wrists <input type="checkbox"/> No <input type="checkbox"/> Yes <i>If yes to all (spine, both hips & both wrists), then ineligible</i></p>	<input type="checkbox"/> No	<input type="checkbox"/> 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	<input type="checkbox"/> No	<input type="checkbox"/> Yes
11. anti-epileptics	Anti-epileptic drugs such as Phenytoin (Dilantin) or Carbamazepine (Tegretol) - for seizures. Acceptable medications include Zonisamide	<input type="checkbox"/> No	<input type="checkbox"/> Yes
12. Prednisone	<p>Oral prednisone with a dose of $\geq 5\text{mg/day}$ for > 3 months in the last year? <i>(or equivalent)</i> Prednisone may be used long term for a variety of inflammatory conditions, such as arthritis, inflammatory bowel disease, lupus.....</p> <p>One or 2 dose packs for poison ivy does not exclude you from participating. <i>**If ineligible for this reason, may re-screen at another time</i></p>	<input type="checkbox"/> No	<input type="checkbox"/> Yes
13. Heparin	<p>Heparin for >3 months in the last year - for blood clots <i>**If ineligible for this reason, may re-screen at another time</i></p>	<input type="checkbox"/> No	<input type="checkbox"/> Yes

MEDICAL CONDITIONS “Have you ever been diagnosed with the following:”		Exclude
14. Osteogenesis Imperfecta/Brittle Bone Disease	<input type="checkbox"/> No	<input type="checkbox"/> Yes
15. Hypogonadotropic hypogonadism	<input type="checkbox"/> No	<input type="checkbox"/> Yes
16. Pan hypopituitarism	<input type="checkbox"/> No	<input type="checkbox"/> Yes

17. Primary hyperparathyroidism	<input type="checkbox"/> No	<input type="checkbox"/> Yes
18. Primary ovarian failure	<input type="checkbox"/> No	<input type="checkbox"/> Yes
19. Hyperthyroidism	<input type="checkbox"/> No	<input type="checkbox"/> Yes
20. Cushing Syndrome	<input type="checkbox"/> No	<input type="checkbox"/> Yes
21. Syndromic Obesity (e.g., Prader-Willi Syndrome, Cohen Syndrome, Bardet-Biedl Syndrome, POM-C mutations, MC4R mutations)	<input type="checkbox"/> No	<input type="checkbox"/> Yes
22. Leukemia or lymphoma	<input type="checkbox"/> No	<input type="checkbox"/> 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: _____

Sample Control/DEXA Visit Checklist

Checklist began on: ____/____/____ **Coordinator:** _____

STUDY VISIT PREPARATION

- ☐ Paper screening form from Redcap, review study/send consent
Availability: _____
- ☐ Schedule visit, grouping multiple if possible
- ☐ Update Enrollment Form and deidentified spreadsheet
- ☐ Enter in EPIC for MRN? Associate patient to study.
- ☐ Do they need a split appt?

ORDERS

- ☐ Prepped, signed by Linda
- ☐ Scanned to e-source
- ☐ Emailed to SRC Scheduling day before (SRCscheduling@cchmc.org)

SCHEDULING PROCEDURES in EPIC

- ☐ Schedule in EPIC for Study Visit w Bionutrition (30min) and DEXA/pQCT (60min) **Time:** _____
 - Appointments (look up patient)
 - Make appointment (visit ~60 minutes) *No MONDAY/late appts unless advance notice (6:45a-2:45p)
 - Appointment notes : RESEARCH ONLY, CTRC Protocol # 1024, CRC Name and number
 - Urine test complete-Positive? ☐ No ☐ Yes
 - Referring (CCHMC, Research)
 - Encounter Information (TLC, Research Only)
 - Attending (Helmrath)
- ☐ Add visit on the pedobesitybank calendar and invite: other coordinator
- ☐ Reminder call to family of agenda

DAY OF VISIT PAPERWORK

- ☐ Review/Sign/Give copy of consent
- ☐ Issue Clincard
- ☐ CRF's- see side box→
- ☐ Copy of orders
- ☐ Consent process note
- ☐ Payment request

AFTER VISIT PROCEDURES

- ☐ Obtain completed orders from CTRC
- ☐ Finish all CRFs & source info
- ☐ Enter data in REDCap
- ☐ AE's & deviations reported to Project Manager
- ☐ Scan and save ALL DOCUMENTS to e-source and originals file in source doc
- ☐ Abnormal results? ☐ No ☐ Yes Sent to participant? ☐ No ☐ Yes
- ☐ If applicable: Please provide Protocol Deviation description in box below

Visit Incentive Information:

Visit	Incentive
Baseline	\$100

Clincard number:

Paper forms:

ANTH	Calcium Intake/VitD
DEXA performance	Fracture history
pQCT performance	IPAC
Medical history	
CI	Reproductive history
W9	Online cognitive testing
CONSENT	ANY NOT COMPLETED ONLINE
DEXA completed?	PQCT completed?

Visit Completed on: ____/____/____

Coordinator Signature:

DXA Result Letter Template (Dr. Kalkwarf will provide letters with results to Coordinators)

Teen



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			<input type="checkbox"/>	<input type="checkbox"/>
Total hip			<input type="checkbox"/>	<input type="checkbox"/>
Femoral neck			<input type="checkbox"/>	<input type="checkbox"/>

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 7 – Psychosocial Measures

7.1 Computerized Cognitive Testing

These tests are offered to the participant only at the 10 year visit. These data collection measures can be administered remotely using the provided links, 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. Also, this will help coordinators to obtain feedback from the participants to confirm completion of each test. Please note that there are two testing sessions that participants will complete, the first is a system called WebNeuro and the second is a system called Millisecond/Inquisit. WebNeuro can only be completed on a Windows computer and Millisecond/Inquisit can be completed on either a Windows computer or Apple device. Instructions for accessing the tests are included at the end of Section 7.

Both systems and their instructions are described below:

7.1.1 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 and appears on the next pages:

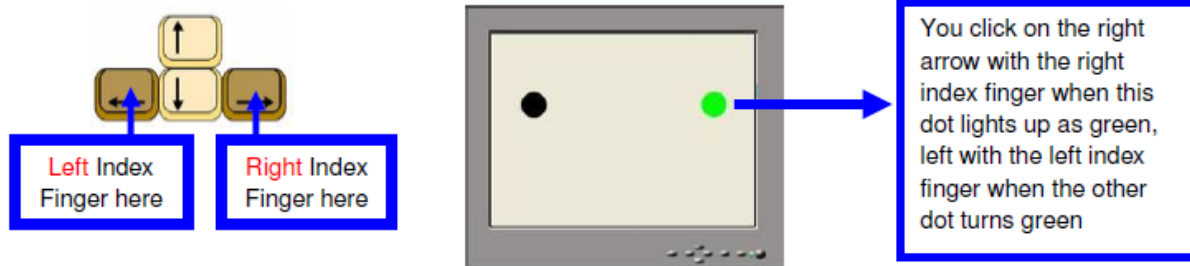
1. Finger Tapping



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.

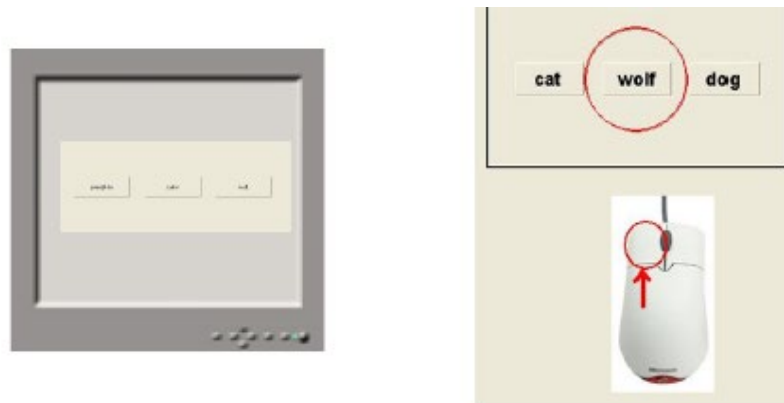
The other fingers remain inert on the table surface, palm down. The dependent variable is total number of taps with the index finger on the dominant hand only. The wrist should not be used in a flapping motion, just the forefinger should rapidly move up and down. The test is tiring, it is meant to be,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

2. Choice Reaction Time



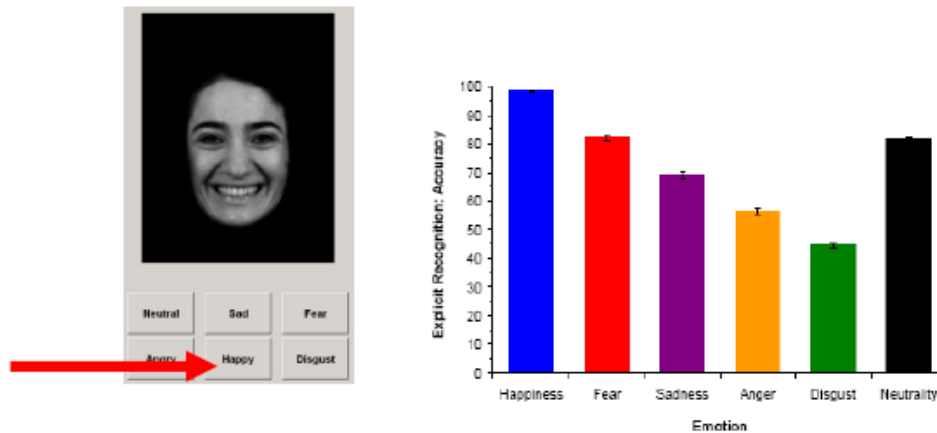
Test procedure: The participant will be required to attend to the computer screen as one of two black target circles, on either the right or left side of the screen, is illuminated in green in pseudo random sequence over a series of trials. For each trial, using the left index finger on the left arrow, 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.

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



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).

4. Emotion Recognition (Explicit recognition)



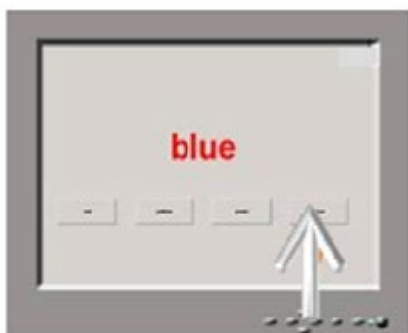
Test Procedure: The participant is presented with a series of faces with different emotional expressions (fear, anger, disgust, sadness, happiness, and neutral) as on the left above. The participant is required to use the mouse to click and identify the correct emotional valence presented by the face 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



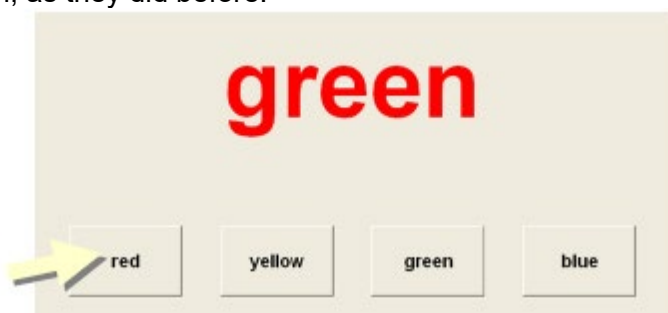
Test Procedure: The participant is presented with a series of digits flashed on the computer screen, separated by a one second interval. The participant is asked to remember what they saw and then enter the digits on a touch pad in the same order as presented, using the mouse to click on the screen touch 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



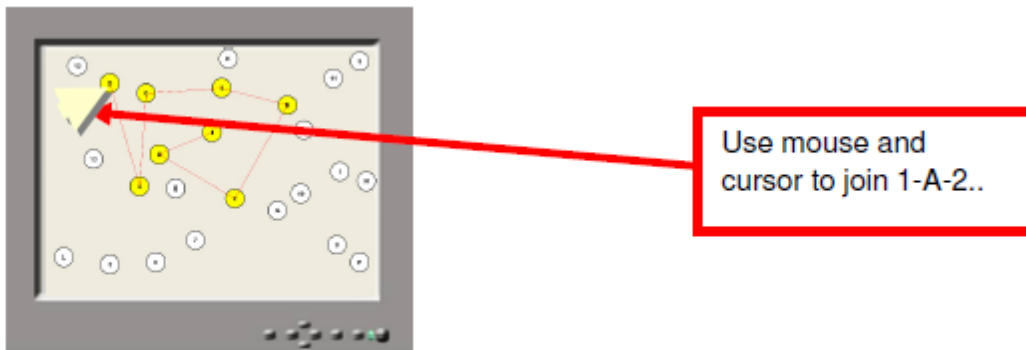
Test Procedure: The participant is presented with four colored words, one at a time. Each word is drawn from the following set of four colors: red, yellow, green and blue. Below each colored word is a response pad with the four possible names of the colors displayed in black and in fixed format. In part 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



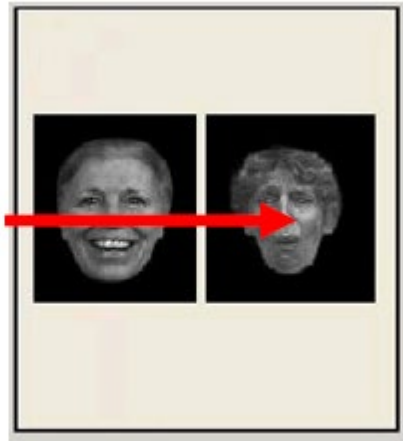
Test Procedure: The color of the word 'PRESS' is frequently presented in green (Go) and infrequently in red (No Go). The object of the test is to press the SPACE BAR once each time the word PRESS appears. The participant is required to inhibit button-press responses when PRESS appears.

9. Delayed Memory Recognition Task



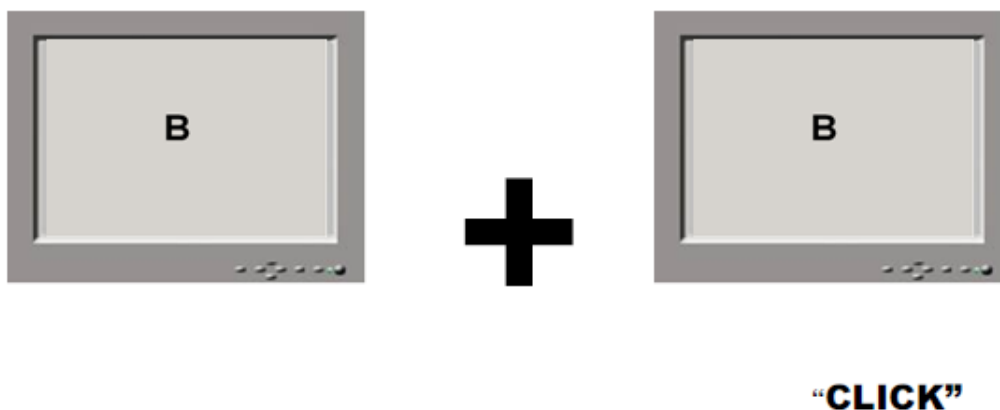
Test Procedure: The participant is required to remember the words presented to the participant 10-15 minutes earlier on the Recognition Memory trials, choosing as before, between one target and two foils, matched to make the task more difficult.

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



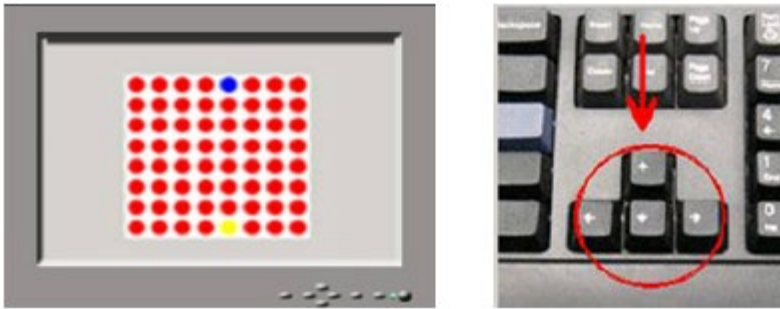
Above is an example of the delayed recall task which asks the participant to click on whichever face they have seen before, in this case, the one on the right. Both speed and accuracy is measured.

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 (ideally). Completion requires a Windows 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 site coordinator will request a login and password from the Central Study Coordinator and/or Deputy Central Study Coordinator to provide to the participant. The login code will look like this or something similar: TEEN-00015 meaning this is the 15th person to do WebNeuro for the study 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, their 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

7.1.2 WebNeuro Safety Procedures

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.

7.1.3 Millisecond/Inquisit 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 or Apple device. 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/Inquisit website information and will use their unique Teen-LABS ID # (ex: CIN1000) to log in (site coordinators will include participant's ID number when they send the website information). 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.

7.1.4 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 each 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.

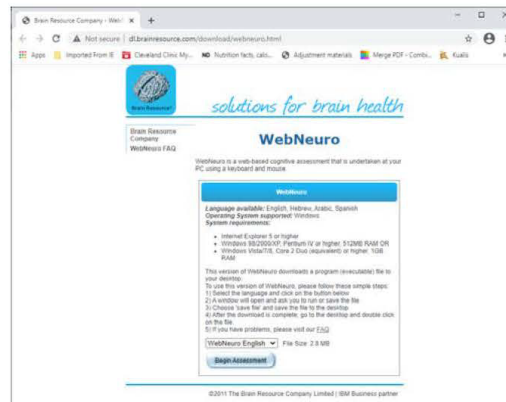
WebNeuro attachment to send with the above email



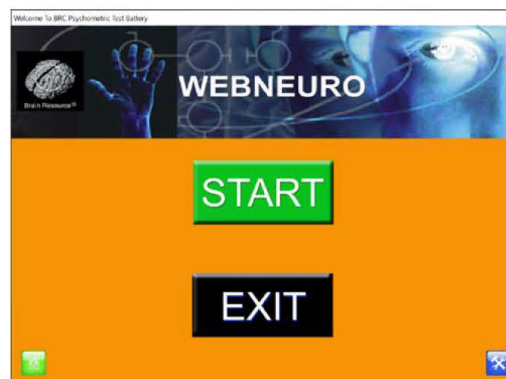
How to Access the WebNeuro Assessment

*Note: Only compatible with Windows

1. Go to <http://dl.brainresource.com/download/webneuro.html>



2. Select the appropriate language and click Begin Assessment to download the test.
3. Double-click the Webneuro exe file. The below window will appear.



4. Enter the Login and Password information provided by your Teen-LABS coordinator.

5. At the completion of testing, data will be automatically uploaded. Close the window and you can delete the exe file.

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

Teen-LABS Millisecond/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 "CIN1000" 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 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 opens 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 "CIN1000" 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 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 8 – Recruitment and Retention

Teen-LABS RECRUITMENT AND RETENTION ACTIVITIES

8.1 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, each Teen-LABS site must design an appropriate retention plan for their participants.

8.2 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.

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

- “We want you to stay in touch. We know there may be times when your research visits 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.

Other strategies to optimize retention during the course of the study may include:

- Occasional phone contact between research visits by site PI 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).

8.2.1 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 research visit
- Difficulty reaching participants by phone or failure to return calls
- Participant reservations about study burden
- Complaints about procedures
- Missed visits
- Forms not completed
- Rescheduling two or more times 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 options that are convenient to participants
- Emphasize the positive; praise all successes (i.e., completing Quest appt, finishing 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

8.2.2 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 study
- 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

8.2.3 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.

8.3 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 and include telephone contact efforts by research coordinator and PI.

Cohort retention plan. 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 obtain the participant's social security number, landline and cell phone numbers, social networking site, e-mail addresses and the physical address of their residence at each study visit. 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 participant to obtain health and anthropometric information from their personal physician(s) in the event that information needs to be gathered from an office visit with 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, 'Page 1' (of the SHORT form) will be utilized to capture current contact information and the "SHORT" REDCap entry to capture 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. 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.
4. Participants will be provided with coordinators' contact information with reminders to notify the coordinator if they move or change phone numbers.
5. 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 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, schools, etc.), and reminders of the upcoming annual study assessment.
6. Frequent communications, including birthday cards, holiday cards, and newsletters, will be employed to facilitate the maintenance of the central database and maintain contact with participants.
7. Compensation for travel to complete a study visit can be provided for participants. The reimbursement schedule set out in section 2 will be followed.
8. A study logo will be created depicting "Teen-LABS" that will establish trust, rapport and pride in participation.
9. 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.

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, National Death Index, 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. 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 available resources including White Pages®, directories (high school, college, alumni, etc.), search engines (Yahoo, Google, etc.), credit bureau (Equifax, Experian), social media websites, and the National Death Index 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 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 participants, not to send out

blanket recruitment messages on the web. Nor are they performed to harass or trouble individuals 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 can complete some or all visit components to the extent that they are able and willing to.

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. 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 participants 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 through 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.

Participants 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.

10. The Central Study Coordinators oversee 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.

National Death Index

The Teen-LABS Study will use the National Death Index (NDI) to search for participants that have been lost to follow-up and obtain additional information on deceased study subjects. As stipulated in Section 4.B. of the protocol, the NDI will only be used to aid in the ascertainment of death for any participant who cannot be located using standard study follow-up methods, and then only after such individuals have been missing for greater than or equal to two years. If NDI query results in our finding that a study participant has likely died, follow-back methodology will be used to obtain information from next-of-kin, physicians, hospitals, and/or others. The Teen-LABS Study will continue to provide appropriate protection to the respondents with respect to minimizing respondent burden, maintaining confidentiality, protecting their privacy, and avoiding or minimizing any emotional or other harm that may affect the respondent.

The NDI stipulates as part of using their resources in support of a research project that steps should be taken to ensure that procedures are in place to provide appropriate protection for next-of-kin and others to avoid or minimize any emotional or other harm that may affect the respondent. Our steps to ensure this are as follows:

- 1) To avoid attempting to secure additional death records in error, any people identified will be matched according to PHI previously collected by the study; participants agreed to PHI collected and stored in central study databases.
- 2) We will have previously checked WhitePages Premium (and other national information sources) and will have attempted to check medical records with doctors' offices listed on forms before engaging the next-of-kin.
- 3) For participants that we are using the NDI to search for, we have not heard from them or their relatives in the past 2 years, potentially ensuring that a significant amount of time has passed since the death.
- 4) We will structure the letter to next of kin in a sensitive manner, and have the wording reviewed by a Social Worker and Psychologist. We will also structure any interactions (including interviews, survey forms, and correspondence) with next of kin or other informant contacted to minimize potential emotional harm and undue respondent burden which may be caused by the proposed follow-back activities.

Example letter to send to family (check with IRB whether site approval is needed):



<<date>>

Dear _____,

Our sincere condolences on the loss of your _____.

We are grateful for _____'s participation in the Teen-LABS Study all these years and know that ____ made a big difference in helping others who suffer from severe obesity by participating.

To help us report the long-term effects of Bariatric Surgery, we are requesting Medical Records, Death Certificate and any Autopsy results.

Please consider this important request and complete the enclosed release of records and return it in the self-addressed envelope so that we may review and report the outcome in an anonymous fashion.

Feel welcome to call us if we can be of assistance or answer questions for you.

Again, we appreciate your collaboration and offer you our deepest sympathy for your loss.

Sincerely,

Thomas H. Inge, MD, PhD
Principal Investigator for the Teen-LABS Study

Michael Helmrath, MD
Principal Investigator for the Teen-LABS Study

Coordinator for the Teen-LABS Study

If you find out that a participant is deceased, confirm the information by searching online for an obituary. Notify the DCC, Central Study Coordinator and Deputy Central Study Coordinator and complete the INF and MRF in REDCap. Send the obituary via secure email to the Central and Deputy Coordinators. Contact the family and provide condolences and let them know that we would like to obtain copies of any medical records, the death certificate, autopsy and toxicology reports (if available). The example letter above can be used as a template and modified for your site (please check whether IRB approval is needed for the letter). The death will be reported to your IRB, who will determine further instructions for reporting immediately or at continuing review.

Send any medical records including copies of the death certificate, autopsy and toxicology reports via secure email to the Central Study Coordinator. The Central Study Coordinator will use the records and participant's research data to prepare an adjudication case that will be reviewed by the Adjudication Committee to determine whether the death was related to bariatric surgery or not.

Section 9 – Operations Memos

List all updates

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

Section 10 – Publications and Presentations

Teen Longitudinal Assessment of Adolescent Bariatric Surgery (Teen-LABS) publications information available per website

<https://www.luriechildrens.org/en/research/research-areas/clinical-research/teen-labs/publications/>

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

<https://www.luriechildrens.org/en/research/research-areas/clinical-research/teen-labs/ancillary-study-guidelines/>

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Section 12 – Old Sections

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