Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix

Research Plan

A. Design Summary:
The study used a prospective, observational cohort design in which the majority of the data are collected at the same time that routine clinical care of bariatric patients is occurring. Teen-LABS is an approved ancillary study of the LABS consortium, with the research methodology and instruments of the LABS-2 study for collection of longer term outcomes adapted for use in adolescents, including clinical assessments, detailed interviews, questionnaires, and laboratory tests at baseline, 30 days postoperatively, and at six months and annually following surgery. Adolescents were recruited prospectively from five clinical sites.

Detailed data about the surgical procedure and peri- and postoperative care was collected by the investigators. Adjudication of pre-specified clinical events was performed by an independent committee in order to determine the relatedness of the events to the bariatric procedure. Biospecimens (serum, plasma, DNA, urine) were obtained to address hypotheses relevant to this study and to provide a resource for future biological studies.

B. Inclusion/Exclusion Criteria

Inclusion Criteria

- Subjects ≤19 years of age who are approved by clinical team and payor to undergo bariatric surgery by a Teen-LABS-certified surgeon
- Primary caregivers of adolescent participants (for their weight, height, and demographic variables only). An adolescent was not excluded if their caregiver declines participation as caregiver.

Exclusion Criteria

- Informed consent not obtained from adolescent or the adolescent's legally authorized representative
- Unable to communicate with local study staff

C. Human Subjects
To avoid bias, every attempt was made to enroll consecutive voluntary participants at every site following IRB approval of the protocol and consent forms at that site. Thus, all eligible adolescent subjects and their caregivers were recruited. Methodologically, after a potentially eligible subject was approved for surgery, a Teen-LABS co-investigator or staff member screened the patient for study eligibility. For adolescents who met criteria and indicated a willingness to participate, the study coordinator reviewed and documented inclusion and exclusion criteria, and discussed in detail the nature of the study and what would be expected of the subject. Written informed consent was obtained after study objectives, benefits and risks were discussed with the subject (and parents for subjects < 18 years of age). If the participant was under 18 years of age, permission was obtained from the parents or guardian and assent was obtained from the subject. Consent was obtained for study participation, access to all medical records, collection of biospecimens, future contact for participation in additional research studies, and storage of the subject's contact information in a central database registry at the study's central retention office. An adolescent was considered enrolled when the informed consent signature was obtained and the DCC received the Preoperative Enrollment Form. Subjects received $60 and caregivers $15 to compensate them for the time burden of participating in the baseline study visit.

Specific consent/permission forms to address the special circumstances of this study:

- Informed parental permission for minor participants, signed by at least one parent or legal guardian; coupled with
    - Assent for minor participants
- Informed consent for participation of parent or legal guardian
- Informed consent for use in re-consenting adolescent participants who become 18 years old during course of the study

- Informed consent for participants enrolling at age 18-19; coupled with
    - Informed Consent for participation of parent or (former) legal guardian of adult (age 18-19) participants

D. Study Visits and Procedures

D.1. General.

At each site, subjects and caregivers were enrolled only after they were approved by the clinical team and 3rd party payor to undergo bariatric surgery, met study eligibility criteria, and agreed to participate in Teen-LABS by signing an informed consent. Caregiver participation was limited to heights and weights of parents, self-report demographics and household information, and their observations of the patient's sleep patterns.

The Teen-LABS preoperative evaluation was completed through patient assessments, including chart review, self-report forms and interview with the patient. After performing the bariatric operation, the Teen-LABS operative form was completed by the Teen-LABS certified operating surgeon. Subjects were seen or contacted no less than 30 days after surgery to collect postoperative event data for events occurring within 30 days of the bariatric surgery. The research coordinator also reviewed subjects' medical records to determine if a reportable outcome event occurred in this period of time.

A summary of the Teen-LABS data elements collected at preoperative and 30 day follow-up time periods is shown below. In addition, Table 1 below names the actual case report forms and indicates time of administration.

D.2. Baseline data elements associated with this manuscript: These data were collected within 30 days prior to operation.

- Participant identifier (alpha-numeric code),
- Date of consent to participate in Teen-LABS
- Month and year of birth, gender, height, weight, race, ethnicity
- Measured height and weight, sagittal abdominal diameter, and vital signs (heart rate, blood pressure)
- Planned procedure, planned approach, previous obesity surgery
- Whether or not the planned procedure is a revision/reversal of prior bariatric procedure
- Co-morbidities (T2DM, ischemic heart disease, hypertension, congestive heart failure, sleep apnea, history of deep vein thrombosis/pulmonary embolus, asthma, functional status, pulmonary hypertension, urinary incontinence, sleep hygiene)
- Polysomnography (sleep study) data files if available and performed within 12 months of baseline evaluation

D.3. Operative data elements associated with this manuscript. These elements were collected by the surgeon immediately after the surgical procedure or prior to discharge from the hospital.

- Date of surgery
- Procedure(s) performed
- Method of surgical procedure
- Whether concurrent procedures were performed
- Deep vein thrombosis prophylaxis
- Whether postoperative anticoagulation was ordered
- Adverse intraoperative events

D.4. a. 30-day postoperative outcome elements related to this manuscript. These following data were collected within a desired window of 30-55 days following operation. For subjects who could not be reached within this window, the objective elements of the form which can be completed by chart review without patient input were collected by coordinator.

- Source(s) of information
- Length of hospital stay (days)

- Discharge location
- Whether the surgical wound edges opened
- Whether the wound edges separated and required packaging or bandaging
- Date of death, if applicable
- Re-hospitalization(s), if applicable
- 30-day postoperative outcomes, i.e., abdominal re-operation, tracheal re-intubation, tracheostomy, endoscopy, placement of percutaneous drain, anticoagulation therapy for presumed/confirmed deep vein thrombosis, anticoagulation therapy for presumed/confirmed pulmonary embolus, other events requiring intervention

Data collection forms		Enrollment	Baseline	Post-Surgery	30 days
EF	Enrollment form	x			
PO	Pre-op Form		x		
ANTH	Anthropometrics		x		
RCAB	Research Coordinator Assessment - Baseline		x		
CAB	Comorbidity Assessment – Baseline		x		
SMAB	Surgeon's Medical Assessment - Baseline		x		
RYB	Roux-en-Y Gastric Bypass form			x	
GS	Sleeve gastrectomy form			x	
AGB	Adjustable gastric band form			x	
SQOP	Surgeon's Questionnaire/Operative Eval			x	
DS	Discharge Summary			x	
POST	Post Operative Evaluation				x
RHB	Reproductive Health - Baseline		x		
HCU	Healthcare Utilization				x

D.4.B. Adjudication Process for Clinical Adverse Events

To accurately and objectively assess the risks of bariatric surgery to adolescents, we considered it important that pre-specified clinical events be clearly classified as related to the surgical intervention or to other causes unrelated to the surgical intervention. The Teen-LABS adjudication process accomplishes this goal.

The Teen-LABS Adjudication Committee (AC) consists of 7 members. Five AC members, including the chairperson, are surgeons. Teen-LABS surgeons were excluded; two physician members are non-surgeons with expertise in pediatric obesity. Each member was appointed for the duration of the study. The adjudication review of each event was conducted by no fewer than 3 AC members. The other AC members for each review were selected by the adjudication coordinator at the clinical coordinating center.

Prospectively developed guidelines specified that case report forms were to be reviewed by Data Coordinating Center (DCC) staff for triggers for an adjudicatable event. These triggers included:

1. Death of a Teen-LABS participant (for any reason);
2. Any operation following the index WLS procedure. (Exception: endoscopic procedures were not subject to adjudication unless occurring in the context of another adjudicatable event);
3. Any admission to a hospital following discharge from the hospitalization for the index WLS procedure.

After identification of an event requiring adjudication, source documents were requested from the site at which the event occurred. In the event that an event was managed at a facility outside of the study site, medical records were obtained by the clinical sites and an outside medical record retrieval agency contracted by the DCC. The specific source documents requested included relevant hospital and procedure reports including:

1. Admission note (history and physical),
2. Relevant radiology reports,
3. Relevant operative and procedure notes,
4. Clinical discharge summary,
5. Pathology report,
6. Any relevant consultant's report,

All documents were redacted of personal and site identifiers, and names of clinicians that could be used to recognize the site. Using these and collateral data from the database, patient information was assembled for review by AC members. The committee members then reviewed and classified the event as to relatedness to bariatric surgery and submitted their determinations via a secure web portal. The resulting attribution information was used in the analysis of risk of surgery.

D.5. Biospecimens and Laboratory Data

Blood (70mL) and urine (3.5mL) are obtained for research purposes from adolescent participants who are undergoing bariatric surgery at baseline and at postoperative study visits at 6, 12 months and annually thereafter. A portion of the plasma, serum, and urine that is not used immediately by Teen-LABS is banked at the NIDDK Biosample Repository for future investigations. Table 2 lists the tests performed using fresh specimens at the central laboratory (Northwest Lipid Metabolism and Diabetes Research Laboratories, Seattle, WA) and those measures that were collected for clinical purposes and then abstracted for research use from the clinical chart at the sites:

Table 2: Laboratory measures

Laboratory Test	Method		
vitamin A	Teen-LABS central laboratory		
parathyroid hormone (PTH)	Teen-LABS central laboratory		
25-OH vitamin D	Teen-LABS central laboratory		
Ferritin	Teen-LABS central laboratory		

vitamin B12	Teen-LABS central laboratory		
hs – CRP	Teen-LABS central laboratory		
Glucose	Teen-LABS central laboratory		
albumin (serum)	Teen-LABS central laboratory		
Insulin	Teen-LABS central laboratory		
Folate	Teen-LABS central laboratory		
Calcium	Teen-LABS central laboratory		
lipids (TG, TC, HDL, LDL)	Teen-LABS central laboratory		
HbA1c	Teen-LABS central laboratory		
Creatinine	Teen-LABS central laboratory		
cystatin C	Teen-LABS central laboratory		
Transferrin	Teen-LABS central laboratory		
urine albumin	Teen-LABS central laboratory		
urine creatinine	Teen-LABS central laboratory		

D.6. Physical Measurements

All Teen-LABS staff were trained and certified by the Central Study Coordinator prior to collection of any data. The following passages contain the manual of procedures that was used as a guide by all coordinators performing physical measurements for data collection in the Teen-LABS study.

D.6.a. Blood Pressure (BP) & Resting Heart Rate

BP readings were standardized using the right arm that was bare from the shoulder.
If for any reason (e.g., mastectomy, arterial-venous fistula, lymph dissection, or other reason) the blood pressure could not be measured using the right arm then the measurement was taken using the left arm.

Materials Needed:

- Welch Allyn Spot Vital Signs monitor 4200B
- Regular adult arm, large adult arm, and thigh blood pressure cuffs
- Gulick II Tape Measure (model 67020)

Preparation:

The proper cuff size must be used to avoid under- or over-estimating BP when using indirect methods of measurement. To determine the proper cuff size, the operator must measure the arm circumference at the midpoint of the right arm. The midpoint of the arm is the point located halfway between the elbow and shoulder. With the patient standing and holding the arm bent at the elbow with hand resting lightly on hip, fingers forward with thumb pointing to the rear, the arm length is measured from the acromion (or bony extremity of the shoulder girdle) to the olecranon (or the tip of the elbow), with a tape measure, allowing the tape to hang freely over the olecranon. The midpoint is marked on the dorsal surface. The patient should then relax the arm along the side of the body. Pull an appropriate amount of tape out of the housing. Ensure that tape is in contact with but not indenting soft tissues. Align the tape at zero "zero line," along side of the tape graduations. Place one end of the tape around the mark on patient's arm. Wrap the tape around the patient's arm. Care must be taken to keep the tape horizontal. Pull on the end of the tensioning mechanism until the calibration point can be seen. Calibration Point: When you pull slightly harder and harder on the tensioning device, two colored beads will be seen, separated by a silver disk separating the two beads. When you see one of the two, you are at the calibration point.

Cuff size is then determined from the chart below. The sizes for cuffs overlap to provide flexibility in cuff-size selection. The first choice for cuff should always be for the larger size. Because it is often difficult to fit a cuff correctly on an obese person's upper arm, an incorrect fit can result in readings that are too high or too low. If a participant's upper arm circumference indicates use of the thigh cuff, but the arm is too short for the cuff, or the cuff does not remain secured when inflated, the long arm cuff or a conical (curved) thigh cuff should be used.

CUFF SIZE INDICATED BY MEASURED ARM CIRCUMFERENCE

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

Measurement:

1. The measurement of heart rate and BP should be performed after the patient has been seated quietly, with feet flat on the floor, in an erect but comfortable posture for at least five minutes, and for at least thirty minutes since the patient has smoked or consumed caffeine-containing beverages.
2. Place the blood pressure cuff, as determined in the arm measurement procedure, around the bare upper right (or left, if right cannot be used) arm so that the midpoint of the length of the bladder lies over the brachial artery and the mid-height of the cuff is at heart level. The lower edge of the cuff, with its tubing connections, should be placed about one inch above the natural crease across the inner aspect of the elbow. The cuff is wrapped snugly about the arm, with the palm of the patient's hand turned upward. The wrapped cuff should be secured firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.
3. Record the blood pressure on the data collection instrument.
4. Record the heart rate on the data collection instrument. Note: Heart Rate is determined as an adjunct to the blood pressure measurement.
5. Remove the cuff, clean according to universal precautions, and store the equipment safely after the last reading.

D.6.b. Neck Circumference

Materials Needed:

- Gulick II Tape Measure (model 67020)

Preparation:

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

Measurement:

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

D.6.c. Midpoint Waist Circumference

Materials Needed:

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

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

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

D.6.d. Iliac Crest Waist Circumference
Materials Needed:
- Gulick II Tape Measure (model 67020)
- Washable marker or cosmetic pencil
- 3 plastic clothespins

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

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

marking will be used later for the Sagittal Abdominal Diameter (SAD) measurement. See page 10 for visual.
8. Release the tape measure and repeat the above steps 2 through 6. If the two measures are not within 2cm of each other, a third measurement must be taken and recorded on the form.
9.. After you have completed all measurements using the Gulick II measuring tape, pull the tape *almost* all the way out and wipe with alcohol pads or appropriate disinfectant.

D.6.e. Body Composition
Materials Needed:
- Tanita Scale Model TBF310
- Printer/Paper for printer

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

Measurement:
1. The Tanita scale should always be used on a flat, stable surface.
2. Ask patient to remove shoes and socks/hose. Because the body composition analyzer uses a minor electric current to measure impedance, best results will be observed when measurement is taken in bare feet. Poor contact between the feet and electrodes may produce an error message. Also, the sole of the feet should be free of excess dirt, as this may act as a barrier to the electric current. *Please note that if there are calluses on the soles of the feet accurate measurement may still be possible. Place 0.5cc of saline or water in the center of each electrode. This will act as a conductive material and may allow the current to pass freely through a thin barrier.*

3. Press the [ON/OFF] key to turn on the Power. Adjust measurements by pressing [kg/lb] if needed, to record patient's weight in lbs.
4. You will then be prompted to enter patient's clothes weight. For the purposes of Teen-LABS, the patients clothes weight must be listed as 0 lbs.
5. Select either standard male or standard female. Teen-*LABS will not be using the athletic male or athletic female settings from the four listed gender and body types.*
6. Enter patient's age.
7. After age is entered, the arrow will automatically advance to height. Using Feet and Inches, measurement is made to the First Decimal Place by 0.5 inch increments, example 5 ft. 7.5 inches, press the [5] [7] [.] [5] keys and for 6 ft 0 inches, press [6] [0] [.] [0] keys. When using the lb. mode, height will automatically round up or down to the nearest 0.5 inch or whole number. Note that coordinators will collect the height from the Teen-LABS Preoperative Evaluation Form. If height is missing from that form, coordinators should measure the height of the patient.
8. After entering the above data, the flashing arrow will appear next to STEP ON, after the LCD displays "8888".
9.. Patient should be asked to step slowly onto the weighing platform. If the patient's inner thighs are touching (which is very likely), a towel should be placed between the thighs because touching legs may affect the measure. Heels should be placed directly on top of the posterior electrodes, while the front part of the foot needs to be in contact with the anterior electrodes.
10. After weight stabilizes, impedance measurement is taken. This is denoted by four "bubbles" which appear on the bottom half of the LCD. As the measurement is being taken, the bubbles will begin to disappear one by one. *The patient must remain on the platform until the final bubble has disappeared and the display emits a short beep.*
11. Weight and percent body fat will be displayed on the LCD and detailed results will print out. It is suggested that you print this report twice; with one copy being given to the patient and the other being kept in the patients research file for reference at later visits. The weight and percent body fat will remain on the screen for ten seconds before returning to gender and body type screen.
12. If all measurements are complete, press the [ON/OFF] key to turn off the power.

13. After each use, the weighing platform should be cleaned with alcohol pads or appropriate disinfectant. Follow directions for cleaning the platform as outlined in the instruction manual provided with your equipment.
14. Repeat the weight a second time and if not within repeat a third time.

D.6.f. Sagittal Abdominal Diameter (SAD)

Materials Needed:

- Holtain-Kahn Abdominal Caliper plus 20 cm extension bar
- Narrow tip eyebrow pencil as marker
- Small folded towel – if needed
- Form for recording measurement

Preparation:

The sagittal abdominal diameter (SAD) measurement will be measured using a portable, sliding-beam, abdominal caliper while participants are in a supine position on the table. Prior to visit, the extension bar should be added to the calipers when the subject's SAD is expected to be greater than 25 cm. If it is suspected that the SAD will be less than 25
cm then the extension bar should NOT be used and the reading taken as marked on the scale.

The sagittal abdominal measurement, when possible, will be taken by two trained individuals: one examiner and one recorder. The examiner will take the measurements and call out the measurement result to the recorder. Recorder will check the participant's position during the procedure and record measurements. The examiner will wait until the recorder verbally repeats and records the measurement before repeating a second time. A third measurement is taken only if the two measurements differ by more than 1.0 cm.

Measurement:

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

13. Ask participant to relax.
14. Raise caliper's upper arm.
15. Repeat the procedure (steps 7 – 14) until two measurements are within 1.0 cm. Record measurements on form.
16. Clean calipers after each use with sanitizing wipe

E. Data definitions and analytic details

E.1. Data definitions

Comorbidities:

The presence or absence of co-morbid conditions was assessed in various ways. A Teen-LABS-certified clinical coordinator or investigator used information (medical records, physical exam, patient interview, and laboratory values) to determine presence or absence of each condition based on standard definitions.

Hypertension. Hypertension was defined as having systolic or diastolic blood pressure ≥ 95th percentile indexed to age, gender, and height during the baseline visit as measured using the standard Teen-LABS protocol, or current use of anti-hypertensive medication.

Specifically, the data for this variable were obtained/analyzed as follows:

- ≥ 95th percentile of systolic or diastolic indexed to age, gender and height (Anthropometric [ANTH] form); or
- Comorbidity Assessment-Baseline (CAB) form, Question 1 – selection equals: "hypertension, treatment with single medication", or "hypertension, treatment with two or more medications"; or
- Medications (MED) form, subject-reported use of antihypertensive medications

Dyslipidemia. The presence of dyslipidemia was defined as triglyceride value ≥ 130 mg/dL or LDL cholesterol ≥ 130 mg/dLor HDL cholesterol < 40 mg/dL or use of medication for dyslipidemia.

Specifically, the data for this variable were obtained/analyzed as follows:

- Central laboratory measured triglyceride, LDL cholesterol, HDL cholesterol; or
- Comorbidity Assessment-Baseline (CAB) form, Question 5 – selection equals: "treatment with single medication for dyslipidemia" or "treatment with two or more medications for dyslipidemia"; or
- Medications (MED) form, subject-reported use of any antilipemic Rx

Fatty Liver Disease. The presence of fatty liver disease (FLD) was presumed in the presence of abnormally elevated serum aminotransferases (ALT, AST, or GGT) or if imaging suggested steatosis, or if biopsy confirmed hepatic steatosis, steatohepatitis, or more advanced fibrosis.

Specifically, the data for this variable were obtained/analyzed as follows:

- Comorbidity Assessment-Baseline (CAB) form, Question 13 – selection equals: "abnormal serum aminotransferases (ALT,AST, or GGT)" or "Imaging suggesting steatosis" or "Biopsy confirmed hepatic steatosis" or "Biopsy confirmed steatohepatitis" or "Biopsy confirmed cirrhosis, compensated" or "Decompensated cirrhosis (end-stage liver disease with synthetic dysfunction)"

Obstructive Sleep Apnea. Obstructive sleep apnea syndrome (OSAS) was defined as provider-diagnosed OSAS. For this assessment, surgical investigators took into account diagnostic polysomnogram findings, or use of continuous positive airway pressure (CPAP).

Specifically, the data for this variable were obtained/analyzed as follows:

- Comorbidity Assessment-Baseline (CAB) form, Question 9 – selection equal: "Yes"

Diabetes. Diabetes was defined by study investigators taking into consideration patient self-report of prior diagnosis, use of medications for diabetes, baseline HbA1c of ≥6.5%, or fasting glucose of at least 126 mg/dL, or oral glucose tolerance results in prior 6 months.

Specifically, the data for this variable were obtained/analyzed as follows:

- Preoperative (PO) form, question 9b;
- Comorbidity Assessment-Baseline (CAB) form, question 6c, 6d, 7, 18;
- Medical Assessment – Baseline (MAB) form, question 14;
- All declared medications from the MED form;
- Central lab measured baseline fasting glucose and HbA1c values

Polycystic ovary syndrome. Presence of polycystic ovary syndrome (PCOS) was defined as presence of symptoms of PCOS (features of hirsutism) with treatment with contraceptive or anti-androgens, or, if confirmed by measured androgen levels, the condition was present even whether or not using contraceptives, anti-androgens, or metformin.

Specifically, the data for this variable were obtained/analyzed as follows:

- Co-morbidity Assessment-Baseline (CAB) form, question 18 – selection equals: "Symptoms of PCOS present, treatment with contraceptive or anti-androgens" or "Confirmed PCOS, no treatment" or "Confirmed PCOS, treatment with contraceptive or anti-androgens" or "Confirmed PCOS, treatment with metformin" or "Combination treatment (contraceptives, anti-androgens, metformin)"

Chronic Kidney Disease. The presence of chronic kidney disease (CKD) was defined [1] using glomerular filtration rate (GFR), determined by cystatin C levels [2], where $GFR=77.24 \times (Cys\ C)^{-1.2623}$; microalbuminuria was defined as urine albumin to creatinine ratio > 0.03; CKD stages were defined as follows:

- Normal = GFR>60 and no microalbuminuria
- CKD stage 1 = Microalbuminuria with GFR ≥ 90
- CKD stage 2 = Microalbuminuria with GFR of 60-89

- CKD Stage 3 = GFR of 30-59
- CKD stage 4 = GFR of 15-29
- CKD stage 5 = GFR < 15

Pseudotumor cerebri. Presence of pseudotumor cerebri (PTC) was defined as having a prior physician diagnosis of PTC, with or without use of medications or cerebrospinal fluid drainage.

Specifically, the data for this variable were obtained/analyzed as follows:

- Co-morbidity Assessment-Baseline (CAB) form, question 19 – selection equals: "Confirmed PTC, no medications" or "Confirmed PTC, medications used (e.g., diuretics)" or "CSF drainage required" or "Persistent symptoms despite medications or drainage"

Blount's disease. Presence of Blount's disease was defined as having a prior physician diagnosis as determined from chart review or participant self-report.

Specifically, the data for this variable were obtained/analyzed as follows:

- Preoperative (PO) form, question 9o – selection equals: "Yes"; or
- Surgeon's Medical Assessment – Baseline (SMAB) form, question 37 – selection equals: "Yes"

Joint Pain. Presence of joint pain was defined as pain in hips or lower extremity joints with ambulation once a week or less, or pain requiring non-narcotic analgesia used regularly (at least monthly) or narcotic analgesia used regularly (at least monthly).

Specifically, the data for this variable were obtained/analyzed as follows:

- Co-morbidity Assessment-Baseline (CAB) form, question 14 – selection equals: "Pain with ambulation once a week or less" or "Pain with ambulation more than once a week" or "Non-narcotic analgesia used regularly (weekly or monthly)" or "Non-narcotic analgesia used frequently (more than once a week)" or "Narcotic analgesia used regularly (weekly or monthly)" or "Narcotic analgesia used frequently (more than once a week)";

Back Pain. Presence of back pain was defined as intermittent back pain, not requiring medication or treatment or requiring non-narcotic analgesia regularly (at least monthly), or narcotic analgesia used regularly (at least monthly).

Specifically, the data for this variable were obtained/analyzed as follows:

- Co-morbidity Assessment-Baseline (CAB) form, question 15 – selection equals: "Intermittent back pain, not requiring medication or treatment" or "Non-narcotic analgesia used regularly (weekly or monthly)" or "Non-narcotic analgesia used frequently (more than once per week)" or "Narcotic analgesia used regularly (weekly or monthly)" or "Narcotic analgesia used frequently (more than once per week)";

E.2. Laboratory Analyses.

Fasting blood specimens were drawn at the preoperative research visit. Laboratory assays were performed by the Northwest Lipid Metabolism and Diabetes Research Laboratories (Seattle, WA). Low-density lipoprotein (LDL) cholesterol was calculated using the Friedewald equation except for participants whose triglycerides were ≥400 mg/dl, for whom LDL cholesterol was measured directly by beta-quantification. Analysis of fasting and stimulated glucose was performed enzymatically using Roche reagents on a Roche Module P Chemistry autoanalyzer (Roche Diagnostics Inc., Indianapolis, IN). The Roche reagent is based on the glucose hexokinase method. Measurement of the relative proportion of hemoglobin subclasses and calculation of the HbA1c levels were performed by a dedicated analyzer (TOSOH, Biosciences, Inc., South San Francisco, CA) using non-porous ion exchange high performance chromatography to achieve rapid and precise separation of stable HbA1c from other hemoglobin fractions. The immunochemical measurement of albumin in urine was performed by using Siemens reagent (Siemens Healthcare Diagnostics Inc., Newark, DE) on a Siemens BN II Nephelometer. The immunochemical measurement of Cystatin C levels was performed by the nephelometric method using Siemens reagents (Siemens Healthcare Diagnostics, Inc, Newark, DE) to estimate kidney function.

E.3. Analysis of Clinical Complications

E.3.a. Classification of complications. The SQOP, DS, POST, and HCU case report forms were used to gather information to inform the objective analysis of clinical events and complications.

Perioperative period.

Major complications. Events that qualified for inclusion as major complications in the perioperative period were those that were life-threatening, had potential for permanent harm, which resulted in organ loss (e.g., splenic injury resulting in splenectomy), which led to re-operation, blood transfusion, or which represented a major deviation in anesthetic or operative management.

Minor complications. Events that qualified for inclusion as minor complications were other unplanned perioperative events (e.g., liver or splenic laceration, mesenteric hematoma, anastomotic revision, injury to adjacent structures) requiring additional testing, specific medical management, use of any non-oral enteral feeds at the time of discharge, or use of any parenteral nutrition at the time of discharge.

Discharge to 30 days postoperative period.

Major complications. Between discharge and 30 days postoperative, events which were life-threatening, or had potential for permanent harm (e.g., anticoagulation for pulmonary embolus or deep vein thrombosis), or which required abdominal reoperation (including minor, contained leaks) were considered major complications.

Minor complications. Between discharge and 30 days postoperative, events requiring outpatient percutaneous or endoscopic intervention, any use of non-oral enteral feeds or parenteral nutrition at 30 days after operation, or any event requiring re-admission for inpatient management without reoperation/intervention, were considered minor complications.

eReferences

1. Levey AS, Eckardt KU, Tsukamoto Y, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int 2005;67:2089-100.
2. Larsson A, Malm J, Grubb A, Hansson LO. Calculation of glomerular filtration rate expressed in mL/min from plasma cystatin C values in mg/L. Scand J Clin Lab Invest 2004;64:25-30.

Dear Reader:

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This is a supplement to Perioperative Outcome of Adolescents Undergoing Bariatric Surgery: The Teen Longitudinal Assessment of Bariatric Surgery (Teen-LABS) Study paper which provides the public links to some of the Teen-LABS forms. However, you will note that some forms/questions have specific copyright agreements and are protected.

Please contact us or the appropriate copyright holder for permission to use.

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

Enrollment year: ☐☐ **For coordinator use only.** Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (EF) Enrollment Form

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

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

1. Consent to Teen LABS:

☐ No ↓

1.1 Reason for refusing or not enrolling *(mark all that apply)*:

- ☐ General lack of interest
- ☐ Does not want to be bothered; follow-up too burdensome
- ☐ Lack of trust (e.g., that personal information will remain confidential)
- ☐ Concerned that information provided will impact ability to have surgery
- ☐ No perceived personal benefit from participating
- ☐ Does not want to be included as subject in medical research
- ☐ Unable to communicate with study staff
- ☐ Less than 14 days notice to surgery
- ☐ Unable to schedule baseline visit
- ☐ Unable to contact prior to surgery
- ☐ Other *specify:* _____
- ☐ Unknown

1.2 Patient's age: ___ *years*

☐ Yes ↓

1.3 Date of consent:

___ / ___ / _____
(mm/dd/yyyy)

1.4 Patient's date of birth:

___ / _____
mm *yyyy*

1.5 Expected date of surgery:

___ / ___ / _____
(mm/dd/yyyy)

1.6 Consent version number:

_____

To be completed on all patients who provide informed consent. ***Sites that have the proper IRB approval should also complete this section for all patients who decline to provide informed consent.***

2. Gender: ☐ Male ☐ Female

3. Height: ☐☐☐.☐☐ cm

3.1 How was height measured: ☐ Standing ☐ Lying flat ☐ Estimate

3.2 If height was NOT measured standing, specify why not:

_____

4. Weight: ☐☐☐.☐☐ kg

4.1 How was weight measured:

☐ Tanita Scale ☐ Other Scale ☐ Last available bed weight ☐ Estimate

4.2 If weight was NOT measured with a Tanita Scale, specify why not:

_____

5. Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

6. Race *(mark all that apply)*:

- ☐ White or Caucasian
- ☐ Black or African-American
- ☐ Asian
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Other *specify:* _____
- ☐ Unknown

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

For coordinator use only. Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (PO) Pre-Operative Form

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

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

1. Previous obesity surgery OR surgery performed on the esophagus, stomach or proximal small intestine not for the purpose of weight loss?

☐ No ☐ Yes

↓

1.1 If yes, specify. *(Mark "No" or "Yes" for each item.)*

	No	Yes	Number of previous surgeries (including revisions and reversals)	Date of most recent surgery *(mm/dd/yyyy -- enter as much as is known)*
Gastric Bypass (Roux-en-Y)	☐	☐	___	___ / ___ / _____
Biliopancreatic div. (BPD)	☐	☐	___	___ / ___ / _____
Biliopancreatic div. w/switch (BPDS)	☐	☐	___	___ / ___ / _____
Adjustable Gastric Band (AGB)	☐	☐	___	___ / ___ / _____
Vertical Banded Gast. (VBG)	☐	☐	___	___ / ___ / _____
Sleeve Gastrectomy (SG)	☐	☐	___	___ / ___ / _____
Prior surgery performed on the esophagus, stomach, or proximal small intestine NOT for the purpose of weight loss	☐	☐	___	___ / ___ / _____
Other previous obesity surgery 1 *Specify:* _____	☐	☐	___	___ / ___ / _____
Other previous obesity surgery 2 *Specify:* _____	☐	☐	___	___ / ___ / _____

2. Smoking status:

☐ Never smoked ☐ Current ☐ Former

↓ ↓

Age started regularly: ___

Average packs/day: ___.___

Age started regularly: ___

Age quit: ___

Average packs/day: ___.___

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

For coordinator use only.

Teen-LABS (PO) Pre-Operative Form

3. Planned procedure:
   - ☐ Gastric bypass (Roux-en-Y)
   - ☐ Biliopancreatic diversion (BPD)
   - ☐ Biliopancreatic diversion with Doudenal Switch (BPDS)
   - ☐ Laparoscopic adjustable gastric band (LAGB)
   - ☐ Sleeve gastrectomy - initial stage
   - ☐ Sleeve gastrectomy - second stage → ☐ Gastric bypass (Roux-en-Y) ☐ BPD ☐ BPDS
   - ☐ Banded Gastric bypass (Gastric bypass & non-adjustable band)
   - ☐ Vertical Banded Gastroplasty
   - ☐ Other *specify:* _____
   - ☐ Unknown at this time

4. Planned approach:
   ☐ Laparoscopic ☐ Open ☐ Unknown

5. Is the planned procedure a revision?
   ☐ No ☐ Yes →
   5.1 Patient status at time of previous procedure:
   ☐ Teen LABS Registered patient ☐ Non-Teen LABS patient

6. Is the planned procedure a reversal?
   ☐ No ☐ Yes →
   6.1 Patient status at time of previous procedure:
   ☐ Teen LABS Registered patient ☐ Non-Teen LABS patient

7. Medications in the past 90 days: *(Mark "No" or "Yes" for each item.)*

No	Yes	
☐	☐	Therapeutic oral/IV immunosuppressant
☐	☐	Therapeutic anticoagulation
☐	☐	Narcotic
☐	☐	Statin or other lipid lowering agent
☐	☐	Antidepressant
☐	☐	Beta-blocker

8. What is the patient's functional status?
   - ☐ Can walk (length of grocery store aisle) 200ft unassisted
   - ☐ Able to walk 200ft with assist device (cane, walker)
   - ☐ Cannot walk 200ft with assist device
   - ☐ Unknown

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

For coordinator use only.

Teen-LABS (PO) Pre-Operative Form

9. Comorbidities: *(Mark "No" or "Yes" to each.)*

Comorbidity	No	Yes		If yes, mark the one best response
a. Hypertension	☐	☐	→	☐ No medication ☐ Single medication ☐ Multiple medications
b. Diabetes	☐	☐	→	☐ No medication ☐ Single oral medication ☐ Multiple oral medications ☐ Insulin ☐ Oral meds and insulin
c. CHF	☐	☐	→	NYHC: ☐ I ☐ II ☐ III ☐ IV ☐ Unknown
d. Asthma	☐	☐	→	☐ History of Intubation ☐ No History of Intubation

Comorbidity	No	Yes		If yes, mark "No" or "Yes" for each item		
				No	Yes	
e. History of DVT/PE	☐	☐	→	☐	☐	Documented DVT
				☐	☐	Documented PE
				☐	☐	Venous edema w/ulceration
f. Sleep apnea	☐	☐	→	☐	☐	C-pap/Bi-pap
				☐	☐	Supplemental oxygen dependent
g. Ischemic Heart Disease	☐	☐	→	☐	☐	History of MI
				☐	☐	No active ischemia
				☐	☐	Abnormal EKG but unable to assess ischemia
				☐	☐	PCI, CABG
				☐	☐	Anti-ischemic medications

Comorbidity	No	Yes
h. Pulmonary hypertension	☐	☐
i. History of venous edema with ulcerations	☐	☐
j. Pseudotumor Cerebri	☐	☐
k. Dyslipidemia	☐	☐
l. Intertriginous zone infection/breakdown	☐	☐
m. Gallstones	☐	☐
n. Acid reflux (heartburn)/GERD	☐	☐
o. Blount's Disease	☐	☐

10. Are there any comorbid conditions the patient may have that could affect clinical outcome following bariatric surgery?

☐ No ☐ Yes →

10.1 If yes, specify. *(Limit one comorbidity per box.)*

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

Visit: ☐☐ **For coordinator use only.** Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (ANTH) Anthropometrics

Evaluation date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

Time of evaluation: ___:___ *(military format)*

Last date/time patient had anything to eat or drink, including water: Date: ___ / ___ / ___ Time: ___:___

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

	Measurement 1	Measurement 2	Measurement 3	Was not assessed
Height:	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐ Height
Measured:	☐ Standing ☐ Lying flat* ☐ Estimate*	☐ Standing ☐ Lying flat* ☐ Estimate*	☐ Standing ☐ Lying flat* ☐ Estimate*	

*Specify why height wasn't measured standing: _____

Weight:	☐☐☐.☐☐ kg	☐☐☐.☐☐ kg	☐☐☐.☐☐ kg	☐ Weight
Percent body fat:	☐☐.☐☐ %	☐☐.☐☐ %	☐☐.☐☐ %	
Measured:	☐ Tanita Scale ☐ Other Scale* ☐ Last available bed weight* ☐ Estimate*	☐ Tanita Scale ☐ Other Scale* ☐ Last available bed weight* ☐ Estimate*	☐ Tanita Scale ☐ Other Scale* ☐ Last available bed weight* ☐ Estimate*	

*Specify why weight wasn't measured with Tanita Scale: _____

Midpoint waist circumference:	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐ Umbilical
Iliac waist circumference:	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐ Iliac
Sagittal abdominal diameter:	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐ Sagittal
Neck circumference:	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐☐☐.☐☐ cm	☐ Neck
Resting heart rate:	☐☐☐ bpm	☐☐☐ bpm	☐☐☐ bpm	☐ Heart rate
Blood pressure: (systolic/diastolic)	☐☐☐ / ☐☐☐	☐☐☐ / ☐☐☐	☐☐☐ / ☐☐☐	☐ BP
Measured:	☐ Mercury ☐ Gauge ☐ Electronic	☐ Mercury ☐ Gauge ☐ Electronic	☐ Mercury ☐ Gauge ☐ Electronic	

DEXA scan information Mark here if DEXA was not performed: ☐

Date of DEXA scan: ☐☐ / ☐☐ / ☐☐ Percent body fat: ☐☐.☐☐ %

Total bone mineral content: ☐☐☐☐ gm → Value in relation to reference range: ☐ High ☐ Within ☐ Low

Total bone mineral density: ☐☐.☐☐☐ gm/cm^2 → Value in relation to reference range: ☐ High ☐ Within ☐ Low

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

Visit: ☐☐ **For coordinator use only.** Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (RCAB) Research Coordinator Assessment Baseline

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

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

1. Clinical test(s) in preparation for bariatric surgery within 12 months. *(Mark "No," "Yes," or "Unk" for each procedure. If completed, specify results.)*

	No	Yes	Unk	*If yes*	Results
1.1 CAT scan of chest	☐	☐	☐	→	☐ Normal ☐ Abnormal
1.2 Stress test: ☐ Exercise ☐ Chemical	☐	☐	☐	→	☐ Normal ☐ Abnormal
1.3 Right Heart Catherization	☐	☐	☐	→	☐ Normal ☐ Abnormal
1.4 Left Heart Catherization	☐	☐	☐	→	☐ Normal ☐ Abnormal
1.5 Cardiac function (Based on an echocardiogram, cardiac MRI, CT imaging, ventriculography, Gated SPECT, MUGA.)	☐	☐	☐	→	LVEF: ☐☐☐.☐☐ % *enter "-3" if no percent available* If no percent available: ☐ Normal ☐ Abnormal LVMI: ☐☐☐.☐☐ $g/m^{2.7}$ LV mass: ☐☐☐.☐☐ gm Relative wall thickness: ☐☐.☐☐
1.6 Endoscopy	☐	☐	☐	→	H. pylori: ☐ No ☐ Yes ☐ Not done Barret's Esophagus: ☐ No ☐ Yes Hiatal Hernia: ☐ No ☐ Yes
1.7 Upper GI series	☐	☐	☐	→	Paraesophageal Hernia: ☐ No ☐ Yes Hiatal Hernia: ☐ No ☐ Yes
1.8 Pulseoximeter	☐	☐	☐	→	SAO_2: ☐☐☐.☐☐ %
1.9 ECG	☐	☐	☐	→	No Yes ☐ ☐ Normal ☐ ☐ Atrial Fib. ☐ ☐ Sinus Tach. ☐ ☐ Other Arrhythmia No Yes ☐ ☐ ST-T waves indicating possible ischemia ☐ ☐ Other, specify: _____
1.10 Polysomnogram	☐	☐	☐	→	Apnea-Hypopnea Index (AHI): ☐☐☐.☐
1.11 Pulmonary Function Test (PFT)	☐	☐	☐	→	FEV1: ☐☐.☐☐ L % of defusing capacity: ☐☐☐.☐☐ FVC: ☐☐.☐☐ L
1.12 Arterial blood gas	☐	☐	☐	→	CO_2: ☐☐ (mmHg) O_2 on room air temp: ☐☐☐.☐☐ (mmHg) O_2 on oxygen: ☐☐☐.☐☐ (mmHg)
1.13 Ultrasound gall bladder	☐	☐	☐	→	Evidence of gallstones: ☐ No ☐ Yes
1.14 Other: _____	☐	☐	☐	→	Results: _____

2. Pre-program height and weight (earliest weight after referral to surgical weight loss program): *(enter "-3" if ht/wt unk or not available)*

Height: ☐☐☐.☐☐ cm Weight: ☐☐☐.☐☐ kg Date height/weight obtained: ☐☐ / ☐☐ / ☐☐

3. Is patient residing in a care facility (for example: personal care home, rehab facility, long-term care facility, assissted living)?

☐ No ☐ Yes

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

Visit: ☐☐ **For coordinator use only.** Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (SMAB) Surgeon's Medical Assessment Baseline

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

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

Has the patient ever had... *(Mark "No" or "Yes" for each item.)*

No	Yes		
☐	☐	1. Leg swelling accompanied by blistering, infections, discolorations or alterations of the skin	
		↳ 1.1 *If yes,* specify treatment(s) within the past 12 months. *(Mark "No" or "Yes" for each item.)*	
☐	☐	Support hose	☐ ☐ Elevation of the legs
☐	☐	Diuretic	☐ ☐ Unna boots
☐	☐	Operation(s)	☐ ☐ Sequential compression boots
☐	☐	Blood thinners	☐ ☐ Other *specify:* _____
☐	☐	2. Filter placement to prevent blood clot	
☐	☐	3. Angina *If yes* →	3.1 Symptoms in past 12 months? ☐ No ☐ Yes ↳ *If yes,* classification level (see page 3): ☐ I ☐ II ☐ III ☐ IV
☐	☐	4. Hypertension	
☐	☐	5. Abnormal EKG but unable to assess ischemia	
☐	☐	6. Treatment for irregular heart beat	
☐	☐	7. Percutaneous Coronary Intervention	
☐	☐	8. CABG	
☐	☐	9. Heart valve operation	
☐	☐	10. CHF *If yes* →	10.1 NYHC (see page 3): ☐ I ☐ II ☐ III ☐ IV ☐ Unknown
☐	☐	11. COPD *If yes* →	11.1 Operation on lungs for COPD? ☐ No ☐ Yes
☐	☐	12. Sleep apnea *If yes* →	12.1 Operation for sleep apnea? ☐ No ☐ Yes 12.2 Currently use C-PAP/Bi-PAP? ☐ No ☐ Yes ↳ *If yes,* frequency of use (see page 3): ☐ Rarely ☐ Often ☐ Sometimes ☐ Always
☐	☐	13. Stroke *If yes* →	13.1 Specify permanent problems resulting from stroke. *(Mark "No" or "Yes" for each item.)*
☐	☐	Sensory	☐ ☐ Speech problems
☐	☐	Motor	☐ ☐ Memory or cognitive

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

Teen-LABS (SMAB) Surgeon's Medical Assessment Baseline

(Continued) Has the patient ever had... *(Mark "No" or "Yes" for each item.)*

No	Yes		
☐	☐	14. Pulmonary hypertension	
☐	☐	15. Hypoxemia/hypercarbia syndrome	
☐	☐	16. Cor pulmonale	
☐	☐	17. Pseudotumor cerebri (PTC)	*If yes* → 17.1 Undergone surgery for PTC? ☐ No ☐ Yes
☐	☐	18. Coagulopathy	
☐	☐	19. History of ventral hernia	

↳ 19.1 *If yes,* specify signs, symptoms, and treatments for hernia. *(Mark "No" or "Yes" for each item.)*

No	Yes		No	Yes	
☐	☐	Asymptomatic hernia, no prior operation	☐	☐	Chronic evisceration through large hernia with associated complication or multiple failed hernia repairs
☐	☐	Symptomatic or incarcerated hernia			
☐	☐	Successful repair			
		↳ *Specify month/year:* ___/____	☐	☐	Recurrent hernia or size > 15 cm

Has the patient ever had any of these surgeries... *(Mark "No" or "Yes" for each and specify how surgery was performed.)*

No	Yes		*If yes*	Method of surgical procedure *(Mark all that apply.)*	
☐	☐	20. GERD surgery	→	☐ Laparoscopic	☐ Open
☐	☐	21. Paraesophageal hernia repair	→	☐ Laparoscopic	☐ Open
☐	☐	22. Diaphragmatic defect repair	→	☐ Laparoscopic	☐ Open
☐	☐	23. Splenectomy	→	☐ Laparoscopic	☐ Open
☐	☐	24. Gastroschisis surgery	→	☐ Laparoscopic	☐ Open
☐	☐	25. Gastrostomy	→	☐ Laparoscopic	☐ Open
☐	☐	26. Appendectomy	→	☐ Laparoscopic	☐ Open
☐	☐	27. Cholecystectomy	→	☐ Laparoscopic	☐ Open
☐	☐	28. Small bowel operation	→	☐ Laparoscopic	☐ Open
☐	☐	29. Large bowel operation	→	☐ Laparoscopic	☐ Open
☐	☐	30. Surgery for stress urinary incontinence	→	☐ Laparoscopic	☐ Open
☐	☐	31. Bladder operation	→	☐ Laparoscopic	☐ Open
☐	☐	32. Ovarian procedure	→	☐ Laparoscopic	☐ Open
☐	☐	33. Other GYN procedure	→	☐ Laparoscopic	☐ Open
☐	☐	34. Other abdominal procedure	→	☐ Laparoscopic	☐ Open
☐	☐	35. Other prior laparoscopy			
☐	☐	36. Other prior laparotomy			
☐	☐	37. Surgery for Blount's disease			
☐	☐	38. Surgery for slipped capital femoral epiphysis			
☐	☐	39. Operation for peripheral edema			

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

Teen-LABS (SMAB) Surgeon's Medical Assessment Baseline

Canadian Cardiovascular Society Classification Level

Class I: Ordinary physical activity, such as walking several blocks or climbing stairs does not cause angina. Angina will occur with strenuous, rapid, or prolonged exertion at work or recreation.

Class II: Moderate exertion, such as walking or climbing rapidly, walking uphill, walking or stair climbing after meals, in wind, or when under emotional stress or during periods after awakening, or walking more than 2 level blocks, or climbing more than one flight of stairs causes limiting anginal symptoms. Comfort at rest. Slight limitation of ordinary activity.

Class III: Ordinary physical activity, such as walking 1-2 level blocks or climbing one flight of stairs at a normal pace, causes limiting anginal symptoms. Comfort at rest. Marked limitation of ordinary activity.

Class IV: Any physical activity that causes limiting symptoms. Anginal symptoms may be present at rest with prior exertional angina.

New York Heart Association Classification

Class I: Symptoms with more than ordinary activity; no limitations. Ordinary physical activity does not cause undue fatigue, dyspnea, or palpitations.

Class II: Symptoms with ordinary activity; slight limitation of physical activity. Such participants are comfortable at rest. Ordinary physical activity results in fatigue palpitations, dyspnea, or angina.

Class III: Symptoms with minimal activity; marked limitation of physical activity. Although participants are comfortable at rest, less-than-ordinary activity leads to fatigue, dyspnea, palpitations, or angina.

Class IV: Symptoms at rest; symptomatic at rest. Symptoms of CHF are present at rest; discomfort increases with any physical activity.

Unknown: The NYHC has not been noted in the participant's chart and the PI or primary surgeon is not able to determine this classification based on the above definitions.

Definitions of "frequency of use" if patients use C-PAP/Bi-PAP

Rarely:	Less than once per week	**Often:**	About every day
Sometimes:	About 3 times per week	**Always:**	I use it every time I sleep

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

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Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

9. Were any DVT prophylaxis administered (pre-operative or intra-operative) or ordered (post-operative)?

☐ No ☐ Yes

↓

9.1 Mark "No" or "Yes" to each item

No	Yes		Pre-Operative Administration Timing					Intra-Operative Administration		Post-operatively ordered	
			None	1-2 hrs	Within 1 hr	Within 30 min	>2 hrs	No	Yes	No	Yes
☐	☐	a. Compression stockings	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐
☐	☐	b. Sequential compression device	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐
☐	☐	c. Prophylactic vena cava filter	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐
☐	☐	d. Foot pump	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐
☐	☐	e. 5000 units sub-cutaneous heparin	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐
☐	☐	f. Other dose heparin; Dose: ____ units	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐
☐	☐	g. Low molecular weight heparin	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐

↳ *If low molecular weight heparin:*
☐ 20 mg ☐ 40 mg ☐ 60 mg ☐ Other, specify: ____.____ mg

☐	☐	h. Other Anticoagulant	→ ☐	☐	☐	☐	☐	→ ☐	☐	→ ☐	☐

↳ Name: _____
Dose: ____.____ ☐ mg ☐ units

10. Were any pre-operative antibiotics used?

☐ No ☐ Yes

↓

Antibiotic code	Dose (mg)	Time given (military)	Location administered	
10.1 ___	____.____	____:____	☐ Pre-surg holding room	☐ Operating room
10.2 ___	____.____	____:____	☐ Pre-surg holding room	☐ Operating room
10.3 ___	____.____	____:____	☐ Pre-surg holding room	☐ Operating room

Antibiotic codes:

code	name		code	name	
01	*Ancef*	*(cephalospirin - 1st generation)*	*08*	*Mefoxin*	*(Cefoxitin)*
02	*Cefotan*	*(cephalospirin - 3rd generation)*	*09*	*Zosyn*	*(Piperacillin/Tazobactam)*
03	*Vancocin*	*(Vancomycin)*	*10*	*Cleocin*	*(Clindamycin)*
04	*Levaquin*	*(Levofloxacin)*	*11*	*Garamycin*	*(Gentamicin/Gentamycin)*
05	*Unasyn*	*(Ampicillin/Sulbactam)*			
06	*Flagyl*	*(Metronidazole)*	*07*	*Other, specify:*	_____

11. Placement of central line?

☐ No ☐ Yes

12. Placement of arterial line?

☐ No ☐ Yes

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

13. Record fluids and blood loss during surgery:

a. Crystalloid fluids: _____ ml c. Blood loss: _____ cc *(if less than 50cc, enter '0')*

b. Colloid fluids: _____ ml d. Blood transfusion: ____ units

14. Overall size of liver: ☐ Normal ☐ Large ☐ Extremely large

15. Liver appearance: ☐ Normal ☐ Abnormal

↓

If abnormal, complete the following:

15.1 Liver color: ☐ Dark red (normal) ☐ Pale pink (fatty) ☐ Congested/Engorged/Nutmeg

15.2 Surface appearance: ☐ Smooth (normal) ☐ Nodular (cirrhotic)
☐ Surface scarring ☐ Other, specify: _____

15.3 Consistency: ☐ Normal ☐ Firm ☐ Hard

15.4 Mass lesion: ☐ No ☐ Single ☐ Multiple

15.5 Evidence of portal hypertension: ☐ No ☐ Yes

↓

If yes, complete the following:

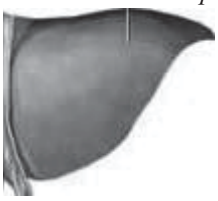
15.5.1 Splenomegaly: ☐ No ☐ Yes ☐ Could not observe

15.5.2 Varices: ☐ No ☐ Yes ☐ Could not observe

15.5.3 Other: ☐ No ☐ Yes, specify: _____

16. On a scale of 1 to 5, with 1 being gauged as normal and sharp and 5 being gauged as thick and rounded, circle the level of the sharpness of the edge of the left lateral segment of the liver.

The left lateral segment of the liver is normal and sharp



1 2 3 4 5

The left lateral segment of the liver is thick and rounded

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

17. Method of surgical procedure:

☐ Laparoscopic →

a. # of ports/incisions for each width *(enter '0' if none)*:

5mm	10-12mm	15mm	>=20mm
___	___	___	___

☐ Laparoscopic converted to open →

a. # of ports/incisions for each width *(enter '0' if none)*:

5mm	10-12mm	15mm	>=20mm
___	___	___	___

b. Specify reason for conversion *(mark "No" or "Yes" for each item)*:

No	Yes		No	Yes	
☐	☐	Exposure	☐	☐	Instrument/equipment failure
☐	☐	Bleeding	☐	☐	Other, specify:
☐	☐	Anatomy			_____

c. Length of open incision:

___.__ cm

☐ Open (no laparoscopic ports) →

a. Length of open incision:

___.__ cm

18. Was a resident or trainee present?

☐ No ☐ Yes

↓

18.1 Was the resident or trainee involved in the Gastric-Jejunum anastomosis?	☐ No	☐ Yes	☐ N/A
18.2 Was the resident or trainee involved in the Jejunum-Jejunum anastomosis?	☐ No	☐ Yes	☐ N/A
18.3 Was the resident or trainee involved in the Duodenal-Jejunum anastomosis?	☐ No	☐ Yes	☐ N/A

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

19. Were any concurrent procedures performed?

☐ No → *Skip to question 20 on page 6*

☐ Yes → *Complete the following table. Mark "No" or "Yes" to each item.*

No	Yes	Concurrent Procedures
☐	☐	a. Liver biopsy

↳ a1. Area of biopsy: ☐ Right lobe ☐ Left lobe ☐ Both lobes

a2. Indication for biopsy:

No	Yes	
☐	☐	Research protocol
☐	☐	Routine/standard of care
☐	☐	Signs or symptoms of liver disease
☐	☐	Abnormal pre-op LFTs
☐	☐	Abnormal appearance of liver in O.R.
☐	☐	Other, specify: _____

a3. Were there any complications? No ☐ Yes ☐ → If complication, specify: _____

No	Yes	Concurrent Procedures	If yes, were there any complications? No	If yes, were there any complications? Yes	If complication, specify:
☐	☐	b. Drain placed at gastrojejunostomy	☐	☐ →	
☐	☐	c. Gastrostomy	☐	☐ →	
☐	☐	d. Unplanned splenectomy	☐	☐ →	
☐	☐	e. Umbilical hernia	☐	☐ →	
☐	☐	f. Crural repair	☐	☐ →	
☐	☐	g. Partial Gastrectomy	☐	☐ →	
☐	☐	h. Subtotal gastrectomy	☐	☐ →	
☐	☐	i. Cholecystectomy	☐	☐ →	
☐	☐	j. Diagnostic EGD/EGJ *Note: This item should NOT be marked if it was only used to check the integrity of the anastomosis.*	☐	☐ →	
☐	☐	k. Truncal Vagotomy	☐	☐ →	
☐	☐	l. Partial Vagotomy	☐	☐ →	
☐	☐	m. Panniculectomy	☐	☐ →	
☐	☐	n. Planned fiberoptic intubation	☐	☐ →	
☐	☐	o. Incisional hernia	☐	☐ →	
☐	☐	p. Lysis of extensive adhesions	☐	☐ →	
☐	☐	q. Other, specify: _____	☐	☐ →	

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

20. Does the patient have a ventral hernia?

☐ No ☐ Yes

↓

20.1 Specify the features of the ventral hernia *(mark "No" or "Yes" for each item)*.

No	Yes	Features
☐	☐	a. Symptomatic
☐	☐	b. Prior abdominopelvic surgery
☐	☐	c. Prior hernia repair in this area
☐	☐	d. Contents incarcerated

↳ If yes, Evidence of bowel compromise? ☐ No ☐ Yes

20.2 Width of fascial defect (largest dimension): ___.___ cm

21. Lowest reported body temperature:

___.___ °C → 21.1 Specify temperature source: ☐ Skin (including cartilage) ☐ Core

22. Did the patient have any Intra-Operative events?

☐ No → *Stop completing this form*

☐ Yes → *Complete the following table, continues on following pages. Mark "No" or "Yes" to each item.*

No	Yes	Intra-Operative Events
☐	☐	22.1 Anesthesia-related complications ↳ 22.1.1 Specify Event(s) by code - *see page 8 for Anesthesia codes and complications* Code # 1. ___ 2. ___ 3. ___ 4. ___ 5. ___
☐	☐	22.2 Hypercapnia *(presence of carbon dioxide in the circulating blood more than 50 for a period of at least 10 minutes)*
☐	☐	22.3 Hypoxemia *(overt signs or symptoms indicative of inadequate oxygen intake or use for a period of at least 10 minutes measured via arterial line measurements)*
☐	☐	22.4 Revision of Anastomosis ↳ 22.4.1 Specify *(mark "No" or "Yes" to each)*: No Yes ☐ ☐ Gastrojejunostomy; No Yes ☐ ☐ Jejunostomy; No Yes ☐ ☐ Other *specify:* _____
☐	☐	22.5 Instrument/equipment failure ↳ 22.5.1 Specify cause *(mark "No" or "Yes" to each)*: No Yes ☐ ☐ Staple misfire; No Yes ☐ ☐ Trocar injury; No Yes ☐ ☐ Other *specify:* _____

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

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Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

No	Yes	Intra-Operative Events, *continued*
☐	☐	22.6 Diaphragmatic injury
	↳	22.6.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.6.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.7 Liver laceration
	↳	22.7.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.7.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.8 Splenic injury
	↳	22.8.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.8.2 Did this lead to organ loss? ☐ No ☐ Yes 22.8.3 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.9 Mesenteric bleeding/hematoma
☐	☐	22.10 Colon laceration
	↳	22.10.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.10.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.11 Urethral injury (including Foley catheter problems)
	↳	22.11.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.11.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.12 Pancreatic injury
	↳	22.12.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.12.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.13 Large vessel (named vessel) laceration
	↳	22.13.1 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.14 Esophageal injury
	↳	22.14.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.14.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.15 Bowel injury
	↳	22.15.1 Specify grade: ☐ Grade I ☐ Grade II ☐ Grade III ☐ Grade IV ☐ Grade V 22.15.2 Did this require suture or other repair? ☐ No ☐ Yes
☐	☐	22.16 Bleeding (>=2 units blood loss)

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

No	Yes	**Intra-Operative Events**, ***continued***
☐	☐	22.17 Serosal tear of intestine that required repair
	↳	22.17.1 Specify number of tears: ___ 22.17.2 Specify location (mark all that apply): ☐ Stomach ☐ Small bowel ☐ Colon 22.17.3 Specify method of serosal tear repair: ☐ Resection ☐ Oversew ☐ No repair necessary
☐	☐	22.18 Enterotomy
	↳	22.18.2 Specify location (mark all that apply): ☐ Stomach ☐ Small bowel ☐ Colon 22.18.3 Specify method of enterotomy repair: ☐ Resection ☐ Oversew ☐ No repair necessary
☐	☐	22.19 Cardiac arrhythmias resulting in significant change in blood pressure and pharmacological intervention
☐	☐	22.20 Cardiac arrest
☐	☐	22.21 Subcutaneous Emphysema
☐	☐	22.22 Pneumothorax
	↳	22.22.1 Did the patient require chest tube or pigtail placement? ☐ No ☐ Yes
☐	☐	22.23 Gas embolism with clinically significant gas introduced into central venous system
☐	☐	22.24 Respiratory arrest (cessation of respiratory function)
☐	☐	22.25 Respiratory failure (requiring continued mechanical ventilation)
☐	☐	22.26 Death
☐	☐	22.27 Other event that required an unexpected course of action
	↳	22.27.1 Specify other event(s) (list one per line):

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

23. Event tracking. Review items 22.1 through 22.27. If any are marked "Yes," they must be recorded in the table below. Specify item number (e.g., 22.17) and outcome as of the form completion date. (See below for outcome status definitions.)

Item	Outcome
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
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☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐☐.☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death

Outcome Status Definitions for question 23

Resolved: Patient returned to previous health status with no subsequent problems.
Continuing: Patient has not yet returned to previous health status and is still being actively managed for the complication.
Controlled: Complication is present, but is controlled (chronic management).
Death: Death has occurred due to complication.

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

APPENDIX A
Bariatric Anesthesia Events

Code	Event	Code	Event
01	Dental fracture or avulsion	25	Failure to extract intact esophageal probes
02	Nose bleeds, severe	26	Allergic reaction, severe
03	Soft tissue injury: upper airway	27	Ocular injury, minor
04	Unplanned fiber optic intubation	28	Ocular injury, major
05	Difficult, successful intubation (>2 attempts by laryngoscopist not in training)	29	Severe endocrine disturbance
06	Cannot intubate, successful mask ventilation	30	Malignant hyperthermia
07	Unsuccessful airway management, wake-up without sequelae	31	Positional injury
08	Use of airway rescue device (LMA, LMA-fastrach, Tracheal Esophageal Combitublightwand, etc.) after failed airway management	32	Integument injury
09	Cannot intubate, cannot ventilate	33	Acute renal insufficiency, failure
10	Invasive airway, by anesthesia	34	Congestive heart failure
11	Surgical airway required	35	Myocardial (cardiac) ischemia
12	Esophageal intubation, unwitnessed	36	Myocardial infarction
13	Laryngospasm	37	Sustained dysrhythmia
14	Bronchospasm	38	Sustained hypoxia
15	Negative-pressure pulmonary edema	39	Sustained hypotension
16	Witnessed aspiration	40	Sustained hypercarbia
17	Pneumothorax	41	Peripheral nerve injury
18	Rupture of bleb (<2 cm), bulla (>2 cm)	42	Stroke
19	Postoperative pneumonia	43	Hypoxic encephalopathy
20	Pulmonary edema	44	Coma or impaired consciousness
21	Re-intubation, within 24 hours	45	Cardiac arrest
22	Re-intubation, within 48 hours	46	Death
23	Prolonged postoperative intubation (>4 hours)	47	Case cancellation, involving anesthesia
24	Perforation of gastronintestinal tract by esophageal probes	48	Miscellaneous

APPENDIX B
Injury Scales

6. Diaphragm injury scale		
Grade	**Injury Description**	**AIS-90**
I	Contusion	2
II	Laceration <=2cm	3
III	Laceration 2-10 cm	3
IV	Laceration >10 cm with tissue loss <=25cm²	3
V	Laceration with tissue loss >25 cm²	3

7. Liver injury scale - laceration		
Grade	**Injury Description**	**AIS-90**
I	Capsular tear, <1cm parenchymal depth	2
II	Capsular tear, 1-3 cm parenchymal depth, <10 cm in length	2
III	>3 cm parenchymal depth	3
IV	Parenchymal disruption involving 25% - 75% of hepatic lob or 1-3 Couinaud's segments within a single lobe	4
V	Parenchymal disruption involving >75% of hepatic lob or >3 Couinaud's segments within a single lobe	5

Teen-LABS (SQOP) Surgeon's Questionnaire/Operative Evaluation

APPENDIX B, continued
Injury Scales

8. Spleen scale - laceration		
Grade	**Injury Description**	**AIS-90**
I	Capsular tear, <1 cm parenchymal depth	2
II	Capsular tear, 1-3 cm parenchymal depth, which does not involve a trabecular vessel	2
III	>3 cm parenchymal depth or involving trabecular vessels	3
IV	Laceration involving segmental or hilar vessels producing major devscularization (>25% of spleen)	4
V	Complete shattered spleen	5

10. Colon injury - laceration		
Grade	**Injury Description**	**AIS-90**
I	Partial thickness, no perforation	2
II	Laceration <50% of circumference	3
III	Laceration >=50% of circumference without transaction	3
IV	Transection of the colon	4
V	Transection of the colon with segmental tissue loss	4

11. Urethra injury - laceration			
Grade	**Injury Type**	**Injury Description**	**AIS-90**
I	Contusion	Blood at urethral meatus: urethrography normal	2
II	Stretch injury	Elongation of urethra without extravasation on urethrography	3
III	Partial disruption	Extravasation of urethrography contrast at injury site with contrast visualized in the bladder	3
IV	Complete disruption	Extravasations of urethrography contrast at injury site without visualization in the bladder; <=2 cm of urethral separation	4
V	Complete disruption	Complete transaction with >2 cm urethral separation, or extension into the prostate or vagina	4

12. Pancreas injury - laceration		
Grade	**Injury Description**	**AIS-90**
I	Superficial laceration without duct injury	2
II	Major laceration without duct injury or tissue loss	3
III	Distal transaction or parenchymal injury with duct injury	3
IV	Proximal transaction or parenchymal injury involving ampulla	4
V	Massive disruption of pancreatic head	5

14. Esophagus injury		
Grade	**Injury Description**	**AIS-90**
I	Contusion/Hematoma Partial-thickness laceration	2 3
II	Laceration <=50% circumference	3
III	Laceration >50% circumference	4
IV	Segmental loss or devascularization <=2 cm	4
V	Segmenatl loss or devascularization >2 cm	5

15. Bowel injury		
Grade	**Injury Description**	**AIS-90**
I	Contusion or hematoma withour devascularization	2
II	Laceration <50% circumference	3
III	Laceration >= 50% circumference without transection	3
IV	Transection of the small bowel with segmental tissue loss	4
V	Devascularized segment	4

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

For coordinator use only. Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (DS) Discharge Summary

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

Date of Surgery: ___ / ___ / 20___ *(mm/dd/yyyy)*

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

1. Were any post-operative anticoagulation therapy received prior to discharge?

☐ No ☐ Yes ↓

Mark "No" or "Yes" for each item. If yes, specify use, number of days, and times per day.

No	Yes		If yes	Prophylactic (preventative) Use? No	Prophylactic (preventative) Use? Yes	# of days	times per day	Therapeutic (as treatment) Use? No	Therapeutic (as treatment) Use? Yes	# of days	times per day
☐	☐	5000 units sub-cutaneous heparin	→	☐	☐	___	___	☐	☐	___	___
☐	☐	Other dose heparin; Dose: _____ units	→	☐	☐	___	___	☐	☐	___	___
☐	☐	Low molecular weight heparin *If yes, specify dose:* ☐ 20 mg ☐ 40 mg ☐ 60 mg ☐ Other, specify: _____.____ mg	→	☐	☐	___	___	☐	☐	___	___
☐	☐	Other Anticoagulant *If yes, specify:* Name: _____ Dose: _____.____ ☐ mg ☐ units	→	☐	☐	___	___	☐	☐	___	___

2. Post-operative pain management. *Mark "No" or "Yes" for each item.*

No	Yes		No	Yes	
☐	☐	Thoracic epidural	☐	☐	Oral narcotics
☐	☐	Abdominal epidural	☐	☐	Intermittent IV narcotics
☐	☐	Patient controlled anesthesia (PCA) pump	☐	☐	Tylenol
☐	☐	Roxicet Elixir	☐	☐	Ketorolac
			☐	☐	Other *specify:* _____

3. Patient disposition after surgery:

☐ ICU →

☐ Floor with telemetry

☐ Floor without telemetry

☐ Same day discharge

If ICU,

3.1 Specify number of days of intubation after surgery: ___
(day of surgery is defined as day zero)

3.2 Was the patient reintubated? ☐ No ☐ Yes → If yes, number of times: ___

4. Nutritional therapy at discharge:

☐ All nutrition per oral

☐ Any non-PO enteral feeds

☐ Any TPN

Teen-LABS (DS) Discharge Summary

5. Was the patient discharged more than 30 days AFTER initial surgery?
   ☐ No ☐ Yes

6. Date of hospital discharge (or date of death if patient died prior to discharge): ___ / ___ / 20___

7. Intended discharge location:
   ☐ Home ☐ Other hospital
   ☐ Rehabilitation facility ☐ Was not discharged (patient died prior to discharge)
   ☐ Skilled nursing facility

8. Did the patient have any in-hospital Post-Operative Complications prior to discharge?
   ☐ No → *End of questionnaire*
   ☐ Yes → *Complete the following table. Mark "No" or "Yes" to each item.*
   If patient was discharged more than 30 days AFTER initial surgery, mark the "Within 30 days" box if complication occurred WITHIN 30 days of surgery.

No	Yes	Within 30 days	Post-operative complications
☐	☐ ↳	☐	8.1 Reoperation ***(NOTE: for each re-operation, please obtain adjudication information)***

8.1.1 Specify reason for surgery *(mark "No" or "Yes" for each)*.

No	Yes		No	Yes	
☐	☐	a. Intestinal obstruction	☐	☐	i. Wound infection/evisceration
☐	☐	b. Subsequent cholecystectomy	☐	☐	j. Fluid or electrolyte depletion
☐	☐	c. Anastomotic leak	☐	☐	k. Vomiting or poor intake
☐	☐	d. Other abdominal sepsis	☐	☐	l. Gastric distension
☐	☐	e. Pulmonary embolism	☐	☐	m. Strictures
☐	☐	f. Pneumonia	☐	☐	n. Bleeding
☐	☐	g. Other respiratory failure	☐	☐	o. Infection/fever
☐	☐	h. Subsequent abdominoplasty	☐	☐	p. Other, specify: _____

☐	☐ ↳	☐	8.2 Gastrojejunostomy leak

8.2.1 Specify grade: ☐ Minimal - small contained leak, patient asymptomatic
☐ Moderate - moderate size forming collection, symptomatic, drain used
☐ Large - not contained, symptomatic, requires re-operation

☐	☐ ↳	☐	8.3 Jejuno-jejunostomy leak

8.3.1 Specify grade: ☐ Minimal - small contained leak, patient asymptomatic
☐ Moderate - moderate size forming collection, symptomatic, drain used
☐ Large - not contained, symptomatic, requires re-operation

☐	☐	☐	8.4 Pancreatitis

Teen-LABS (DS) Discharge Summary

8. Post-Operative Complications (continued)

No	Yes	Within 30 days	Post-operative complications
☐	☐ ↳	☐	8.5 Post operative bleeding 8.5.1 Specify location *(mark "No" or "Yes" for each)*. No Yes — Upper intestine; No Yes — Lower intestine; No Yes — Intra-peritoneal; No Yes — Unknown; No Yes — Other, specify: _____ 8.5.2 Specify number of units of blood required: ___ units
☐	☐ ↳	☐	8.6 Abdominal abscess 8.6.1 Specify location *(mark "No" or "Yes" for each)*. No Yes — Left upper quadrant; No Yes — Subhepatic; No Yes — Lower abdomen; No Yes — Other, specify: _____
☐	☐	☐	8.7 Esophageal injury
☐	☐	☐	8.8 Wound infection (Cellulitis around incision site accompanied by fever)
☐	☐	☐	8.9 Fascial dehiscence
☐	☐	☐	8.10 Seroma of wound
☐	☐ ↳	☐	8.11 Small bowel obstruction 8.11.1 Specify obstruction: ☐ Partial obstruction ☐ Complete obstruction 8.11.2 Specify cause: ☐ Internal hernia ☐ Obstructed JJ Anastomosis ☐ Adhesions ☐ Unknown ☐ Anastomotic anatomy ☐ Other, specify: _____
☐	☐	☐	8.12 Stomal/gastric outlet obstruction
☐	☐	☐	8.13 Stomal stenosis
☐	☐	☐	8.14 GI ulcer(s)
☐	☐	☐	8.15 Ateletasis (significant) (Diagnosis by chest X-ray accompanied by fever)
☐	☐	☐	8.16 Pneumothorax
☐	☐	☐	8.17 Pleural effusion
☐	☐	☐	8.18 Pulmonary embolism

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

For coordinator use only.

Teen-LABS (DS) Discharge Summary

8. Post-Operative Complications (continued)

No	Yes	Within 30 days	Post-operative complications
☐	☐	☐	8.19 Deep vein thrombosis
☐	☐	☐	8.20 Pneumonia
☐	☐	☐	8.21 Respiratory failure requiring intubation
	↳		8.21.1 Specify cause: ☐ ARDS ☐ PE ☐ Other, specify: ☐ Pneumonia ☐ Unknown _____
☐	☐	☐	8.22 Renal/urinary tract infection
☐	☐	☐	8.23 Renal failure
	↳		8.23.1 Specify type of diagnosis *(mark "No" or "Yes" for each)*. No ☐ Yes ☐ Oliguric/anuric; No ☐ Yes ☐ Creatinine
☐	☐	☐	8.24 TIA
☐	☐	☐	8.25 Stroke
	↳		8.25.1 Specify type of diagnosis: ☐ Ischemic ☐ Hemorrhagic
☐	☐	☐	8.26 Urinary retention
☐	☐	☐	8.27 New decubitus ulcers (bed sores)
☐	☐	☐	8.28 Rhabodomyolysis (defined as CPK's of 5000 or more)
☐	☐	☐	8.29 Jaundice
☐	☐	☐	8.30 Hepatitis
☐	☐	☐	8.31 Liver failure
☐	☐	☐	8.32 Acute cholecystitis/bilaric colic
☐	☐	☐	8.33 Common bile duct stones/cholangitis
☐	☐	☐	8.34 Arrhythmia
☐	☐	☐	8.35 Persistent Tachycardia
☐	☐	☐	8.36 Myocardial infarction
☐	☐	☐	8.37 Cardiac arrest
☐	☐	☐	8.38 Death ***(Please obtain adjudication information)***
☐	☐	☐	8.39 Other event that resulted in an unexpected course of action, specify: _____

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

For coordinator use only.

Teen-LABS (DS) Discharge Summary

9. Complication tracking. Review items 8.1.1 through 8.39. If any are marked "Yes," they must be recorded in the table below. Specify item number (e.g., 8.5), date of occurrence, and outcome as of the form completion date. If a complication occurred more than once, record EACH INSTANCE on a separate line. NOTE: for 8.1.1 specify item number out to the furthest point (e.g., 8.1.1c). (See below for outcome status definitions.)

Use this table for item 8.1.1 only

Item	**Date** *(mm/dd/yy)*	**Outcome**
☐.☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death

Use this table for items 8.2 through 8.39

Item	**Date** *(mm/dd/yy)*	**Outcome**
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death

Outcome Status Definitions for question 9

Resolved: Patient returned to previous health status with no subsequent problems.
Continuing: Patient has not yet returned to previous health status and is still being actively managed for the complication.
Controlled: Complication is present, but is controlled (chronic management).
Death: Death has occurred due to complication.

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

For coordinator use only. Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (POST) Post-Operative Evaluation Form

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)* **Completed by (certification no.):** _____

Date of surgery: ___ / ___ / 20___ *(mm/dd/yyyy)*

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

1. Source(s) of information: *(Mark "No" or "Yes" to each.)*

	No	Yes		If yes, specify date of most recent contact *(mm/dd/yy)*
a. Patient in person	☐	☐	→	___ / ___ / ___
b. Patient by telephone	☐	☐	→	___ / ___ / ___
c. Patient representative	☐	☐	→	___ / ___ / ___
d. Other physician	☐	☐	→	___ / ___ / ___
e. Chart review	☐	☐	→	___ / ___ / ___

2. Length of hospital stay for obesity surgery:

_____ days

3. Discharge location:

☐ Home →
☐ Rehabilitation facility →
☐ Skilled nursing facility →
☐ Other hospital →
☐ Was not discharged

3.1 Discharge date: ___ / ___ / _____

4. Did the patient die?

☐ No → 4.1 Status date: ___ / ___ / _____ (Most recent date participant known to be alive.)

☐ Yes → 4.2 Date of death: ___ / ___ / _____ ***(Please obtain adjudication information.)***

5. Was the patient re-hospitalized after initial discharge?

☐ No ☐ Yes →

5.1 Number of times re-hospitalized: ____

5.2 Date of first re-hospitalization: ___ / ___ / _____

5.3 Were any of these related to a cardiac event: ☐ No ☐ Yes

5.4 Were any of these related to hydration or nutrition: ☐ No ☐ Yes

For EACH hospitalization:
1. Complete an HC
2. Obtain adjudication information

6. Current nutritional therapy:

☐ All nutrition per oral
☐ Any non-PO enteral feeds
☐ Any TPN

Teen-LABS (POST) Post-Operative Evaluation Form

7. Did the patient have any post-discharge complications?

☐ No → *Skip to question 9 on page 5*

☐ Yes → *Complete the following table. Mark "No" or "Yes" to each item.*

No	Yes	Post-discharge complications
☐	☐	7.1 Wound infection
☐	☐	7.2 Fascial dehiscence
		↳ 7.2.1 Did the wound edges open within 30 days following surgery? ☐ No ☐ Yes 7.2.2 Did the wound edges separate within 30 days following the surgery requiring packing or bandage? ☐ No ☐ Yes
☐	☐	7.3 Small bowel obstruction
		↳ 7.3.1 Specify obstruction: ☐ Partial obstruction ☐ Complete obstruction 7.3.2 Specify cause: ☐ Internal hernia ☐ Anastomotic anatomy ☐ Unknown ☐ Adhesions ☐ Obstructed JJ Anastomosis ☐ Other *specify:* _____
☐	☐	7.4 Incisional/ventral hernia
☐	☐	7.5 Acute cholecystitis/bilaric colic
☐	☐	7.6 Common bile duct stones/cholangitis
☐	☐	7.7 Stomal/gastric outlet obstruction
☐	☐	7.8 Stapleline breakdown
☐	☐	7.9 Leakage of intestinal contents

↳ 7.9.1 Specify details of leak *(mark "No" or "Yes" to each)*.

No	Yes		No	Yes	
☐	☐	a. Contained	☐	☐	k. From esophagus
☐	☐	b. Diffuse	☐	☐	l. From stomach
☐	☐	c. Staple line	☐	☐	m. From small bowel
☐	☐	d. Operative repair or drainage	☐	☐	m. From JJ
☐	☐	e. Percutaneous drainage	☐	☐	n. From other source, specify: _____
☐	☐	f. Non-operative management			
☐	☐	g. Proximal to GJ junction	☐	☐	o. Duodenum or biliopancreatic limb
☐	☐	h. Gastrojejunostomy anastomosis	☐	☐	p. Roux (not anastomosis)
☐	☐	i. Gastric pouch	☐	☐	q. Common channel small bowel
☐	☐	j. Gastric remnant			

☐	☐	7.10 Anastomotic stricture: Gastro-jejunostomy
☐	☐	7.11 Anastomotic stricture: Jejuno-jejunostomy
☐	☐	7.12 Gastric band stenosis
☐	☐	7.13 Gastric band erosion
☐	☐	7.14 Gastric band slippage
☐	☐	7.15 Gastric band leakage

Teen-LABS (POST) Post-Operative Evaluation Form

7. Post discharge complications, continued.

No	Yes	Post-discharge complications
☐	☐	7.16 Port or tube problems
☐	☐	7.17 Gastric prolapse
☐	☐	7.18 Esophageal motility disorder or dilation
☐	☐	7.19 Gastroesophageal reflux
	↳	7.19.1 How was it identified: ☐ Symptoms ☐ pH probe → # measured: ___
☐	☐	7.20 Primary dumping syndrome *(including nausea, bloating, diarrhea, colic, within 1 hour of a meal)*
☐	☐	7.21 Late-dumping symptoms *(including light-headedness, palpitations, sweating, diarrhea, >=1 hour of a meal)*
☐	☐	7.22 Nausea or vomiting
	↳	7.22.1 Specify severity and frequency levels

	Severity level*					Frequency level**				
	None	Mild	Moderate	Severe	Extremely severe	None	Rare	Occasional	Frequent	Extremely frequent
Nausea	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Vomiting	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

*Severity definitions
None: does not have this complication.
Mild: not influencing usual activitites.
Moderate: diverting from, but not urging modification.
Severe: influencing usual activitites, severely enough urge modifications.
Extremely severe: requiring hospitalization or bed rest.

*Frequency definitions
None: does not have this complication.
Rare: 1 time per week.
Occasional: 2 to 3 times per week.
Frequent: 4 to 6 times per week.
Extremely frequent: 7 or more times per week.

☐	☐	7.23 Flatulence *(defined as excessive interference with lifestyle)*
☐	☐	7.24 Persistent diarrhea *(defined as excessive interference with lifestyle)*
☐	☐	7.25 Constipation *(defined as excessive interference with lifestyle)*
☐	☐	7.26 Dehydration *(defined as requiring hospitalization)*
☐	☐	7.27 Acute renal failure
☐	☐	7.28 Liver failure
☐	☐	7.29 Myocardial infarction
☐	☐	7.30 Cardiac arrest
☐	☐	7.31 Hypoglycemia *(defined by abnormally low blood glucose measured within 3 hours after a meal)*
☐	☐	7.32 Symptomatic hypoglycemia *(defined by abnormally low blood glucose measured within 3 hours after a meal; plus altered mental status, or loss of consciousness, or seizure, or blurred vision, or weakness, or dizziness)*
☐	☐	7.33 Other event that resulted in an unexpected course of action, specify: _____

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐

For coordinator use only.

Teen-LABS (POST) Post-Operative Evaluation Form

8. Complication tracking. Review items 7.1 through 7.33. If any are marked "Yes," they must be recorded in the table below. Specify item number (e.g., 7.3), date of occurrance, and outcome as of the form completion date. If a complication occurred more than once, record EACH INSTANCE on a separate line. (See below for outcome status definitions.)

Item	**Date** *(mm/dd/yy)*	**Outcome**
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death
☐.☐☐	☐☐ / ☐☐ / ☐☐	☐ Resolved ☐ Continuing ☐ Controlled ☐ Death

Outcome Status Definitions for question 8

Resolved: Patient returned to previous health status with no subsequent problems.
Continuing: Patient has not yet returned to previous health status and is still being actively managed for the complication.
Controlled: Complication is present, but is controlled (chronic management).
Death: Death has occurred due to complication.

Table of codes for suspected reason for an intervention
(use with question 9 on page 5)

Code	Suspected reason	Code	Suspected reason	Code	Suspected reason
1	Anastomotic leak	6	Pneumonia	11	Gastric distension
2	Other abdominal sepsis	7	Other respiratory failure	12	Strictures
3	Intestinal obstruction	8	Wound infection/evisceration	13	Bleeding
4	DVT	9	Fluid or electrolyte depletion	14	Infection/fever
5	Pulmonary embolism	10	Vomiting or poor intake	15	Other

Teen-LABS (POST) Post-Operative Evaluation Form

9. Did the patient have any post-bariatric procedures or undergo unplanned post-discharge anticoagulation therapy?

☐ No ☐ Yes → *Specify all of the bariatric procedures or anticoagulation therapies below. Mark "No" or "Yes" to each item.*

Event			Date first performed after surgery *(mm/dd/yy)*	Suspected reason for intervention *(see codes on page 4)*	Was the reason for the intervention confirmed?	
No	**Yes**				**No**	**Yes**
☐	☐	9.1 Abdominal re-operation				
	↳	9.1.1 Specify approach: ☐ Laparoscopic ☐ Laparoscopic converted to open ☐ Open				
		9.1.2 Specify procedure:				
No	**Yes**					
☐	☐	a. Operative drain placement	___/___/___	___	☐	☐
☐	☐	b. Gastrostomy	___/___/___	___	☐	☐
☐	☐	c. Anastomotic revision				
		Specify revision: ☐ GJ	___/___/___	___	☐	☐
		☐ JJ	___/___/___	___	☐	☐
		☐ DJ	___/___/___	___	☐	☐
☐	☐	d. Band replacement	___/___/___	___	☐	☐
☐	☐	e. Band/port revision	___/___/___	___	☐	☐
☐	☐	f. Wound revision or evisceration	___/___/___	___	☐	☐
☐	☐	g. Re-exploration	___/___/___	___	☐	☐
☐	☐	h. Other *specify:*	___/___/___	___	☐	☐
☐	☐	9.2 Tracheal reintubation	___/___/___	___	☐	☐
☐	☐	9.3 Tracheostomy	___/___/___	___	☐	☐
☐	☐	9.4 Endoscopy	___/___/___	___	☐	☐
☐	☐	9.5 Dilation	___/___/___	___	☐	☐
☐	☐	9.6 Placement of percutaneous drain	___/___/___	___	☐	☐
☐	☐	9.7 Anticoagulation therapy for presumed/confirmed DVT			☐	☐
☐	☐	9.8 Anticoagulation therapy for presumed/confirmed PE			☐	☐
☐	☐	9.9 Readmission (other 1) *specify:*	___/___/___	___	☐	☐
☐	☐	9.10 Readmission (other 2) *specify:*	___/___/___	___	☐	☐
☐	☐	9.11 Readmission (other 3) *specify:*	___/___/___	___	☐	☐

Teen-LABS (POST) Post-Operative Evaluation Form

10. Procedure tracking. Review items 9.1.2 through 9.11. If any are marked "Yes," they must be recorded in the table below. Specify item number and date of occurrance. If a procedure was done more than once, record EACH INSTANCE on a separate line. NOTE: for 9.1.2 specify item number out to the furthest point (e.g., 9.1.2b or 9.1.2cJJ).

Use this table for item 9.1.2 only*

Item	Date (mm/dd/yy)
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐
☐.☐.☐☐☐☐	☐☐ / ☐☐ / ☐☐

Use this table for items 9.2 through 9.11*

Item	Date (mm/dd/yy)
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐
☐.☐☐	☐☐ / ☐☐ / ☐☐

***Please obtain adjudication information**

11. Were any planned post-discharge anticoagulation therapies received?

☐ No ☐ Yes ↓

Mark "No" or "Yes" for each item. If yes, mark "No" or "Yes" for each type of use, and specify number of days, and times per day if used.

No	Yes		If yes	Prophylactic (preventative) Use? No	Prophylactic Use? Yes	# of days	times per day	Therapeutic (as treatment) Use? No	Therapeutic Use? Yes	# of days	times per day
☐	☐	5000 units sub-cutaneous heparin	→	☐	☐	___	___	☐	☐	___	___
☐	☐	Other dose heparin; Dose: ______ units	→	☐	☐	___	___	☐	☐	___	___
☐	☐	Low molecular weight heparin *If yes, specify dose:* ☐ 20 mg ☐ 40 mg ☐ 60 mg ☐ Other, specify: ____.___ mg	→	☐	☐	___	___	☐	☐	___	___
☐	☐	Other Anticoagulant *If yes, specify:* Name: ____________ Dose: ____.___ ☐ mg ☐ units	→	☐	☐	___	___	☐	☐	___	___

Site ID: ☐☐☐ Subject ID: ☐☐☐☐☐ Reviewed by (certification no.): ☐☐☐☐

Visit: ☐☐ **For coordinator use only.** Review date: ☐☐ / ☐☐ / ☐☐

Teen-LABS (RHB) Reproductive Health Baseline

Form completion date: ___ / ___ / 20___ *(mm/dd/yyyy)*

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

This form is for females only.

1. Have you had irregular menstrual periods (less than 8 periods a year) throughout life starting in your teens?
   ☐ No ☐ Yes ☐ I have never had a menstrual period or I have only had menstrual periods for less than a year

2. Have you ever had the following symptoms? *(Mark "No" or "Yes" for each.)*

No	Yes	
☐	☐	Excess facial, chest, or body hair
☐	☐	Male pattern baldness, such as thinning of hair at the crown or temple
☐	☐	Severe acne

3. Has a health care professional ever told you that you have/had polycystic ovary syndrome (PCOS)?
   ☐ No ☐ Yes →
   ↓
   Skip to question 4

   3.1 Are you currently treating your PCOS?
   ☐ No ☐ Yes
   ↓ ↓
   Skip to question 4

   3.1.1 How are you currently treating your PCOS? *(Mark "No" or "Yes" for each.)*

No	Yes	
☐	☐	Exercise
☐	☐	Diet
☐	☐	Prescription medication

4. In the **past 12 months**, have you taken any hormonal medication, such as hormone replacement therapy (HRT), the pill, or fertility medication?
   ☐ No ☐ Yes →
   ↓
   Skip to question 5

   4.1 Please indicate which type of hormonal medication you have taken in the **past 12 months**:
   ☐ Hormone replacement therapy
   ☐ Hormonal birth control (such as pill, ring, shot, Mirena)
   ☐ Fertility medication

5. Have you ever had a menstrual period?
   ☐ No ☐ Yes →
   ↓
   Skip to question 12

   5.1 How old were you when you got your first menstrual period?
   ___ *years old*

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Teen-LABS (RHB) Reproductive Health Baseline

Thinking back over the past **12 months...**

6. In how many of those months did you have a menstrual period?

___ *months* ***If you answered zero (0) months, skip to question10.***

7. Usually, how many days are between your menstrual periods? (This is the interval from the first day of one menstrual period to the first day of your next menstrual period.)

☐ Less than 21 days ☐ 21-35 days ☐ More than 35 days ☐ Too irregular to estimate

8. On average, how many days did your menstrual period (bleeding) last?

☐ 1-4 days ☐ 5-7 days ☐ 8-9 days ☐ More than 9 days

9. Did you have spotting or bleeding that occurred at times other than your menstrual period?

☐ No ☐ Yes →

9.1 In how many of the past 12 months did this occur?

___ *months*

10. When was your last menstrual period?

___ *months ago (if less than 3 months ago, go to question 12)*

11. If your last period was 3 or more months ago, why did your natural menstrual period stop?

☐ Birth control or other medication
☐ Hysterectomy alone
☐ Hysterectomy and oophorectomy
☐ Oophorectomy alone
☐ Endometrial ablation
☐ Chemotherapy
☐ Chronic illness
☐ Prolactin, adrenal gland or thyroid problem
☐ Pregnancy
☐ No known reason
☐ Other *specify:* _____

12. How old are you now?

☐ Under 18 years old → ***DO NOT CONTINUE -- END OF QUESTIONNAIRE***
☐ 18 years old or older

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CONTINUE QUESTIONNAIRE ONLY IF SUBJECT IS 18 YEARS OLD OR OLDER

13. Have you **ever** tried to become pregnant?
    - ☐ No → *Skip to question 17*
    - ☐ Yes

14. Has there **ever** been at least 12 months in your life when you were regularly having sexual intercourse with a man and not using any form of birth control and yet you did not become pregnant?
    - ☐ No ☐ Yes →

    14.1 Specify age this first happened:

    ___ *years old*

15. Have you **ever** talked to a doctor or had tests done because of problems becoming pregnant?
    - ☐ No → *Skip to question 17*
    - ☐ Yes

16. Have you ever taken any fertility medication to help you become pregnant (such as Clomid, Serophene, Gonal-F, Follistim)?
    ☐ No ☐ Yes

17. Total number of times you have been pregnant: ___ *times* ***If you answered zero (0) times, please skip to question 18.***

    If at least one pregnancy,

    Starting with your first pregnancy, please use the table below to report the following:
    - your age when you became pregnant
    - whether you were taking fertility medication when you became pregnant
    - whether you had a live birth, still birth (baby lost after 20 weeks or 5 months), miscarriage (fetus lost before 20 weeks or 5 months), or other outcome.

		fertility med used?		*Please mark **one** outcome per pregnancy*			
	your age	No	Yes	live birth	still birth	miscarriage	other outcome
Preg. 1	___	☐	☐	☐	☐	☐	☐
Preg. 2	___	☐	☐	☐	☐	☐	☐
Preg. 3	___	☐	☐	☐	☐	☐	☐
Preg. 4	___	☐	☐	☐	☐	☐	☐
Preg. 5	___	☐	☐	☐	☐	☐	☐
Preg. 6	___	☐	☐	☐	☐	☐	☐
Preg. 7	___	☐	☐	☐	☐	☐	☐
Preg. 8	___	☐	☐	☐	☐	☐	☐

☐ I have had more than 8 pregnancies

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18. In the past 12 months, how often have you used birth control when having sexual intercourse with a man?
- ☐ Not sexually active with a man
- ☐ Never
- ☐ Rarely
- ☐ About half the time
- ☐ Most of the time
- ☐ All of the time

19. In the **past 12 months**, have you used (or has your partner used) birth control for any reason?

☐ No ☐ Yes

↓ ↓

Skip to question 20

19.1 Specify method of birth control you have used in the past 12 months. *(Mark "No" or "Yes" for each item.)*

No	Yes		No	Yes	
☐	☐	Pills, monthly (including one week of placebo or no pills, get period)	☐	☐	Diaphragm
☐	☐	Pills, continuous use (new pack every 3 weeks, no period)	☐	☐	Cervical cap
☐	☐	Mini Pill, continuous use (progestin only, get period)	☐	☐	Male or female condom
☐	☐	Patch or ring	☐	☐	Contraceptive foams, creams, jellies
☐	☐	Injections of medications (shots) or implantation of a medication release device	☐	☐	Natural family planning, rhythm method or having sex during "safe" times
☐	☐	IUD *If yes, specify:* ☐ Mirena ☐ Copper ☐ Don't know	☐	☐	Withdrawal
			☐	☐	Hysterectomy: your uterus was surgically removed
			☐	☐	Tubal ligation: your tubes were tied
			☐	☐	Vasectomy: your partner was sterilized
			☐	☐	Other, specify: _____

20. Please rate how important it is to you to be able to ever become pregnant in the future on a scale from 0 to 10, where 0 is of no importance and 10 is the most important thing in your life.

Enter a number from 0 to 10: ___

21. When do you think you will try to become pregnant?

☐ Never ☐ In next 12 months ☐ In next 13-24 months ☐ After 24 months ☐ Not sure

eTable 1. Central Laboratory Measures by Reference Category

Test	N	Below normal limits	Within normal limits	Above normal limits	Reference Range
Serum Creatinine	238	1 (0.4%)	237 (99.6%)	0 (0%)	Female: 0.4-1.1 mg/dL Male: 0.5-1.2 mg/dL
Cystatin C	238	3 (1.3%)	199 (83.6%)	36 (15.1%)	Normal: 0.53-0.95 mg/dL
Urine Albumin-Creatinine Ratio	226	n/a	186 (82.3%)	40 (17.7%)	Normal: <0.030
Insulin	234	2 (0.9%)	66 (28.2%)	166 (70.9%)	Normal: 3-17 uU/mL
hsCRP	238	12 (5.0%)	47 (19.7%)	179 (75.2%)	Low: <0.1 Average: 0.1-0.3 High:>0.3
HbA1c	231	n/a	217 (93.9%)	14 (6.1%)	Elevated: ≥6.5
Test	**N**	**Low**	**Borderline**	**Acceptable**	**Reference Range**
HDL	234	149 (63.7%)	48 (20.5%)	37 (15.8%)	Low: <40 mg/dL Borderline: 40-45 Acceptable: >45
Test	**N**	**Acceptable**	**Borderline**	**High**	**Reference Range**
LDL	234	171 (73.1%)	43 (18.4%)	20 (8.5%)	Acceptable:<110 mg/dL Borderline: 110-129 High: ≥130
Triglycerides	234	71 (30.3%)	69 (29.5%)	94 (40.2%)	Acceptable: <90 mg/dL Borderline: 90-129 High: ≥130
Cholesterol	234	211 (90.2%)	21 (9.0%)	2 (0.9%)	Acceptable: <200 mg/dL Borderline: 200-239 High: ≥240
Test	**N**	**Normal**	**Impaired**	**Diabetes**	**Reference Range**
Glucose (fasting)	234	173 (73.9%)	41 (17.5%)	20 (8.5%)	Normal: 70-99 mg/dL Impaired: 100-125 Diabetes: ≥126

eTable2. Laboratory Measures Summarized

	N	Mean	Median	SD	Min	Max
Serum Creatinine (mg/dL)	238	0.68	0.67	0.14	0.29	1.11
Cystatin C (mg/dL)	238	0.81	0.79	0.18	0.47	1.75
Urine Albumin-Creatinine Ratio	226	0.05	0.01	0.20	0.001	1.76
Insulin (uU/mL)	234	36.7	25.8	86.65	0.80	1314.2
hsCRP (mg/dL)	238	1.02	0.63	1.42	0.004	15.3
HbA1c	231	5.4	5.2	0.95	4.1	11.2
HDL (mg/dL)	234	37.6	37.0	9.07	13.0	72.0
LDL (mg/dL)	234	93.2	89.0	25.95	31.0	169.0
Triglyceride (mg/dL)	234	131.5	113.0	69.69	33.0	387.0
Cholesterol (mg/dL)	234	157.0	154.0	29.92	83.0	252.0
Glucose (fasting) (mg/dL)	234	97.1	90.5	26.31	67.0	281.0

eTable3. Reasons for Readmission Within 30 Days of Operation

Subject	Event Count	Operation	POD	Reason(s) readmitted	Length of stay (days)	Adjudication outcome
1	1	RYGB	9	hypotension, acute renal insufficiency due to inadvertant overdosing of antihypertensive medication	5	Not Related
2	2	RYGB	16	contained gastric leak requiring 4 day readmission for initiation of 14 day course of intravenous antibiotics	3	Related
3	3	RYGB	15	gastrojejunal anastomotic stricture requiring overnight admission after first of three endoscopic dilations	2	Related
4	4	LAGB	13	pulmonary embolus requiring initiation of anticoagulation therapy	6	Related
5	5	RYGB	9	wound dehiscence after open RYGB and splenectomy; admission for initiation of negative pressure wound therapy	2	Related
6*	6	RYGB	4	management of abdominal pain with negative diagnostic evaluation	1	Related
6*	7	RYGB	17	management of abdominal pain, nausea, vomiting with negative diagnostic evaluation	3	Related
7	8	RYGB	24	management of abdominal pain, nausea, vomiting with negative diagnostic evaluation except for microlithiasis of gallbladder; no procedures performed	1	Related
8	9	RYGB	14	nausea, vomiting, diarrhea, Clostridium difficil positive; initiation of antibiotic therapy	1	Related
9	10	RYGB	29	elective left tibial osteotomy with external fixator placement for Blounts disease	7	Not Related
10	11	RYGB	3	nausea and vomiting with negative diagnostic evaluation; required short term nasogastric decompression	6	Related
Subject	**Event Count**	**Operation**	**POD**	**Reason(s) readmitted**	**Length of stay (days)**	**Adjudication outcome**
11*	12	RYGB	20	gastrojejunal anastomotic stricture; readmitted after first of four endoscopic dilations	1	Related
11*	13	RYGB	25	gastrojejunal anastomotic stricture; readmitted after second of four endoscopic dilations	4	Related
12	14	RYGB	9	abdominal pain, diarrhea, dehydration requiring	0	Related

				intravenous fluids		
13	15	RYGB	5	abdominal pain, nausea, loose stools; negative diagnostic evaluation except for incidental ovarian teratoma	1	Related
14	16	VSG	8	management of abdominal pain, diarrhea, dehydration requiring intravenous fluids; negative diagnostic evaluation	0	Related
15	17	RYGB	10	management of abdominal pain, nausea requiring intravenous fluids; negative diagnostic evaluation	1	Related
16	18	RYGB	7	pulmonary embolus requiring initiation of anticoagulation therapy	12	Related
17	19	LAGB	3	nausea and vomiting requiring intravenous fluids; negative diagnostic evaluation	0	Related
18	20	VSG	7	gastric leak requiring open laparotomy	87	Related
19	21	RYGB	21	acute on chronic abdominal pain, acute mild pancreatitis requiring intravenous fluids; sphincter of Oddi dysfunction presumed after negative diagnostic evaluation; nasojejunal tube placed for enteral feeds	9	Not Related
20	22	RYGB	3	dehydration, urinary tract infection requiring intravenous fluids and initiation of antibiotic therapy	3	Related
21	23	RYGB	29	acute pancreatitis requiring intravenous fluids and analgesics	7	Related
22	24	VSG	19	dehydration with negative diagnostic evaluation requiring intravenous fluids and antiemetics	2	Related
Subject	**Event Count**	**Operation**	**POD**	**Reason(s) readmitted**	**Length of stay (days)**	**Adjudication outcome**
23	25	RYGB	11	gastric leak, intra-abdominal abscess requiring percutaneous drainage, endoscopic intraluminal stent placement	24	Related
24	26	RYGB	13	abdominal pain, nausea, dehydration attributed to single gallbladder stone that was pre-existing at time of bariatric surgery	2	Not Related
25	27	VSG	27	suicidal ideation, self-injurious behavior requiring inpatient psychiatric care	4	Related

POD, postop day; RYGB, roux en Y gastric bypass; VSG, vertical sleeve gastrectomy; LAGB, laparoscopic adjustable gastric banding