

Entered: __/__/20__ Initials: _____ Verified: __/__/20__ Initials: _____

For office use only.

Research Coordinator Assessment Baseline (RCAB) – Version: 06/15/2006

Patient ID _____ - _____ - _____

Form Completion Date ____/____/20____
mm dd yy

Certification number: _____

Visit: 1

1. Measurements: Date of when physical measures were taken: ____/____/20____

<p>1.1 Weight: ____ (lb) → How was weight measured?</p> <p>1.2 Blood Pressure: ____ / ____ (mmHg) (systolic) (diastolic)</p> <p>1.4 Waist circumference: <i>Record the first two measurements. If they are not within 2 cm of each other, record a third measurement.</i> ____ . ____ (cm) ____ . ____ (cm) ____ . ____ (cm) <i>record only if first two are not within 2 cm of each other.</i></p>	<p><input type="checkbox"/> 1. Tanita Scale → (Percent Body fat: ____ . ____ %)</p> <p><input type="checkbox"/> 2. Other Scale</p> <p><input type="checkbox"/> 3. Last available bed weight</p> <p><input type="checkbox"/> 4. Estimate</p> <p>1.3 Resting Heart Rate ____ (bpm)</p> <p>1.5 Neck circumference: <i>Record the first two measurements. If they are not within 2 cm of each other, record a third measurement.</i> ____ . ____ (cm) ____ . ____ (cm) ____ . ____ (cm) <i>record only if first two are not within 2 cm of each other.</i></p>
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2. Clinical test(s) in preparation for bariatric surgery within 12 months (*check no or yes to each procedure completed. If completed, specify results.*)

No	Yes	Unk		If yes,	Results																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.1 CAT scan of chest	→	<input type="checkbox"/> 1. Normal <input type="checkbox"/> 2. Abnormal																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.2 Stress Test : Exercise Chemical	→	<input type="checkbox"/> 1. Normal <input type="checkbox"/> 2. Abnormal																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.3 Right Heart Catherization	→	<input type="checkbox"/> 1. Normal <input type="checkbox"/> 2. Abnormal																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.4 Left Heart Catherization	→	<input type="checkbox"/> 1. Normal <input type="checkbox"/> 2. Abnormal																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.5 Cardiac function*	→	LVEF: ____ % → if no percent available: <input type="checkbox"/> 1. Normal <input type="checkbox"/> 2. Abnormal																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.6 Endoscopy	→	Barret's Esophagus: <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes Hiatal Hernia: <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.7 Upper GI series	→	Paraesophageal Hernia: <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes Hiatal Hernia: <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.8 Pulseoximeter	→	SAO ₂ : ____ %																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.9 ECG	→	<table border="0"> <tr> <td>No</td> <td>Yes</td> <td>No</td> <td>Yes</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/> 1. Normal</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/> 2. Atrial Fib</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/> 3. Sinus Tach</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/> 4. Other Arrhythmia</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/> 5. ST-T waves ind/possible ischemia</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/> 6. Other (specify: _____)</td> </tr> </table>	No	Yes	No	Yes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 1. Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 2. Atrial Fib	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 3. Sinus Tach	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 4. Other Arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 5. ST-T waves ind/possible ischemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 6. Other (specify: _____)
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.10 Polysomnogram	→	Apnea-Hypopnea Index (AHI) ____																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.11 Pulmonary Function Test (PFT)	→	FEV1: ____ (liters) % of diffusing capacity: ____ FVC: ____ (liters)																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.12 Arterial blood gas	→	CO ₂ : ____ (mmHg) O ₂ on room air temperature: ____ (mmHg) O ₂ on oxygen: ____ (mmHg)																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.13 Ultrasound gall bladder	→	Evidence of gallstones: <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes																												
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.14 Other: Specify: _____	→	Results: _____																												

*Based on an echocardiogram, cardiac MRI, CT imaging, ventriculography, Gated SPECT, MUGA .

RESEARCH COORDINATOR ASSESSMENT BASELINE (RCAB)

PURPOSE:	To collect physical measures and clinical tests that are done in preparation for bariatric surgery within 12 months of patients aged 18 years or older enrolled in LABS-1, who have provided informed consent for LABS-2, prior to bariatric surgery.
PERSON(S) RESPONSIBLE:	Clinician/Coordinator
SOURCES OF INFORMATION:	Patient/Patient chart/ordered reports
WHEN TO ADMINISTER FORM:	Once patient provides informed consent for LABS-2, prior to surgery. This questionnaire should be completed at the baseline visit by coordinator.
GENERAL INSTRUCTIONS (Patient)	N/A
GENERAL INSTRUCTIONS: (Clinician)	Measurements must be completed in accordance to the guidelines as specified in the relevant sections of the LABS-2 Manual of Operations, under Protocols and Measures. Reporting clinical test(s) should be based on reports/notes gathered from chart review or other source documents.
SCORING ALGORITHM:	N/A

DATA SECTION	COMPLETION INSTRUCTIONS
PATIENT ID:	Record the patient's ID number. The ID number is assigned via the ID registration application of the MATRIX Web Data Management System (MATRIX). Instructions on using this application are included in the MATRIX Manual.
	<i>NOTE: The patient ID number is the same as that assigned to the patient as part of the LABS-1 study.</i>
VISIT:	For this form the visit number has been pre-printed on the form. It is only to be administered at the baseline visit.
FORM COMPLETION DATE:	Record the date of form completion (mm/dd/20yy).
MEASUREMENTS	<p>1. Record the date of when the physical measures were taken in mm/dd/20yy format.</p> <p>Record Weight and how weight was measured, blood pressure, resting heart rate, waist and neck circumference.</p> <p><i>These measurements must be completed in accordance to the guidelines as specified in the relevant sections of the LABS-2 Manual of Operations, under Protocols and Measures.</i></p> <p>1.1 Record patient's weight in lbs. and specify how the weight measurement was taken. If patient was weighed using a Tanita Scale, record their percent body fat in the space provided. Note that cloths estimates should "NOT" be entered into the Tanita and values should be entered as zero (0).</p> <p>1.2 Record patient's blood pressure. See LABS-2 Manual of Operations, under Protocols and Measures for details.</p> <p>1.3 Record patients resting heart rate. <i>Resting is defined as having the patient sit quietly, with feet flat on the floor, in an erect but comfortable posture for at least five minutes, and for at least thirty minutes without smoking or consuming caffeine-containing beverages.</i> This values should be measured based on the blood pressure machine. See LABS-2 Manual of Operations, under Protocols and Measures for details.</p>

	<p>1.4 Record the first 2 measurements of the patient's waist circumference in cm. If the measurements are not within 2 cm of each other, record a 3rd measurement</p> <p>1.5 Record the first 2 measurements of the patient's neck circumference in cm. If the measurements are not within 2 cm of each other, record a 3rd measurement.</p> <p>2. Record "No" or "Yes" for each clinical test that patient has completed within the <i>past 12 months</i>.</p> <p><u>Select "Yes"</u> if the clinical test was identified in the patient's chart or in other source document or notes. Also, record the results of each clinical test in the column to the right.</p> <p><u>Select "No"</u> if the clinical test was not completed within the past 12 months and go to the next item listed.</p> <p>2.1 <u>CAT scan of the chest:</u> Check "yes" if a patient had a CAT (Computed Axial Tomography) scan of the chest otherwise, check "no" and go to the next item listed. If the patient had a CAT scan, record whether the results were normal or abnormal.</p> <p>2.2 <u>Stress Test:</u> Check "yes" if a patient had a Stress Test and then check if it was done via exercise or chemical otherwise, check "no" and go to the next item listed. If the patient had a stress test, record whether the results were normal or abnormal.</p> <p>2.3 <u>Right Heart Catherization:</u> Check "yes" if a patient had a right heart catherization otherwise check "no" and go to the next item listed. If the patient had a right heart catherization, record whether the results were normal or abnormal.</p> <p>2.4 <u>Left Heart Catherization:</u> Check "yes" if a patient had a left heart catherization otherwise check "no" and go to the next item listed. If the patient had a left heart catherization, record whether the results were normal or abnormal.</p>
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	<p>2.5 <u>Cardiac function:</u> Check “yes” if a patient had a cardiac function test otherwise check “no” and go to the next item listed. If the patient had a cardiac function test, record LVEF (left ventricular Ejection Fraction). If no percent is available, record whether the results were normal or abnormal. Note that the cardiac function test can be based on a MUGA, Echocardiogram, Nuclear Stress Test or a cardiac catheterization.</p> <p>2.6 <u>Endoscopy:</u> Check “yes” if a patient had an endoscopy otherwise check “no” and go to the next item listed. If the patient had an endoscopy, record whether Barrett’s Esophagus was present and record whether a hiatal hernia was present.</p> <p>2.7 <u>Upper GI Series:</u> Check “yes” if a patient had an Upper GI Series otherwise check “no” and go to the next item listed. If yes, record whether a paraesophageal hernia was present and whether a hiatal hernia was present.</p> <p>2.8 <u>Pulse oximeter:</u> Check “yes” if a patient had an pulse oximeter test otherwise check “no” and go to the next item listed. If the patient had an pulse oximeter test, record the SAO2 percent.</p> <p>2.9 ECG: Check “yes” if a patient had an ECG test otherwise check “no” and go to the next item listed. If the patient had an ECG test, check “yes” or “no” for each as to whether the results were normal, atrial fib., sinus tach., ST-T waves, or other arrhythmia.</p> <p>2.10 Polysomnogram: Check “yes” if a patient had an polysomnogram test otherwise check “no” and go to the next item listed. If the patient had an polysomnogram, record the Apnea-Hypopnea Index, defined as the number of Apnea-Hypopnea’s per hour. Note that the AHI index can be derived via Portable polysomnogram, as well.</p>
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	<p>2.11 Pulmonary Function Test (PFT): Check “yes” if a patient had a PFT test otherwise check “no” and go to the next item listed. If the patient had an PFT test, record the FEV₁ in liters and the percent of defusing capacity. Also record the FVC in liters.</p> <p>2.12 Arterial blood gas: Check “yes” if a patient had an arterial blood gas test otherwise check “no” and go to the next item listed. If the patient had an arterial blood gas test, record the patient’s CO₂, O₂ on room air temperature, and O₂ on oxygen. These should be recorded in mmHg.</p> <p>2.13 Ultrasound gall bladder: Check “yes” if a patient had an Ultrasound gall bladder test otherwise check “no” and go to the next item listed. If the patient had an Ultrasound gall bladder test, record the whether there was evidence of gallstones.</p> <p>2.14 Other: Check “yes” if a patient had an other test not mentioned above otherwise check “no” and go to the next item listed. If the patient had an other test, record what the test was and the pertinent results.</p>
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