Entered: _ _ / _ _ / 20_ _ Initials: _____ Verified: _ _ / _ _ /20 _ _ Initials: _____
mm dd yy mm dd yy

Patient ID __ __ __ - __ __ __ __ - __ __ **Visit: 1**

For office use only.

MAB Form –Version 12/15/2006

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

The next set of questions ask about various medical conditions that you may or may not have had.

1. Have you **ever** had surgery on... *(check "no" or "yes" to each)*:

	No	Yes
1.1 your back, such as disc surgery, laminectomy, or fusion surgery?	□	□
1.2 your hip(s), such as joint replacement, reconstructive or arthroscopic surgery?	□	□
1.3 your knee(s), such as joint replacement, reconstructive or arthroscopic surgery?	□	□
1.4 your ankle(s), such as joint replacement, reconstructive or arthroscopic surgery?	□	□

2. In the **past 4 weeks,** have you suffered from back or leg pain, such as pain that radiates or shoots down the back of the leg to the knee or foot? □ 0. No □ 1. Yes

If yes, *(answer the questions in this box*):

2.1 In the **past 4 weeks,** how bothersome have each of the following symptoms been?

	Not at all bothersome	Slightly bothersome	Moderately bothersome	Very bothersome	Extremely bothersome
a. Back pain	□	□	□	□	□
b. Leg pain	□	□	□	□	□

2.2 In the **past 4 weeks**, how much did pain interfere with your normal work, including both work outside the home and house work?

Not at all	A little bit	Moderately	Quite a bit	Extremely
□	□	□	□	□

2.3 If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?

Very dissatisfied	Dissatisfied	Somewhat dissatisfied	Neither satisfied nor dissatisfied	Somewhat satisfied	Satisfied	Very satisfied
□	□	□	□	□	□	□

2.4 In the **past 4 weeks**, about how many days did you cut down on the things you usually do for more than half the day because of back pain or leg pain?

_____ (Number of days)

2.5 In the **past 4 weeks**, how many days did low back pain or leg pain, keep you from going to work or school?

_____ (Number of days) *(write "n/a" if you did not go to work or school in the past 4 weeks)*

4. Can you walk, assisted or unassisted? □ 0. No □ 1. Yes

If yes,

4.1 Check the description below that best characterizes your walking ability:
- □ 1. I can walk 200 ft (length of grocery store aisle) unassisted.
- □ 2. I can walk 200 ft with an assistive device (such as a cane or walker)
- □ 3. I cannot walk 200 ft with an assistive device.

4.2 Do you **currently** use any of the following to aid with walking *(check "no" or " yes" to each, if yes specify how often):*

	No	Yes	*If yes, how often?*	**Rarely** *(less than once per week)*	**Sometimes** *(about 3 times per week)*	**Often** *(almost every day)*	**Always** *(I can't walk without it)*
a. A wheelchair	□	□	→	□	□	□	□
b. A walker	□	□	→	□	□	□	□
c. A cane	□	□	→	□	□	□	□

5. Have you **ever** had surgery for acid reflux, heartburn or a hiatal hernia? □ 0. No □ 1. Yes

6. Have you **ever** had surgery to remove your gallbladder? □ 0. No □ 1. Yes

If no,

6.1 In the **past 3 months**, have you had upper abdominal pain shortly after eating food? □ 0. No □ 1. Yes

7. Have you **ever** been told by a doctor or other health care professional that you had a blood clot of the **lung(s) also know as a pulmonary embolism (PE)** requiring blood thinners? □ 0. No □ 1. Yes

8. Have you **ever** been told by a doctor or other health care professional that you had a blood clot of the **leg(s) also known as deep phlebitis, deep vein thrombosis or DVT** requiring blood thinners? □ 0. No □ 1. Yes

9. Have you **ever** been told by a doctor or other health professional that you had a myocardial infarction or heart attack? □ 0. No □ 1. Yes

If yes,

9.1 Was it within the past year? □ 0. No □ 1. Yes

10. Are you **currently** using supplemental oxygen such as an oxygen tank to help you breathe? □ 0. No □ 1. Yes

If yes,

10.1 How often do you use supplemental oxygen such as an oxygen tank to help you breathe?

Rarely *(less than once per week)*	**Sometimes** *(about 3 times per week)*	**Often** *(almost every day)*	**Always** *(I can't breath without it)*
□	□	□	□

11. Have you **ever** been told by a doctor or other health care professional that you have asthma[1]? □ 0. No □ 1. Yes

If yes,

11.1 In the past **4 weeks** how much of the time did your **asthma** keep you from getting as much done at work, school or at home?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
□	□	□	□	□

11.2 During the past **4 weeks**, how often have you had shortness of breath?

More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all
□	□	□	□	□

11.3 During the past **4 weeks**, how often did your **asthma** symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?

4 or more nights a week	2 or 3 nights a week	Once a week	Once or twice	Not at all
□	□	□	□	□

11.4 During the past **4 week**s, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all
□	□	□	□	□

11.5 How would you rate your **asthma** control during the past **4 weeks**?

Not controlled at all	Poorly controlled	Somewhat controlled	Well controlled	Completely controlled
□	□	□	□	□

11.6 Have you **ever** been intubated (had a breathing tube placed) or undergone mechanical ventilation (been placed on a respirator) because of your asthma? □ 0. No □ 1. Yes

12. Have you ever had a kidney stone? □ 0. No □ 1. Yes

13 Have you experienced low blood sugar in the **past 3 months[2]?**

□ 0. No → Go to question 14 (next page)

□ 1. Yes→

a. How many times was your low blood sugar so severe that you had to be admitted to the hospital (for at least 24 hour) for low blood sugar? __ __ (# of times)

b. How many times was your low blood sugar so severe you had to visit the emergency room, but not be admitted to the hospital? __ __ (# of times)

c. How many times was your low blood sugar so severe that you needed someone to help you (but not ER visit or hospitalization)? __ __ (# of times)

d. How many times during the last 7 days did you think that you had low blood sugar? __ __ (# of times)

e. Was your blood sugar checked during the most severe episode of low blood sugar?
□ 0. No
□ 1. Yes → What was the glucose value? __ __ __ (mg/dL)

14. Do you **currently** have diabetes and/or are you currently being treated for diabetes? ☐ 0. No ☐ 1. Yes

If yes,

14.1 Are you **currently** taking oral medication or insulin for diabetes (check "no" or "yes" for each)?

No	Yes		
☐	☐	a. Oral medication	
☐	☐	b. Insulin →	13.1 How many years have you been taking insulin? _____ (years) 13.2 How many daily doses of insulin do you take? _____ (daily dose)

15. These next set of questions[3] ask about the feeling in your legs and feet. Check "No" or "Yes" based on how you usually feel?

	No	Yes
15.1 Are your legs and/or feet numb?	☐	☐
15.2 Do you ever have any burning pain in your legs and/or feet?	☐	☐
15.3 Are your feet too sensitive to touch?	☐	☐
15.4 Do you get muscle cramps in your legs and/or feet?	☐	☐
15.5 Do you ever have any prickling feelings in your legs or feet?	☐	☐
15.6 Does it hurt when the bed covers touch your skin?	☐	☐
15.7 When you get into the tub or shower, are you able to tell hot water from the cold water?	☐	☐
15.8 Have you ever had an open sore on your foot?	☐	☐
15. 9 Has your doctor ever told you that you have diabetic neuropathy?	☐	☐
15.10 Do you feel weak all over most of the time?	☐	☐
15.11 Are your symptoms worse at night?	☐	☐
15.12 Do your legs hurt when you walk?	☐	☐
15.13 Are you able to sense your feet when you walk?	☐	☐
15.14 Is the skin on your feet so dry that it cracks open?	☐	☐
15.15 Have you ever had an amputation?	☐	☐

LABS gratefully acknowledges the following sources for questions contained on this form:

[1] Asthma Control Test, American Lung Association, www.asthmacontrol.com

[2] Look AHEAD study

[3] Michigan Diabetes Research and Training Center, http://www.med.umich.edu/mdrtc/survey/index.html

MEDICAL ASSESSMENT BASELINE (MAB)

PURPOSE:	To collect information regarding medical conditions 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: **SOURCES OF INFORMATION:**	Clinician/Coordinator Patient
WHEN TO ADMINISTER FORM:	Once patient provides informed consent for LABS-2, prior to surgery. This question should be administered after the MED and before the RHB This questionnaire should be completed at the baseline visit or sent to patient by mail for patient to complete at home and return to coordinator prior to bariatric surgery. If the patient completes the MAB at home, the coordinator or other study staff must review the document at patient's clinic visit to ensure that all fields have been completed appropriately.
GENERAL INSTRUCTIONS (Patient)	This questionnaire is to be completed by the patient. If the patient is not able to complete the form without help, the coordinator or patient designee may read the questions and answers to the patient.
GENERAL INSTRUTIONS: (Clinician)	After patient completes survey: (1) Record whether the survey was completed by the patient alone or completed by the patient with assistance. (2) Review the form for any missing items. Follow-up with patient if necessary to record missing items, or to clarify responses. (3) Make sure that each item has a single response marked, unless directions state otherwise. (4) If the patient does not understand the question, a coordinator or patient designee may read the question to them. Do not answer the question. Indicate whether the response is unknown or if the patient refused to provide an answer.
SCORING ALGORITHM:	**See Algorithm for details**

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. *NOTE: The patient ID number is the same as that assigned to the patient as part of the LABS-1 study.*
VISIT:	The visit number that the MAB corresponds to on the right hand corner of the cover page has been preprinted on the form.
FORM COMPLETION DATE:	Patient records date of form completion (mm/dd/20yy) 1. Patient records "No" or "Yes" if they have *ever* had surgery on: 1.1 Back 1.2 Hip(s) 1.3 Knee(s) 1.4 Ankle(s) 2. Patient records "No" or "Yes" if they have suffered from back or leg pain over the *past 4 weeks.* <u>If patient selects "No":</u> They may skip to question 3. 2.1 Patient records how bothersome each of the following symptoms were in the *past 4 weeks:* a. Back pain b. Leg pain 2.2 Patient records how much pain interfered with their normal work, including work inside and outside of the home or house work over the *past 4 weeks.* 2.3 Patient records how satisfied they would be if they had to spend the rest of their life with the symptoms that they experience right now. 2.4 Patient records the number of days over the *past 4 weeks* that they've cut down on the things that they usually do for more than half of the day because of back or leg pain.

DATA SECTION	COMPLETION INSTRUCTIONS
	2.5 Patient records the number of days over the *past 4 weeks* that lower back or leg pain kept them from going to work or school. 4. Patient records "No" or "Yes" if they can walk. <u>If patient selects "No":</u> Patient may skip to question 5. 4.1 Patient records the option that best describes their walking ability. 4.2 Patient records "No" or "Yes" for each walking aid listed and records frequency of use. 5. Patient records "No" or "Yes" if they have *ever* had surgery for acid reflux, heartburn or hiatal hernia. 6. Patient records "No" or "Yes" if they have *ever* had surgery to remove their gallbladder. <u>If patient selects "Yes":</u> Patient may skip to question 7. 6.1 Patient records "No" or "Yes" if they have had upper abdominal pain shortly after eating food in the *past 3 months*. 7. Patient records "No" or "Yes" if they have *ever* been told by a doctor or other health care professional that they had a blood clot of the lungs, also known as a pulmonary embolism (PE) requiring blood thinners. 8. Patient records "No" or "Yes" if they have *ever* been told by a doctor or other health care professional that they have and a blood clot of the legs, also knows as deep phlebitis, deep vein thrombosis (DVT) requiring blood thinners.

DATA SECTION	COMPLETION INSTRUCTIONS
	9. Patient records "No" or "Yes" if they have *ever* been told by a doctor or other health care professional that they had a myocardial infarction or heart attack. If patient selects "No": Patient may skip to question 10. 9.1 Patient records "No" or "Yes" if they were told *in the past year* by a doctor or other health care professional that they had a myocardial infarction or heart attack. 10. Patient records "No" or "Yes" if they are *currently* using supplemental oxygen such as an oxygen tank to help them breathe. If patient selects "No": Patient may skip to question 11. 10.1 Patient records how often they are *currently* using supplemental oxygen such as an oxygen tank to help them breathe. 11. Patient records "No" or "Yes" if they have *ever* been told by a doctor or other health care professional that they have asthma. If patient selects "No": Patient may skip to question 12. 11.1 Patient records how much of the time in the *past 4 weeks* their asthma kept them from getting as much done as they would have liked. 11.2 Patient records how much of the time in the *past 4 weeks* they experienced shortness of breath. 11.3 Patient records how much of the time in the *past 4 weeks* their asthma symptoms woke them up at night or earlier than usual in the morning. 11.4 Patient records how much of the time in the *past 4 weeks* they have had to use their rescue inhaler or nebulizer medication. 11.5 Patient rates their asthma control during the *past 4 weeks.*

DATA SECTION	COMPLETION INSTRUCTIONS
	11.6 Patient records “No” or “Yes” if they have *ever* been intubated or undergone mechanical ventilation because of their asthma. 12. Patient records “No” or “Yes” if they have ever had a kidney stone. 13. Patient records "No" or "Yes" if they have experience low blood sugar in the past 3 months. <u>If patient selects "No":</u> Patient may skip to question 14. <u>If patient selects "Yes":</u> Patient records the number of times for each. a. low blood sugar was so severe it required hospital admittance of at least 24 hrs in the past 3 months. b. low blood sugar was so severe it required a visit to the ER, but no hospital admittance in the past 3 months. c. low blood sugar so severe it required help from someone but no ER visit or hospitalization in the past 3 months. d. the participant thought they had low blood sugar in the last 7 days. e. Patient records "No" or "Yes" if their blood sugar was checked during the most severe episode of their low blood sugar in the past 3 months. <u>If patient selects "Yes":</u> Patient records the glucose value in mg/dL. 14. Patient records “No” or “Yes” if they are currently being treated for diabetes. <u>If patient selects “No”:</u> Patient may skip to question 15. 14.1 Patient records “No” or “Yes” for each medication, if they are *currently* taking any medication or insulin for diabetes. a. Oral medication b. Insulin <u>If patient selects “Oral medication”:</u> Patient may skip to question 15.

	14.1.1 Patient records number of years that they have been taking insulin. 14.1.2 Patient records number of years that they have been taking insulin. Daily dose = the total daily dose taken on a normal day. If the dose is not consistent from day-to-day, then an average daily dose can be reported. If using an insulin pump, record the total units on a typical day. *Example*: *20 units Novolog injection - breakfast* *15 units Novolog injection - lunchtime* *20 units Novolog injection - dinner* *29 units Lantus injection - evening* *84 = daily dose* 15. Patient records "No" or "Yes" regarding each sensation listed about the feeling that they have in their legs and feet.