Entered:/	_/20 Initia	ls: Verified: / _ For office use only.	/ 20 Initials:
		Pre-operative Form (PO1) – Version: 12/15/2006	; ;
Patient ID			<b>Evaluation Date</b> / / 20 mm dd yy
Certification numb	oer:		
		<b>to provide informed consent</b> . Clinical sites that who decline to provide informed consent.	t have the proper IRB approval should
1. Consent to LAB	S 1: □ 0. No → (if no		l impact ability to have surgery. cipating. n medical research.
	$\Box 1. \text{ Yes } \rightarrow $ (if yes	1.3 Date of consent:       / / 20         mm       dd       yy         1.4 Patient's date of birth:       / / 19         mm       dd       yy	
2. Gender:	<ul><li>1. Male</li><li>2. Female</li></ul>	<ul> <li>3. Height:(ft),(in)</li> <li>3.1 How was height measured?</li> <li>□ 1. Standing</li> <li>□ 2. Lying Flat</li> <li>□ 3. Estimate</li> </ul>	<ul> <li>4. Weight: (lbs)</li> <li>4.1 How was weight measured?</li> <li>1. Tanita Scale</li> <li>2. Other Scale</li> <li>3. Last available bed weight</li> <li>4. Estimate</li> </ul>
5. Ethnicity:	<ul><li>0. Hispanic</li><li>1. Non-Hispanic</li></ul>	<ul> <li>6. Race (check all that apply):</li> <li>White or Caucasian</li> <li>Black or African-American</li> <li>Asian</li> <li>American Indian or Alaska Native</li> <li>Native Hawaiian or other Pacific Islander</li> <li>Other (specify)</li> </ul>	

\*\* Continue ONLY if there is written informed consent for LABS-1. Otherwise, do not complete the rest of this form. \*\*

Patient ID \_\_\_\_ - \_\_\_ - \_\_\_ - \_\_\_

- 7. Previous obesity surgery OR surgery performed on the esophagus, stomach or proximal small intestine not for the purpose of weight loss?
- □ 0. No

🗆 1. Yes

7.1 If yes, specify (check "no" or "yes" for each item):

No	Yes		Number of previous surgeries (including revisions and reversals)	Date of most recent surgery
		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:)		//

8. Smoking status:	□ 1. Never smoked	$\Box$ 2. Current: $\rightarrow$	Age started regularly: Average packs/day:	□ 3. Former: →	Age started regularly: Age quit: Average packs/day:
<ol> <li>9. Is this patient a go</li> <li>9.1 If no,</li> </ol>		ABS-2? "no" or "yes" for eacl		1. Yes	

No Yes	No Yes	No Yes
$\Box$ $\Box$ Lives too far away	□ □ Prior bariatric surgery	$\Box$ $\Box$ Unable to communicate with study staff
□ □ Follow-up too burdensome	$\Box$ $\Box$ Unlikely to comply with	□ □ Reading difficulty/illiteracy
□ □ Not interested	protocol	□ □ Other (Specify:)
$\Box$ $\Box$ < 14 days notice of surgery		

10. Planned procedure:

- $\Box$  1. Gastric bypass (Roux-en-Y)
- $\Box$  2. Biliopancreatic diversion (BPD)
- $\Box$  3. Biliopancreatic diversion with Doudenal Switch (BPDS)
- □ 4. Laparoscopic adjustable gastric band (LAGB)
- $\hfill\square$  5. Sleeve gastrectomy-initial stage

- $\Box \quad 6. \text{ Sleeve gastrectomy-} \rightarrow \text{ second stage}$
- □ 1. Gastric bypass (Roux-en-Y)

)

- □ 2. BPD □ 3. BPDS
- $\Box$  7. Other (Specify:
- □ 8. Banded Gastric bypass (Gastric bypass + non-adjustable band)
- □ 9. Vertical Banded Gastroplasty
- $\Box$  -3. Unknown at this time

Patient ID \_\_\_\_\_ - \_\_\_ - \_\_\_\_ - \_\_\_\_

#### 11. Planned approach: $\Box$ 1. Laparoscopic $\Box$ 2. Open $\Box$ -3. Unknown

12. Is the planned procedure a <u>revision</u>?  $\Box$  0. No  $\Box$  1. Yes

If yes,

12.1 Patient status at time of previous procedure:	□ 1. LABS-1 Registered patient
	□ 2. Non-LABS-1 Patient

13. Is the planned procedure a <u>reversal</u>?  $\Box$  0. No  $\Box$  1. Yes If yes,

13.1 Patient status at time of previous procedure:	□ 1. LABS-1 Registered patient
	□ 2. Non-LABS-1 Patient

14. Most recent laboratory value within 180 days:

	Blood Draw Date	Not done		Blood Draw Date	Not done
Fasting Glucose: mg/dl	/_/		AST (SGOT): IU/L	/_/	
Creatinine: mg/dl	/_/		Hematocrit:%	/_/	
Albumin: g/dl	/_/		Triglycerides: mg/dl	/_/	
HbA1C:%	//		HDL: mg/dl	//	
Normal HbA1C <b>High</b> range:	%		Total Cholesterol: mg/dl	/_/	
ALT (SGPT): IU/L	//		Alkaline Phosphatase: IU/L	/_/	

	No	Yes
15. Medications in the past 90 days:		□ Therapeutic oral/IV immunosuppressant
(check "no" or "yes" for each item)		□ Therapeutic anticoagulation
		□ Narcotic
		□ Statin or other lipid lowering agent
		□ Antidepressant
		□ Beta-blocker

16. Blood pressure:

\_\_\_\_\_ / \_\_\_\_(mmHg) Systolic / Diastolic

16.1 How was blood pressure measured?

 $\Box$  1. Mercury

- □ 2. Gauge
- $\square$  3. Electronic

Patient ID \_\_\_\_ - \_\_\_ - \_\_\_ - \_\_\_\_

	Comorbidity	No	Yes		If yes, check the <u>one</u> best response
a.	Hypertension			>	□ 1. No □ 2. Single □ 3. Multiple medication medications
b.	Diabetes			<i>→</i>	□ 1. No □ 2. Single oral □ 3. Multiple oral □ 4. Insulin □ 5. Oral meds medication medication and insul
c	CHF			÷	NYHC: I III III IV Unknown
d.	Asthma			÷	□ 1. History of Intubation □ 2. No History of Intubation
e.	Functional Status		gr	ocery	k (length of store aisle)       2. Able to walk 200 ft with assist device with assist device (cane, walker)       3. Cannot walk 200 ft with assist device with assist device       -3. Unknown
(	Comorbidity	No	Yes		Check "No" or "Yes" for each item
					No Yes
f.	History of DVT/PE			→	<ul> <li>Documented DVT</li> <li>Documented PE</li> <li>Venous edema w/ ulceration</li> </ul>
g.	Sleep apnea			→	<ul> <li>C-pap/ Bi-pap</li> <li>Supplemental oxygen dependent</li> </ul>
h.	Ischemic Heart Disease			<b>→</b>	<ul> <li>History of MI</li> <li>No active ischemia</li> <li>Abnormal EKG but unable to assess ischemia</li> <li>PCI, CABG</li> <li>Anti-ischemic medications</li> </ul>
	Pulmonary hypertension			<u>.</u>	
i.	nypertension				

Entered:// 20 Initial	s:		Verified:/	/ 20	Initials:	
	For	office use	only.			
 	-operative Update	Form (PU1	) Version: 12/15/	2006		
		Form (FOT	<i>i – v ci sion. 12/13/2</i>		Data / /	20
Patient ID					Date / / / /	уу
Certification number:	-			Consent Da	ite / / 2 mm dd	0 yy
Instructions: This form should be administered was completed more than 90 day patient's weight must be recorded	s prior to surgery.	Note that if t	his form was compl	eted more than 30 c	Pre-operative (PO1)	form
<ol> <li>Weight: (lbs)</li> <li>If this form was completed more than thirt</li> </ol>		-	□ 3. I □ 4. F	Other Scale Last available bed w Estimate	Ū.	s of
surgery.	y aays bejore sarge.				an <u>waan</u> mary aay	
2. Smoking status:  1. Never  smoked			gularly: s/day:	$\Box$ 3. Former: $\rightarrow$	Age started regular Age quit: Average packs/day	
3. Planned procedure:						
<ul> <li>1. Gastric bypass (Roux-en-Y)</li> <li>2. Biliopancreatic diversion (BPI</li> <li>3. Biliopancreatic diversion with</li> <li>4. Laparoscopic adjustable gastri</li> <li>5. Sleeve gastrectomy-initial stage</li> </ul>	Doudenal Switch ( c band (LAGB)		<ul> <li>6. Sleeve gastre second stage</li> <li>7. Other (Speci</li> <li>8. Banded Gast</li> <li>9. Vertical Ban</li> <li>-3. Unknown at</li> </ul>	fy: 3	Gastric bypass (Rou 2. BPD 3. BPDS ) bypass + non-adjusta	
4. Planned approach:  □ 1. Laparo	oscopic 🗆 2. C	Dpen 🗆	-3. Unknown			
5. Most recent laboratory value within 180 days	s of surgery:					
	Blood Draw Date	Not done			Blood Draw Date	Not done
Fasting Glucose: mg/dl	/_/		AST (SGOT):	IU/L	//	
Creatinine: mg/dl	/_/		Hematocrit:	%	//	
Albumin: g/dl	//		Triglycerides: _	mg/dl	//	
HbA1C:%	//		HDL:	mg/dl	//	
Normal HbA1C <b>High</b> range:	%		Total Cholestero	l: mg/dl	//	
ALT (SGPT): IU/L	//		Alkaline Phosph	atase: IU/L	//	
<ol> <li>Medications in the past 90 days: (check "no" or "yes" for each item)</li> </ol>	Image: Constraint of the second secon	apeutic antico	V immunosuppressa bagulation d lowering agent	ant		
7. Blood pressure: / (mmHg Systolic / Diastolic			1 How was blood p	ressure measured?	<ul><li>1. Mercury</li><li>2. Gauge</li><li>3. Electronic</li></ul>	

Patient ID \_\_\_\_ - \_\_\_ - \_\_\_ - \_\_\_

### 8. Comorbidities:

Com	orbidity	No	Yes	!	If yes, check the <u>one</u> best response			
a.	Hypertension			<i>→</i>	□ 1. No □ 2. Single □ 3. Multiple medication medications			
b.	Diabetes			<i>→</i>	□ 1. No □ 2. Single oral □ 3. Multiple oral □ 4. Insulin □ 5. Oral meds medication medication and insulin			
c.	CHF			<i>&gt;</i>	NYHC: I II III III IV DUnknown			
d.	Asthma			<i>→</i>	□ 1. History of Intubation □ 2. No History of Intubation			
e.	Functional Status <ul> <li>1. Can walk (length of grocery store aisle)</li> <li>2. Able to walk 200 ft with assist device</li> <li>200 ft unassisted</li> <li>2. Able to walk 200 ft with assist device</li> <li>3. Cannot walk 200 ft with assist device</li> <li>with assist device</li> <li>with assist device</li> <li>with assist device</li> </ul> <ul> <li>3. Cannot walk 200 ft</li> <li>3. Unknown</li> <li>3. Cannot walk 200 ft</li> <li>4. Cannot walk 200 ft</li> <li>5. Cannot walk 200 ft</li> <li></li></ul>							
Co	morbidity	No	Yes		Check "No" or "Yes" for each item			
f.	History of DVT/PE			÷	No     Yes       Documented DVT     Documented PE       Venous edema w/ ulceration			
g.	Sleep apnea			<i>&gt;</i>	<ul> <li>C-pap/Bi-pap</li> <li>Supplemental oxygen dependent</li> </ul>			
h.	Ischemic Heart Disease			→	<ul> <li>History of MI</li> <li>No active ischemia</li> <li>Abnormal EKG but unable to assess ischemia</li> <li>PCI, CABG</li> <li>Anti-ischemic medications</li> </ul>			
i.	Pulmonary hypertension							
j.	History of venous	s edem	a with u	lcerati	ons? $\Box$ 0. No $\Box$ 1. Yes			
Arcon	e there any comorbid uld affect clinical ou 9.1 If yes, sp	tcome	followii	ng bari	ent may have that $\Box$ 0. No $\Box$ 1. Yes atric surgery?			

Entered:// 20 1	nitials: For office	Verified:// 20 e use only.	Initials:
Patient ID Surgeon Certification Number:	Operative Evaluation Form		n Date / / 20 mm dd yy
1. Date of Surgery / / 20	_ (mm/dd/yy)		
<ol> <li>Operative times:         <ol> <li>Time patient entered the operating r</li> <li>Time in which the first open or lapa</li> <li>Time in which the final skin closure</li> <li>Time in which the patient left the op</li> </ol> </li> <li>Is this procedure a revision? □ 0. No</li> <li>Is this procedure a reversal? □ 0. No</li> </ol>	roscopic incision was made: was made: perating room: □ 1. Yes	(military time) :(hr : min) :(hr : min) :(hr : min) :(hr : min)	
<ul> <li>2. Dis</li> <li>3. Biliopancreatic diversion (BPD)</li> <li>4. Biliopancreatic diversion with Du</li> <li>5.1 Was the stomach divided?</li> <li>5.2 How was the Gastrojejunostic</li> </ul>	ximal (Roux length < 250 cm) tal (Roux length $\ge 250$ cm) $\rightarrow$ ( nodenal Switch (BPDS) 0. No 0. No 0. No 0. Yes	omplete the remainder of this form.         → (Roux Length: cm )         (Common Channel Length: cm )         1. Yes	
Duodenal-jejunostomy don	🗆 🗆 b. Li	and sewn near stapled rcular stapled (EEA)	
5.3 Was the Gastrojejunostomy 5.3.1 If yes, specify how:	/ Duodenal-jejunostomy reinfor No Yes a. Sutures b. Omental Buttro c. Fibrin glue	No Yes	
<ul> <li>S. Adjustable band → Specify Id</li> <li>Sleeve gastrectomy – initial stage</li> <li>Sleeve gastrectomy – 2nd stage → Complete items 5.1, 5.2, 5.3 and 5.3.1 (if applicable)</li> <li>S. Vertical Banded Gastroplasty</li> <li>Other (Specify:</li></ul>	□ 2. BPD □ 3. BPDS	<ul> <li>□ 11 cm (or Vanguard )</li> <li>□ Other (specify:</li> <li>□ 1. Proximal (Roux length &lt; 250 cm)→(</li> <li>□ 2. Distal (Roux length ≥ 250 cm)→(Coordinate)</li> </ul>	Roux Length: cm )
6. Was a resident or trainee present?	□ 0. No □ 1. Y	Vas	

Patient ID \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

7. Method of Surgical Procedure	<b>e</b> :
---------------------------------	------------

8.

9.

. Meth	nod of Surgical I	Procedure:														
		_		<i>,.</i>	0		•••			5 n	nm	10-12	mm	15 mi	n	
	1. Laparoscopi	c: →	# of ports	s/incisic	ons for ea	ach wi	dth ( <i>en</i>	ter '0' if n	one):	#		#		#	_	
	2. Laparoscopi converted		a. #	# of por	ts/incisio	ons for	each v	width (ente	er '0' if 1	none):	5 mm #		-12 mm #		15 mm #	
			f	Specify for conv	ersion:		No 	□ b.	Exposur Bleedin Anatom	g	No □					nt failure )
	3. Open (no la	paroscopic	ports): 🗦	→ (Leng	th of inc	ision (	cm): _	·	_)							
	any concurrent					0. No		□ 1.	Yes							
Ν	Yes				No	Yes							N	o Yes		
0		ver biopsy . Right lob	be □ 1.1	Left lob	e		f. Cr	ural repair	<b>.</b>						k. Pann	iculectomy
	🗆 b. Dr	ain placed a rojejunosto	at				g. G	astrectomy	$\rightarrow$	$\Box 1. \Box 1. \Box 2. \Box 0$	Partial Subtotal				intub	ned fiberoptic
		strostomy						holecystec agnostic E								sional hernia s of extensive
	🗆 e. Un	nbilical her	nia				ch	DT be chec eck the int agotomy —	egrity of	the and $\Box$ 1.		s. ype		]	o. Othe	sions er fy:)
	n method used to If yes, check "no			em in th	e box:	0. No sults		□ 1. If any o	Yes		2. N/A (	band)			Action	
No	Yes			1	. Neg.	2. I	os.		e, was ar		No	Yes	cne	CK no	item.	s" for each
		ir by Tube		$\rightarrow$			]		taken?				Sutu	re repai	r	
		tir by ndoscopy *	k	$\rightarrow$			]	□ 0. No	□ 1.	Yes 🗦			Glue	;		
		fethylene E		→			]						Com	plete ar	nastomos	sis redo
NO	TE: Air by End	oscopy sho	uld only b	e check	ed if it w	eas use	d to te:	st the integ	grity of ti	he anasi	tomosis					
.1 If	e any DVT prop f yes, check "no"	-				or intra	a-opera	tive) or or	dered (p	ost-ope	rative)?	□ 0.	No		1. Yes	
		mpression s	-	4		—			e-Operat istration				Intra-Op Adminis	erative tration	F	Post-operative Ordered
		quential cor								-	30 > 2					

🗆 d. Foot pump

|\_▶

e. 5000 units sub-cutaneous heparin

□ g. Low molecular weight heparin

□ h. Other Anticoagulant

Name:

f. Other dose heparin (Dose: \_\_\_\_ units)

If low molecular weight heparin:

None

(0)

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

Dose

20 mg

hours

(1)

□ 40 mg

1 hour

(2)

minutes

(3)

60 mg

Specify whether mg or unit:  $\Box$  1. mg

hours

(4)

No

(0)

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

mg)

Yes

(1)

No

(0)

Other (specify:

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

Yes

(1)

 $\Box$  2. unit

		Patient ID
<ol> <li>Record fluids and blood loss during surgery:</li> </ol>		(ml) Blood loss: (cc) ( <i>if</i> < 50 cc, enter "0") (ml) Blood transfusion: (units)
2. Anesthesia risk-derived classification:	□ 1. Stage I	□ 2. Stage II □ 3. Stage III □ 4. Stage IV
13.1 If yes, check "no" or "yes" to each item in No Yes	n the box:	1. Yes
<ul> <li>a. Instrument/equipment failure</li> <li>b. Revision of anastomosis (if yes)</li> </ul>		<ul> <li>e. Intra-operative transfusion</li> <li>f. Anesthesia event(s) (if yes)</li> </ul>
NoYes $\Box$ Gastrojejunostomy $\Box$ Jejunostomy $\Box$ Other (Specify: $\Box$ Other (Specify: $\Box$ Spleen $\rightarrow$ $\Box$ Liver $\Box$ Bowel $\Box$ Named Blood Vessel $\Box$ Other (Specify:)	er repair (if yes) II III IV V	No       Yes         Image: Surgical airway required         Image: Surgical airway required
d. Subcutaneous emphysema		
		(Specify:)

14. Lowest reported or known body temperature:  $(C^{\circ}) \rightarrow 14.1$  Specify temperature source:  $\Box$  1. Skin (including cartilage)  $\Box$  2. Core

Entered:// 20	_ Initials: Verified:/ / 20 For office use only.	Initial	s:		
	Post -Operative Evaluation Form (POST1) – Version: 08/28/2006				
Patient ID	Form Completion Date	e/			
Certification number:	Date of Surgery	mm / /		/ 20 _	уу уу
	Date of most recent contact:				
1. Source(s) of Information	$\therefore  \square  \text{Patient in Person} \qquad \underline{ \ } / \underline{ \ } / 20 \underline{ \ }$				
(check all that apply)	$\Box  Patient by Telephone \qquad \ / \ / 20 \ $				
	$\Box  Patient Representative \qquad \_ \_ / \_ \_ / 20 \_ \_$				
	$\Box  \text{Other Physician} \qquad \underline{} / \underline{} / 20 \underline{} \underline{}$				
	$\Box  \text{Chart Review}  \_\_ / \_\_ / 20 \_\_$				
2. Length of hospital stay for	or obesity surgery: (days)				
	<ol> <li>Home 3.1 Discharge Date://20</li> <li>Rehabilitation facility</li> <li>Skilled nursing facility</li> <li>Other hospital</li> <li>Was not discharged</li> <li>Hedges opened within 30 days following surgery? □ 0. No □ 1. Yes</li> </ol>				
5. Did the wound edges sep	parate within 30 days following surgery requiring packing or bandage? $\Box$ 0. N	0	□ 1.	Yes	
6 Did the patient die?	0. No 1. Yes $\rightarrow$ Date of death:// 2 0 mm dd yy				
6.1 Status Date:/	/ 20 (Most recent date participant known to be alive)				
If Y	alized after initial discharge?				
	7.2 Date of first re-hospitalization: $ / / 20$ mm dd yy				
7	7.3 Were any of these related to a cardiac event? $\Box$ 0. No $\Box$ 1. Yes				

#### Patient ID \_\_\_\_

8. Did the patient have any post-bariatric surgical operations or undergo **unplanned** post-discharge anticoagulation therapy?

If yes, specify all of the bariatric surgical operations or anticoagulation therapies below:

No	Yes	Event	Date first performed after surgery (mm/dd/yy)	Suspected reason for intervention (see codes on next page)	Was reason th interve confirm No	n for e ention
		8.1 Abdominal re-operation				
		<ul> <li>8.1.1. Specify approach: □ 1. Laparoscopic</li> <li>→ □ 2 Laparoscopic</li> <li>converted to Open</li> <li>□ 3. Open</li> </ul>				
		8.1.2. Specify procedure:				
		No Yes				
		a. Operative drain placement	// 20			
		D b. Gastrostomy	/ / 20			
		□ □ c. Anastomotic revision	/ / 20			_
		Specify revision: $\rightarrow$ $\Box$ GJ $\Box$ JJ	/ / 20			
		□ DJ				
		$\Box$ $\Box$ d. Band replacement				
		e. Band/port revision				
		□ □ f. Wound revision or evisceration				
		□ □ g. Re-exploration				
		h. Other (Specify:)	/ / 20			
		8.2 Tracheal reintubation	// 20			
		8.3 Tracheostomy	// 20			
		8.4 Endoscopy	// 20			
		8.5 Placement of percutaneous drain	// 20			
		8.6 Anticoagulation therapy for presumed/confirmed DVT	n/a	n/a		
		8.7 Anticoagulation therapy for presumed/confirmed PE	n/a	n/a		
		8.8 Readmission (other) 1 (Specify:)	// 20			
		8.9 Readmission (other) 2 (Specify:)	// 20			
		8.10 Readmission (other) 3 (Specify:)	/ / 20			

## 9. Were any post-discharge anticoagulation therapies <u>received</u>? If yes,

0. No 1. Yes

			Prophylactic (preventative) Use?	# of	Times	Therapeutic (as treatment) Use?	# of	Times
No	Yes		No Yes	Days	per day	No Yes	Days	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	Oth	er (Specify:	mg)		
		Other Anticoagulant If yes,						
		Specify name:	Specify dose	e:	1.mg	2. units		

# Table of codes forsuspected reason for an intervention

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