LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

MANUAL OF OPERATIONS

Epidemiology Data Center
University of Pittsburgh

LABS-1

MANUAL OF OPERATIONS

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Consent Form

[local institution]

LABS-1 CONSENT FORM

Please Note: This is NOT the consent for your surgery

Longitudinal Assessment of Bariatric Surgery (LABS)

Local Personnel

Principal Investigator
Surgical Investigators
Research Coordinators

National Sites

East Carolina University
Neuropsychiatric Research Institute
New York Columbia-Presbyterian / Cornell University Medical Center
Oregon Health & Science University / Legacy Good Samaritan Hospital
University of California, Davis
University of Pittsburgh Medical Center
University of Washington / Virginia Mason

Data Coordinating Center

University of Pittsburgh, Graduate School of Public Health

Emergency Phone (24 hours): (XXX) XXX-XXXX. This is the XX paging operator; ask that [local investigator] be paged.

INTRODUCTION:

You have been asked to participate in a research study pertaining to bariatric surgery. Before agreeing to be included in the study, it is important that you read and understand the following explanation. It describes the purpose of this study. It also describes the choice not to be included in the study. No guarantee or assurance can be made as to what information can be gained from this study. Inclusion in the research study is completely voluntary. ***Your refusal to be included will involve no penalty or loss of benefits to which you are otherwise entitled***. In addition, if you decide not to participate in this research, it will not impact your ability to have bariatric surgery. You may ask to be removed from the study at any time without penalty. You will also be given the choice as to whether you want to be contacted for possible participation in future research studies.

RESEARCHER'S STATEMENT

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to decide whether or not to be in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. After we have answered all your questions, you can

decide if you want to be in the study or not. This process is called 'informed consent.' We will give you a signed copy of this form for your records.

PURPOSE OF THE STUDY

Why is this research being done?

The goal of this study is to learn more about patients undergoing weight-control surgery. Specifically, we are trying to find out what types of patients do best after surgery and what kinds of treatment are most helpful for patients. Because you intend to have weight-control surgery, you are being asked to allow hospital information about your procedure and your health to be collected by the Longitudinal Assessment of Bariatric Surgery (LABS), and to allow us to ask you questions about your health in the future.

Who is being asked to take part in this research study?

Patients at least 18 years old who will have weight-control surgery are eligible for this study.

Who is conducting the research study?

The LABS-1 study is being conducted by researchers at six medical centers in the United States, with the [local institution] being one of the six sites. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), and the Office of Research on Women's Health (ORWH), the Department of Health and Human Services are providing the funding for the study.

How many people will take part in the research study?

Approximately 12,000 patients, men and women, will participate in LABS-1. We hope to enroll approximately XX patients at the [local institution].

STUDY PROCESS

What information will be collected for this study?

If you choose to participate in this study, information about your health, your weight-control surgery, and your response during the first 30 days following surgery will be collected by your surgeon or his/her research staff. We will record information obtained from you and from your medical record about your health and treatment before and after your surgery. We will record your height, weight and additional information about your health. Some of this information will be updated if your surgery is more than 90 days away, and you will be weighed again within 30 days of surgery, if you wait that long between the initial evaluation and surgery. We will also collect information about your surgery. Your surgeon will fill out information on what type of surgery you had and your medical condition during the operation. Approximately 30 days after your surgery, additional information will be collected. If you do not return 30 days after your surgery, we will call you and ask about how you have been doing since your surgery.

You may also be invited to participate in other research studies about weight and weight-control surgery. You do not have to participate in those studies unless you want to. Participating in this study does not prevent you from participating in other research studies now or in the future. If you decide not to have the surgery, or the surgery does not occur for other reasons, your involvement in this research project will end. In this circumstance, once it has been learned that you did not have surgery, you will not be contacted further concerning

this research study and any information that you had earlier provided will be removed from the research records and destroyed.

What will happen to the information collected if I decide not to have weight-control surgery?
If you decide to consent to participate in this study and then do not have surgery, we will destroy the information we have collected. If you do have surgery at some point in the future, you will again have the option of being a part of this study as long as the study is ongoing and your doctor is involved.

What if I decide not to take part in this research project?
You do not have to join this research study to have weight-control surgery. We will collect information that cannot identify you to document the number of people who have been asked to participate in the study. Your gender, age, race/ethnicity, height, and weight will be kept for this purpose. Whether or not you decide to participate in this study, you will receive the same medical care.

RISKS, STRESS, OR DISCOMFORT
What are the possible risks, side effects, and discomforts of this research study?
There are no risks of physical harm associated with participating in the LABS-1 study. Of minimal risk to you is the possible inconvenience of reporting your medical status to the research coordinator.

BENEFITS TO BEING IN STUDY
What are possible benefits from taking part in this study?
There are no direct benefits to you from participation in the LABS-1 study. The knowledge gained from your participation, however, may help other patients who are considering having this procedure to better understand the risks and benefits of weight-control surgery.

CONFIDENTIALITY OF RECORDS
Your participation in this study will be kept confidential and your name, address, and other personal identifying information will not be made known to anyone other than study personnel at the clinic. Your research information will be sent to the Data Coordinating Center located at The University of Pittsburgh, Graduate School of Public Health in Pittsburgh, Pennsylvania. The information will be labeled with only an identifying number and code that cannot be linked to your name or other personal identifiers except at the clinical center where you complete visits.

As this is a multi-center federally funded study, the study data for all study patients may be made available in an anonymous fashion to aid other researchers across the country. When results from this study are published, you will not be identified by name.

Representatives of the National Institutes of Health, the Data Coordinating Center, or other experts may review your records at visits to the clinic as part of the ongoing monitoring of the progress of the study. In addition, representatives from the United States Food and Drug Administration (FDA) or the Institutional Review Board at this clinic may review your study records, including your medical records. To help us protect your privacy, we have obtained a

Certificate of Confidentiality from the National Institutes of Health, which will allow us to resist any demands for your health information, with a few exceptions as explained below.

The Certificate of Confidentiality protects the study from being forced to disclose information that may identify you, even if by a court subpoena. We are also protected from demands for your information made by federal, state, local civil, criminal, administrative, legislative, or other sources. However, the Certificate cannot be used to resist a demand from the U.S. Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the U.S. Food and Drug Administration. The Certificate does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in the research. If an insurer, employer, or other person obtains your written consent to receive research information, then we may not use the Certificate to withhold that information. Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse or neglect or a risk of harm to yourself or others, we are required to notify the proper authorities.

You will receive a copy of this consent form and a copy will be placed in your hospital medical record so that any doctors who are treating you will also know that you are participating in the study.

Will I be paid if I take part in this research study?
No. You will not be paid for participation in this study. We will not pay for your weight-control surgery as a part of this study or for any complications you may have as a result of your surgery.

Will my insurance provider or I be charged for the costs of any procedures done as part of this research study?
No. There will be no costs to you or your insurance provider for participating in this study and there are no procedures performed as part of this research study.

OTHER INFORMATION
Who will know about my participation in this research study?
All records related to your involvement in this research study will be stored in a locked file cabinet. In this study, you will be given a unique study identification number which will be written on your study forms. Your study identification number will be kept separate from the research records. However, your name will appear on some study related forms such as this consent form and our private study information records. Your name, study identification number, this consent form and any information that could identify you will be kept separate from the research records. During quality assurance visits, the study's sponsor (NIDDK) (or designee), or the Institutional Review Board may wish to review your medical record. The representative from these agencies will be supervised by one of the investigators and will not record your name anywhere.

Who will have access to information related to my participation in this research study?
In addition to all members of the research team, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the [local institution] Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law.

Authorized representatives of the Data Coordinating Center will view medical information related to your participation in this study, and authorized representatives of the sponsor of this research study, the NIDDK, may request medical information related to your participation in this research study. The purpose of providing this information is to monitor the accuracy and completeness of the research data.

Authorized representatives of the [local institution]'s or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for internal hospital operations (called quality assurance).

May I have access to my medical information that results from my participation in this research study?
Yes. You are allowed to access medical information contained in your medical records, including information resulting from your participation in this research study.

Will my information for this study be used for any other studies?
Yes. If you choose to be in this study, other researchers may use your unidentifiable study information for their studies in the future.

Do I have to take part in this study?
No. You do not have to take part in this study to have weight-control surgery. Participating in this study is voluntary. If you decide not to be in this study or decide to stop participating in this study after enrolling, it will not affect your medical care in any way.

You have the right to change your mind about allowing us to have access to your personal health information. If you chose to take away this permission you must inform [local investigator] in writing. Any information collected up to the time you chose to take away your permission will still be used. Deciding to remove your information from the study will not result in any penalty or loss of benefits to you.

What if I decide later that I no longer want to participate in the study?
You may tell us at any time that you no longer wish to participate in this study. You may also tell us that you no longer allow us to use or disclose your de-identified information for this

study. Any information collected up to the time you choose to take away your permission may still be used.

You may revoke (choose to withdraw) this Authorization as provided under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) at any time after you have signed it by providing the LABS-1 Study staff at the [site] with a written statement that you wish to withdraw this Authorization. Your withdrawal of this Authorization will be effective immediately and your Protected Health Information can no longer be used/disclosed for research purposes by [site] and the other persons or entities that are identified in the "Confidentiality of Records" section of this consent, except to the extent that [site] and/or the other persons or entities identified above have already taken action in reliance upon your consent. In addition, your Protected Health Information may continue to be used/disclosed to preserve the integrity of an ongoing study.

What do I do if I have any problems or questions about the study?
If you have any questions concerning this study, would like to withdraw from the study, or think you may have experienced a research study-related problem, contact [local investigator][telephone number].

PERMISSION TO CONTACT PRIMARY CARE PHYSICIAN AND EMERGENCY CONTACT

In order to help with the follow-up process we would like to be able to contact your primary care physician or another person just in case all of the other information we have for you is no longer current. If you do not wish us to contact anyone except you, it will not affect your ability to participate in this study. Please indicate your choice below:

Yes: ____ I will allow the investigator to contact my primary care physician and an emergency and secondary contact if I am not able to be reached.
No: ____ I will <u>not</u> allow the investigator to contact my primary care physician, or emergency or secondary contact if I am not able to be reached.

If you marked yes above please give us the name, address and phone number of 2 people who will always know how to contact you (preferably people that are unlikely to move).

Contact 1 Name:
How do you know this person?
Street Address:
City, State, Zip
Phone #:

Contact 2 Name:
How do you know this person?
Street Address:
City, State, Zip
Phone #:
Primary Physician Name:
Street Address:
City, State, Zip
Phone #:

RESEARCHER'S STATEMENT

I have explained this study to this patient. Based on my clinical judgment, this patient is able and competent to independently consent to participation in this research study.

_____ _____

Signature of researcher Date

_____

Printed name of researcher

SUBJECT'S STATEMENT

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at [phone number of Human Subjects]. I give permission to the researchers to use my medical records as described in this consent form. I will receive a signed copy of this consent form.

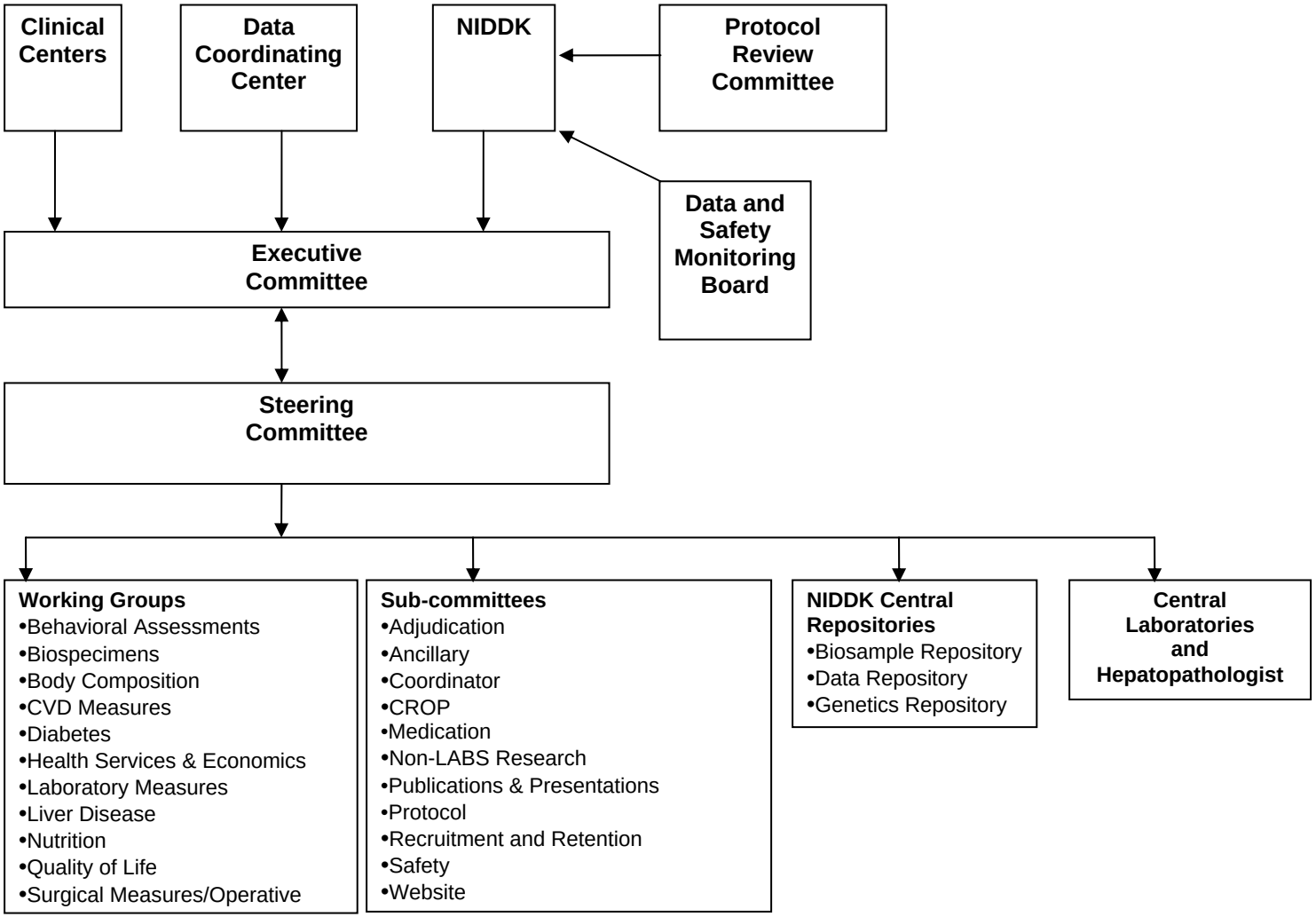
_____ _____

Signature of subject Date

_____

Printed name of subject

Copies: Subject, Investigator's file, Medical Record


Clinical Centers
Data Coordinating Center
NIDDK
Protocol Review Committee
Data and Safety Monitoring Board
Executive Committee
Steering Committee
Working Groups
•Behavioral Assessments
•Biospecimens
•Body Composition
•CVD Measures
•Diabetes
•Health Services & Economics
•Laboratory Measures
•Liver Disease
•Nutrition
•Quality of Life
•Surgical Measures/Operative
Sub-committees
•Adjudication
•Ancillary
•Coordinator
•CROP
•Medication
•Non-LABS Research
•Publications & Presentations
•Protocol
•Recruitment and Retention
•Safety
•Website
NIDDK Central Repositories
•Biosample Repository
•Data Repository
•Genetics Repository
Central Laboratories and Hepatopathologist

Committee Statements

Executive Committee: Manages day-to-day issues of the study; makes decisions required between the Steering Committee meetings as needed for efficient progress of the study, and reports its actions to the Steering Committee on a regular basis; organizes and sets agendas for Steering Committee meetings. Members consist of the two Steering Committee co-chairpersons, the Data Coordinating Center PI, and the NIDDK Project Scientist.

Steering Committee: Serves as the primary governing body of the study; responsible for policy decisions; votes on and approves all major decisions, provides oversight in planning the overall study design, approves protocols and subsequent amendments, facilitates study conduct and reporting of study results. Members consist of principal investigators of the clinical centers and the Coordinating Center, and the NIDDK project scientist. Two co-chairpersons were appointed by the NIDDK from among the clinical center investigators.

Subcommittees and Workgroups. Subcommittees work on specific areas of the study and make recommendations to the Steering Committee. Members consist of investigators from the clinical sites, Data Coordinating Center, and NIDDK, including individuals with expertise in the relevant areas.

Adjudication Committee (AC): The AC periodically reviews and classifies deaths and specified post surgical interventions for which the reason for the intervention could not be confirmed at the site (criteria for confirmation are detailed in the Manual of Operations). The AC will use information provided by the clinical sites through the Data Coordinating Center (DCC). Data, masked with respect to patient and medical staff (physician, surgeon, etc.) will be sent to the DCC from the clinical center at which the death or unconfirmed event occurred. The AC will not interact directly with the LABS clinical investigators concerning the results or the classification of events.

Ancillary Studies Subcommittee (ASC): The ASC evaluates protocols that enhance the ability of LABS: [1] to document the efficacy and complications of bariatric surgery and its role in the overall management of obesity; and [2] to address other important questions related both to clinical aspects of obesity and its co-morbidities and underlying mechanistic and other basic science issues. The LABS Steering Committee has designated the ASC to conduct an initial review of all proposed ancillary studies. The Steering Committee must ultimately approve all ancillary studies recommended for its consideration by the ASC to ensure that they do not impose an unacceptable burden on LABS staff or participating patients or conflict with the aims of LABS. Data collection for funded ancillary studies may not proceed without the approval of the Steering Committee.

Committee to Review Outside Participation (CROP): The CROP supports and develops LABS through industry relationships while maintaining the integrity of LABS research. The CROP works together with the NIDDK to solicit and oversee sponsored research agreements, materials transfer agreements and cooperative research and development agreements. Through

t hese relationships, LABS hopes to further its mission to provide a platform for future bariatric surgery research.

Coordinators Subcommittee: The Coordinators Subcommittee attends to the day-to-day operations of the study including recruitment, protocol adherence, consistent and complete data collection at each clinical center; and makes recommendations to the Steering Committee regarding any study issues that may require modification or resolution.

Protocol Subcommittee: The Protocol Subcommittee prepares the final written protocol and thus prepares summary, background information, study design, inclusion and exclusion criteria, definitions for surgical methods, monitoring schedule, adverse event grading, statistical analysis, patient protection, and references sections of the protocol; develops details of the protocol and study design for Steering Committee and DSMB approval. A subcommittee of the Protocol Committee will prepare the template consent forms for the study.

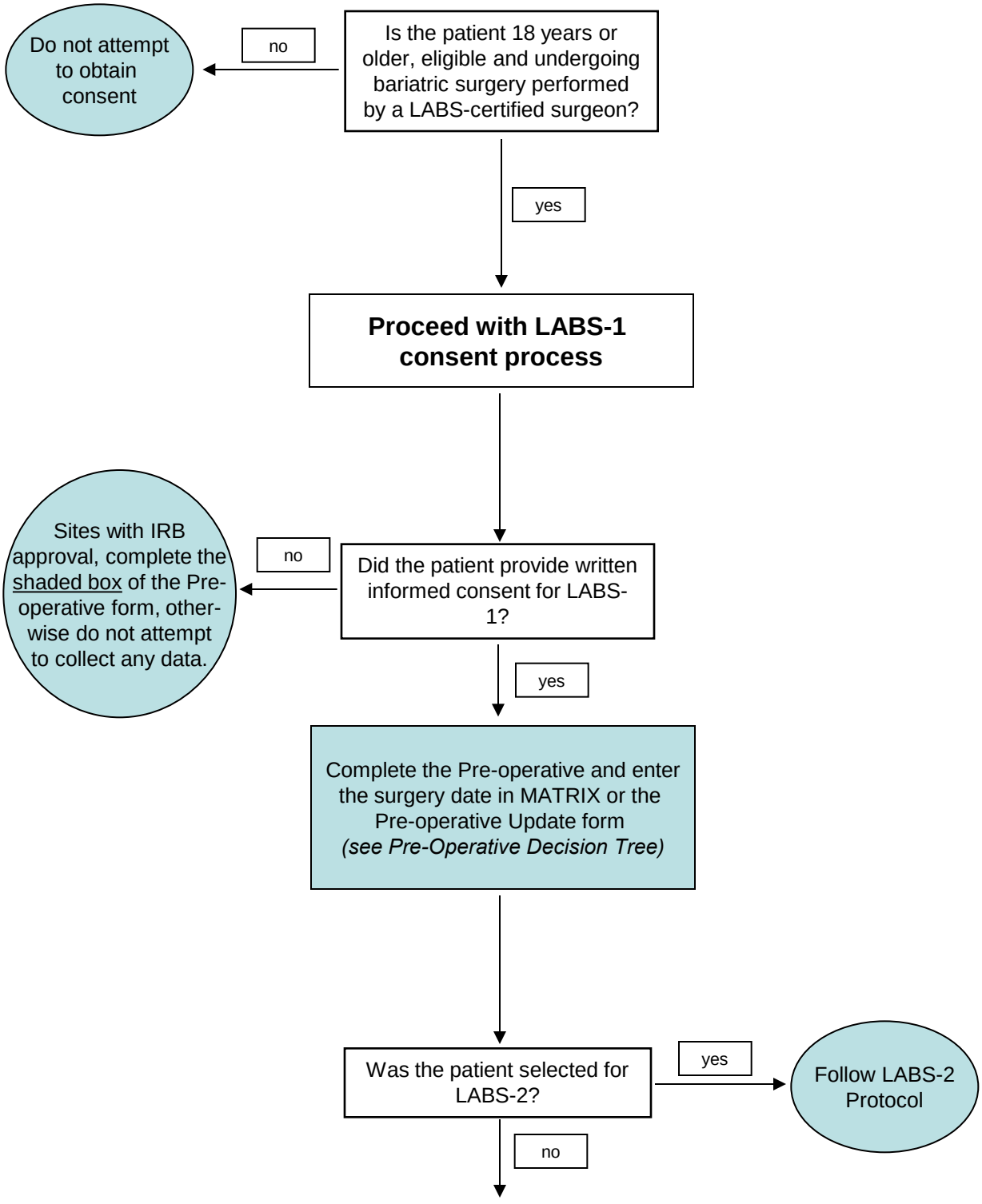
Publications/Presentations Subcommittee: Develops the policy for publications regarding preparation of abstracts, presentations, and manuscripts; policy as regards to requesting data analysis, authorship policy, and other issues related to publications; prepares a formal publication policy for full manuscripts and abstracts; prepares a list of possible publications that will arise from this study, and prepares paragraphs regarding the scope of each and how they intersect with the designated final major manuscript to arise from this study.

Recruitment and Retention Subcommittee: Attends to all facets of participant recruitment and retention. Committee members prepare strategies that can be implemented study wide to maximize recruitment and to maintain participants in the study.

Safety Committee: The Safety Committee provides on-going review of safety issues related to all of LABS studies. In defining the role of the Safety Committee, it is important to emphasize that LABS-1 and-2 are observational cohort studies so that the decision to perform bariatric surgery, the type of bariatric surgery and related pre-operative and post-operative management of the individuals who agree to be study participants in LABS is governed by clinical decision making and is not specified by the study protocol *per se*. The Safety Committee will be kept apprised of the summary findings of the Adjudication Committee, but the main charge of the Safety Committee is to focus upon the risk of procedures specific to the various LABS protocols, including LABS-3 mechanistic studies and separately funded ancillary studies.

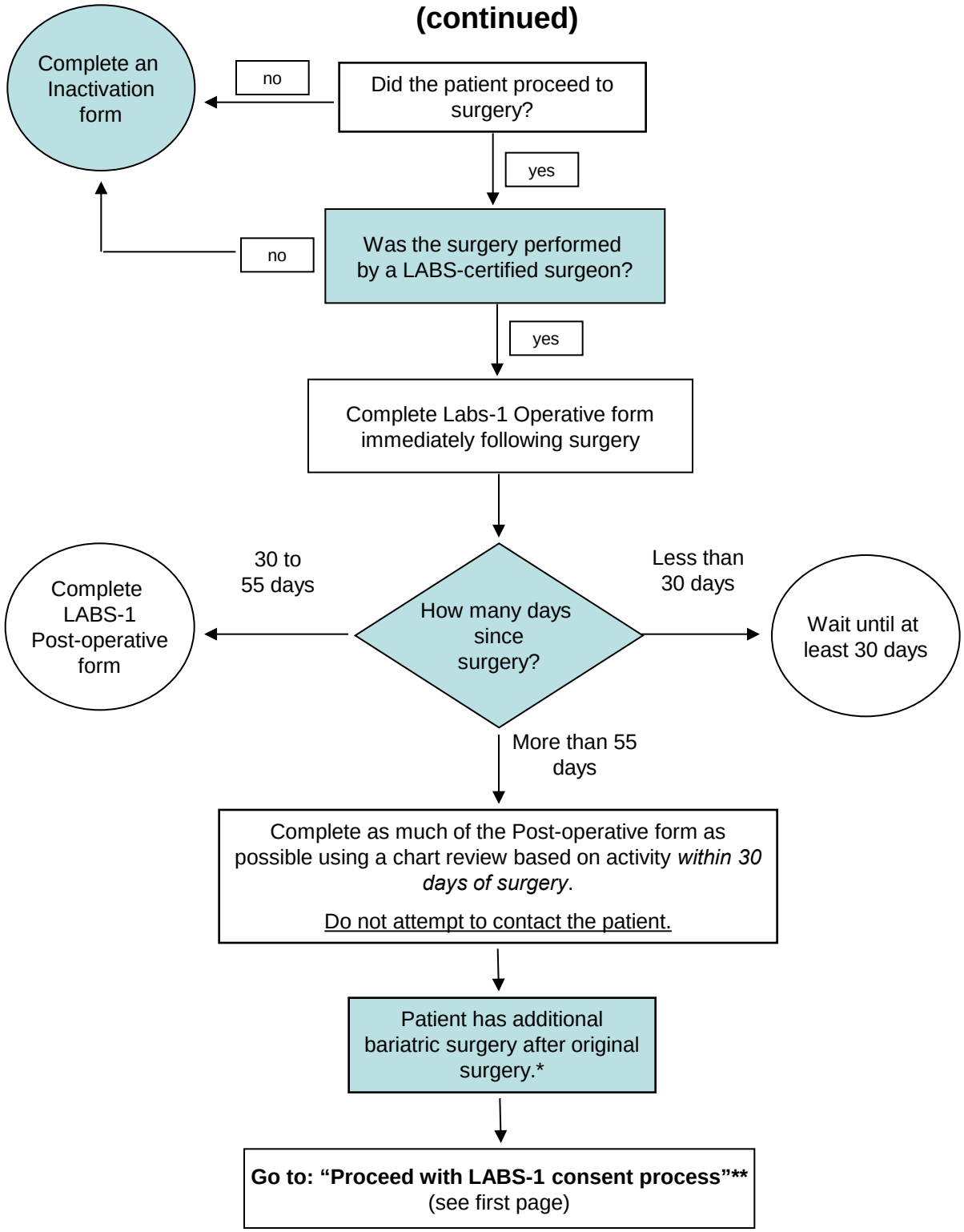
Non-LABS Research: Committee statement to be added at a later date.

LABS-1 Data Collection Flow



LABS-1 Data Collection Flow

(continued)

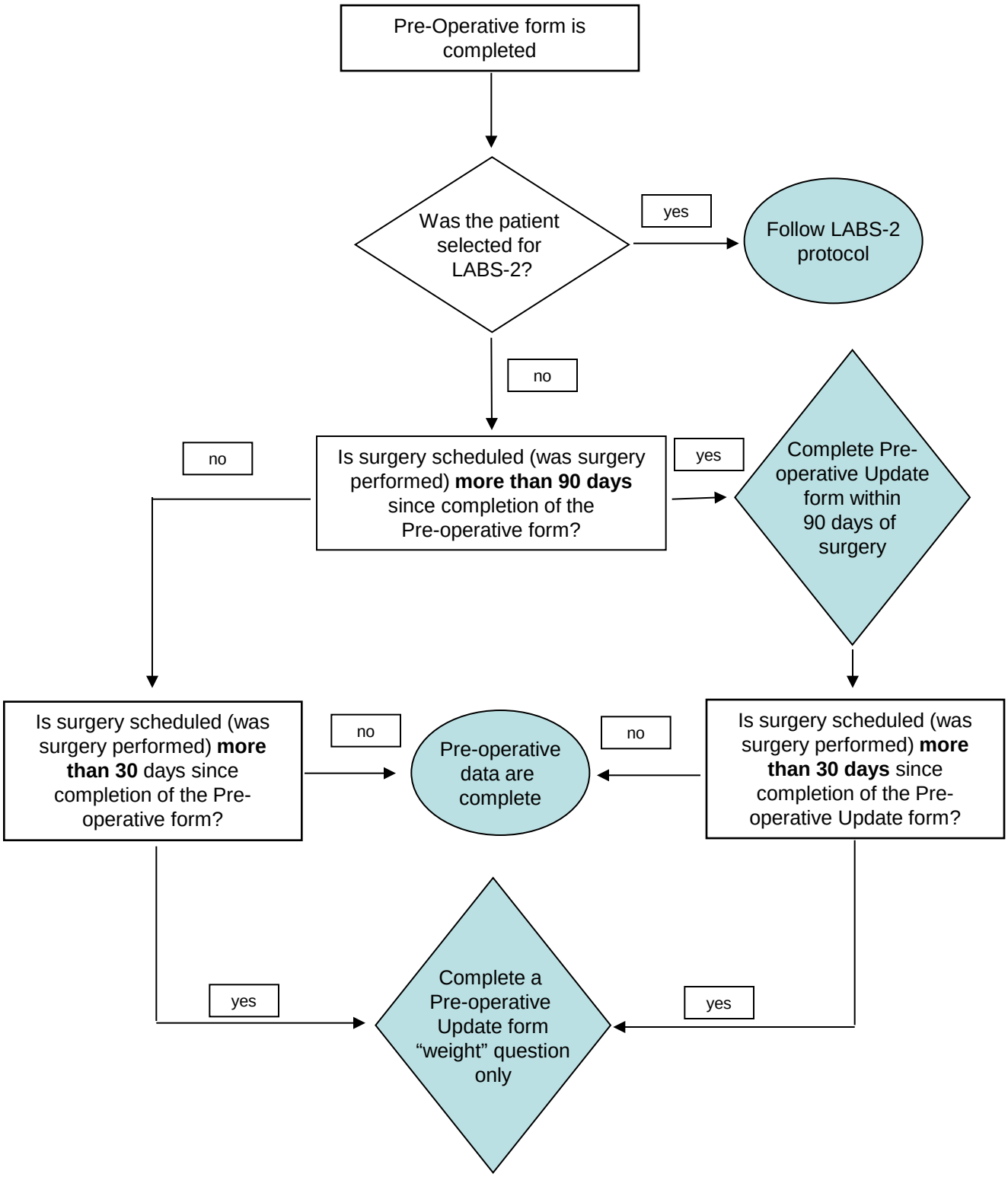


***If original surgery was cancelled after anesthesia induction, it would include the rescheduled surgery. If original surgery proceeded, this would include revision, reversal, second stage procedure.**

****If your consent form does not have an expiration timeline and/or your IRB does not require the Participant to be reconsented, it is not necessary to reconsent.**

LABS-1 Pre-operative

Decision tree



Operations Memos

LABS-1 will incorporate Operations Memo when study processes are either introduced or updated.

All operations memos will be numbered and should be kept for future reference. All memos should be placed in this section of the Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #1

DATE: March 24, 2005

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: RECORDING THE VALUE FOR "ALBUMIN" ON THE LABS-1 PRE-OPERATIVE AND PRE-OPERATIVE UPDATE FORMS

Please note that this is the **LABS-1** Operations Memo #1. All operations memos will be numbered and should be kept for future reference. All memos should be placed in the appropriate section of the relevant Manual of Operations. This memo should be placed in the LABS-1 Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.

This memo addresses issues for the:

Coordinators/Data Managers/Data Entry personnel

Please distribute this memo to the appropriate personnel at your site.

ISSUE: Question #14 on the LABS-1 Pre-operative Form and question #5 on the Pre-operative Update Form record values for laboratory tests done within the past 90 days. On the current versions (v1.0 dated 10/11/2004, v1.1 dated 10/25/2004, v2.0 dated 01/26/2005), the unit for albumin is listed as mg/dl. However, the accepted standard unit for albumin is g/dl.

SOLUTION: Clinical centers should record and enter albumin in g/dl. Do NOT attempt to convert the value to mg/dl. The next version of these forms will list the correct unit. Standard range checks will ensure that values entered for albumin are in g/dl.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #2

DATE: April 25, 2005

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: UPDATES MADE TO THE PRE-OPERATIVE, PRE-OPERATIVE UPDATE AND OPERATIVE FORM QXQ'S

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the:

Primary Investigators/Surgeons/Coordinators/Data entry personnel

Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs)for the Pre-Operative, Pre-Operative Update and Operative forms have been modified to clarify study procedures. Details regarding each change are provided in this Operations Memo. In addition to changes to the QxQs, revisions were made to the pages that list the variable names. These revisions were required to accurately reflect the LABS-1 database. The revised QxQs and variable name/code pages (modified April 11, 2005) are available in the manual of operations folder under LABS-1 in the researchers section of the LABS website (http://www.edc.gsph.pitt.edu/LABS/research/Documents/LABS-1/ManualofOperation/Version2/)

Please replace the pages in your MOP with the updated pages..

I. Pre-Operative and Pre-Operative Update forms

A. Recording ethnicity and race:

ISSUE: Question #5 and #6 on the LABS-1 Pre-operative Form record Ethnicity and Race: "Ethnicity," or origin, is defined as "the heritage, nationality group, lineage, or country of birth of the person or person's parents or ancestors before their arrival in the United States. People who identify their origin as Spanish, Hispanic, or Latino may be of any race" (U.S. Census Bureau). Two categories for ethnicity are provided: Hispanic and Non-Hispanic.

Some may identify their race as "Hispanic" or "Latino," but they are actually stating their ethnicity or origin, while their race is one of the LABS-1 race categories: White or

Caucasian, Black or African-American, Asian, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, or Other.

Others may identify their race with a specific country, such as indicating that they are "Scottish" or "Spanish" or "Swedish." Again, they are describing their ethnicity/origin, which should be correctly categorized as either Hispanic or Not Hispanic, while their race is one of the six given race categories.

SOLUTION: If a participant mistakenly provides an ethnicity for the race, please clarify the difference between race and ethnicity with the participant. If after the clarification, the participant continues to insist the ethnicity is their race, please record 'unknown' (-3) for the race. The LABS-1 form completion instructions (QxQ's) have been updated to include this detail.

B. Age started smoking:

ISSUE: An inquiry was made regarding the definition of "age started smoking" if a patient is either a current or former smoker. Should "aged started smoking" be in reference to when the patient smoked his/her first cigarette or should it be in reference to when the patient started smoking regularly?

SOLUTION: When asking patients their age when started smoking, the question should be in reference to when he/she started smoking regularly. The form completion instructions (QxQ's) have been updated to reflect this clarification.

C. Average packs/day:

ISSUE: An inquiry was made regarding the definition of "average packs/day" if a patient is either a current or former smoker. Should "average packs/day" be in reference to present average (or most recent average) or should it be in reference to the patient's lifetime average?

SOLUTION: When asking patients the average packs/day of cigarettes that they smoke(d), the question should be in reference to the patients lifetime average. The form completion instructions (QxQ's) have been updated to reflect this clarification.

D. Distinguishing laboratory values that are not done.

ISSUE: It is important to be able to distinguish between laboratory values that have not been entered into the MATRIX Data Management System (MATRIX) but will be at a later date and those that have not been entered into MATRIX because laboratory tests have not been ordered/done. Presently, the value "-2" is being entered in both situations.

SOLUTION: When laboratory values are not available at the time data entry but will be at a later date, the appropriate value to enter onto the paper form and into MATRIX is "-1." If the labs are not done (for any reason) and are not expected to be done, the "not done" box

should be checked on the data collection form and "-5" (the study "not done" code) should be entered into MATRIX. The data entry screens in MATRIX will be revised to indicate that "-5" should be entered when the laboratory tests are not done/expected. The LABS-1 form completion instructions (QxQ's) have been updated to include this detail.

E. Single vs. multiple medication reported when recording comorbidities:

ISSUE: If a patient has hypertension or diabetes (see items "a" and "b" in the comorbidity section), a follow-up response must be made to report the number of medications (no medication, single medication, multiple medication) that the patient is taking. The Data Coordinating Center received an inquiry of how to report combination medication taken in single dosage form.

SOLUTION: If a patient is taking a combination medication in single dosage form, the appropriate follow-up response is "multiple medications" for hypertension and diabetes in the comorbidity section of the pre-operative and pre-operative update forms. The LABS-1 form completion instructions (QxQ's) have been updated to include this detail.

II. Operative form

A. Standard method of measuring carbon dioxide levels on the operative form:

ISSUE: An inquiry was made as to the LABS standard method of measuring the carbon dioxide levels in patients in order to determine whether a patient had experienced sustained hypercarbia. Sustained hypercarbia is listed as a follow-up item under anesthesia event(s) for question #11 (Were there any intra-operative events?) of the operative form.

SOLUTION: The LABS standard method of measuring carbon dioxide levels in patients is end tidal CO_2. The LABS-1 form completion instructions (QxQ's) have been updated to include this detail.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #3

DATE: May 27, 2005

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: UPDATES MADE TO QxQs

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the:

Coordinators/Data entry personnel

Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs)for the Pre-Operative, Pre-Operative Update, Operative and Post-Operative forms have been modified to clarify study procedures. Details regarding each change are provided in this Operations Memo. The revised QxQs (modified May 27, 2005) are available in the manual of operations folder under LABS-1 in the researchers section of the LABS website (http://www.edc.gsph.pitt.edu/LABS/research/Documents/LABS-1/ManualofOperation/Version2/)

Please replace the pages in your MOP with the updated pages.

Pre-Operative Form

I. Fasting Plasma Glucose Lab Values.

ISSUE: Glucose tests that are not both 1) fasting and 2) plasma.

SOLUTION: The glucose tests must be fasting, plasma and completed within the defined window (90 days for the 1/25/2006 versions). If the glucose value is not fasting plasma glucose (or if it is not certain that the sample was a fasting sample), check the “not done” box on the pre-operative form (entered as -5 into the database).

Operative Form

II. Blood Loss less than 50 cc.

9. Record fluids and blood loss during surgery:
Blood loss: __ __ __ (cc)

ISSUE: Less than 50 cc of blood is hard to accurately measure.

SOLUTION: If blood loss is under 50 cc, the value of 0 (zero) should be recorded and entered into the database.

Post-Operative Form

III. Length of Hospital Stay if still hospitalized at day 30 (for the initial surgery).

2. Length of hospital stay for obesity surgery: _____ (days).

ISSUE: How many days should be entered for Length of Hospital Stay, Question #2 when the patient has not been discharged by the end of day 30 (for the initial surgery).

SOLUTION: If the patient was not discharged by the end of day 30, enter “31” as the length of hospital stay. In addition, please be sure to correctly answer Question #3. Discharge location as “Was not discharged”.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #4

DATE: July 20, 2005

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: Reporting information on the Operative and Post-Operative forms.

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Surgeons/Coordinators/Data entry personnel.** Please distribute this memo to the appropriate personnel at your site.

I. Pre-Operative/Pre-Operative Update Form

Recording blood pressure.

ISSUE: If blood pressure is not taken at the pre-operative office visit and the blood pressure in the patient chart is more than 90 days prior to surgery, there was question of whether or not the blood pressure should be recorded.

SOLUTION: If the blood pressure is not taken at the pre-operative office visit and the blood pressure in the patient's chart is more than 90 days prior to surgery, the blood pressure should not be recorded. Instead, -5 (code value for "not done") should be entered into the MATRIX database.

II. Operative Form

Clarification of Question 3.2 on the Operative form

3.2 How was the Gastrojejunostomy / Duodenal-jejunostomy done?

No Yes

a. Hand sewn
b. Linear stapled
c. Circular stapled (EEA)

ISSUE: Because linear stapling requires a small amount of hand sewing, there was a request to clarify how the option "hand sewn" should be answered if linear stapling is the primary method.

SOLUTION: All applicable methods for the Gastrojejunostomy/Duodenal-jejunostomy should be recorded. If linear stapling was performed and hand sewing was also involved, then the options "linear stapled" and "hand sewn" should both be marked as "Yes". A quality control check has been added to the data management system that will flag any records where linear stapling is "Yes" but hand sewn is "No". Clinical site personnel should review these records to determine if hand sewing was involved and update the record, if appropriate.

III. Post-Operative Form

A. Clarification of the questions regarding wound edges

ISSUE: A query was received regarding questions 4 and 5 of the Post-Operative form when the wound edges are opened or separated during a surgical procedure (intentionally opened or separated).

4. Were the surgical wound edges opened within 30 days following surgery?

5. Did the wound edges separate within 30 days following surgery requiring packing or bandage?

SOLUTION: Both questions refer to unintentional wound opening or separating. If the wound edges were either intentionally opened or intentionally separated, the appropriate answer to this question is "no."

B. Multiple post-bariatric surgical operations or unplanned post-discharge anticoagulation therapies.

ISSUE: The LABS-1 Post-Operative Evaluation form is not designed to permit recording of multiple interventions of the same type that occur on different dates and/or for different suspected reasons within 30 days of surgery. How should this information be recorded/captured and entered?

SOLUTION: This information is relevant to the objectives of LABS-1 and, therefore, should be recorded and included in the LABS-1 database. If multiple interventions of the same type occur within 30 days of surgery, record the first intervention on Page 2 of the Post-Operative Evaluation form. The additional interventions should be recorded on a copy of Page 2 (attaching that copy to the original Post-Operative form). The information recorded on the additional Page 2 will be entered into database via the ADDEV (Additional Events) form/screen in the MATRIX Data Management System (MATRIX). The ADDEV has not yet been released in MATRIX. Clinical sites will be notified as soon as it is available.

C. Reporting post-bariatric interventions that are not surgical operations or unplanned post-discharge anticoagulation therapy?

ISSUE: Are interventions that are neither surgical interventions nor unplanned post-discharge anticoagulation therapies to be recorded on the Post-Operative form?

SOLUTION: The Post-Operative form is designed to only capture surgical interventions or "unplanned" post-discharge anticoagulation therapies that occur with 30 days of the surgery date as per the LABS-1 protocol. Other interventions should **not** be reported on the Post-Operative form.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #5

DATE: October 21, 2005

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: Reporting information on Pre-Operative/Pre-Operative Update Forms.

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Coordinators/Data entry personnel.** Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs) for the Pre-Operative and Pre-Operative Update forms have been modified to clarify study procedures. Details regarding each change are provided in this Operations Memo. The revised QxQs are available in the manual of operations folder under LABS-1 in the researchers section of the LABS website http://www.edc.gsph.pitt.edu/LABS/research/Documents/LABS-1/ManualofOperation/Version3/)

Please replace the pages in your MOP with the updated pages.

I. Pre-Operative (PO1)/Pre-Operative Update (PU1) Forms:

HbA1c Low Range Values.

ISSUE: The HbA1c normal low value is often not included in standard laboratory reports. How should this information be reported/recorded on the PO1 and PU1 forms?

SOLUTION: It has been determined that the normal low value is not a useful data point. This data point will be removed from the PO1 and PU1 forms on the next version of these forms. In the meantime, it is no longer necessary to record the HbA1c low range value. The proper value that should be entered for this data point, until the new version is distributed and is IRB-approved, is -2 (special code for not applicable).

HbA1c High Range Values.

ISSUE: It was noted that some laboratory reports list normal high and diabetic high range values for HbA1c. Which high range value should be reported – normal high or diabetic high?

SOLUTION: For this data point, the NORMAL high range value should be reported

regardless of the patient's diabetic condition.

Fasting Plasma Glucose.

ISSUE: Some clinical sites are routinely collecting fasting ***serum*** glucose rather than fasting ***plasma*** glucose. The PO1 and PU1 forms and QxQs indicate that fasting PLASMA glucose should be reported/recorded. Is fasting ***serum*** glucose acceptable?

SOLUTION: During a recent SC meeting, it was determined that the difference between PLASMA and SERUM is minute and that LABS could accept either plasma or serum. Clinical sites may update previously completed PO1 and PU1 forms with the values for fasting serum glucose, if applicable. The label for this data point will be updated on the next version of PO1 and PU1 data collection forms.

Intended vs. labeled medication usage:

ISSUE: At times, medications are reported as being used for purposes other than their original labeled use. For example, a patient may be taking the drug Amitriptyline to treat migraines (intended use); however it's therapeutic class is listed as an anti-depressant (labeled use). It is unclear whether medication should be reported based on its intended use or labeled use.

SOLUTION: All medications must be recorded by therapeutic class/labeled use, regardless of the intended use.

A pharmaceutical therapeutic classification listing (i.e. medication guide, skyscape) or pharmacist may be consulted for clarification. In addition, a LABS help desk ticket may be submitted.

II. Adjudication Handbook (*Revisions are italicized.*)

V. **Statement of Purpose**

The purpose of the LABS Adjudication Committee (AC) is to periodically review and classify deaths and unconfirmed reasons (causes) for: (i) surgical re-operations; and (ii) unplanned post-discharge anticoagulation therapies recorded in LABS-1 using information provided through the LABS Data Coordinating Center (DCC). This adjudication process is conducted to accurately classify patient events for subsequent analyses as part of the LABS project. All findings and decisions of the AC are confidential. Data, masked with respect to patient and medical staff (physician, surgeon, clinical center, etc.) are sent to the DCC from the clinical center at which the death or event with unconfirmed reason (cause) occurred. *The DCC forwards the data, along with a summary of LABS data to two or more initial AC reviewers, none of which will be from the same site at which the event occurred.* These committee members then return their determinations to the DCC following their review. The resulting outcome data are used to prepare monitoring reports for review by the LABS Data Safety Monitoring Board, and to report endpoint results.

VI. **General instructions for Adjudication Committee (AC) Member Review**

Review each patient's file and make a determination by completing the form. *To assist with your determination, you may consult with a surgeon or other health professional to gain insight on medical and surgical issues at large, but not to share any specific characteristics of the case.*

VIII.**Process of Adjudication.**

Each event distributed for adjudication will be initially reviewed by two or more members of the AC. If there is unanimous agreement among the two or more members, the event will be considered adjudicated. Unanimous adjudication is defined as either: (i) rating of ***definite*** *or* ***probable*** *level of certainty for the same primary cause assigned by all two or more members; or (ii) rating of* ***indeterminate*** *cause by all two or more members. None of the two or more members selected for review will be from the same institution in which the event to be adjudicated originated.*

If the initial two or more-member review does not result in unanimous adjudication, the DCC will schedule a meeting, led by the AC Chair, among the two or more participating members by either teleconference or in person. The two or more members will discuss their reviews and attempt to reach consensus. If this is not achieved, the review material will be distributed to all remaining members of the committee excluding those from the institution in which the event originated. The DCC will schedule a meeting, to be led by the AC Chair, among the full committee with final adjudication determined by majority vote. In the unlikely event of a voting tie (i.e. 4-to-4 vote), a member of the DCC will cast the final vote required for adjudication.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #6

DATE: October 21, 2005

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: Administering the Pre-Operative Update Form.

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Coordinators/Data entry personnel.** Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs) for the Pre-Operative and Pre-Operative Update forms have been modified to clarify study procedures. Details regarding each change are provided in this Operations Memo. The revised QxQs are available in the manual of operations folder under LABS-1 in the researchers section of the LABS website http://www.edc.gsph.pitt.edu/LABS/research/Documents/LABS-1/ManualofOperation/Version3/)

Please replace the pages in your MOP with the updated pages.

I. Pre-Operative Update Form

ISSUE: Clarification of Pre-Operative Update Form administration:

SOLUTION:

The Pre-operative Update Form and Laboratory values

The LABS-1 protocol states the laboratory values (blood draw date) must be obtained within 180 days of surgery; medication and comorbidities information must be obtained within 90 days of surgery; and weight must be obtained within 30 days of surgery. If any of these variables expire before surgery they must be updated via the Pre-operative evaluation Update form. The following instructions have been written to clarify when a Pre-operative evaluation Update (PU1) form should be completed. These instructions also clarify when and where to properly enter laboratory values.

Completing only weight on the PU1 form:
If the initial Pre-operative (PO1) form is completed 31-90 days prior to surgery, the patient's weight must be obtained within 30 days prior to surgery and recorded on a PU1 form. Data, other than weight, entered into the Data Management System (MATRIX) for this situation is inappropriate and will be flagged and site personnel will be requested to change the values to the appropriate -2 (n/a) code.

Completing the entire PU1 form:
If the initial PO1 form is completed 91 days or more before surgery, the patient should be re-evaluated within 30 days prior to surgery and the **entire** PU1 form should be completed. ***Special note on laboratory values:*** If no additional laboratory tests have been completed since the initial pre-operative evaluation and the results/values on the PO1 have not expired (blood draw date is within 180 days of surgery date), then those same laboratory values should be recorded on the PU1. If the laboratory values have expired (blood draw date is more than 180 days prior to surgery) and additional laboratory tests were not done prior to surgery, then the laboratory tests should be marked as "not done" on the PU1 and the special code -5 (not done) should be entered into MATRIX for these laboratory tests.

Entering -1 (pending) vs. -5 (not done) for the laboratory variables:
If the results for **ordered** laboratory tests are not available when the PO1 form is completed, coordinators should code laboratory values as -1 (pending). When laboratory results are received, the PO1 form as well as the data in MATRIX should be updated from -1 to the appropriate laboratory values. If laboratory tests have not been ordered when the PO1 form is completed or if any existing laboratory results have expired (blood draw date more than 180 days prior to surgery date), then the coordinator should mark the laboratory tests as "not done" and the special code -5 (not done) should be entered into MATRIX for these laboratory tests.

Automated alerts of expired laboratory values:
To assist the coordinators in ensuring that valid and recent laboratory results are maintained in the LABS database, the Data Coordinating Center will provide periodic reminders to alert coordinators of patients who do not have acceptable laboratory values. Using the blood draw date of the laboratory values on the PO1/PU1 forms and the surgery date, coordinators will be requested to review laboratory status/information for any patients who have proceeded to surgery but either do not have required laboratory results or the recorded results have expired (blood draw date is more than 180 days prior to surgery). Patients with pending (-1) results on either the PO1 or PU1 will not be included in this reminder. If more recent information is available, it should be recorded/updated on the PO1 form if the PO1 evaluation date is within 90 days of surgery. Otherwise, the information should be recorded/updated on the PU1 form.

If a PU1 form expires before surgery:
On the rare occasion when surgery is rescheduled more than 30 days after a PU1 form is completed, another PU1 form must be completed within 30 days of the rescheduled surgery. If the latest PU1 form was done 31-90 days before the new surgery date then only the weight needs to be recorded on a new PU1 form, otherwise the entire form must be completed..

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #7

DATE: February 15, 2006

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: Clarifications to the Pre-operative Form, Pre-operative Update Form, Operative Form, Post-Operative Form, Adjudication Handbook and all corresponding QxQs.

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Coordinators/Data entry personnel.** Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs) for the Pre-Operative and Pre-Operative Update forms have been modified to clarify study procedures. Details regarding each change are provided in this Operations Memo. The revised QxQs are available in the manual of operations folder under LABS-1 in the researchers section of the LABS website http://www.edc.gsph.pitt.edu/LABS/research/Documents/LABS-1/ManualofOperation/Version3/)

Please replace the pages in your MOP with the updated pages.

Pre-Operative & Pre-Opertive Update Form

I. Clarification of "principal mechanism of action", Pre-Operative Form QxQ #15, Pre-Operative Update Form QxQ #6.

"Principal Mechanism of Action" will be known as:

The mechanism by which a pharmacologically active substance produces an effect on a living organism or in a biochemical system. (the drug's original labeled use).

II. Clarification of CPAP and BiPAP treatment for sleep apnea, Pre-operative Form QxQ 17.g. and Pre-operative Update Form QxQ 8.g and corresponding QxQs.

ISSUE: Recording if a Patient uses a CPAP or BiPAP machine for the treatment of sleep apnea does not capture those patients who have been prescribed a CPAP or BiPAP machine, but do not use the equipment.

SOLUTION: Record if a Patient has been prescribed a CPAP or BiPAP machine for the treatment of sleep apnea, regardless of patient compliance.

III. Clarification of Multiple Previous Bariatric Surgeries, Pre-operative Form #7.1, Pre-operative Form QxQ #7.

ISSUE: Multiple previous bariatric surgeries in the "other" category cannot be captured.

SOLUTION: In the event that the patient has had multiple "other" previous bariatric (surgeries that are not listed in 7.1), record the date of the most recent surgery and under "specify", record how many other previous bariatric surgeries the patient has had. For example, "3 previous bariatric surgeries".

If the patient has had one other previous bariatric surgery, record the type of surgery under "specify".

NOTE: you must write all previous other bariatric surgeries on the PO1 form to keep in the patient file, for future reference and auditing purposes.

Operative Form

IV. Clarification of "Primary Surgeon", Operative Form QxQ General Instructions

The following definition of "Primary Surgeon" will be added to the General Instructions as follows.

NOTE: The primary surgeon noted on the Hospital Operative Notes will be considered as the surgeon who performed the operation. If the primary surgeon is not LABS certified, the patient is not eligible for LABS, even if a LABS certified surgeon was present.

Post-Operative Form

V. Clarification of the "Source(s) of Information" Definitions, Post-Operative Form #1, Post-Operative Form QxQ#1.

"Patient in Person" – The information listed on the Post-Operative Form was obtained from the patient by LABS certified personnel (normally the coordinator, but may be the surgeon).

The information must be obtained within the protocol window.

"Patient by Telephone" – The information listed on the Post-Operative Form was obtained from the patient, over the telephone, by LABS certified personnel (normally the coordinator, but may be the surgeon). The information must be obtained within the protocol window.

"Patient Representative" – The information listed on the Post-Operative Form was obtained from a representative of the patient, who was defined by the patient in their LABS-1 consent form, by LABS certified personnel (normally the coordinator, but may be the surgeon). The information must be obtained within the protocol window.

"Other Physician" – The information listed on the Post-Operative Form was obtained from another Physician, by LABS certified personnel (normally the coordinator, but may be the surgeon). The information must be obtained within the protocol window.

Adjudication Handbook

V. Adjudication Handbook

ISSUE: Clarification of DVT on the Mortality Form

SOLUTION: DVT will be further defined by Superior to the Vena Cava and Inferior to the Vena Cava.

☐ 4. Deep vein thrombus (DVT)

☐ 1 superior to the vena cava

☐ 2 inferior to the vena cava

VI. Adjudication Handbook

ISSUE: Previously, adjudication was necessary for all tracheostomy/trachial intubations. The Adjudication Committee has decided that mandatory adjudication is no longer required.

SOLUTION: Adjudication for tracheostomy/tracheal intubations are only required when the suspected reason is unconfirmed.

Appendix B, of the Post-Operative QxQs, will be revised to read:

Tracheal reintubation	An endotracheal tube was replaced after having been removed.
Tracheostomy	A surgical procedure was performed to gain access to the trachea to maintain mechanical ventilation.

LABS-1

OPERATIONS MEMO #8

DATE: September 7, 2006

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: LABS-1 surgeries

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **PIs/Surgeons/Coordinators/Data collection personnel.** Please distribute this memo to the appropriate personnel at your site.

The LABS-1 MOP has been updated to clarify study procedures. Details regarding each option are provided in this Operations Memo. The revised Section 9 of the LABS-1 MOP which is available in the manual of operations folder under LABS-1 in the researchers section of the LABS website: http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/ManualofOperation/Version5/.

Surgeon and Coordinator Training materials have also been revised. Please refer to Section 13 of the LABS-1 MOP which is available in the manual of operations folder under LABS-1 in the researchers section of the LABS website: http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/ManualofOperation/Version5/

Please replace the pages in your MOP with the updated pages.

ISSUE: Clarification of bariatric surgery definitions.

SOLUTION: Section 9 of the LABS-1 MOP, Surgeons Experience, (pg. 10) will be revised to read as follows:

1. Primary Operations
    a. Vertical Banded Gastroplasty
    b. Adjustable Gastric Banding
    c. Gastric Bypass and Variants
        i. R-Y short
        ii. R-Y long
        iii. Banded
        iv. Distal
    d. Biliopancreatic Diversion
    e. Biliopancreatic Diversion + Duodenal Switch
    f. Sleeve Gastrectomy
    g. Sleeve Gastrectomy 2nd Stage
        i. RY Gastric Bypass
        ii. BPD-DS
    h. Banded Gastric Bypass (GB + Non-Adjustable Band)

2. Conversions, Revisions and Reversals of Bariatric Operations

3. Exclusions
    a. Investigational procedures
    b. Non-standard procedures (omenectomy, gastric bypass with adjustable band)
    c. Gastric pacing, endoluminal weigth loss procedures
    d. Non-bariatric surgeries (ventral hernia, decubitus ulcers, cholecysterctomy, cosmetic surgery)

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1
OPERATIONS MEMO #9

DATE: October 24, 2006

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: LABS-1 Pre-Operative, Pre-Operative Update & Post-Operative QxQ Clarifications

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Coordinators/Clinical personnel.** Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs) for the Pre-Operative, Pre-Operative Update and Post-Operative forms will be updated in the newest version of the QxQs, which are forthcoming. Details regarding each change are provided in this Operations Memo. LABS-1 Operations Memos may be found under the Researchers Section of the LABS website http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/OperationsMemos/.

Please add this memo to Section 13 of the LABS-1 MOP.

I. Pre-Operative Form QxQ Updates

A. Good Candidate for LABS-2:

9. 1 If no, specify why (check "no" or "yes" for each item):

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

ISSUE: Defining which reasons for LABS-2 candidacy are participant driven.

SOLUTION: The QxQs have been updated to clarify which reasons should be participant driven only. Please see QxQs below:

Lives too far away: Check "yes" box if, due to distance from home, the participant states that they are unlikely to travel to the clinic in order to adhere to follow-up evaluations.

Follow-up too burdensome: Check "yes" box if the participant indicates that they will be unable to adhere to LABS-2 follow-up schedule for reasons other than living too far away.

Not interested: Check "yes" box if the participant indicates that he or she is not interested and does not give more detail or insight for not being a good candidate.

< 14 days notice of surgery: Check “yes” If research personnel are informed of a scheduled surgery date fewer than 14 days prior to surgery AND the coordinator does not intend to approach the participant for LABS-2.

Prior bariatric surgery: Check “yes” box if the participant has had prior bariatric surgery and the participant has not been previously enrolled in LABS-2.

Unlikely to comply with protocol: Check “yes” box if the coordinator feels that participant compliance is unlikely. This includes, but is not limited to, having any untreated major psychiatric disorder that would interfere with ability to participate in the study and unwillingness to provide biospecimens. Unable to communicate effectively with staff: Check “yes” box if the coordinator feels that the participant is unable to communicate effectively with staff.

Reading difficulty/illiteracy: Check “yes” box if the participant is unable to read English or has any cognitive impairment that would interfere with their ability to participate in study.

Other: Check “yes” box if the participant states any other reason(s) he/she would not to be a good candidate for LABS-2, and specify reason(s) in the space provided.

B. Borderline Comorbidities:

ISSUE: Participants may report a diagnosed 'borderline' comorbidity. Should it be recorded on the Pre-Operative Form and Pre-Operative Update Form as a comorbidity?

SOLUTION: If a participant self-reports a borderline comorbidity or a borderline comorbidity is diagnosed in the patient's medical chart, look for other documented evidence of that comorbidity (ex. lab results). If there is other documented evidence supporting the comorbidty, include it on the Pre-Operative Form and Pre-Operative Update Form.

II. Post-Operative Form QxQ updates

A. Source of Information:

ISSUE: Multiple sources of information may be used to complete the Post-Operative Form. Clarification is needed to ensure that all sites are using source and date of information consistently.

SOLUTION: The QxQs have been updated to clarify source and date of information. Please see QxQs below:

Source(s) of information: Check all sources of information used to complete the Post-Operative Evaluation Form. For each source of information checked, record the date of most recent contact.

"Patient in Person" – The information listed on the Post-Operative Evaluation Form was obtained, in person, from the patient by LABS certified personnel. For this source of information, the "date of most recent contact" is the date that the participant was seen in person. Note, it is assumed that **all** data points on the Post-Operative Evaluation Form were updated on this date. If chart notes indicate that LABS certified personnel met with the participant and assessed **all** data points on the post-op form, but recorded the information in the chart rather than completing the post-op form him/herself, "Patient in Person" may also be checked. However, if a LABS surgeon or other LABS certified personnel only recorded some of the post-op data points in the chart, "Patient in Person" may not be checked.

"Patient by Telephone/E-mail" – The information listed on the Post-Operative Evaluation Form was obtained from the patient, over the telephone or from email, by LABS certified personnel. For this source of information, the "date of most recent contact" is the date that LABS certified personnel spoke with the participant on the phone or the date that the e-mail was sent by the participant. It is assumed that **all** data points on the Post-Operative Evaluation Form were updated on this date. If chart notes indicate that LABS certified personnel spoke with the participant and assessed **all** data points on the post-op form, but recorded the information in the chart rather than completing the post-op form him/herself, "Patient by Telephone" may also be checked. However, if a LABS surgeon or other LABS certified personnel only recorded some of the post-op data points in the chart, "Patient by Telephone" may not be checked.

"Patient Representative" – The information listed on the Post-Operative Evaluation Form was obtained from a representative of the patient, who was designated by the patient in his/her LABS-1 consent form, by LABS certified personnel. For this source of information, the "date of most recent contact" is the date that LABS certified personnel met the patient representative; spoke with the patient representative, or the date that an e-mail was sent by the participant representative.

"Other Physician" – The information listed on the Post-Operative Evaluation Form was obtained from non-LABS certified person(s), with a clinical background who had contact with the participant, by LABS certified personnel. For this source of information, the "date of most recent contact" is the date that the non-LABS certified personnel with a clinical background, saw, spoke with or had other correspondence with the participant.

"Chart Review" – The information listed on the Post-Operative Evaluation Form was obtained via a review of the participant's chart or other clinical notes, by LABS certified personnel. If chart notes indicate that LABS certified personnel spoke with the participant and assessed **all** data points on

the post-op form, but recorded the information in the chart rather than completing the post-op form him/herself, “Patient in Person” or “Patient by Telephone” may also be checked. However, if a LABS surgeon or other LABS certified personnel only recorded some of the post-op data points in the chart, “Patient in Person” and “Patient by Telephone” may not be checked. For this source of information, the “date of most recent contact” is the **event date** that is recorded in the chart. Note that “event date” is defined as the actual date that the event occurred. For example, if a participant’s chart was updated on 06/15/2006 of an event that occurred on 06/01/2006, the correct date to report is 06/01/2006. Also note that an “event” can consist of any event activity that is recorded in the participant’s chart by any person who has clearance to update the chart.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #10

DATE: November 17, 2006

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: UPDATES MADE TO QxQs

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the:

Coordinators/Data entry personnel

Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs) for the Pre-Operative and Pre-Operative Update forms will be updated in the newest version of the QxQs, which are forthcoming. Details regarding each change are provided in this Operations Memo. LABS-1 Operations Memos may be found under the Researchers Section of the LABS website http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/OperationsMemos/.

Please replace the pages in your MOP with the updated pages.

Pre-Operative Form and Pre-Operative Update Form

I. Weight.

ISSUE: An updated patient weight is required <30 days from surgery date, but the participant is not able to be weighed in a clinical setting prior to their surgery.

SOLUTION: After every possibility of obtaining a participant weight in a clinical setting has been exhausted, a self-reported weight may be used. For self-reported weights, use "Estimate" to define how the weight was measured. All estimated weights will be monitored.

II. Byetta reported as diabetes treatment.

ISSUE: A participant reports using Byetta as a diabetes treatment, but the only choices available are:

1. No medication
2. Single oral medication
3. Multiple oral medication
4. Insulin
5. Oral meds and insulin

SOLUTION: Byetta should be captured by using 4: Insulin.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #11

DATE: February 19, 2007

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: UPDATES MADE TO QxQs

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the:

Coordinators/Data entry personnel

Please distribute this memo to the appropriate personnel at your site.

The form completion instructions (QxQs) for the Pre-Operative and Pre-Operative Update forms have been modified to clarify study procedures. Details regarding each change are provided in this Operations Memo. The QxQs will be updated in the newest version, which are forthcoming. LABS-1 Operations Memos may be found under the Researchers Section of the LABS website (http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/OperationsMemos/.)

Please replace the pages in your MOP with the updated pages.

Pre-Operative Form and Pre-Operative Update Form

I. Documented History of DVT & PE.

ISSUE: What is meant by a documented history of DVT or PE?

SOLUTION: The documented history of DVT or PE needs to be verified against source documents. If the participant reports that they have a history of DVT or PE, medical charts must be requested to confirm the documentation. Documentation is defined as proof of diagnosis or treatment (not including preventative treatment). If there is evidence of treatment at another facility, those outside source documents are not necessary as long as the P.I. interprets the available documentation as diagnosis or treatment. The P.I. at each site is ultimately responsible for cases in question.

II. Smoking Calculation.

ISSUE: Former smokers may report several periods of smoking throughout their lives, while smoking different average packs/day during each period. How is the lifetime average calculated?

SOLUTION: The earliest smoking start date and the latest smoking quit date should be used to capture the *span of years* the participant smoked by way of subtraction.

span of years = smoking quit age or current age - smoking start age

Ave = (__ years * __ pack/day) + (__ years * __ pack/day) + (__ years * _0_ pack/day)

1st period of smoking | 2nd period of smoking | yrs NOT smoking

Ave (from above) / *span of years* smoked = ave packs/day to record on Pre-Operative or Pre-Operative Update Form.

Example 1:

1st Start age: 16	2nd Start age = 44
1st End age: 24	2nd End age = 49
Avg packs/day = 1	Avg packs/day = 3

Age started = 16
Age quit = 49
span of years smoked = (49 - 16) = 33
Ave packs/day = (8 years *1 pack/day + 20 years *0 packs/day + 5 years*3 packs/day)/33 years=.7 packs/day
(note: participant smoked for 8 years, didn't smoke for 20 years and then smoked again for 5 years)

Example 2:

1st Start age: 16	2nd Start age = 44
1st End age: 24	2nd End age = current (pt is 55 yrs old)
Avg packs/day = 1	Avg packs/day = 3

Age started = 16
span of years smoked = (55 - 16) = 39
Ave packs/day = (8 years *1 pack/day + 20 years *0 packs/day + 11 years*3 packs/day)/39 years=1.05 packs/day
(note: participant smoked for 8 years, didn't smoke for 20 years and then smoked again for 5 years)

III. Smoking Tobacco.

ISSUE: A participant does not smoke cigarettes, but does smoke cigars and/or a pipe. Should this be recorded?

SOLUTION: No. Only record cigarette smoking.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #12

DATE: March 16, 2007

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: LABS-1 Tanita Scale

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Coordinators/Clinical personnel.** Please distribute this memo to the appropriate personnel at your site.

LABS-1 Operations Memos may be found under the Researchers Section of the LABS website http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/OperationsMemos/.

Tanita Scale

ISSUE: The body composition mode on the Tanita cannot be used (i.e., participant cannot remove their shoes, body composition mode not working properly). Can I still obtain a weight if there is no other scale available?

SOLUTION: Weight may and should be taken on the Tanita scale, without utilizing the body composition mode. Directions may be found below or under "WEIGHT ONLY FUNCTION" in the Tanita Manual.

1. **After turning on the unit, press the [WEIGHT ONLY] key.**
   After a momentary display check, "0.0" will appear on the LCD. If measuring units need to be changed, do so at this time by pressing the [kg/lb] key.
   An arrow on the LCD will follow the selection of weighing units.

2. **Weight Measurement**
   Step on the weighing platform. Weight will be displayed on the LCD.

3. **When measuring is complete, press the [ON/OFF] key to turn off the power.**
   - No printer is available when measuring weight only.
   - If body composition analysis is desired, turn the unit off and then on, using the [ON/OFF] key.

   Important Note: There is no automatic weight lock function.

LONGITUDINAL ASSESSMENT OF BARIATRIC SURGERY

LABS-1

OPERATIONS MEMO #13

I never released this memo but it is complete for the manuals.

DATE: February 1, 2008

TO: LABS CLINICAL CENTERS

FROM: LABS DATA COORDINATING CENTER

RE: LABS-1 Miscellaneous Issues

*This memo should be placed in the appropriate section of the **LABS-1** Manual of Operations. If you notice at any point during the study that your memos are not in consecutive order, please contact the LABS Data Coordinating Center to obtain the memo that is missing or print it from the LABS website.*

This memo addresses issues for the **Coordinators/Clinical personnel.** Please distribute this memo to the appropriate personnel at your site.

LABS-1 Operations Memos may be found under the Researchers Section of the LABS website http://www.edc.gsph.pitt.edu/labs/Research/Documents/LABS-1/OperationsMemos/.

Weight

ISSUE: A participant cannot make it to an in-person visit to be weighed, but they do have a weight from their Primary Care Physician or other Professional Organization (ex. Jenny Craig, Weight Watchers). Can this be used?

SOLUTION: Yes. However, coordinators must confirm that the participant has been weighed and that the value is not an estimate. “How was weight measured?” should be recorded under "other scale". Also, the date of when the weight was collected should be recorded in the measurement date field, not the date of when the coordinator spoke with the participant or the date of when the form was completed.

Pregnancy

ISSUE: A participant reports that they are pregnant during a follow-up visit. Should the Tanita scale still be used?

SOLUTION: Yes. The Tanita scale should be restarted in manual weight-only mode (LABS-1 OP MEMO #12). The body composition mode is not reliable due to water distribution during pregnancy.

In-person visits >55 days after surgery

ISSUE: A participant rescheduled their 30-day follow up appointment and now it is outside of the 55 day window for the Post-Operative Form. Can the Post-Operative Form be completed based on this visit?

SOLUTION: Yes. In-person visits that have been rescheduled outside of 55 days may now be used to complete the 30-day Post-Operative Forms. It is of the utmost importance that the information recorded on the 30-day Post-Operative Form be limited to 30-days post-surgery regardless of when the information is collected. Any events/information more than 30 days after surgery should not be recorded. However, the status date on the form should reflect that date of the in-person visit. In addition, in-person visits outside of the 55 day window will be monitored at each site.