

## **LABS-3 Psychosocial Interview Protocol:**

### **Enrollment:**

- LABS-3 Psychosocial participating clinical centers:
  - The Neuropsychiatric Research Institute, Fargo ND
  - The University of Pittsburgh Medical Center, Pittsburgh PA
  - Columbia, New York NY

### **Interview Schedule:**

- LABS-3 Psychosocial Interview will occur according to the following schedule:

Measure/Test*	Form Details	Baseline/ Presurgery	6 month follow up	12 month follow up	18 month follow up	24 month follow up (and annually thereafter up to 60 months and then at the 84 month visit	Minimum Assessment Visits (starting at 72 months)	
<b>PSYCHOPATHOLOGY N= 200</b>								
<b>INTERVIEW</b>								
ICD3	Impulse Controls Disorders Module					X	X	
SCID/IP	Structured Clinical Interview for DSM-IV	X				X		
EDE- BSV	Eating Disorders Examination- Bariatric Surgery Version	X		X		X	X (short version)	
M-FED-BSV	MFED- Bariatric Surgery Version	X	X	X	X	X	X (including pathology questions)	
CTQ	Childhood Trauma Questionnaire	One time assessment						

\*In cases where the participant may not be able complete the entire interview, abbreviated follow-up visits will be accepted:

### **LABS-3 Brief Call form**

The LABS-3 Brief Call form is intended to collect information deemed crucial by the Principal Investigators: weight status, binge status (previous month), purging status (previous month), importance of shape/weight, fear of weight gain, and feelings of fatness. This form is designed to be completed in 5 or fewer minutes and is intended for

two scenarios: 1) a participant is unwilling to schedule further interviews but will answer a few questions, 2) a participant is willing to schedule a call time but is deemed a “no-show” risk.

### **LABS-3 Abbreviated Follow-up visits**

The LABS-3 Short Form is an abbreviated version of the EDE. It is designed for participants who are unwilling or unable to complete the entire EDE assessment. When the LABS-3 short form is administered, efforts should be made to complete all other visit assessments. Assessors should follow the forms administration hierarchy.

12 month visit form administration hierarchy:

1. Full assessment (EDE, MFED-F)
2. Abbreviated assessment (EDE Short, MFED-F)

24 month visit, or annual thereafter up to 60-month visit and then at the 84 month visit, forms administration hierarchy:

1. Full assessment (EDE, MFED-F, SCIDA and the ICD3 module)
2. Abbreviated assessment 1 (EDE Short, MFED-F, SCIDA and the ICD3 module)
3. Abbreviated assessment 2 (EDE short, MFED-F including psychopathology questions and the ICD3 module)

- Interviews for this study can be conducted by face-to-face in person interviews or by telephone. The phone interviews will be an option for participants in this study to assist in minimizing burden and time constraints.
- Interviews for the LABS-3 Psychosocial protocol may need to be split up into two separate appointments for assessor scheduling reasons as well as to avoid participant burden.
- If a phone interview is going to be done, a few days prior to the interview date the coordinator at each site should mail out the following materials:
  - A **blank non-dated calendar** and a **blank pre-dated calendar** that includes the last 28 days prior to the date of interview (or prior to the liquid diet start date).
    - The participant should be told not to fill this calendar out before the interview, but simply to use it to jog their memory when they are asked questions that pertain to the last 4 weeks.
  - A copy of the **EDE-BSV Night Eating Questionnaire**
  - A copy of the **NDS Eating GRID** and the **NDS Amount Estimation Tool** for those also participating in the NDS part of the protocol (see NDS Manual of Operations for more details).
- Interviews will attempt to coincide with the LABS-2 schedule, however, in most cases, LABS 3 interviews will need to be done prior to the LABS 2 visit in order to complete the necessary study requirements before a participant starts the liquid diet (Optifast or similar liquid diet).
- Ideally, the EDE should be completed prior to the liquid diet start date.
  - However, the EDE can only be completed up to day “7” of the liquid diet.

- In these cases, be sure to pre-date the participant's calendar to the 28 days prior to the liquid diet start date rather than 28 days before the interview date.
- The SCID can be completed anytime while the participant is on the liquid diet as long as it is completed before their surgery date.
- The NDS interviews (when applicable) must be completed before a participant starts the liquid diet (see NDS Manual of Operations for more details).

### Minimum Assessment Visits

As of January 1, 2013, the LABS-3 Psychosocial study follow-up assessment protocol for the 72-month visit has been modified to an abbreviated visit. For these visits, the abbreviated follow-up assessment 2, which consists of the EDE-Short and the MFED-F (including the psychopathology questions) and the ICD3 module, will be utilized. If the participant is unwilling to complete either of these assessments, study personnel should attempt to complete the Brief Call form.

Full assessment visits will be required during the 84-month visit. These visits will include the EDEC (full EDE), MFED-F, SCIDA (Annual SCID) and the ICD3 module. If the participant is unwilling to complete a full assessment, assessors should follow the forms administration hierarchy:

1. Abbreviated assessment 1 (EDE Short, MFED-F, SCIDA and ICD3)
2. Abbreviated assessment 2 (EDE short, MFED-F including psychopathology questions and ICD3)
3. Brief Call form

### LABS-3 Psychosocial Interview Protocol:

- All three participating LABS Clinical Centers have trained Bachelor, Masters or Ph.D. level interviewer(s). LABS-3 Psychosocial protocol specific training will be outlined below.
- The data collection window for the LABS-3 Psychosocial **Baseline** Interview data should be within 60 days of scheduled surgery.
  - If a surgery is rescheduled, the EDE and MFED do not need to be repeated if they are done within 90 days of surgery.
  - If a surgery is rescheduled, the SCID does not need to be repeated regardless of the amount of time into the future that the surgery is rescheduled for.
- The data collection window for the LABS-3 Psychosocial **6 and 18 month follow up** data should be within 30 days before the anniversary date or 30 days after the anniversary date.
  - If the data is collected within 90 days prior to or within 90 days after the anniversary date, the data is still considered acceptable, although it is off-protocol.

- If this visit is scheduled more than 90 days prior to the anniversary date this visit should be rescheduled.
- Any data collected more than 90 days after the anniversary date is considered missing.
- The data collection window for the LABS-3 Psychosocial **12 month follow up** Interview data should be within 60 days before the anniversary date or 60 days after the anniversary date.
  - If the data is collected within 90 days prior to the anniversary date or within 90 days after the anniversary date it is still considered acceptable data, but is considered off-protocol.
  - If a visit is scheduled more than 90 days prior to the anniversary date, this visit should be rescheduled.
  - Anything collected after 90 days from the anniversary date is considered missing data.
- The data collection window for the LABS-3 Psychosocial **annual follow up** Interview data should be within 60 days before the anniversary date or 60 days after the anniversary date.
  - If the data is collected within 90 days prior to the anniversary date or within 180 days after the anniversary date it is still considered acceptable data, but is considered off-protocol.
  - If a visit date is scheduled for more than 90 days prior to the anniversary date, reschedule the visit.
  - Anything collected after 180 days from the anniversary date is considered missing data.
- Reminder emails will be sent by the DCC to the coordinators at all participating sites to remind them of when follow-up assessments and questionnaires are coming due.

### **Interview Training:**

- All clinical centers have interviewers trained in behavioral assessment instruments.
- The Neuropsychiatric Research Institute will provide additional interview training for the Bariatric Surgery Versions of each of the instruments used in this protocol prior to enrollment of participants.
- The Neuropsychiatric Research Institute's head clinical interviewer will conduct a phone training session for all assessors involved in this study as well as for any new staff that joins the study and needs to be trained on the Bariatric Surgery Versions of each of the instruments.
  - For any staff members who miss the phone training session(s) and/or any new staff members who will need to be trained, a cassette recording of the original EDE training session can be provided for them to listen to as an alternative to complete the required training.
- Ongoing monthly clinical interviewer conference calls will be conducted to clarify any assessment questions or concerns that may come up at the participating clinical centers. If it is necessary to conduct these more frequently, the schedule will change to reflect that.

**Reliability Rating for Interviews:**

- Reliability will only be done on the EDE interview (not the SCID or MFED).
- Each participating clinical center will circulate 1 in every 5 taped interview sessions to the other clinical centers for reliability ratings.
- The DCC will randomly select the taped interview sessions as well as the clinical center to perform the reliability rating.

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**Data Analysis:**

- Data from the Labs 3 Psychosocial protocol Interviews will be exported from MATRIX WEB and analyzed by the Data Coordinating Center at the University of Pittsburgh, Graduate school of Public Health.