

LABS – 3 Psychosocial Self-Report Measures Protocol:

Self-Report Measures 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)
PSYCHOPATHOLOGY N= 200 SELF-REPORT MEASURES						
PETS	Psychiatric and Emotional Test Survey	X	X	X	X	X
MED	Medication Form	X	X	X	X	X
BDI	Beck Depression Inventory	X	X	X		X
SF-36	Short Form-36	X	X	X		X
IWQOL- Lite	Impact of Weight on Quality of Life- Lite	X	X	X		X
CTQ	Childhood Trauma Questionnaire	One time assessment, completed at earliest follow-up visit.				

- All measures above that are marked with an asterisk (*) are already being collected as part of the LABS 2 study.
- The only assessment interview that is given at the 6 and 18 month follow-up (FU) visits is the MFED.

Since the following measures (at the specified time points) are NOT given as part of Labs 2:

- The **IWQOL at the 6 month FU** will either need to be:
 - Mailed out to the participant prior to the 6 month visit and then mailed back to the clinical site OR
 - Given over the phone by the assessor or RA/RC along with the MFED if the MFED assessment is done as a phone interview OR
 - Completed by the participant if they come in for a face to face MFED assessment at this visit
 - Completed in person at their 6 month LABS 2 visit
- The **MEDF at the 18 month FU** will either need to be:
 - Mailed out in advance prior to the 18 month visit and then mailed back to the clinical site OR
 - Given over the phone by the assessor or RA/RC along with the MFED if the MFED assessment is done as a phone interview OR
 - Completed by the participant if they come in for a face to face MFED assessment at this visit
- The **PETSF at the 6 and 18 month FU** will either need to be:
 - Mailed out to the participant prior to the 6 and/or 18 month visit and then mailed back to the clinical site OR

- Given over the phone by the assessor or RA/RC along with the MFED if the MFED assessment is done as a phone interview OR
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- Completed by the participant if they come in for a face to face MFED assessment at these visits.
- The **CTQ (one time assessment)**:
 - Mailed out to the participant at earliest timepoint and then mailed back to the clinical site. This can be done either with the packet of other self assessment forms or, preferably, independently between assessments.

Data Collection Windows:

Baseline Self-Report Measures: (same as Labs 2)

- The data collection window for the LABS 3 Psychosocial **Baseline** Self-Report Measures should be within 30 days of the scheduled surgery.
 - If a surgery gets rescheduled after the baseline measures were already completed, and more than 30 but less than 91 days have gone by since the baseline has been completed, then the baseline update forms for the self-report measures will need to be completed.
 - If a surgery gets rescheduled after the baseline measures were already completed, and more than 90 days have gone by since these measures were completed, then all of the baseline self-report measures will need to be repeated.

Follow-up Self Report Measures: (same as Labs 2)

- 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** self-report 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 (*note: follow the LABS 2 protocol collection times for the forms administered as part of the Labs 2 visit*).
 - 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. (*note: follow the LABS 2 protocol collection times for the forms administered as part of the Labs 2 visit*).

- 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 (*note: follow the LABS 2 protocol collection times for the forms administered as part of the Labs 2 visit*).
 - If a visit date is scheduled for more than 90 days prior to the anniversary date, reschedule the visit (*note: follow the LABS 2 protocol collection times for the forms administered as part of the Labs 2 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.

SPECIAL NOTE REGARDING ABBREVIATED ASSESSMENTS:

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, forms administration hierarchy:

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

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), 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 the 84-month visit. These visits will include the EDEC (full EDE), MFED-F, SCIDA (Annual SCID). 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)
2. Abbreviated assessment 2 (EDE short, MFED-F including psychopathology questions)
3. Brief Call form