

## **The Longitudinal Assessment of Bariatric Surgery (LABS) Study Data Archive**

The Longitudinal Assessment of Bariatric Surgery (LABS) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

The Longitudinal Assessment of Bariatric Surgery (LABS) observational study was established by the LABS Consortium to assess the risks and health benefits associated with bariatric surgery and to identify aspects of the procedures and patient characteristics associated with optimal outcomes. The study is organized into three phases: LABS-1, which evaluates the short-term safety of bariatric surgery; LABS-2, which evaluates the longer-term safety and efficacy of bariatric surgery, in addition to examining patient characteristics associated with short- and intermediate-term outcomes; and LABS-3, which examines the psychosocial, quality-of-life, and health economics aspects of obesity, as well as the mechanisms of obesity-related diseases.

The current data package includes data from LABS-1, LABS-2, and one ancillary study: Psychosocial Changes Associated with Weight Loss.

Archive files are organized into the following directories:

- Documentation
- Forms
- Data
- Dataset Integrity Check (DSIC)

### **Documentation**

The LABS Documents directory contains:

- LABS StudyBibliography 6-1-16 .doc – A listing of all published manuscripts from the LABS study, as of June 1, 2016
- LABS-1 – This subdirectory contains the following documentation from phase 1 of the LABS study:
  - LABS-1 Documentation Summary.pdf – General description of the LABS 1 study, including inclusion and exclusion criteria, descriptions of the database documentation, and form conventions
  - LABS-1 Manual of Operations.pdf – Manual of Operations for LABS-1
  - LABS1 Protocol V4 02-16-06.pdf – Protocol for LABS-1
  - LABS1\_filenames.pdf – Listing of all file names corresponding to each dataset
- LABS-2 – This subdirectory contains the following documentation from phase 2 of the LABS study:
  - LABS-2 Documentation Summary.pdf – General description of the LABS 2 study, including inclusion and exclusion criteria, descriptions of the database documentation, and form conventions

- LABS-2 Protocol.pdf – Protocol for LABS-2
- LABS-2 filenames.pdf – Listing of all file names corresponding to each dataset
- Manual of Operations – This subdirectory contains the Manual of Operations for LABS-2, separated by chapter
- Ancillary – This subdirectory contains the following documentation:
  - Psychosocial\_Changes\_Associated\_with\_Weight\_Loss\Protocol 10-30-08.pdf – Protocol for the ancillary study “Psychosocial Changes Associated with Weight Loss”
  - Psychosocial\_Changes\_Associated\_with\_Weight\_Loss\Psychosocial Changes Bibliography.docx – A listing of all published manuscripts from this particular ancillary study
  - Psychosocial\_Changes\_Associated\_with\_Weight\_Loss\Psychosocial Changes Documentation Summary.pdf – General description of the ancillary study “Psychosocial Changes Associated with Weight Loss”, including descriptions of the database documentation and form conventions
  - Psychosocial\_Changes\_Associated\_with\_Weight\_Loss\Psychosocial Changes Filenames.pdf – Listing of all file names corresponding to each dataset

## **Forms**

The LABS Forms directory contains:

- LABS-1 – This subdirectory contains the following forms from phase 1 of the LABS study:
  - LABS1\_Forms\_List.pdf – Description and timeline for each form listed below
  - ADDEV\_20050126\_vars.pdf – Annotated version of the Post-Operative Additional Events form.
  - LEAK\_20100914\_vars.pdf – Annotated version of the Site of Leak Form
  - MORT\_20050615\_vars.pdf – Annotated version of the Mortality Report Form
  - OP1\_20061215\_20070731\_vars.pdf – Annotated version of the Operative Evaluation Form.
  - PATHL\_20051117\_vars.pdf – Annotated version of the Pathology Form
  - PO1\_20061215\_vars.pdf – Annotated version of the Pre-Operative Form
  - POST1\_20060828\_vars.pdf – Annotated version of the Post-Operative Evaluation Form (LABS-1)
  - POST2\_20060828\_vars.pdf – Annotated version of the Post-Operative Evaluation Form (LABS-2)
  - PU1\_20061215\_vars.pdf – Annotated version of the Pre-Operative Evaluation Update Form (LABS-1)
  - PU2\_20061215\_vars.pdf – Annotated version of the Pre-Operative Evaluation Update Form (subsequent surgeries only, LABS-2)
  - SEF\_20050126\_vars.pdf – Annotated version of the Surgeon’s Experience Form
  - SQ\_20070731\_vars.pdf – Annotated version of the Surgeon’s Questionnaire Form

- UEVNT\_20090228\_20100203\_vars.pdf – Annotated version of the Reason for Unconfirmed Intervention Form
- LABS-2 – This subdirectory contains the following forms from phase 2 of the LABS study:
  - LABS-2 forms list.pdf – Description and timeline for each form listed below
  - AE\_20060615\_vars.pdf – Annotated version of the Adverse Event Form
  - AGB\_20070731\_vars.pdf – Annotated version of the Adjustable Gastric Band Form
  - AGBP\_20080630\_vars.pdf – Annotated version of the Adjustment to Gastric Band Procedure Form
  - ASCF\_20140901\_vars.pdf – Annotated version of the Abdominal Surgery Classification Form
  - BB\_20090228\_vars.pdf – Annotated version of the Behavior Baseline Form
  - BF\_20120416\_vars.pdf – Annotated version of the Behavior Follow-Up Form
  - BPDS\_20070731\_vars.pdf – Annotated version of the Biliopancreatic Diversion with Duodenal Switch Form
  - BU\_20070831\_vars.pdf – Annotated version of the Baseline Update Questionnaire Form
  - CALCVAR\_vars.pdf – Annotated version of the Calculated Variables Form
  - CD\_20110401\_vars.pdf – Annotated version of the Cancer Diagnosis Form
  - CDF\_20110401\_vars.pdf – Annotated version of the Cancer Diagnosis Follow-Up Form
  - CDFM\_20111130\_vars.pdf – Annotated version of the Cancer Diagnosis Follow-Up Modified Form
  - DIB\_20060615\_vars.pdf – Annotated version of the Demographic Information form
  - DIF\_20110401\_vars.pdf – Annotated version of the Demographic Information form
  - DS\_20060828\_vars.pdf – Annotated version of the Discharge Summary Form
  - EC\_20130601\_vars.pdf – Annotated version of the Events and Complications Form
  - EF\_20080630\_vars.pdf – Annotated version of the LABS-2 Enrollment Form
  - ESS\_20111130\_vars.pdf – Annotated version of the Excessive Skin Survey Form
  - FO6\_20080630\_vars.pdf – Annotated version of the 6-Month Follow-Up Form
  - GS\_20070731\_vars.pdf – Annotated version of the Gastric Sleeve Form
  - IN2\_20080630\_vars.pdf – Annotated version of the Inactivation Form
  - LEAK\_20100914\_vars.pdf – Annotated version of the Site of Leak Form
  - LL\_20060131\_vars.pdf – Annotated version of the Local Laboratory Form
  - MAB\_20090228\_vars.pdf – Annotated version of the Medical Assessment Baseline Form
  - MAF\_20100901\_vars.pdf – Annotated version of the Medical Assessment Follow-Up Form
  - MAQ\_20100901\_vars.pdf – Annotated version of the Modifiable Activity Questionnaire Form
  - MED\_MEDRX\_20060828\_vars.pdf – Annotated version of the Medication

Form

- MORT\_20050615\_vars.pdf – Annotated version of the Mortality Report Form
- MVF\_20111130\_vars.pdf – Annotated version of the Minimum Visit Follow-Up Form
- MWF\_20100901\_vars.pdf – Annotated version of the 400 Meter Walk Data Collection Form
- NIV\_20090228\_vars.pdf – Annotated version of the Retention Survey No In-Person Visit Form
- OFF\_20130601\_vars.pdf – Annotated version of the Off Protocol Form
- PATH\_20051117\_vars.pdf – Annotated version of the Pathology Evaluation Form
- PETS\_B\_20080630\_vars.pdf – Annotated version of the Psychiatric & Emotional Test Survey
- PETS\_F\_20100901\_vars.pdf – Annotated version of the Psychiatric & Emotional Test Survey Follow-Up
- PO1\_20080101\_vars.pdf – Annotated version of the Pre-operative Form
- POST2\_20060828\_vars.pdf – Annotated version of the 30-Day Post-Operative Evaluation Form
- PU2\_20061215\_vars.pdf – Annotated version of the Pre-Operative Update Form
- RCAB\_20080201\_vars.pdf – Annotated version of the Research Coordinator Assessment Baseline Form
- RCAF\_20130601\_vars.pdf – Annotated version of the Research Coordinator Assessment Follow-Up Form
- RHB\_20080201\_vars.pdf – Annotated version of the Reproductive Health Baseline Form
- RHF\_20100101\_vars.pdf – Annotated version of the Reproductive Health Follow-Up Form
- RHP\_20100101\_vars.pdf – Annotated version of the Reproductive Health Pregnancy Questionnaire Form
- RSF\_20100101\_vars.pdf – Annotated version of the Retention Survey (Follow-Up Visits) Form
- RSI\_20070731\_vars.pdf – Annotated version of the Retention Survey (Inactivations) Form
- RYB\_20070731\_vars.pdf – Annotated version of the Roux-en-Y Gastric Bypass Form
- SBP\_20060828\_vars.pdf – Annotated version of the Subsequent Bariatric Surgery Form
- SBQ\_20120416\_vars.pdf – Annotated version of the Suicide Behavior Questionnaire Form
- SBQF\_20120416\_vars.pdf – Annotated version of the Suicide Behavior Questionnaire Follow-Up Form
- SFB\_20060828\_vars.pdf – Annotated version of the Sexual Functioning Baseline Form
- SFF\_20100901\_vars.pdf – Annotated version of the Sexual Functioning Follow-Up Form
- SHORT\_20130601\_vars.pdf – Annotated version of the Short Form

- SLS\_20100101\_vars.pdf – Annotated version of the SAM Diary/Log
- SL\_SLS\_20060828\_vars.pdf – Annotated version of the SAM Diary/Log Summary
- SMAB\_20070731\_vars.pdf – Annotated version of the Surgeon’s Medical Assessment Baseline
- SMAF\_20110401\_vars.pdf – Annotated version of the Surgeon’s Medical Assessment Follow-Up
- SQ\_20070731\_vars.pdf – Annotated version of the Surgeon’s Questionnaire Form
- UEVNT\_20100203\_vars.pdf – Annotated version of the Reason for Unconfirmed Intervention Form
- UIB\_20060828\_vars.pdf – Annotated version of the Urinary Incontinence Baseline Form
- UIF\_20061215\_vars.pdf – Annotated version of the Urinary Incontinence Follow-Up Form
- VTYPE\_20110411\_vars.pdf – Annotated version of the LABS Visit Type Form
- WEF\_20120416\_vars.pdf – Annotated version of the 400 Meter Walk Eligibility Form
- WGT\_20100316\_vars.pdf – Annotated version of the Weight Form
- WPAI\_20050630\_vars.pdf – Annotated version of the Work Productivity and Activity Impairment Form
- Ancillary\Psychosocial\_Changes\_Associated\_with\_Weight\_Loss – This subdirectory contains the following forms from this ancillary LABS study:
  - Psychosocial Changes Form List.pdf – Description and timeline for each form listed below
  - AD\_20061128\_vars.pdf – Annotated version of the Activity Diary form
  - BIQOL\_20060630\_vars.pdf – Annotated version of the Body Image Quality of Life Inventory form
  - BSQ\_20060630\_vars.pdf – Annotated version of the Body Shape Questionnaire form
  - COMAR\_20111130\_vars.pdf – Annotated version of the Sarwer Education Comorbidity form
  - DAS\_20060630\_vars.pdf – Annotated version of the Dyadic Adjustment Scale form
  - EFQB\_20060630\_vars.pdf – Annotated version of the Erectile Function Questionnaire Baseline form
  - EFQF\_20060721\_vars.pdf – Annotated version of the Erectile Function Questionnaire Follow-Up form
  - FSFIB\_20060630\_vars.pdf – Annotated version of the Female Sexual Function Index Baseline form
  - FSFIF\_20060630\_vars.pdf – Annotated version of the Female Sexual Function Index Follow-Up form
  - PEF\_20060630\_vars.pdf – Annotated version of the Enrollment Form
  - PINS\_20060630\_vars.pdf – Annotated version of the Inactivation Form – Surgery Patients
  - PINT\_20090228\_vars.pdf – Annotated version of the Inactivation Form –

#### Treatment Comparison

- POFF\_20120101\_vars.pdf – Annotated version of the Off Protocol form
- PPM\_20070213\_vars.pdf – Annotated version of the Physical Measures – Treatment Comparison form
- SSQ\_20070206\_vars.pdf – Annotated version of the Participant Screening Questionnaire Form
- STQ\_20070731\_vars.pdf – Annotated version of the Status Questionnaire form
- STQF\_20070731\_vars.pdf – Annotated version of the Status Questionnaire Follow-Up form

## **Data**

The LABS Data directory contains:

- LABS-1 – This subdirectory contains the following subdirectories, and the following raw datasets in Windows-based SAS, v. 7-8-9 format. The datasets correspond to the form of the same name.
  - addev.sas7bdat
  - leak.sas7bdat
  - mort.sas7bdat
  - op1.sas7bdat
  - pathl.sas7bdat
  - po1.sas7bdat
  - po2.sas7bdat
  - post1.sas7bdat
  - post2.sas7bdat
  - pu1.sas7bdat
  - pu2.sas7bdat
  - sef.sas7bdat
  - sq.sas7bdat
  - uevnt.sas7bdat
  - age\_at\_surgery.sas7bdat – This dataset contains the ages and surgery dates for each participant in LABS-1
  - formats.sas7bcat – Formats listing for the SAS datasets
  - Data Contents – This subdirectory contains output from the SAS Contents procedure for each of the forms datasets listed above
  - Data Dictionaries – This subdirectory contains detailed listings of the names and characteristics of each form’s data points for each of the form datasets listed above
  - Data Enumerations – This subdirectory contains a detailed listing of coding definitions provided for special “enumerated” data types as well as

output from the SAS Format procedure for each of the form datasets listed above

- Data Information – This subdirectory contains information about associated documentation files, special coding, and any additional information which could be of use to researchers obtaining this dataset for each of the form datasets listed above
- LABS-2 – This subdirectory contains the following subdirectories, and the following raw datasets in Windows-based SAS, v. 7-8-9 format. The datasets correspond to the form of the same name. Note that the forms corresponding to the bdi.sas7bdat (Beck Depression Inventory), bs.sas7bdat (Berlin Sleep), eq5d.sas7bdat (EQ-5D), gsrs.sas7bdat (Gastrointestinal Symptoms Rating Scale), isel.sas7bdat (Interpersonal Support Evaluation List), iw.sas7bdat (Impact of Weight Questionnaire), sf36.sas7bdat (SF-36 Health Survey), and whq.sas7bdat (Weight History Questionnaire) datasets are not included in this data package due to copyright.
  - ae.sas7bdat
  - agb.sas7bdat
  - agbp.sas7bdat
  - ascf.sas7bdat
  - bb.sas7bdat
  - bdi.sas7bdat
  - bf.sas7bdat
  - bpds.sas7bdat
  - bs.sas7bdat
  - bu.sas7bdat
  - calcvar.sas7bdat
  - cd.sas7bdat
  - cdf.sas7bdat
  - cdfm.sas7bdat
  - dib.sas7bdat
  - dif.sas7bdat
  - ds.sas7bdat
  - ec.sas7bdat
  - ef.sas7bdat
  - eq5d.sas7bdat
  - ess.sas7bdat
  - fo6.sas7bdat
  - gs.sas7bdat
  - gsrs.sas7bdat
  - in2.sas7bdat
  - isel.sas7bdat
  - iw.sas7bdat
  - leak.sas7bdat
  - ll.sas7bdat
  - mab.sas7bdat
  - maf.sas7bdat
  - maq.sas7bdat

- med.sas7bdat
- medrx.sas7bdat
- mort.sas7bdat
- mvf.sas7bdat
- mwf.sas7bdat
- niv.sas7bdat
- off.sas7bdat
- path.sas7bdat
- petsb.sas7bdat
- petsf.sas7bdat
- po1.sas7bdat
- post2.sas7bdat
- pu2.sas7bdat
- rcab.sas7bdat
- rcaf.sas7bdat
- rhb.sas7bdat
- rhf.sas7bdat
- rhp.sas7bdat
- rsf.sas7bdat
- rsi.sas7bdat
- ryb.sas7bdat
- sbp.sas7bdat
- sbq.sas7bdat
- sbqf.sas7bdat
- sfb.sas7bdat
- sff.sas7bdat
- sf36.sas7bdat
- short.sas7bdat
- sls.sas7bdat
- sl.sas7bdat
- smab.sas7bdat
- smaf.sas7bdat
- sq.sas7bdat
- uevnt.sas7bdat
- uib.sas7bdat
- uif.sas7bdat
- vtype.sas7bdat
- wef.sas7bdat
- wgt.sas7bdat
- whq.sas7bdat
- wpai.sas7bdat
- age\_at\_surgery.sas7bdat – This dataset contains the ages and surgery dates for each participant in LABS-2
- central\_lab\_results.sas7bdat – This dataset contains laboratory results from testing performed at the Central Lab

- ef\_nocons.sas7bdat – This dataset contains eligibility information on subjects that were excluded from the study due to not giving consent. More information on the variables in this dataset can be found in the ef.sas7bdat dataset.
- in2\_excluded.sas7bdat – This dataset contains inactivation information on subjects that were excluded from the study due to not giving consent. More information on the variables in this dataset can be found in the in2.sas7bdat dataset.
- ndi.sas7bdat – This dataset contains information from the National Death Index
- preg\_max\_by\_id.sas7bdat – This dataset contains information on the number of pregnancies per subjects in LABS-2
- sw\_summary.sas7bdat – This dataset contains a summary of the stopwatch data
- sw\_minute.sas7bdat – This dataset contains stopwatch minute data
- formats.sas7bcat/formats.sas7bdat – Formats listing for the SAS datasets
- Data Contents – This subdirectory contains output from the SAS Contents procedure for each of the forms datasets listed above
- Data Dictionaries – This subdirectory contains detailed listings of the names and characteristics of each form’s data points for each of the form datasets listed above.
- Data Enumerations – This subdirectory contains a detailed listing of coding definitions provided for special “enumerated” data types as well as output from the SAS Format procedure for each of the form datasets listed above
- Data Information – This subdirectory contains information about associated documentation files, special coding, and any additional information which could be of use to researchers obtaining this dataset for each of the form datasets listed above
- Ancillary\Psychosocial\_Changes\_Associated\_with\_Weight\_Loss– This subdirectory contains the following subdirectories, and the following raw datasets in Windows-based SAS, v. 7-8-9 format. The datasets correspond to the form of the same name. Note that the forms corresponding to the bdi.sas7bdat (Beck Depression Inventory), iw.sas7bdat (Impact of Weight Questionnaire), and sf36.sas7bdat (SF-36 Health Survey) datasets are not included in this data package due to copyright.
  - ad.sas7bdat
  - bdi.sas7bdat
  - biqol.sas7bdat
  - bsq.sas7bdat
  - comar.sas7bdat
  - das.sas7bdat
  - efqb.sas7bdat
  - efqf.sas7bdat

- fsfib.sas7bdat
- fsfif.sas7bdat
- iw.sas7bdat
- pef.sas7bdat
- pins.sas7bdat
- pint.sas7bdat
- poff.sas7bdat
- ppm.sas7bdat
- sf36.sas7bdat
- ssq.sas7bdat
- stq.sas7bdat
- stqf.sas7bdat
- lab\_results.sas7bdat – This dataset contains laboratory results, such as total testosterone, estradiol, luteinizing hormone, etc.
- formats.sas7bcat – Formats listing for the SAS datasets
- Data Contents – This subdirectory contains output from the SAS Contents procedure for each of the forms datasets listed above
- Data Dictionaries – This subdirectory contains detailed listings of the names and characteristics of each form’s data points for each of the form datasets listed above.
- Data Enumerations – This subdirectory contains a detailed listing of coding definitions provided for special “enumerated” data types as well as output from the SAS Format procedure for each of the form datasets listed above
- Data Information – This subdirectory contains information about associated documentation files, special coding, and any additional information which could be of use to researchers obtaining this dataset for each of the form datasets listed above

## **DSIC**

The LABS DSIC directory contains:

- LABS1\_DSIC.pdf – A report of an examination of the LABS-1 datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Tables 1, 2, 3, 4, and 5 from the paper “Comparison of 30-day outcomes after non-LapBand primary and revisional bariatric surgical procedures from the Longitudinal Assessment of Bariatric Surgery study” by Inabnet et al. Published results from the LABS-1 data sets compared to values recalculated from LABS-1 raw datasets in the NIDDK repository.
- LABS2\_DSIC.pdf – A report of an examination of the LABS-2 datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Tables 1, 2, and 3 from the paper “Weight Change and Health Outcomes at 3 Years after Bariatric Surgery among Individuals with Severe

Obesity” by Courcoulas et al. Published results from the LABS-2 data sets compared to values recalculated from LABS-2 raw datasets in the NIDDK repository.

- Psychosocial\_Changes\_Associated\_with\_Weight\_Loss\_DSIC.pdf – A report of an examination of the Psychosocial Changes Associated with Weight Loss ancillary datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Tables 1, 2, 3, 4, 5A, and 5B from the paper “Sexual functioning and sex hormones in persons with extreme obesity and seeking surgical and nonsurgical weight loss” by Sarwer et al. Published results from the ancillary data sets compared to values recalculated from ancillary raw datasets in the NIDDK repository.