# Nutritional Data System for Research: NDS-R
# BACKGROUND

**Definition**:
The NDS-R is a Windows-based software package incorporating a well tested, accurate database with an up-to-date interface in which to assess dietary intake. The Nutritional Coordinating Center (NCC) data entry and analysis system permits timely updating to reflect the most recent nutrient data available and facilitates the incorporation of a comprehensive quality control system to ensure the accuracy and internal consistency of the database.

The Nutritional Data System (NDS) contains over 18,000 foods, 8,000 brand name products, as well as many ethnic foods. Values for up to 139 nutrients, nutrient ratios and other food components are available.

The NDS has built-in quality control with a multiple-pass approach interview methodology. Default food description assignments standardize data collection when a subject is unable to provide the necessary level of detail. These defaults are based on up to date nationally representative market research data.

NDS calculates nutrient intake and presents the data in several formats, including daily nutrient totals, nutrient amounts per individual food, and daily totals compared to the RDAs.

**Features of NDS-R Include:**

- Familiar Windows-based interface with the NCC food and nutrient database.
- Multiple-pass approach interview methodology (There are multiple "passes" through the instrument.  The first "pass" yields a brief overview, the second pass clarifies the patient's report, the third pass involves eliciting very specific detail and the fourth pass allows for final clarification and addition of any other information.)
- Captures level of detail required for highly accurate nutrient calculation
- Built-in standardization and quality control for the interview process
- Sophisticated food search operations
- Interview prompts which guide data collection
- User defined recipes which can be inserted into other records
- Import and export utilities for record header information
- Back-up and restore utilities
- Ability to add extensive text notes
- Drop-down menus
- Microhelp, Online Help, and Online Users Manual
- Cut, copy, and paste functions for easy editing

**Additional Measure:**

- An additional measure called the NDS Eating Grid will be given in conjunction with the NDS interview. This measure captures additional detailed information about each eating episode reported during the interview. This Eating Grid data will be entered into the MATRIX WEB system.

**Data Collection Methods:**

- 24-hour recalls using the multiple-pass approach
- Intake records
- Record-assisted 24-hour recalls
- Recipes
- Menus

**Report Options:**

- An output file will be exported in standard .txt format for statistical analysis.
- *Note: If any data for a given day is left as **missing or unanswered** during the NDS interview, none of the data will export for that day and will all be missing until this question or missing data is answered.*

# LABS 3 Psychosocial NDS:

**Enrollment :**

- 100 LABS-3 Psychosocial participants will be enrolled into the NDS portion of the protocol
    - Once 100 participants are enrolled in the NDS protocol, enrollment should NOT be stopped until <u>100 participants have completed a baseline NDS and gone through surgery.</u>
- Equal number of males and females across sites, but there does not need to be equal enrollment at each site
- Equal number of Lap Bands and Roux-en-Y Gastric Bypass (RYGBP) across sites, but there does not need to be equal enrollment at each site
- Approximately 34 participants at each participating LABS Clinical Center, but this number can vary depending on how recruitment is going at each site.

**Interview Center:**

- The Neuropsychiatric Research Institute will be conducting the NDS and Eating Grid interviews for all three participating LABS Clinical Centers.
    - NRI has NDS trained staff
    - Contributes to reliability of interviews if conducted at one center
- NRI will provide each participating LABS Clinical Center with a "master copy" of the NDS handbook (Amount Estimation Tool) to give to participants. Each site will be responsible for making photocopies to distribute to participants. This manual will provide participants with the information that they will need to accurately report data during the interview.
    - For those participating in this part of the protocol, a copy of the Eating GRID and the NDS Handbook (Amount Estimation Tool) should be mailed out along with the EDE Calendar and Night Eating Questions (refer to LABS 3 Interview Manual of Operations for more details).

- Since NRI is conducting all the NDS interviews, <u>for ALL of the sites</u>, the coordinator from each site (Columbia and Pittsburgh) will need to email or call in *(email is okay as long as NO last names of the patients are included)* the following information to the coordinator at NRI:
    - Date of surgery
    - Liquid Diet start date (if applicable) *(for baseline NDS)*
    - LABS Patient ID #
    - First Name, Last Initial
    - Participant Phone Number(s)
    - Participant Availability (ex: daytime, evenings, weekends)
- This contact information should be given to the NRI coordinator **within 3 days of consenting a patient** so that they can call the participant and get the NDS baseline interviews scheduled and completed.
    - For Follow-up NDS interviews, if a participant's contact information has changed for a participant at any participating site, this updated information must be provided to the NRI coordinator **as soon as it becomes available**.

**LABS-3 Psychosocial NDS Protocol:**

- 48 hour recall will be collected via 2 consecutive 24 hour recalls
- LABS-3 Psychosocial data collection time points will be at baseline, 6mo., 12mo., and 24 mo. following surgery
- NDS information must NOT be gathered on "liquid diet" days
- One of the two recall days must be a weekend day and the other must be a weekday
    - Even though it is preferred to include a weekend day, if you are absolutely unable to get an NDS recall data collection for a weekend day due to scheduling conflicts then two weekdays of NDS data will be considered acceptable data.
    - If you are unable to collect a weekday, but are able to collect 2 weekend days, this will also be considered acceptable data.
- (Ideal) Options for data collection windows:
    - Calls occur on Saturday (Friday's data) and Sunday (Saturday's data)
    - Calls occur on Monday (Sunday's data) and Tuesday (Monday's data)
- Window for data collection (baseline) - 60 days before surgery
- If a surgery is rescheduled, any NDS data collected within 90 days of the surgery date is still considered acceptable. If the data collected was collected more than 90 days before surgery, the NDS data will need to be re-collected.
- Window for data collection (follow-up) - 30 days before and 30 days after the week it is due.
- If participant misses one interview call in the two days of data collection that data will then be collected on the next scheduled call. (For example: participant is interviewed on Monday, misses Tuesday's call- this call should be made up on Wednesday. The data that was to be collected on Tuesday will be gathered on Wednesday (hence the intake data for Monday would be collected on Wednesday). <u>This gives data on two consecutive days</u>. If a participant misses the call on Wednesday also, interviewer will call on Thursday and gather recall data from Wednesday (so will not gather 2 consecutive days of data, but instead will have Sunday's data collected on Monday, and Wednesday's data collected on

Thursday). If a participant is not reachable on Thursday, then they can be called one last time on Friday (day 5) and Thursday's data would be collected. However, if a participant is not reachable on Friday, then the only data collected will be Sunday's data that was collected on Monday.

- If participant is not available for the second day of data collection within the data collection week (5 days), that day will be considered missed and only 24 hours of recall data will be available for analysis.
- If there are scheduling conflicts or it is participant preferred, and the only way to collect 2 consecutive days of data is to do a 48 hour recall on the same day (ex: call Tuesday to gather Monday's and Sunday's data) this is acceptable.
- Reminder emails will be sent by the DCC to the NRI coordinators to remind them of when follow-up NDS interviews are coming due.

**NDS "Header" Section:**

- For purposes of consistency and data handling, the NDS interviewer should use the following definitions when entering data into the "Header" section of the NDS interview program:
  o Participant ID: LABS Participant Number (Ex:2429999AB)
  o Date of Intake: (date the recall is for)
  o Participant Name: only enter initials (first, middle, last) (NO NAMES)
  o Visit Number:
    ▪ Enter a "1" for baseline NDS day #1
    ▪ Enter a "1" for baseline NDS day #2
    ▪ Enter a "6" for 6 month FU NDS day #1
    ▪ Enter a "6" for 6 month FU NDS day t #2
    ▪ Enter a "12" for 12 month FU NDS day #1
    ▪ Enter a "12" for 12 month FU NDS day #2
    ▪ Enter a "24" for 24 month FU NDS day #1
    ▪ Enter a "24" for 24 month FU NDS day #2
  o Interviewer ID: enter your <u>LABS certification</u> number
  o Site:
    ▪ Enter **242** for NRI
    ▪ Enter **299** for Columbia
    ▪ Enter **244** for Pittsburgh Medical Center

**Data Collection on NDS GRID:**

- Each separate eating episode that is collected through the NDS computer program (Breakfast, Lunch, Dinner, and each separate snack) should be captured on the eating grid as it's own separate episode <u>except the following</u>:
  o During the NDS interview, if a participant reports having only a non-caloric beverage <u>as a separate eating episode</u> (most likely a snack) then this item should not be counted as a separate eating episode on the GRID. (It will still be a separate eating episode in the NDS computer program, just not on the GRID)
    ▪ Examples of this include (but are not limited to)
      • Water
      • Diet Soda
      • Coffee or Tea (without any creamer or sugar)

- If a participant reports that they drink large amounts of water each day, but are unable to distinguish the amounts they drink at specific times throughout the day because they "sip on their water container throughout the entire day", then it is okay to list their water consumption as one snack (at the very end of the day) and to list the entire amount of water they drank throughout that entire intake day.

**Data Analysis:**

Data for the LABS-3 Psychosocial NDS protocol will be analyzed by the Data Coordinating Center at the University of Pittsburgh, Graduate school of Public Health.

- As long as there is new data that has been collected, the output files (in .txt format) will be emailed to the DCC (from NRI) on an agreed upon schedule.
  - There will be 2 file formats; **File 3**: Meal File and **File 4**: Intake Properties File mailed to the DCC from each NDS computer that data is collected on. This is necessary in order to obtain all of the variables desired for the data file.
  - The NDS program itself may get updated several times throughout the duration of the study. NRI will let the DCC know when the files they are sending are from an updated version of the program so the DCC is aware before merging the files together.
- The following variables will be pulled from the emailed .txt files by the DCC and be merged into the database for the psychosocial Labs 3 study:
  - Participant ID (File 3 and 4: can use this variable to match files)
  - Date of Intake (File 3 and 4: can use this variable to match files)
  - Visit Number *(File 4)*
  - Interviewer ID *(File 4)*
  - Meal File ID *(File 3)*
  - Meal Time *(File 3)*
  - Meal Name *(File 3)*
  - Meal Location *(File 3)*
  - Energy (Kilocalories) *(File 3)*
  - Total Fat *(File 3)*
  - Total Carbohydrate *(File 3)*
  - Total Protein *(File 3)*
  - Alcohol *(File 3)*
  - Total Vitamin A Activity (International Units) *(File 3)*
  - Thiamin (vitamin B1) *(File 3)*
  - Total Folate *(File 3)*
  - Vitamin B12 (cobalamin) *(File 3)*
  - Calcium *(File 3)*
  - Iron *(File 3)*
  - % Calories from Fat *(File 3)*
  - % Calories from Carbohydrate *(File 3)*
  - % Calories from Protein *(File 3)*
  - % Calories from Alcohol *(File 3)*
  - Total Vitamin A Activity (Retinol Equivalents) *(File 3)*
  - Total Vitamin A Activity (Retinol Activity Equivalents) *(File 3)*
- The DCC will make sure to delete duplicate records from the files that are emailed to them before they get merged into the database.

- o **Each file that is emailed to the DCC will include "all" records (previous and most recent) that have been collected by the NDS program as there is no way to weed out these duplicate files ahead of time.**