National Children's Study Diet Data Collection

Manual of Procedures

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1   Overview of the Dietary Data Collection

The purpose of the National Children's Study (NCS) is to evaluate the feasibility, burden and data quality of collecting dietary data on pregnant women, infants and toddlers in the NCS using the 24-hour recall method rather than or in conjunction with a food frequency method. Study participants will be recruited through each site. Sample population will include:

- **Pregnant women**: 18-49, non-institutionalized, <28 weeks gestation, English speaking and of the ethnicity identified for each center;
- **Infants**: 11-13 months of age, living with mother, of mother's ethnicity identified for each center, free of birth defects and any major chronic health conditions that would interfere with feeding (i.e. inborn errors of metabolism, tube feeding, and cystic fibrosis);
- **Children**: 24 months to 4.9 years of age, living with mother, of mother's ethnicity identified for each center, free of birth defects and any major chronic health conditions that would interfere with feeding (i.e. inborn errors of metabolism, tube feeding, and cystic fibrosis).

1.1   ASA24

The National Cancer Institute (NCI) Automated Self Administered 24-Hour Dietary Recall (ASA24) online system will be used to collect 24-hour dietary recalls from the participants https://asa24beta.westat.com/index.htm. The software includes all foods available from USDA's most current Food and Nutrient Database for Dietary Studies (FNDDS) database. It features built-in, tutorials for respondents on how to complete the interview; an animated audio character to guide respondents through the interview, with an option to turn off the audio portion standard interview prompts for obtaining detailed food descriptions, including preparation method and ingredient information. The ASA24 software produces individual-level nutrient and in the near future, My Pyramid Equivalent Database (MPED) estimates for researchers based on USDA's FNDDS.

1.2 **Food Record**
Food records will be collected prospectively by the participant the day before the ASA24 hr recall is completed using a standard format and entered using Nutrition Data System for Research (version 2010). Developed by the Nutrition Coordinating Center of the University of Minnesota, NDSR offers top of the line software in dietary data collection. NDSR is a Windows-based application that provides standardized entry methods, immediate nutrient calculations, a large data output file and built in security measures. NDSR is updated annually and currently includes more than 18,000 foods, over 7,000 brand-name products and 160 nutrients, nutrient ratios and other food components. Three sites will be entering the data. These centers include: Miami (entering all preschooler records), Baylor (entering all pregnant women records) and Minnesota (entering all infant records). In addition, at the Hawaii VC, food records will also be entered into the Pacific Tracker (PacTRAC) to obtain information on foods specific to their region.

1.3 **Food Frequency Questionnaire**
Originally developed by the National Cancer Institute, the Food Frequency Questionnaire for the mothers is a tool used to measure dietary intake of food and nutrients over a three month period of time. The infant feeding and the child questionnaires cover a one month time period. The FFQs are in paper form to be completed by the participant on their own and then scanned or data entered to provide data output files.

2 **Collection Site Preparation**

2.1 **Staffing**
At least two research staff (including a lead research assistant who may or may not be needed to collect data) will be needed at each center to collect dietary data.

2.1.1 **Characteristics and Training**
- All staff must be IRB certified.
- All staff involved in the dietary collection will be required to be trained on the tools used at that site.

2.1.2 **Responsibilities**
- The research staff will assist with data collection and follow written protocols. He/she will contribute to the overall study by assisting with the lead coordinator.
- The lead coordinator will supervise data collection and serve as primary liaison of that data collection site. This will include providing quality assurance of data, following protocols, participating in regular meetings, ensuring staff compliance, and the correct flow of data collection.

3   Documents and Materials

Each site is responsible for providing a private space and necessary tools and supplies necessary to complete specific tasks associated with the NCS nutrition formative study.

3.1   Hardware

Adequate computer, telephone and secure storage for participant information will be available (i.e. locked file cabinet behind locked doors). Access to a copier and printer may be necessary. Laptop or desktop computer(s) that are FISMA compliant will be used.

3.2   Software
- NDSR must be loaded for each site entering food records
- Internet access with Flash player 10 with screen resolution 1024x768 is required for completing the ASA24 by the participant.

3.3   Documents and forms
- NCS Diet Data Collection Manual of Procedures (1 per research site)
- Participant Information Sheet (Appendix 1)
- Socio-Demographic Questionnaire (Appendix 2)
- ASA24 Instruction Brochure (Appendix 3)
- Food Portion Size Guide (Appendix 4)
- Food Record Directions, blank and sample forms (Appendix 5)
- Acceptability Questionnaire (Appendix 6)
- Food Frequency Questionnaire, mom (Appendix 7)
- Child/infant Feeding Questionnaires (Appendix 8)
- ASA24 protocol (Appendix 9)
- ASA24 site technical difficulties form (Appendix 10)
- Diet and Questionnaire tracking (Appendix 11)
- Food Record Protocol (Appendix 12)
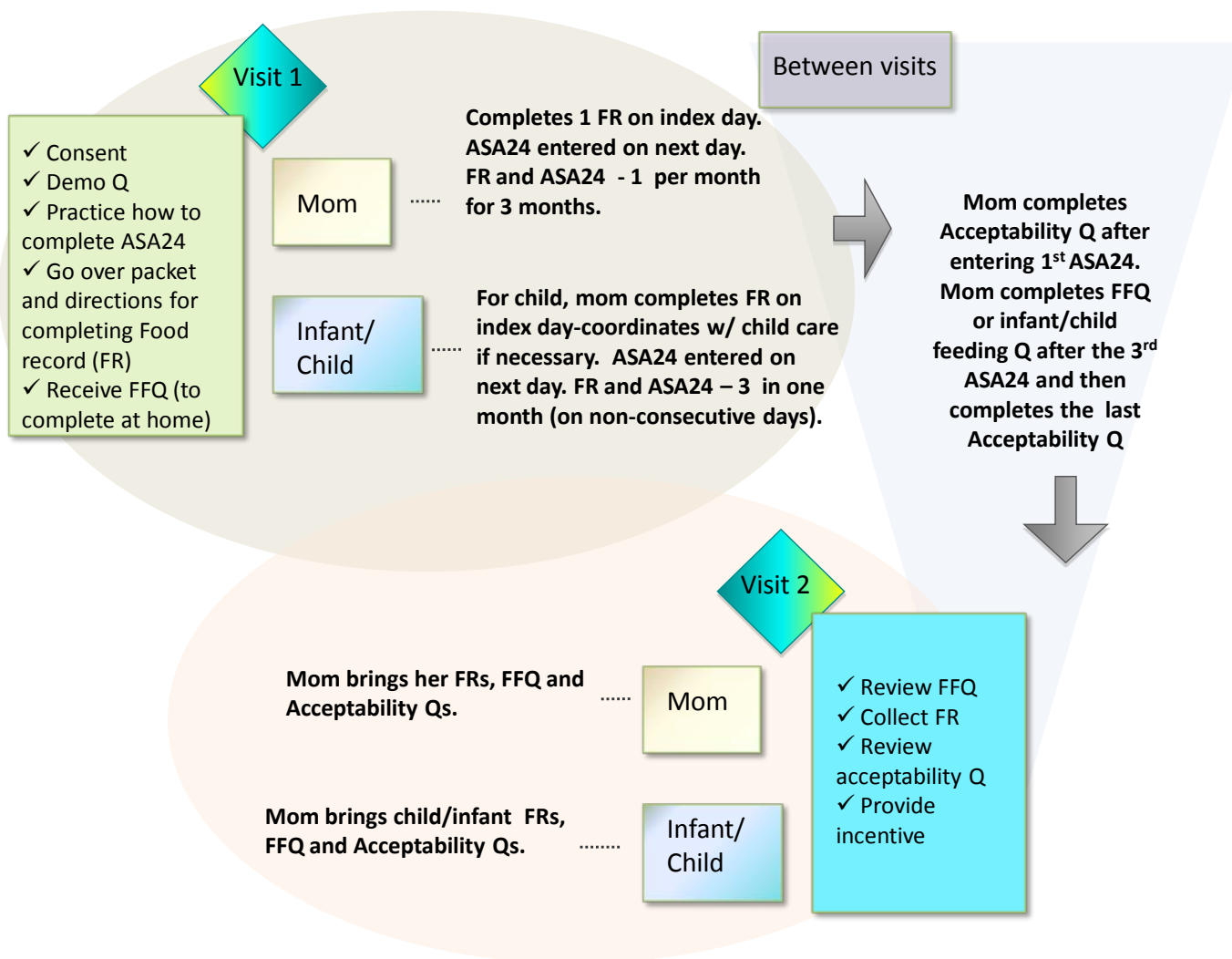
4   Site Procedures

4.1   Guidelines for working with NCS participants
- As part of the NCS team, you represent your site and the entire study. It is expected that research staff be professional, are able to gain trust and yet remain neutral when working with the participant.
- Privacy and confidentiality will be demonstrated and practiced. This starts with being IRB certified. Conversation between research staff about a specific dietary recall or issue should be done in private. The participant's personal information should be kept in a folder and locked file cabinet in accordance with FISMA compliance. Communication between site and the UNC center will be done using the assigned participant ID.

4.2   Tasks

The diagram below illustrates the events expected to occur.

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Visit 1

Between visits

✓ Consent
✓ Demo Q
✓ Practice how to complete ASA24
✓ Go over packet and directions for completing Food record (FR)
✓ Receive FFQ (to complete at home)

Mom ⋯⋯ Completes 1 FR on index day. ASA24 entered on next day. FR and ASA24 - 1 per month for 3 months.

Infant/ Child ⋯⋯ For child, mom completes FR on index day-coordinates w/ child care if necessary. ASA24 entered on next day. FR and ASA24 – 3 in one month (on non-consecutive days).

Mom completes Acceptability Q after entering 1st ASA24. Mom completes FFQ or infant/child feeding Q after the 3rd ASA24 and then completes the last Acceptability Q

Visit 2

Mom brings her FRs, FFQ and Acceptability Qs. ⋯⋯ Mom

Mom brings child/infant FRs, FFQ and Acceptability Qs. ⋯⋯ Infant/ Child

✓ Review FFQ
✓ Collect FR
✓ Review acceptability Q
✓ Provide incentive

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This table describes all sites including the number of participants from each age.

Center	Ethnicities	Pregnant women	Infants 11-12 months	Preschoolers 2-5
UCLA (U)	Chinese, South East Indian, Filipino,	X (n=36)		X (n=36)
Hawaii (H)	Pacific Islander, Chinese, Filipino	X (n=36)		X (n=36)
Hopkins (J)	African-Americans	X (n=12)	X (n=12)	X (n=12)
UC Denver (D)	Mexican American and Caucasians	x-from existing Healthy Study (approximately 50)		
Univ Minnesota (N)	Caucasians, African-Americans, Hmong, American Indians, Latino		X (n=60)	
Miami (M)	Hispanics (Cubans, Columbian, Dominican, Honduran, Puerto Rican)			X (n=60)
Total Sample		**84 (plus 50 Healthy study)**	**72**	**144**

4.2.1 First visit (total estimate of participant burden 60 minutes)
Prior to the collection of any dietary data, your NCS site will:

- Consent the participant into the study. (20 minutes)
- Assist with completing the participant information sheet (Appendix 1)
- Have participant fill out the Socio-Demographic Questionnaire at the center (Appendix 2) (10 minutes)
- Assign given identification and passwords to each participant. This information will be provided by the UNC Epidemiology core.
- Provide study "kit" to each participant which includes:
  - ASA24 Instruction Brochure (Appendix 3)
  - Food Portion Size Guide (Appendix 4)
  - Food Record Forms and Instructions (Appendix 5)
  - Acceptability questionnaire (Appendix 6)
  - Maternal NCS FFQ or the infant/child feeding questionnaire (Appendix 7 & Appendix 8)
- Demonstrate how to use the ASA24. Have the participant practice by entering one meal from the previous day. Then instruct participant that we want two weekdays and one weekend day during the specified time period. It is important to emphasize that once the participant starts the recall it needs to be completed within 24 hours.
- Provide food record forms, including sample record, blank food record forms and instructions for completion.
- Explain the Acceptability Questionnaire and how it should be prospectively completed as they proceed. The first questionnaire after completing the first ASA24 and then the second and after completing the last ASA24 and the Maternal NCS FFQ or the infant/child feeding questionnaire.
- Provide instructions on how to complete the Maternal NCS FFQ or the infant/child feeding questionnaire.
- Schedule a follow up visit for participant to bring back all the food records and questionnaires.
  - For pregnant women this will be three months from the first visit date
  - For infants and children this will be one month from the first visit date
- Enter tracking information for the participant into a data management system. To include the following information at a minimum:
  - Participant ID
  - contact information-names, telephone, email,
  - enrollment date,
  - EDC,
  - follow-up visit date,
  - Completion date of questionnaires

4.2.2 Ongoing

Information to be shared with UNC to track participant's completion of the ASA24 recalls includes the following de-identified data: Participants ID, Enrollment Date, EDC, and Follow-Up visit date. This information will be transmitted on a weekly basis for newly enrolled participants

4.2.3 Follow-up Visit (15 minutes)

The participant will return to the center to turn in the Food records, Acceptability questionnaires and either the maternal NCS FFQ or the infant/child feeding questionnaire. Once reviewed by staff as described below, the participant will be provided an incentive for their participation.

5 Dietary Data Collection and Management

5.1 Collect three, 24 hour diet recalls using the ASA24

The NCS dietary recalls will be completed by the participant using the ASA24 online dietary system, https://asa24beta.westat.com/index.htm. Each participant will complete three ASA24 recalls and the parent will serve as proxy for the infant/child participant. The participants will enter the type and amount of foods and beverages consumed during a complete 24-hour period (from midnight-to-midnight) for the previous day. Dietary recalls are automatically entered and saved to the ASA24 system. After 1 hour of inactivity on the account, ASA24 will automatically log the participant off the program. However, information already entered should be saved. Additionally, if a participant refreshes or reloads the site, ASA24 will log the participant off. It is estimated that each recall may take 20 to 30 minutes to complete for a total estimate of 60-90 minutes of participant burden.

- This system uses a multiple pass approach. See (Appendix 9) for full description.
- Pregnant women will complete three ASA24 one-time per month for three months.
- The infant and child participants (and using the parent as proxy) will complete three ASA24 in one month (preferably) but two months will be allowed.

5.1.1 Tools for Entering

Participants will be given an ASA24 Instruction Brochure (Appendix 3) and the Food Portion Size Guide (Appendix 4) to assist with entering into the ASA24 system.

5.1.2 Problems Using ASA24

- *Important:* Because this is a feasibility study for the use of this diet assessment tool, if the participant has technical difficulties in using the ASA24, she will be instructed to contact the study site. The study site is

responsible for documenting all technical difficulties reported by study participants. As a feasibility study, it is important that any program errors or technical difficulties of ASA24 are clearly and accurately recorded by each site. The study participant ID, the reported problem, and the date should be noted (Appendix 10).

5.1.3 For the Research Assistant at the Study Site

- Document any problems reported by the participant.
- Recall progress will come from the UNC main site. UNC will send a weekly report to each site that details information about the progress of the ASA24 recall completion for participants at that site.

5.2 Collect Food Records using NDSR

On the day prior to the completion of the ASA24 recall, participants are being asked to record their food intake. Thus pregnant women will complete one food record per month. Parents of the infant (age 11-13mo) and child (2-5 years of age) will complete three days of food records in one month on non-consecutive days. They will be instructed to keep a food record for two weekdays and one weekend day. Keeping track of food intake on the record is estimated to take approximately 20-30 minutes for the entire record. Thus a total of 60-90 minutes will be required for the participant to complete this task. Food records will be turned in to the study site at the follow-up visit.

- See Appendix 5 for Food Record Data Instructions for the participant.

- See Appendix 12 for the Food Record Protocol.

5.3 Collect NCS FFQ or Infant/child feeding questionnaire and acceptability questionnaires

5.3.1 Complete One NCS FFQ

After completing the three ASA 24 hour recalls, the participant will receive and then complete the NCS FFQ or infant/child feeding questionnaire. This may take up to 30 minutes to complete.

- For pregnant woman, this instrument covers 3 month time period and includes just a list of foods (Appendix 7).
- For infants and children the questionnaire covers foods and additional eating behaviors (see Appendix 8).

5.3.2 Complete Two Acceptability Questionnaires

The participant will also complete an Acceptability Questionnaire (Appendix 6) after the first ASA24 and at the end when they have completed the third ASA24 and the NCS FFQ. Total time to complete will be 20 minutes.

6   Quality Assurance and Site Data Management

6.1   Diet and Questionnaire Tracking
The staff will document that the participant has completed the questionnaires on the Diet and Questionnaire Tracking File (Appendix 11). This basic excel tracking sheet will include headers for each column where study events will be tracked.

6.2   ASA24 Updates to Each Site
UNC will check for ASA24 completion weekly for each site as follows. The research assistant will:

ASA24 Analysis Updates

*Enter the ASA24 Researcher Site, https://asa24beta.westat.com/ResearcherSite.html and log in. Go to the Analysis tab and Select the study site from the drop down list. On the "submit request" screen, you will request an analysis for "All participants (Batch)". **This analysis will take 24 hours to complete.***

The following day, go to the Researcher Site and select Analysis tab at the top of screen and the specific study site project from the drop down list below the Analysis tap, then navigate to the View Requests screen. The last request submitted the previous day will be displayed first on the list of requests. Download and unzip the file, you will have four individual workbooks at this point. Create a new folder with the date of the analysis request. Save each file from the ASA analysis within this folder.

Open the TN file and filter the data in order of largest to smallest for the intake day. Scroll through the data until you reach the date 8 days before the previous analysis request. All requests will be made on a 7 day schedule. Select all new recalls that lie within specified dates and copy them into a new spreadsheet.

This is a screen shot of what the first request looks like.

6.3   ASA24 Recall Verification

Using the Total Nutrients (TN) output file from the ASA24, the UNC research assistant has two ways to identify issues with the quality of the diet recall.

- The first way is to check any **5** in the *RECALL STATUS* column from the ASA24. The number 5 indicates that the recall is incomplete. Reasons for this might include that the program froze, amount usual column is empty (this is the last question the pt must answer), pt did not log out or the computer shut down/failed.
- The second way is to check for the number **2** in the *COMPLETE DATA* column. A **2** indicates that data is missing.

Since this is a feasibility study we are not going to correct foods entered into the ASA24. Missing foods will be transparent by comparing the foods document in the ASA24 to the food records.

SAMPLESTUDY11000	411e48	6	0	5	4122010	2	4132010
SAMPLESTUDY11000	411e48	7	0	2	5022010	1	5032010
SAMPLESTUDY11000	bfbf629	1	0	2	12152009	3	12162009
SAMPLESTUDY11000	bfbf629	2	0	2	2152010	2	2162010
SAMPLESTUDY11000	bfbf629	3	0	2	4292010	5	4302010

6.4 Food Record

The research assistant who collects the food record will check for completeness of the record by examining legibility, names of foods, portion sizes and any obvious errors. They will enter the date received into the tracking system (see Appendix 11). Once the participant has completed the study protocols, the site will send a copy of the food records to the corresponding center responsible for data entry. Centers responsible for entering food records include:

- Miami – enter only for preschoolers
- Baylor – enter only for pregnant women records
- Minnesota – enter only for infant records
- In addition, at the Hawaii VC, food records will also be entered into the Pacific Tracker (PacTRAC) to obtain information on foods specific to their region.

6.4.1 Food Record Data Entry

Each site will follow the NDSR Data Entry Rules and Quality Assurance Procedures (Appendix 12). Once food records have been entered and cleaned, output files will be generated and sent to UNC in a timely fashion.

6.5   **FFQ**
Once the participant completes the NCS FFQ or Infant/child questionnaire, the research assistant will enter the date into the tracking system and check for completeness.

6.5.1   Completed FFQs
- Returned FFQ is entered into the tracking system by date received.
- Check FFQ for errors: 1) make sure FFQ was filled out in pencil, 2) check to make sure it was filled out correctly (ie. few or no missed questions)
- If there are many missed questions, ask the participant to complete them at the follow-up visit. If there are too many questions missed $> 25\%$-mark as incomplete into the tracking system.
- Make sure respondent Pat ID # (top left corner) is bubbled in correctly.
- Make a photocopy of the questionnaire.
- File questionnaires and their copies by Pat ID # in the designated folder.
- Send questionnaires to UNC at the end of the month by mail. Also send a notice via email that includes: 1) Site ID, 2) List of Pat ID's in the batch listed in chronological order, 3) Date it was mailed to study site.

    o   Mailing Address:

    NCS Nutrition
    Carolina Population Center
    University of North Carolina at Chapel Hill
    CB 8120, University Square East
    123 West Franklin Street
    Chapel Hill, North Carolina 27516-2524

6.6   **Socio-Demographic and Acceptability Questionnaires**
The socio-demographic questionnaire will be completed in person and administered by the research assistant during the first visit. A question by question (Q x Q) format will be followed. The research assistant will guide the participant through questionnaire and provide guidance if needed in accordance to the Q x Q format. The acceptability questionnaire will be self-administered and completed by the participant prospectively as they complete each part of the protocol (first recall, all three recalls, and the FFQ or infant/child feeding questionnaire). The research assistant will review it for completeness and address any omissions at the last visit.
- The date of completion is entered into the tracking system.
- Copies of these questionnaires will be made at each site.
- The originals will be sent to UNC at the same time the FFQ/child feeding questionnaires are sent following similar procedures.

7 Data Collection at UC Denver Healthy Start Study

At UC Denver, an on-going study called the Healthy Start study is recruiting pregnant women and following them up through the postpartum period. This study is already using the ASA24 to collect dietary information; one recall per month through all of pregnancy (the first recall is collected in person with study staff as a training tool). To help with understanding how the NCS can collect dietary data, this study will consent women to do the following as an amendment to their existing protocols:

- After completion of the second ASA24 hour recall which is completed by the woman at home, the first Acceptability Questionnaire will be completed

- After completion of the third ASA24 hour recall, she will complete the NCS FFQ and the second Acceptability Questionnaire.

- At her 24-26 week Health Start visit, she will bring the acceptability questionnaires and the NCS FFQ to the study visit. Staff will review them for completeness and she will be provided with an additional incentive.

- Data from the NCI web site for the 50 participants included in this amended protocol will be extracted by the UNC study staff and sociodemographic data comparable to the questionnaire being used will be given to UNC by Denver. These data will then be used in the analytical strategy described below.

8 UNC Data Analysis

For analysis, the following files will be made available:

8.1 ASA24

- My Selections (MS) – Food and supplement names from quick list, probe questions and answers
- Individual Foods and Nutrients (INF) – FNDDS food codes, gram weights and nutrients
- Daily Total Nutrients (TN) – FNDDS nutrients from all foods in a given day

8.2 Food Record

- Component/Ingredient File (#1) – intake at the ingredient level
- Food File (#2) – intake at the whole food level
- Meal File (#3) – intake at the meal level
- Total Intake File (#4) – intake totals/participant
- User-recipe File (#5) - recipe nutrient totals
- Menu Properties File (#6) - menu nutrient totals

- Food Group Serving Counts File (#7) - serving count at whole food
- Food Group Serving Counts File (#8) - serving count at meal/eating occasion
- Food Group Serving Counts File (#9) - serving count for total intake

8.3   NCS FFQ and Infant/child Questionnaires

The Maternal FFQ Will be scanned and processed into NCI diet calc for the food items. An ascii file of the frequency of consumption and nutrient totals will be generated. The Infant/child feeding Questionnaires will be scanned and data analysis files will be generated.

8.4   Analysis strategies

The feasibility, respondent burden, and data quality of ASA24 recalls compared to NCS DHQ among pregnant women and parents of children from specified ethnic groups (Hispanic, African-American, Chinese, Filipino, South East Indian, and Native Hawaiian or Pacific Islander, and Caucasian) and test their ability to respond and responses to the ASA24 and NCS DHQ.

8.4.1   The feasibility of collecting ASA24 recalls among individuals of various subpopulations, and ethnicities.
- From the ASA tracking system we will be able to determine the proportion of individuals who completed one, two and all three days of recalls for each sub life cycle group. We will compute frequencies by ethnicity, educational status, and acculturation.
    - We will also have this information from the Healthy Study in Denver. Similar descriptive statistics will be calculated.
- The acceptability of collecting ASA24 recalls among individuals of various ethnicities (including reaction to the user interface and other usability factors).
    - From the information collected on the acceptability questionnaire we will generate overall frequencies of the responses and then stratify by ethnicity, educational status, and acculturation to explore the differences in the responses by these characteristics.
- Assess the burden of the ASA24 and Maternal NCS FFQ or the infant/child feeding questionnaire for each group, including any gains in completion time that might be achieved after multiple administrations over time.
    - Time to complete each recall and the FFQ or the infant/child questionnaire will be determined and compared.
    - We will explore to what extent times for completion varied by ethnicity, acculturation or educational status.

- Determine the quality of the data, the extent of reporting and the breadth of foods reported with the ASA24 by comparing the responses to the food records administered to the same subjects.
  - o Food level data for each day of the ASA 24 and the food record will be compared. For this comparison, the Food record is being used as the reference tool and thus foods not found in the ASA24 data base will be recorded as missing. These foods will be grouped and sorted by ethnicity to provide input into the high priority food items that will need to be entered in the ASA24 data base.
- Assess what questions people have as they complete the ASA24 and the NCS DHQ and difficulties encountered.
  - o From the ASA 24 difficulties encountered form and the Acceptability Questionnaire, we will group difficulties reported as to 1) problems with the internet, 2) problems with accessing ASA24 web site, 3) problems with maneuvering in the web site, 4) problems with finding foods, and 5) overall preference between the two modes of data collection.
  - o We will explore to what extent these groups of difficulty varied by ethnicity, acculturation or educational status.
  - o From the Acceptability questionnaire we will determine the proportion of the population who stated they had difficulty completing the FFQ or infant/child questionnaire.
  - o We will also determine the % of missing items on the questionnaires and the extent to which responses show a lack of variability that may be a proxy for poor quality data.
  - o We will explore to what extent these responses to the difficulty of completing the FFQ and its completion rates varied by ethnicity, acculturation or educational status.