NCS Formative Research Template for OIRA Clearance

TO BE COMPLETED BY STUDY CENTER:

LOI #: LOI2-QUEX-14, Phase 2
Title of Formative Research: Improving Dietary Assessment in Infants and Children
Participating Institutions: University of North Carolina; Johns Hopkins University; University of California-Los Angeles; University of Hawaii; University of Miami; University of Minnesota

SME: Ruth Brenner
COTR: Various

Purpose of the Study: To compare feasibility (scientific robustness), acceptability (burden), and cost of the Automated Self-Administered 24-hour Recall (ASA24) methods and Infant and Child Feeding Questionnaires to inform the NCS Vanguard and Main Study design. Additionally, scientific robustness of the proposed measures by acculturation status such as 1st generation or 2nd generation status, identity with ethnic group and years living in the US will be evaluated.

Previously, the NCS requested and received approval for testing the ASA24 in a sample of 150 pregnant women (Phase 1). For this current substudy (Phase 2), we will test the same materials, as adapted for use by parents reporting on their infants and children, in a sample of 216 mothers answering for their infants or children.

Benefit to NCS Vanguard or Main Study: Utilization of the Web-based ASA24 tool may reduce participant burden and will improve accuracy in participant response compared to the paper-based Infant and Child Feeding Questionnaires. Additionally, if ASA24 can be keyed by the respondent rather than a data collector (for example, upon receipt of a mail-in reminder), the web-based ASA24 would be a more cost-effective method than the mail-in NCS Infant and Child Feeding Questionnaire. Suitability of both measures by acculturation status will inform measurement of key outcomes for the NCS.

Multiple days of 24-hour dietary recall (24HR) provide the highest-quality, least biased dietary data, and most culturally-sensitive manner of collecting data across various ethnic groups, and are therefore considered to be the gold standard approach in dietary assessment methodology to measure usual intake. Typically, each 24HR is administered by a trained interviewer. This increases the cost of research studies involving large samples, such as the NCS. As a result, a Food Frequency Questionnaire (FFQ) is often used instead of multiple 24HRs because it can be self-administered and is therefore less expensive.

The ASA24 is a standard measure developed by the National Cancer Institute and is available at http://riskfactor.cancer.gov/tools/instruments/asa24/ for use as a dietary assessment tool in a self-administered setting without copyright fees (see Attach B5. The most recent version of the ASA24 was released in 2011. Unique features of this tool include: graphic enhancements and animated characters that guide the participants in completing the recall, audio language/cues to enhance use in low-literacy populations, translation into Spanish (forthcoming), and the capacity to accommodate other languages. We will continue to collaborate with Dr. Nancy Potischman, Division of Cancer Control and Population Science, National Cancer Institute, in our use and evaluation of the ASA24. The NCS 12-Month Infant Feeding Questionnaire (Attach B11) was approved for use in the NCS Vanguard Study (OMB #: 0925-0593; Expiration Date: 8/31/2014) on 4/13/2011. The Child Feeding Questionnaire (Attach B12) is a food frequency questionnaire used in a project titled Project Viva at Harvard University, and is under consideration for use in the Vanguard Study.

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Study Design: This formative research substudy has been divided into two phases. The first phase (approved by OMB/OIRA on 8/23/2011) collected dietary data from pregnant women using the ASA24, food records, and the NCS FFQ. In addition, sociodemographic and acceptability questionnaires were administered to allow analyses of acceptability by sociodemographic characteristics. Data collection is complete for the adult phase and data are being entered and cleaned in preparation for analyses. The second phase, requested here, focuses on dietary assessments in infants (ages 11-12 months) and young children (ages 2-5 years).

Phase 2 includes two in-person visits and multiple self-administered collections (See Attach B14).

1st Visit:
The first visit will occur in a clinic/office setting and include enrollment into the substudy and consent (Attach A.22). The first visit will also include review of ASA24 instructions (Attach B4), ASA24 Protocol (Attach B5) and the Food Diary instructions (Attach B6) the Socio-Demographic Questionnaire (Attach B3).

Between Visits:
Following the first visit each mother will complete a total of three sets of measures, including the ASA24 and a Food Record/Diary for her infant or child during a one month time period. Mothers will also complete the appropriate Acceptability Questionnaires (Attach B7- Attach B10) after completing the first and third ASA24. The completion of these activities will be done independently by the mother in the home. After the third (and final) ASA24 /Food Diary/acceptability Questionnaire is completed, the mother will complete the Infant and Child Feeding Questionnaire (Attach B11 or Attach B12).

2nd Visit:
At a second in-person visit (Contact 2), conducted one month after Contact 1, participants will be asked to return the three sets of questionnaires and food records/diaries and the Infant or Child Feeding Questionnaire to NCS staff. NCS Staff will review these for completeness, and the mother will be provided with an incentive thanking her for her participation in the substudy.

In summary, there will be two in-person contacts and three data collection activities conducted at home by the mother Accuracy of the ASA24 will be compared to food records, and missing foods will be identified in the ASA24. The preference for each tool will be assessed by the acceptability questionnaires. Burden will be evaluated by acceptability questionnaires and time to complete each measure. Sociodemographic characteristics including information on acculturation mentioned above will be compared across outcome measures (feasibility, time to completion, amount of missing data) to help inform this evaluation of whether or not a self-administered web tool can be used in the National Children's Study to assess dietary intake. The sample size for this study was determined based on our ability to recruit individuals from a variety of backgrounds and differs by age category since infants at the ages of 11-12 months have less variation in their diets than preschoolers.

Target Respondents: We will invite mothers of infants and pre-school aged children to participate in this substudy. These are non-NCS participants. The participants are individuals who are demographically similar but not necessarily geographically eligible for the NCS Vanguard Study There are five Study Locations recruiting a convenience sample of participants for this substudy with total recruitment targets of 72 mothers of infants and 144 mothers of preschoolers aged 2-5 years. The table below shows the recruitment targets for each Study Location. We estimate that 180 potential participants will need to be screened (30 screened by JHU and 150 screened by MN) to meet the infant recruitment target of 72. We estimate that 430 potential participants

will need to be screened (100 screened by UCLA, 100 screened by Hawaii, 30 screened by JHU, 200 screened by University of Miami) to meet the preschooler recruitment target of 144 (see Attach B16).

Center	Infants 11-12 months	Preschoolers 2-5
UCLA	N/A	n=36
Hawaii	N/A	n=36
Hopkins	n=12	n=12
Univ Minnesota	n=60	N/A
Miami	N/A	n=60
Total Sample	**72**	**144**

Participants with infants or children who have birth defects or any major health conditions that would interfere with feeding (e.g., inborn errors of metabolism, tube feeding, and cystic fibrosis) will be excluded.

Sample Size Calculation: This is a feasibility study thus sample size and power calculation are not considered appropriate. We are exploring if participants are capable of using a web-based tool to collect information on dietary intake and what foods are missing in the ASA24 data base for children. As previously mentioned the number of infants and children per site was based on the feasibility of recruitment given the time frame we have to complete the study and the difference in the number of infants verses children is due to the lack of variation in the diets of 11-12 month olds.

Method of Recruiting: Because the target populations for this project are non NCS infants and children, recruitment is occurring in a variety of settings –clinics, care providers, preschools, WIC, university residential areas that provide housing for families with young children, organizations serving ethnic groups of interest (e.g., houses of worship) -- only some of which already have an NCS presence and existing relationship because of that presence. In many cases new relationships with these community organizations are forged; however, many of these organizations are familiar with research and have a history with research facilitation. By and large, burden to clinic, university or non-NCS staff is minimal because their facilitation is entirely voluntary. In almost all cases, clinic, university and non-NCS staff are asked only to post flyers, provide a small space for brochures, or provide study contact information to interested persons. In a few cases, recruiters from the research team are working in clinic, university or non-NCS facilities with which they have already established a relationship as recruiters; in these cases, they are permitted to use the space and interact with clients but request no time or effort from facility staff. Recruitment scripts generally include questions to screen for: child's age; mother's age; internet access; whether child has any medical conditions that would affect growth, weight or eating habits; whether child resides with mother; whether infant attends child care; race and/or ethnicity of child and mother. Study participants are required to have internet access to be able to record food consumption using the ASA24. Recruitment advertisements state that having internet access is one requirement for study participation to minimize inquiries from potential participants who lack it. In addition, research staff are encouraged that this eligibility requirement will be met whenever potential respondents use e-mail to contact them with inquiries about study participation. However, because neither of these filtering mechanisms establish absolutely whether potential participants have internet access, potential participants are still formally asked (or asked to confirm) whether they have internet access during the screening/recruitment process.

Participants will call the number listed on the advertisement, and NCS staff will screen (see Attach B16) for eligibility. If eligible, participants will be asked to come in for informed consent, completion of the sociodemographic questionnaire (see Attach B3) and training related to use of the ASA web site (see Attach B4

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– Attach B6) and completion of the food records and questionnaires (Attach B11 and Attach B12) by study staff at each center (please refer to Manual of Procedures Attach B14).

***Confidentiality:** Study Centers must abide by the terms of their Data Use Agreement, which should reference all formative research efforts involving the collection or management of NCS restricted-use data. All participating Study Centers will have approved Data Use Agreements and Security Plans prior to launch.

***IRB Approval:** Local IRB clearances for these activities have been obtained by the participating Study Centers. Please see the attached IRB approval letters.

Incentives: Consistent with the approved NCS Expanded Vanguard Study Phase 2 incentive structure and the incentives that were implemented in the pregnant women component of this study, we propose to offer a $25 monetary incentive for each participant contact of this formative research project, up to 1 hour of information collection activity. Additionally, consistent with the NCS Expanded Vanguard Study Phase 2 incentive structure, we may offer participants up to $25 in non-monetary incentives during the course of their participation.

Sensitive Questions: We ask about income in the SocioDemographics Questionnaire.

Proposed Project Schedule: We will begin this project upon receipt of all regulatory approvals.

Data Collection Burden:

Estimates of Annual Hour Burden – Formative Research: LOI2-QUEX-14-2, "Improving Dietary Assessment in Pregnant Women and Children" Respondents are biological mothers of infants ages 11-12 months and children ages 2-5 years.

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours
Eligibility Screener	Potential participants	610	1	1/60	20
Demographics Questionnaire	Parent of Infant/Child	216	1	10/60	36
In-Person Contact #1 Training on Questionnaires	Parent of infant/child	216	1	90/60	324
ASA24	Parent of infant/child	216	3	30/60	324
Food Diary	Parent of infant/child	216	3	30/60	324
Acceptability Questionnaire #1	Parent of infant/child	216	1	20/60	72
Acceptability Questionnaire #2	Parent of infant/child	216	1	20/60	72
Infant Feeding Questionnaire	Parent of infant	72	1	20/60	24

* To be completed before project proposal is submitted for OIRA clearance.

Child Food Questionnaire	Parent of child	144	1	30/60	72
In-Person Contact #2 Return Questionnaire Sets	Parent of infant/child	216	1	15/60	54
TOTAL		**610**			**1,322**

Annualized Cost to Respondents -- Formative Research: LOI2-QUEX-14-2, "Improving Dietary Assessment in Pregnant Women and Children" Respondents are mothers of infants ages 11-12 months and children 2-5 years.

Data Collection Activity	**Type of Respondent**	**Estimated Total Annual Burden Hours**	**Hourly Wage Rate**	**Respondent Cost**
Eligibility Screener	Potential Participants	20	$10/hr	$200.00
Demographics Questionnaire	Parent of Infant/Child	36	$10/hr	$360.00
In-Person Contact #1 Training on Questionnaires	Parent of infant/child	324	$10/hr	$3,240.00
ASA24	Parent of infant/child	324	$10/hr	$3,240.00
Food Diary	Parent of infant/child	324	$10/hr	$3,240.00
Acceptability Questionnaire #1	Parent of infant/child	72	$10/hr	$720.00
Acceptability Questionnaire #2	Parent of infant/child	72	$10/hr	$720.00
Infant Feeding Questionnaire	Parent of infant	24	$10/hr	$240.00
Child Food Questionnaire	Parent of child	72	$10/hr	$720.00
In-Person Contact #2 Return Questionnaire Sets	Parent of infant/child	54	$10/hr	$540.00
TOTAL		**1,322**		**$,$13,220.00**

☒ **Please check here after ensuring that all calculations have been verified**

Estimated Costs: Staff Hours: 2,644
Supervisor Hours: 661

Attachments:
Attach B1. LOI2-QUEX-14 Phase 2 OIRA Template
Attach B2. LOI2-QUEX-14 Exemplar Consent Form;
Attach B3. LOI2-QUEX-14 SocioDemographics Questionnaire;

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Attach B4. LOI2-QUEX-14 ASA24 Instructions;
Attach B5. LOI2-QUEX-14 ASA24 Protocol;
Attach B6. LOI2-QUEX-14 Food Diary Instructions-Parent;
Attach B7. LOI2-QUEX-14 Infant Acceptability #1
Attach B8. LOI2-QUEX-14 Infant Acceptability #2
Attach B9. LOI2-QUEX-14 Child Acceptability #1
Attach B10. LOI2-QUEX-14 Child Acceptability #2
Attach B11. LOI2-QUEX-14 Infant Feeding Questionnaire
Attach B12. LOI2-QUEX-14 Child Food Questionnaire
Attach B13. LOI2-QUEX-14 IRB Approval Letters
Attach B14. LOI2-QUEX-14 Manual of Procedures
Attach B15. LOI2-QUEX-14 Exemplar Recruitment Flyer
Attach B16. LOI2-QUEX-14 Recruitment Screener

☒ **Please check here after ensuring that the OMB #: 0925-0593 and Expiration Date: 08/31/2014 have been inserted as first-page headers on each proposed instrument.**

☒ **Please check here after ensuring that the following OMB burden statement has been inserted as a first-page footer on each proposed instrument.**

Public reporting burden for this collection of information is estimated to average [SC insert estimated response time] minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

Appendix 1. Maximum NCS Incentives, by Study Activity and Impact on Participants (Approved by OMB 1/5/12)

Data Collection Activity Characteristics	Initial NCS Vanguard Study	NCS Recruitment Substudy and Formative Research		
		Phase 1	Phase 2	Formative Research
Time for encounter	3 hours	0.5 to 1 hour	0.5 to 1 hour	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions	Few sensitive questions	Few sensitive questions
Physical measures	Yes	No	No	Yes*
Environmental specimens	Yes	No	Yes	Yes*
Biospecimens	Yes	No	Yes	Yes*
Participant observation	Yes	No	No	No
Monetary incentive, per visit	$100	$25	$25 for the group of study questionnaires, plus $25, in total, for any bio-specimens collected during a contact and, where appropriate for environmental specimens	$25, in total, for any bio-specimens collected during a contact. For questionnaires, or any environmental specimens – up to $25 when deemed necessary
Non-monetary incentives (tote bags, post its, key chains, etc.)	In addition to the monetary incentive, non-monetary incentives valued at $25 or less may be offered to participants	As an alternative to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants in lieu of cash or local incentives not exceeding $25 in value and deemed non-coercive by local IRBs	In addition to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs	Instead of monetary incentives, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs