OMB #: 0925-0590
Expiration Date: June 30, 2011

NCS Formative Research Template for OIRA Clearance

TO BE COMPLETED BY STUDY CENTER:

LOI #: LOI - [ ] - QUEX - 25 - [ ]

Title of Formative Research: NCS Recruitment and Retention Network

Participating Institutions: **West Virginia University; University of Delaware; Baylor; University of Hawaii; University of Louisville; Mount Sinai Medical Center; University of Massachusetts; Northwestern University; CHOP; University of Pittsburgh**

Recruitment Study Arms: **Initial Vanguard Study and Recruitment Substudy**

SME: Jessica Graber

COTR: **Various**

Purpose of the Study: To systematically identify barriers to recruitment and retention in the National Children's Study (NCS) for the general target population (that is, women of child bearing years, mothers, and fathers) and hard-to-reach populations (for example, teenage mothers), receive evaluations of existing recruitment materials/messages used in the NCS, and identify areas for improvement prior to launch of the NCS Main Study.

Benefit to NCS Vanguard or Main Study: Receiving systematic information from persons representing the NCS target population regarding their understanding of the purposes of the Study is critical to understand prior to NCS Main Study launch to support enhancement of informed recruitment and retention.

Study Design: We propose to conduct a series of focus groups designed to evaluate currently-used Vanguard and Recruitment Substudy recruitment materials and messaging for general target and hard-to-reach populations. In preparation for the proposed information collection, we have collected and cataloged existing NCS recruitment materials and messages for key messages, target audience, clarity and organization. We prepared a focus group moderator guide to support focus group review of NCS materials and messages; reaction to descriptions of NCS recruitment activities; and generate ideas about additional methods, materials and messaging to address identify gaps. We now propose to host a series of focus groups (approximately 5 persons per target population, for each of 8 focus group sessions, at approximately 30 to 60 minutes each). Discussion of focus groups will be audiotaped and transcribed with personal identifiers redacted. Themes will be identified and recommendations made for revisions of NCS recruitment materials in advance of the NCS Main Study.

Target Respondents: This project will recruit persons not geographically eligible to participate in the NCS Vanguard Study, but who represent the target population of NCS participants (that is, women of child bearing years, mothers, and fathers). Specifically, persons will be recruited from neighborhoods not selected for the secondary sampling unit. Additionally, persons providing services to hard-to-reach populations will be recruited for their guidance.

Method of Recruiting: To recruit members of the general target population, we will advertise in neighborhoods not selected to participate in the NCS Vanguard Study. To recruit hard-to-reach populations and service providers for those populations, we will approach community centers and service providers and request their support. We will leverage our relationships with community stakeholders to support these connections.

*__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.

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

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***IRB Approval:** Local IRB clearance for this activity has been requested by all participating Study Centers; Local IRB clearance will be obtained prior to contact with participants, including legal guardian consent per local jurisdiction requirements.

Remuneration: We propose to offer a $25 monetary incentive for the anticipated 30-60 minute focus group activity. This amount is consistent with the approved incentive schedule for the NCS Vanguard and Recruitment Substudy.

Sensitive Questions: We will not ask sensitive questions as a component of this study.

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

Data Collection Burden: *Please click on the table below and enter the total number of respondent hours.*

Table 1. Data Collection Burden for Proposed Formative Research Project

	Age-Eligible Women (Not Mothers)	Mothers (Ages 18-49)	Mothers (Ages 15-17)	Fathers	Family Members	Support Services
# of Respondents per Focus Group	5	5	5	5	5	5
Length of Interaction (in hours)	1	1	1	1	1	1
Number of Focus Group Events	8	8	8	8	8	8
Total Respondent Burden (in hours)	40.0	40.0	40.0	40.0	40.0	40.0
GRAND TOTAL BURDEN HOURS	240.0					

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

Estimated Costs: Staff Hours: 480 hours.
Supervisor Hours: 120 hours.
Incentives: $25 X 8 (number of events) X 5 (respondents per event) x 6 (target populations)=$6,000.

Attachments: Exemplar Screening Tool, Consent, and Moderator's Guide. Note: The exemplar screening tool, consent, and moderator's guide will be customized for each participating study center and target population, as appropriate, and approved by the local IRB prior to use.

☒ **Please check here after ensuring that the OMB #: 0925-0590 and Expiration Date: June 30, 2011 date 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 (0925-0590*). Do not return the completed form to this address.

Appendix 1. NCS Incentives, by Study Activity and Impact on Participants, Stage 1 *(Approved by OMB 7/23/10)*

Data Collection Activity Characteristics	Initial NCS Vanguard Study	NCS Recruitment Substudy
Time for encounter	3 hours	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions
Physical measures	Yes	No
Environmental specimens	Yes	No
Biospecimens	Yes	No
Participant observation	Yes	No
Monetary incentive, per visit	$100*	$25
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