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.

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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

[STUDY CENTER]

Screening Tool for Recruitment and Retention Network Focus Groups

[TARGET POPULATION] will be invited to participate in one of four focus group interviews.

Inclusion criteria will be: [EXEMPLAR CRITERIA: Adult, English-speaking men who are expectant fathers or new fathers (infant less that 1 year of age].

Potential participants will be screened prior to the consent process to verify eligibility.

[EXEMPLAR SCREENING QUESTIONS TO MEET INCLUSION CRITERIA]

1. Do you have any children?

If No: advise that they are not eligible and thank them for their time

If Yes: Continue to question 2

If expecting first child: Continue to question 3

2. What is/are the age(s) of your child(ren)?

If youngest child is older than 1 year: advise that they are not eligible at this time and thank them. Ask if it would be alright to keep their contact information and potentially call them at a later date for additional groups.

If youngest child is less than 1 year of age: proceed to question 3

3. How old are you?

If less than 18 years of age: advise that they are not eligible and thank them for their time

If 18 years of age or older: invite individual to participate

Review Consent Form with all eligible participants over the phone. Assign to Focus group.

[STUDY CENTER]
[COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH]

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Title: Assessing National Children's Study Recruitment Materials

Principal Investigator: [PROJECT PRINCIPAL INVESTIGATOR]

Sponsor: National Children's Study

Research Subject's Name:_____ Date:_____ _____

INVITATION TO TAKE PART AND INTRODUCTION

You are invited to volunteer for a research study. You are asked to take part because you are an [TARGET POPULATION] living in [PRIMARY SAMPLING UNIT] County. We will be adding the information we find out from volunteers in [PRIMARY SAMPLING UNIT] County, to the information we collect in other places across the United States. You will be asked to view materials and videos and discuss your reaction to these materials.

PURPOSE OF RESEARCH

The goal of this study is to collect individuals' feedback on materials, procedures, and strategies used to encourage people to participate in the National Children's Study.

YOUR RIGHTS

It is important for you to know that:

Your participation is entirely voluntary.

You may decide not to take part or decide to quit the study at any time, without any changes in the quality of the health care you receive.

You will be told about any new information or changes in the study that might affect your willingness to participate.

PROCEDURES

1. The moderator will collect information about you prior to the meeting, including race and ethnicity, age, zip code, and a few other items regarding family status. This information will not include your name or any other identification.

2. You will be asked to review a series of items providing information about the National Children's Study.

3. Once you have viewed the materials, you will participate in a group discussion so that you may provide more information about how effective you think these materials, procedures, and strategies might be. The group meeting will be recorded.

4. There will be about 8 to 10 people in the group. It will take about 30 minutes to review the items and another 30 minutes to participate in the follow up sessions with the moderator.

CONFLICT OF INTEREST DISCLOSURE
None

RISKS
We do not expect you to be harmed in any way as a result of helping in this research. However, if you are uncomfortable answering a question, you can skip that question. You can stop participating at any time.

BENEFITS
There are no direct benefits to you as a result of helping in this research. However, information you share in this study will be useful in developing effective procedures to recruit people to join the National Children's Study.

REASONS YOU MIGHT BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT
You may be taken out of the research study if the investigator decides that continuing in the study would be harmful to you.

COSTS
There will be no additional cost to you from being in this research study.

COMPENSATION
You will be paid $25 to reimburse you for your time and travel.

CONFIDENTIALITY
Your privacy is important to us. Your research records will be confidential to the extent possible. In all records, you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. However, the study sponsor (*National Children's Study)* and/or their representatives and the [STUDY CENTER] Institutional Review Board and/or their representatives may inspect your records that pertain to this research study. We will not allow them to copy down any parts of your identifiable information (e.g. your name) or take any of your identifiable information from our offices.

YOUR PARTICIPATION IN THIS PROJECT IS ENTIRELY VOLUNTARY. YOU MAY WITHDRAW FROM THE STUDY AT ANY TIME.

THE QUALITY OF CARE YOU RECEIVE AT THIS [LOCATION] WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

QUESTIONS

Before you sign this consent form, please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, you may ask [PROJECT PRINCIPAL INVESTIGATOR] [CONTACT TELEPHONE NUMBER], the Principal Investigator. You may take as much time as you need to think this over. If at any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the research study, you may contact the [LOCAL IRB CONTACT FOR STUDY CENTER]. The telephone number is [LOCAL IRB CONTACT NUMBER FOR STUDY CENTER].

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Title: National Children's Study Recruitment and Retention Formative Research Project Focus Group

Principal Investigator: [PROJECT PRINCIPAL INVESTIGATOR]

Subject's Name:_____

I understand the purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result. I have been told that unforeseen events may occur. I have had an opportunity to discuss the risks and benefits of this research with the investigator and all of my questions have been answered. I agree to participate as a volunteer in this research project. I understand that I may end my participation at any time. I have been given a copy of this consent form.

_____ Date:_____
Subject's signature

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, have fully explained the details of this clinical study as described in the consent form to the subject named above.

_____ Date: _____
Signature of person obtaining consent

INVESTIGATOR'S DECLARATION

As the principal investigator or co-investigator on this study, I attest to the following:

- the nature and purpose of the study and study procedures, as well as the foreseeable risks, discomforts and benefits have been explained to the above-named subject
- this subject has been given the opportunity to ask questions and to have those questions answered by knowledgeable research staff
- this subject meets the inclusion/exclusion criteria for this study

I have considered and rejected alternative procedures for answering this research question.

_____ _____
PI Signature Date

MODERATOR'S GUIDE FOR FOCUS GROUPS

Introduction

Welcome and thank you for being here today. My name is _____ and I will be the person talking with you this evening. This session will last about 60 minutes. We also have _____ from _____who will be taking notes as you speak tonight. In addition, we will audio record our discussion so that the conversation can be listened to again and can be typed into a transcript. These allow us to catch important information you share that we might have missed along the way.

Before we start I am going to give you some background information. What we are doing here tonight is a small project that will help us understand the best ways to communicate with people about a study called the National Children's Study, or the NCS. Before we ask people to join the NCS, it is important that we know what draws them to it and what information we need to keep in mind to tell them about the study.

The National Children's Study will be largest and most detailed study in history looking at children's health and development in the US. The goal of the National Children's Study is to identify ways to improve the health of our children. Project teams will work with doctors, nurses, community leaders and public health officials in communities like [PRIMARY SAMPLING UNIT] and surrounding towns to collect information from mothers AND from fathers. They will collect information about the places children live, the people in their lives, and their health from before they are born until their 21st birthday.

Now you know a little bit about the National Children's Study. I want to make it very clear that you are not being asked to participate in the National Children's Study and right now we do not know if your community will be selected for the Study.

You have been asked here today to share your thoughts, feelings and attitudes about things that we should consider when we talk with people about the National Children's Study. Information that you share with us today will help us explain the National Children's Study in the future so that parents will feel comfortable hearing more about the study and getting involved. Any questions?

Ground Rules

I will ask some questions that I would like you all to discuss among yourselves. NOT everyone has to answer every question, but it is important that we hear everyone's point of view by the end of the meeting. It's important that we hear everything that each one of you is saying, so please speak one at a time; remember that everyone's opinion is valuable, so please respect each other's point of view, even if you don't agree; and finally, we would like everyone to agree not to share any information you learn about other group members with anyone outside of this group. You each have a table tent card in front of you. You can write your name on it, or if you would like to keep your name private, you can use an alias or nickname.

Start Digital Recorder

1. The first thing I want to do is show you a video to introduce you to the National Children's Study. *(Use most recent NCS promotional video.)*
    a. Now that you have seen the video, how would you describe the study to someone else in your community?
    b. What did you like about the video? Was there anything you disliked about the video? What stood out in your mind from the video?
    c. What questions do you have as a result of watching this video?

2. A major part of our discussion today is to explore how we can best communicate with families to interest them in becoming a part of the NCS.
    a. First, how can we best make [FOCUS GROUP POPULATION], such as yourself aware of the study;

b. Second, how can we communicate with [FOCUS GROUP POPULATION] to encourage them to support the study and perhaps enroll their own families?

3. So how can we build awareness about NCS? When people hear about the NCS for the first time, they often hear about it through some kind of advertising – like a newspaper or radio ad, billboard, brochure, or maybe even by going to a community meeting and seeing the video you just watched. We are going to show you professionally-developed advertising which has been created for cities and counties where the National Children's Study has already begun. We will talk about each ad to find out how well it catches your attention, how much information it provides, and how effective it is in (motivating you) or (motivating those to whom you provide services) to seek more information about the NCS and possibly to enroll in the study. Let's look at print media.

4. (Show the materials – approach to this can be individualized by site) – present these outside of the focus group session with the same format asking them to comment/rank each as described below (sticker examples on those most attractive, or individually list their thoughts putting them into categories, etc.) as they come in and/or while they are waiting through the consent process.
    a. Do these (name type of material; i.e. Billboard, poster, etc.) make you want to look at them? Do you think (sub-population) would look at them?
    b. If these ads are seen many times and in different places, would they make (you) or (sub-population) want to know more about the study?
    c. What sorts of questions would you have?
    d. Do the ads leave a positive impression?
    e. What would make them better?

5. (Show the materials.)
    a. Do these (name type of material; i.e. radio ads and video) get your attention?
    b. Do you think (sub-population) would look at them?
    c. If you heard or saw them frequently, would they get a message across? What message would that be?

d. What other ways (designs, formats) would work just as well or better, but are not represented here?
e. How would you go about telling someone in your neighborhood about the study? What documents might you use? What would you tell them?

6. Now we are going to show you some videos. These videos were developed just to get your opinions about how recruiters can do a good job providing information to POPULATION about the NCS. The scenes are portrayed by actors. I'd like your initial reaction to each. Then, I'll ask a question or two before we move to the next video..

a. Overall, was this a realistic conversation?
b. Was the recruiter's approach effective for you?
c. What did the recruiter do best? What got your attention?
d. Were there things in the conversation that you would find annoying, and if so what were they?
e. Would this approach be effective?

(Show video of mother and recruiter with father. Sample script appends.)

f. Do you think that the responses of the parents are realistic?
g. What do you think the common response of the mother, father, and family members would be based on this information? Explain why they would react that way.
h. How might [FOCUS GROUP POPULATION] help spread the word in a positive way about the NCS?
i. If you were the staff member, how would you be sure to include all of the important information but make it easier for the woman, father, and family members to understand?

7. Imagine a woman is considering participation in the NCS. How might her husband or partner influence her decision?

a. What information would be useful to [FOCUS GROUP POPULATION] about the study? For instance, how could the recruiter best explain to the family what to expect when the NCS visits the home?
b. How accurately does the video represent the concerns a husband or partner may have about participating in the NCS?
c. How could the staff member help relieve these concerns?

8. Now, let's talk about what it would take to get a commitment from [FOCUS GROUP POPULATION] to enroll in and want to stay in the NCS study.
    a. From the initial explanation we gave and the media you have seen, how do you think that the NCS can encourage women to participate in the study?
    b. How should the NCS engage the baby's father?
    c. How should the NCS help a woman to feel comfortable and committed to the long-term activities of the NCS?

9. Finally, let me summarize what we have discussed so far (hit key points about poster and print ads, radio, and video). Now, is there anything else that we need to think about as we go out into the community to spread the word about the NCS? How about when we encourage women and their families to join the NCS? Are there things we should think about when putting together print materials or radio or video announcements?

    Thank you for attending. I am going to stop the recording now.

    Stop Digital Recorder

The National Children's Study (NCS) is the nation's largest long-term study of child health and well being. This longitudinal study will examine the effects of social, behavioral, biological, community and environmental factors on human health and development of 100,000 children in communities across the United States from pre-birth to age 21. Marion County, WV is 1 of 105 host sites across the United States.

A team from the National Children's Study is interested in understanding the factors that are important to women, fathers, and their families when asked to participate in a longitudinal study like NCS. One of our goals in this study is to identify the most effective materials and procedures for recruiting women, fathers, and their families into the study and keeping them invested over time. We invite you to participate in a study on these issues by participating in a focus group discussion.

If interested, we will try to accommodate your work and family schedules when selecting a time and date for these sessions. You will be asked to participate in one of these sessions; each session will not take longer than 1 hour. No personal information about you will be used to identify focus group participants.

We have enclosed the necessary forms for participation in this study. At this time, we ask that you review these forms and complete them if you are interested in participating.

We hope you will work with us on this very important project. If you have questions, please feel free to contact Lesley Cottrell at 304-293-1149 of Michelle Nesselrotte at 304-293-8056.