

DATE: October 1, 2010

TO: Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget

FROM: Dr. Jennifer Park

THROUGH: Dr. Steven Hirschfeld

SUBJECT: Request for Non-Substantive Change to National Children's Study, Vanguard (Pilot) Study (OMB Control #0925-0593, Expiration July 13, 2013)

CC: Dr. Sarah Glavin, Ms. Jamelle Banks, Ms. Mikia Currie

We request non-substantive change to the National Children's Study Vanguard (Pilot) Study protocol approved as revised by the Office of Information and Regulatory Affairs on July 23, 2010.

1. We ask that minimal visit instruments approved for use in the Alternate Recruitment Substudy (locations=30) also be approved for implementation in the initial Vanguard Study (locations=7). This alignment will assist in the evaluation of study visit measures over the course of the Vanguard Study while minimizing data collection until evaluation of study visit measures is completed. A list of these instruments appears in Table 1, below.
2. We also ask that instruments approved for use in the Alternate Recruitment Substudy be administered in alternate modes. Mode evaluation would assist in the development of efficient and less burdensome data collection for the Vanguard Study and Main Study. With an anticipated recruitment of 2,500 to 3,000 participants, each with multiple encounters, we believe we will have sufficient sample size to examine mode effects statistically. A list of these instruments and proposed modes appears in Table 2, below.

In separate requests, we will ask for OIRA approval of the revised Women's Informed Consent Form and new study instruments, which largely borrow from instruments previously approved by OIRA.

Table 1. Minimal Visit Instruments to be Implemented in Initial Vanguard Study

Item	Instrument Name	Initial Proposal		Proposed Change
		Strategy 1/	Clearance	Strategy
1	Address Lookup Tool	PBR	07/23/10	Same plus TT-LI
2	Pregnancy Screener (EH)	EHR, TT-HI	07/23/10	EHR, IVC
3	Pre-Pregnancy Visit Information Sheet	PBR, EHR, TT-HI	07/23/10	Same plus IVC
4	Pre-Pregnancy Interview	PBR, EHR, TT-HI	07/23/10	Same plus IVC
5	Pre-Pregnancy Visit SAQ	All ARS	07/23/10	Same plus IVC
6	Pregnancy Probability Group Follow Up - CATI Instrument	All ARS	07/23/10	Same plus IVC
7	Pregnancy Probability Group Follow Up - Self-Administered	All ARS	07/23/10	Same plus IVC
8	Pregnancy Visit 1 Visit Information Sheet	PBR, EHR, TT-HI	07/23/10	Same plus IVC
9	Pregnancy Visit 1 Interview	PBR, EHR, TT-HI	07/23/10	Same plus IVC
10	Pregnancy Visit #1 SAQ	PBR, EHR, TT-HI	07/23/10	Same plus IVC
11	Pregnancy Visit 2 Visit Information Sheet	PBR, EHR, TT-HI	07/23/10	Same plus IVC
12	Pregnancy Visit 2 Interview	PBR, EHR, TT-HI	07/23/10	Same plus IVC
13	Pregnancy Visit #2 SAQ	PBR, EHR, TT-HI	07/23/10	Same plus IVC
14	Birth Visit Information Sheet	All ARS	07/23/10	Same plus IVC
15	Birth Visit Interview	PBR, EHR, TT-HI	07/23/10	Same plus IVC

1/ARS: Alternate Recruitment Strategies, including Provider-Based Recruitment, Enhanced Household Recruitment, and Two Tier High-Low Recruitment.

IVC: Initial Vanguard Study Centers.

PBR: Provider Based Recruitment.

EHR: Enhanced Household Recruitment.

TT-LI: Two-Tier Low Intensity Recruitment.

TT-HI: Two Tier High Intensity Recruitment.

Table 2. Proposed Alternate Modes of Instrument Administration, by Minimal Visit Instrument

Item	Instrument Name	Initial Proposal		Proposed Change
		Mode	Clearance	Mode
1	Low-intensity Questionnaire (Non- & Pregnant)	CATI	07/23/10	Plus Mail/Web
2	Pre-Pregnancy Interview	CATI/CAPI	07/23/10	Plus Mail/Web
3	Pre-Pregnancy Visit SAQ	SAQ	07/23/10	Plus Mail/Web

1/CATI=Computer Assisted Telephone Interview. CAPI=Computer Assisted Personal Interview.

SAQ=Self Administered Questionnaire.