

DATE: March 31, 2011

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

FROM: Dr. Jennifer Park

THROUGH: Dr. Steven Hirschfeld

SUBJECT: Generic Sub-Study: LOI2-QUEX-25-B, "National Children's Study Recruitment and Retention Network" (OMB Control #0925-0590-6, Expiration June 30, 2011)

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

The National Children's Study (NCS) proposes to conduct a series of focus groups to systematically identify barriers to recruitment and retention in the NCS Vanguard Study for target populations, receive evaluations of existing recruitment materials/messages used in the NCS, and identify areas for improvement prior to launch of the NCS Main Study.

The information gathered from these focus groups regarding their understanding of the purposes of the Study will support enhancement of informed recruitment and retention of Study participants and engagement of stakeholders prior to NCS Main Study launch. Please see attached a project description and accompanying exemplar focus group materials. Exemplar materials will be customized as noted for each target population and collaborating NCS Study Center, as noted in the attached text. All project materials will be reviewed by appropriate local IRBs prior to use.

The aims, target groups, and procedures for information collection proposed align with the Request for Generic Clearance approved on 6/12/2008 (sections A.2; B.1; and B.2, respectively); the estimated 240 burden hours for this activity are available in the bank of hours awarded.

Table 1. Respondent Burden Table (OMB Collection # 0925-0590-6, Expiration Date 6/30/2011)						
Formative Research Project Number	Type of Respondent	Number of Respondents per Focus Group	Number of Focus Groups	Number of Focus Group Events	Hours per Response	Hour Burden
LOI2-QUEX-25-B	Age-Eligible Women, Mothers, Fathers	5	6	8	1	240

Attachments (4):

1. Formative Research OIRA Template, LOI2-QUEX-25-B
2. Exemplar Screening Tool, LOI2-QUEX-25-B
3. Exemplar Informed Consent, LOI2-QUEX-25-B
4. Exemplar Moderator's Guide, LOI2-QUEX-25-B