

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Centers for Disease Control and Prevention
U.S. ENVIRONMENTAL PROTECTION AGENCY



DATE: December 22, 2010

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

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) – Revision to 3-Month, 9-Month, and Health Care Provider Instrumentation

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 (OIRA) on September 22, 2008.

We request non-substantive change to the 3-Month and 9-Month Visit Instruments and the Health Care Provider Questionnaire of the National Children's Study for implementation in the Vanguard (Pilot) Study protocol among the seven Initial Vanguard Study Centers. These instruments were approved in concept by OIRA on September 22, 2008; they are now minimized in length, and therefore represent a reduction of anticipated burden to Study participants. Please see attached the referenced instrumentation for your consideration.

Attachments (3):

1. 3 Month Instrument (Minimal Visit Revision)
2. 9 Month Instrument (Minimal Visit Revision)
3. Health Care Provider (Minimal Visit Revision)