REQUEST FOR OMB CLEARANCE
Generic Clearance Renewal, OMB #0925-0590
Formative Research and Pilot Methodology Studies for the National Children's Study

Part A only

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Faced with the challenge of how to address the potential risks of many environmental factors that may be affecting the health and development of children, the President's Task Force on Health Risks and Safety Risks to Children concluded in 1999 that a large study to define the actual risks associated with broad environmental exposures is an essential first step. Following the recommendation of the task force, the U.S. Congress passed the Children's Health Act of 2000 which directed the National Institute of Child Health and Human Development (NICHD) to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial influences) on children's health and development. The National Institute of Environmental Health Sciences (NIEHS), the Centers for Disease Control and Prevention (CDC), and the U.S. Environmental Protection Agency (EPA) joined the NICHD in planning the study.

The Children's Health Act of 2000 (Public Law 106-310, Sec. 1004 shown in Appendix C.1) specifies that the study should extend from the prenatal period to adulthood, following a sample of children through their developmental life stages. It should investigate the short-term and long-term influences of physical, chemical, biological, and psychosocial environmental exposures on children's health and development, including not only physical health, but behavioral, emotional, and educational outcomes as well. The study should elucidate both those factors that protect children from detrimental outcomes and those that put them at risk. The study population must be sufficiently diverse to address the existence and consequences of health disparities among children in the United States. The scientific rationale for this program of research has evolved as the National Children's Study.

The National Children's Study rests on the principle that both health and susceptibility to disease are determined by dynamic processes that occur throughout life. Changes to these developmental processes can affect growth, viability, differentiation of major organ systems, and maturation, and specific health and disease trajectories. A range of determinants acting either in concert or synergistically may impact growth and development. These include the built and natural environments with their chemical and physical components, the social environment, individual behaviors, and biological factors, including genetics. Of particular importance are the earliest stages of human development, pregnancy and early childhood, when cell division, differentiation, and maturation are most rapid.

The National Children's Study (NCS) is the largest, long-term study of environmental and genetic influences on children's health ever conducted in the United States. By following 100,000 children from before birth to age 21, researchers hope to better understand how children's genes and their environments interact to affect their health and development. In the NCS, "environment" includes factors such as: air, water, and house dust; what children eat; how they are cared for; the safety of their neighborhoods; how often they see a doctor; and other factors. By tracking children's development through infancy, childhood, and early adulthood, the NCS hopes to identify the many factors that affect the developmental process and to assess

root causes of both good health and disease. Findings from the NCS will benefit *all* Americans by providing researchers, health care providers, and public health officials with information from which to develop prevention and treatment strategies and health and safety guidelines.

The **NCS Main Study** plans to follow a sample of 100,000 children, born to women recruited from about 105 proposed study locations (generally corresponding to counties) within the US, from before birth to age 21 years. By studying children through different phases of growth and development, researchers may be better able to understand the role these factors have on health and disease.

The National Children's Study is an observational research study. Participants will not be asked to change what they normally do, nor will they or their child be asked to take any medicines or drugs. Initially, researchers will collect information on women's pregnancies, including their diets, environments, chemical exposures, and emotional stress. When their children are born, and periodically thereafter, researchers will ask questions about the family and their environment, and collect biologic samples and environmental samples like air, water, and dust from their environments. Researchers will meet with families in both their homes and in clinical settings, and data also will be collected via telephone or mail-in questionnaires.

The NCS is unique because of its large size, broad scope, complex interactions among variables, and long-term time frame. Although other research efforts have incorporated some of these features, the NCS is unprecedented in its overall design and structure. To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the **Vanguard Study**. The purpose of the Vanguard Study is to assess the feasibility (technical performance and reliability), acceptability (impact on study participants and study infrastructure), and cost (level of effort, personnel, resources, and money) of the recruitment strategy, study logistics and operations, and study visit assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study. Currently, the Vanguard Study includes a component known as the Recruitment Substudy. The Recruitment Substudy is designed to conduct additional methodological research to evaluate the feasibility, acceptability, and cost of three specific alternate recruitment strategies for enrollment of pregnant women into the NCS: 1) Provider-Based Recruitment; 2) Enhanced Household-Based Recruitment; and 3) Two-Tiered "High-Intensity/Low-Intensity" approach.

In conjunction with the Vanguard Study and its Recruitment Substudy component, the NCS has conducted preliminary and proof-of-concept assessments of study recruitment, retention, and questionnaire items through smaller-scale **formative research projects** approved through OMB Generic Clearance (0925-0590). This clearance mechanism allowed preliminary, proof-of-concept evaluation of innovative recruitment and retention materials and approaches, as well as questionnaire items, needed to address the complexity of the NCS design in an efficient manner prior to further testing with a larger group of participants in the Vanguard Study, if warranted. Moreover, this clearance mechanism will allow the NCS to receive crucial feedback regarding questionnaire items and recruitment and retention materials from providers,

community representatives, and other stakeholders before these materials or approaches are presented to potential or actual NCS Vanguard participants. The NCS would continue to benefit from the burden and cost efficiencies generated by formative research projects reviewed through the generic clearance mechanism, since our efforts to systematically improve the study will continue, both before and after launch of the NCS Main Study.

A.2 Purpose and Use of the Information Collection

The results from formative research and methodology studies proposed will inform the feasibility, acceptability, and cost of NCS Vanguard and Main Study recruitment, retention, study visit measures and study logistics in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study.

Past information collection approved through the 2008 Generic Clearance mechanism included focus group and small, focused survey activities have informed outreach and engagement activities for the NCS Vanguard and Main Studies. Recruitment and retention activities also approved through this clearance mechanism continue to inform our approach to communicating Study goals to potential participants.

With this submission, the NCS seeks to renew its OMB generic clearance to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider feedback information collection surrounding outreach, engagement, recruitment, consent and questionnaire design, and retention activities.

Under separate request, the NCS also requests OMB generic clearances for formative research featuring environmental, neurodevelopmental, biospecimen, and study logistic information collection. These separate and distinct generic clearances will facilitate the efficiency of submission and review of these projects as requested by the OMB Office of Information and Regulatory Affairs.

A.3 Use of Information Technology and Burden Reduction

The specific focus of these formative research data collections is the improvement of recruitment, retention, and data collection methodologies for the NCS, and may include computer-assisted interviewing, automated data collection, and other procedures designed to decrease participant burden, study costs, and improve data accuracy. Other appropriate information technology solutions will be embraced to reduce respondent burden and improve data quality.

A.4 Efforts to Identify Duplication and Use of Similar Information

Formative research projects will be utilized as a way to demonstrate proof-of-concept in a manner that minimizes participant burden and study costs, prior to testing in the NCS Vanguard Study protocol if results warrant. For example, formative research projects submitted through this clearance mechanism may evaluate the efficiency of web-based instruments versus in-person self-administered questionnaires. In this example, if results suggest that responses to the web-based approach present lower participant burden and higher response rates at commensurate or reduced cost to the Study, the NCS may implement the web-based approach

in the context of the NCS Vanguard Study to further test logistics of implementation among a larger, and perhaps more diverse, study population. In this way, formative research projects will not duplicate, but rather, guide NCS Vanguard Study and Main Study information collection.

Additionally, formative research projects proposed would not impair our ability to evaluate the feasibility, acceptability, and cost of the recruitment and retention strategies tested within the scope of the NCS Vanguard Study. Specifically, for each formative research project proposed that relates to recruitment or retention methods, we will describe how implementation of these projects will: a) provide information not otherwise available to inform the NCS Vanguard or Main Study; and b) not impair evaluation of the Alternate Recruitment Substudy of the Vanguard Study. For example, a small, focused formative research survey of health care providers (in adjacent, but non-NCS eligible counties) regarding their preferences or recommendations to best communicate NCS goals could inform communication and recruitment in NCS-eligible counties featuring the Provider-Based Recruitment approach. For larger context, before the planning and initiation of the NCS was launched, an inventory and review of longitudinal studies was conducted. The review examined whether the study goals could be addressed without embarking on an entirely new study. The systematic review of all available longitudinal cohort studies found no study capable of answering the questions and concerns that led to the proposed National Children's Study regarding potential long-term effects in children from environmental exposures.

In addition, a systematic review was conducted to assess the information available to inform the experience of the Initial Vanguard Study with respect to recruitment and retention. The review found that there was insufficient information to enable the NCS to determine the feasibility, acceptability, and cost of alternate recruitment strategies for enrollment of pregnant women into the NCS. The literature on recruitment and retention strategies in epidemiological and clinical research did not include sufficient research on recruitment into studies that were comparable to the NCS in size, length, longitudinal design, scope of coverage, diversity of participants, and types of information requested. Nonetheless, lessons from other studies were identified and incorporated into the Recruitment Substudy design.

Recruitment and retention practices, outcomes, and "lessons learned" were reviewed from the following studies (among others): the National Health Interview Survey; the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial; the Early Childhood Longitudinal Studies (Kindergarten and Birth Cohorts); the Health Outcomes and Measure of the Environment Study; the Sister Study; the Family and Child Experiences Study; the Fragile Families and Child Well-being Study; the Survey of Income and Program Participation; and the National Health and Nutrition Examination Survey. The recruitment yields in these studies, the feasibility and cost data, and the differences in yields by respondent characteristics varied considerably. Consequently, reviewing this information has not been sufficient to build a model to determine the feasibility, acceptability, and cost of different recruitment strategies for the NCS Main Study, and a Recruitment Substudy is necessary to obtain this information.

Additionally, selected NCS Vanguard study visit assessment measures were revised based on data from the Initial Vanguard Study. These measures now require testing before implemented responsibly in the NCS Main Study. User acceptance testing complements, but does not

adequately replace, use and evaluation of measures in a large-scale data collection environment.

A.5 Impact on Small Business and Other Small Entities

The potential impact of these formative research projects on small businesses will include largely health care providers such as physicians, nurses, and others. Local NCS staff will work with physicians and other medical care providers or facilities to provide information about the study to their patients. With the consent of the participant, key medical diagnostic and treatment information on study participants will also be requested of medical providers. Where requested, the study will reimburse providers for any expenses incurred as part of filling requests for information.

A.6 Consequences of Collecting the Information Less Frequently

These formative research data collections will be conducted as needed on an on-going and concurrent basis, and are designed to decrease participant burden and improve data collection for the both the NCS Vanguard Study (currently on-going) and the NCS Main Study, a crucial requirement given the mandated scope of the Study. Without these small studies, data collection for the NCS is likely to be less efficient than it could be.

A.7 Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

There are no special circumstances that would cause this information collection to be conducted in a manner inconsistent with 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60 day Federal Register Notice regarding the NCS is published on pages 23608-23609 of the Federal Register on April 27, 2011.

Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. One of the individuals requested additional information about the study, particularly if the study was active in his local geographic area, and additional information was provided. The second verbal commenter requested a more detailed explanation of the formative research program, and expressed satisfaction that the NCS was proposing to do formative research and pilot testing before committing scarce federal taxpayer dollars to the full-scale study.

The two written comments were identical. They opposed the NCS in general, stating that it was too costly, and expressed concerns about the effects of federal programs. The comments are provided below:

I OPPOSE THIS LONGITUDINAL STUDY. I BELIEVE IT IS INEFFECTIVE AND IT IS ALSO TOO COSTLY. AND I DONT BELIEVE THE RESULTS WOULD BE TRUTHFUL BECAUSE THIUS AGENCY HIDES FROM THE PUBLIC. IT HAS SECRET, DECEPTIVE MEETINGS THAT NEVER INCLUDE MEMBERS OF THE PUBLIC TO SIT IN. IT HAS ALWAYS HAD SECRET MEETINGS WHERE THEY DO WHAT THEY WANT TO DO INSTEAD OF RESPONDING TO WHAT THE PUBOLIC WANTS AS PUBLIC SERVANTS. THIS AGENCY IS IN FACT OUT OF CONTROL. THIS IS MY COMMENT FOR THE PUBLIC RECORD. THIS AGENCY IN FACT HURTS CHILIDREN. 70 DOSES OF VACCINES

WITH TOXICES LIKE MERCURY, ALUMINUM FORMALDEHYDE, GELATIN WHICH COULD BE FROM MAD COWS AND OTHER TOXICS ALL INJECTED INTO KIDS. WITH NO REAL CUMULATIVE TESTING AT ALL DONE. I DO NOT WANT ONLY FAT CAT FEDERAL BURAEUCRATS SITTING IN SECRET TO MAKE HEALTH DECISIONS ANY MORE. ALL OF THEIR COMMITTEES SHOULD INCLUDE MEMBERS OF THE AMERICAN PUBLIC, CHOSEN AT RANDOM TO SIT IN TO BRING SOME COMMON SENSE TO WHAT THIS AGENCY IS GETTING AWAY WITH. MEMBERS OF THE AMERICAN PBULIC WITH NO FINANCIAL INTEREST IN DRUGS OR VACCINES SHOUDL SIT IN AS 51% OF ALL MEMBERS OF ANY DECISION MAKING COMMITTEE AND YOU HAVE TO EXPLAIN TO THEM WHAT YOU PLAN. BECAUSE YOUR PLANS ARE GOING COMPLETELY OUT OF CONTROL. WE ARE NOT "HERDS" .WE ARE PEOPLE WITH DIFFERNT SYSTEMS, DIFFERENT DNA, ETC. YOU CANNOT CONSIDER US A "HERD". YOU ALSO SEEM TO BE WANTING TO VIOLATE THE NUREMBERG DECISIONS, WHICH SAID PEOPLE HAVE THE RIGHT TO CONTROL THEIR OWN BODY. WHERE DO YOU GET OFF THINKING YOU CAN INJECT ANYTHING you WANT INTO SOMEBODY'S BODY. THAT IS OUTRAGEOUS. THEY PUT PEOPLE TO DEATH AND IN JAIL IN GERMANY FOR THAT CRAP AND YOU ARE APPROACHING THE SAME STUFF HERE IN AMERICA. THE SAME APPROACH. THE SAME WANTING TO DO TO SOMEBODY'S BODY WHAT YOU WANT. GET OFF IT PLEASE. YOU HAVE CAUSED THE AUTISM EPIDEMIC IN AMEICA AND THEN YOU HIDE FROM INVESTIGATING IT BECAUSE YOU KNOW YOU CAUSED IT.

Response to the comment(s): The National Children's Study was mandated by Congress through the Children's Health Act of 2000 (Public Law 106-310), which states:

PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.*
(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—*
(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.
(c) REQUIREMENT.—The study under subsection (b) shall—
(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;
(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and
(3) consider health disparities among children, which may include the consideration of prenatal exposures.

The NCS is designed to fulfill the Congressional mandate provided above. The generic clearance requested for formative research will enable the NCS to fulfill these requirements and produce research that benefits the American public, with the lowest possible burden and cost to taxpayers.

A.9 Explanation of Any Payment or Gift to Respondents

To maximize response rate, many research studies, particularly those involving medical procedures, offer compensation for participants. For example, the National Health and Nutrition Examination Survey (NHANES) has offered their participants compensation since the 1970's. Incentives are effective in increasing response rates for in-person surveys and can help increase response rates especially for minorities and low-income households.

Participants in NCS formative research projects and pilot studies will receive monetary and non-monetary incentives for their time, effort, and any expenses incurred (for example, transportation costs). The incentive amount will be determined by the amount of time required of the participant, as well as the type of activities that will be required. Incentive amounts will be consistent with the approved incentive schedule for the NCS Vanguard and Recruitment Substudy. We expect participants will receive a remuneration equivalent to $25 for completion of questionnaires ranging from 30-60 minutes to complete. Additionally, participants agreeing to provide biospecimen or environmental samples will be offered a monetary incentive or equivalent not exceeding $25. Should a particular formative research project proposed through this generic clearance request testing of a slight modification of the incentive structure described in Table A.1, we will provide appropriate justification in that request. Compensation amounts will be addressed specifically in IRB submissions for each pilot. Small gifts of appreciation for participation may also be provided to participants. These may include items of small monetary value (for example, t-shirt, tote bags, etc.) and are intended as tokens of appreciation.

Table A.1. NCS Incentives, by Study Activity and Impact on Participants

Data Collection Activity Characteristics	**Initial NCS Vanguard Study**	**NCS Recruitment Substudy and Formative Research Projects**	
		Phase 1	Phase 2 and FR
Time for encounter	3 hours	0.5 to 1 hour	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions	Few sensitive questions
Physical measures	Yes	No	No
Environmental specimens	Yes	No	Yes
Biospecimens	Yes	No	Yes
Participant observation	Yes	No	No
Monetary incentive, per visit	$100	$25	$25 for study questionnaires, plus $25 for any bio-specimens or any environmental specimens
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	As an alternative to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants in lieu	In addition to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the

	be offered to participants	of cash or local incentives not exceeding $25 in value and deemed non-coercive by local IRBs	participants if these are deemed acceptable by local IRBs

A.10 Assurance of Confidentiality Provided to Respondents

NCS formative research projects will follow the same procedures and standards of confidentiality applicable to the NCS Initial Vanguard Study and Recruitment Substudy. Participants will be informed about the Certificate of Confidentiality granted to NCS to protect data from involuntary disclosure.

The study centers, under contract to conduct the NCS, will have policies and procedures regarding confidentiality and protection of study data which will be reviewed and monitored by the NCS Program Office.

In addition to their own confidentiality procedures and policies, study centers will implement all federally required study-related confidentiality and data security procedures. All NCS Project Office staff, NCS study center staff, and other NCS contracting staff with access to NCS data must receive data confidentiality and security training provided by the NCS Program Office or its agent. These include completion of the NIH Computer Security Awareness Training, completion of a Human Subjects Protection Training, and signing an Assurance of Confidentiality or similar pledge that NCS data will only be used for the intended scientific purpose. All NCS Staff are required to complete security background checks consistent with Office of Personnel Management requirements. Only those cleared for Security Level D or higher will be eligible to request NCS data access.

To further assure confidentiality of participant data, the study will employ rigorous methods to provide security for personal identifying information. Each study center and the NCS Program Office Data Warehouse will be required to submit an NCS Security Plan and Assessment that complies with the Federal Information Security Management Act (FISMA) . This Security Plan will include: a) certification and accreditation of proposed data capture and case management software; b) configuration of those systems on study equipment; c) full disk encryption and two-factor authentication of study computers housing NCS data; and d) security assessment of the physical computing environment. After study centers complete the self-assessment of their security plans, the NICHD Chief Information Officer will review all study center security plans to determine study center's authority to operate. Frequent and regular monitoring visits will assist in compliance with these terms.

Privacy Impact Assessments will be conducted prospectively and recurrently as needed.

Specific NCS data and materials to be collected, disclosure review, and data access are described in detail in the Data Access and Confidentiality Committee Manual. Principles and policies are available at http://www.nationalchildrensstudy.gov/about/organization/dacc/Pages/PolicyManualandDataUseAgreements.aspx; the manual is available to the public upon request. Specifically, all NCS data files will undergo disclosure review for personally identifiable

information, using procedures consistent with or exceeding those named in Working Paper 22 of the Federal Committee on Statistical Methodology, and steps will be taken to appropriately manage disclosure risk. For example, genome-wide scans conducted on NCS specimens will be considered personally identifiable information and treated as such. Some biologic analyses (for example, HIV status, exposure to specific toxicants), results of some mental health screening tests, and reports of abuse are also considered sensitive.

A.11 Justification for Sensitive Questions

There are a number of questions that may be contained in NCS formative research questionnaires that could be considered sensitive such as pregnancy status, reproductive and medical histories, and income. As part of the informed consent process, women will be informed that their participation in NCS is voluntary and that they may refuse to answer any question. Fathers and other family members may also be asked to participate through the informed consent process. All study questionnaires that would be proposed for formative research under this clearance mechanism have been or will be reviewed by Human Subjects Review Boards at NICHD and participating institutions.

Each of these sensitive questions is necessary to allow comparisons between the formative research sample and persons potentially eligible for the Main Study, thereby informing whether proposed questionnaire items and recruitment approaches would warrant further testing in the NCS Vanguard Study.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Table A.2 Estimated Hour Burden and Cost for Formative Research and Pilot Testing

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested	Estimated Total Annual Respon-dent Cost
Small, focused survey and instrument design and administration	NCS participants	4,000	2	1	8,000	$80,000
	Members of NCS target population (not NCS participants)	4,000	2	1	8,000	$80,000
	Health and Social Service Providers	2,000	1	1	2,000	$20,000
	Community Stakeholders	2,000	1	1	2,000	$20,000
Focus groups	NCS participants	2,000	1	1	2,000	$20,000
	Members of	2,000	1	1	2,000	$20,000

	NCS target population (not NCS participants)					
	Health and Social Service Providers	2,000	1	1	2,000	$20,000
	Community Stakeholders	2,000	1	1	2,000	$20,000
Cognitive interviews	NCS participants	500	1	1	1,000	$10,000
	Members of NCS target population (not NCS participants)	500	1	1	1,000	$10,000
Total		**21,000**			**30,000 hrs**	**$300,000**

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

Participants will be reimbursed for any expenses resulting from their participation in formative research. This may include transportation costs to and from activities, and babysitting or elder care expenses. There are no other known costs to participants.

A.14 Annualized Cost to the Federal Government

The estimated cost to the federal government for these pilot and formative studies is $300,000 per year over the three year period.

A.15 Explanation of Program Changes or Adjustments

This request for renewal proposes both a program change and an adjustment in burden hours. We request generic clearance to conduct small, focused surveys and instrument design and administration, focus groups, cognitive interviews, provider feedback information collection surrounding outreach, engagement, recruitment, consent, and questionnaire design and retention activities for several groups of stakeholders, including NCS participants, (and, explicitly with this program change) members of the NCS target population who are not NCS participants, health and social service providers, and other community stakeholders.

We also request additional burden hours for these activities (see Table A.2). Information collected will inform outreach, engagement, recruitment, consent and questionnaire development, and retention activities for the NCS Vanguard and Main Study design while minimizing burden and cost that would have been anticipated had these tests occurred within the context of the Vanguard Study without benefit of prior testing.

Under separate request, the NCS also requests OMB generic clearances for formative research featuring environmental, neurodevelopmental, and study logistic information collection. These separate and distinct generic clearances will facilitate the efficiency of submission and review of these projects as requested by the OMB Office of Information and Regulatory Affairs.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The proposed data collections are focused survey and instrument design and administration, focus groups and cognitive interviews, intended to increase recruitment and data collection efficiency for the NCS. Each formative research project will adhere to a customized information collection evaluation and publication schedule, among other study deliverables. The studies will take place over the three year period specified in this submission.

A.17 Display of Expiration Date of OMB Approval

The NCS is not seeking an exemption from displaying the expiration date of OMB approval.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The NCS is not requesting any exceptions.