1SUPPORTING STATEMENT
U.S. Department of Commerce
U.S. Census Bureau
National Immunization Survey Evaluation Study
OMB Control Number 0607-<XXXX>

Part A - Justification

Question 1. Necessity of the Information Collection

On behalf of the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, the U.S. Census Bureau requests the authorization of the Office of Management and Budget (OMB) to conduct an evaluation study of an alternative sampling methodology for the National Immunization Survey (NIS). The purpose of this study is to explore how collaborating with the CDC and using the American Community Survey (ACS) as the sampling frame for selecting eligible households could result in improvements to the NIS. Use of the ACS as a sampling frame, which includes non-landline households and also identifies households with age-eligible children, would provide a more complete sampling frame for the NIS and could substantially reduce data collection costs.

The NIS is currently a continuing, nationwide random-digit-dialing (RDD) landline telephone survey of families with children aged 19 to 35 months, and teens aged 13-17 years, followed by a mailed survey to children's immunization providers. Since the survey's inception to the present, private contractors have conducted the NIS for the CDC. National, state, and local level estimates of vaccine-specific coverage, including newly licensed vaccines, are produced annually.

The NIS was established to provide an on going, consistent data set for analyzing vaccination coverage among young children in the United States and disseminating this information to state and local health departments and other interested public health partners. Legal authorization to conduct the survey is granted by Title 13, United States Code, Section 8 and by the Public Health Service Act, Title 42, United States Code, Sections 306 & 2102(a)(7). One of the goals of the 1993 Childhood Immunization Initiative was to achieve target vaccination coverage levels for 2-year-old children. One of the activities for meeting these goals was to improve surveillance for vaccine coverage As a result, funding for the NIS was provided and data collection began in April 1994. Subsequently, national Healthy People 2000 and 2010 objectives included targets for childhood and adolescent vaccination rates. Currently, the NIS provides vaccination coverage estimates annually for children aged 19-35 months and teens aged 13-17 years, by state and at least six city/county areas. The information collected is used to evaluate state and local immunization programs, to develop health care policies, and to assist in the determination of funding allocations for the Vaccines for Children (VFC) program. Since 1994, the VFC program has helped families of children who may not otherwise have access to vaccines by providing free vaccines to doctors who serve them.

In recent years, the NIS has covered a decreasing portion of the target population as more households rely solely on cell phone telephone service. Based on data from January-June 2008 from the National Health Interview Survey (NHIS), 29 percent of children under three years of age lived in households without landline services. Among households with both landline and cell phone service, some may primarily use their cell phones and be less likely to respond to calls to their landlines. As part of the CDC's continuing effort to evaluate and refine the NIS, this study is intended to explore how sampling from the ACS for households with age-eligible children having landline, cell phone only, and no telephone service could result in improvements to the survey, particularly in terms of coverage, response, and cost, and whether the ACS and supplemental administrative files can be used to identify a sufficient sample of children for national, state and local level assessment.

The overarching goal of this study is to evaluate the feasibility of using the ACS as the potential future sampling frame for the NIS. For this evaluation, the geographic scope of the study is limited to the state of Florida. A more comprehensive approach with a multiple state sample was not possible given available funds. However, by focusing on one state and including geographic sampling areas within the state, we can efficiently test all operational aspects of conducting the NIS with the Census Bureau using the ACS as the sampling frame. Evaluation of the study will include three areas of focus: frame coverage; non-response bias and response rates; and cost and operational aspects.

This evaluation will answer the key research questions for Florida. Findings comparing vaccination coverage estimates with the NIS to assess bias from exclusion of non-landline households will complement findings from other studies being conducted by CDC, including a national study using the National Health Interview Survey to estimate vaccination coverage for children in landline and non-landline households, an address-based experiment conducted with a contractor that will include national and local (Bexar County, TX) samples, a national cell-only sample conducted with a contractor, and a two-state study using Immunization Information Systems (IIS, or immunization registries) as the NIS sampling frame.

Findings related to the success of this study in including non-landline households in the sample, and in obtaining provider participation, are likely to apply broadly to other parts of the U.S. However, significant variations across states might be expected. Uncertainty in the degree to which study findings would generalize to other states will be taken into account when decisions are made regarding future design of the NIS. This will include evaluating potential cost and bias related to incorporating non-landline households into the sampling frame across different approaches (e.g., address-based frame to replace or supplement landline RDD frame, cell phone frame to supplement landline RDD frame, ACS frame to replace landline RDD frame). Qualitative evaluations will also factor into decisions, including operational aspects such as flexibility, timeliness and need to access data via a Census Research Data Center.

The primary research question asks if use of the ACS as a sampling frame significantly increases the proportion of children in the sample that live in non-landline households (households with only wireless phone service, or no phone service), which is zero in the current NIS. With a state sample size of 630, alpha at 0.05, and design effect of 1.4 (effective sample size 450), power is

90% to detect an increase of 10 percentage points in the percentage of the study sample living in non-landline households. The expected increase is over 30%, based on NHIS estimates for the first half of 2008 for children which indicated that 29% of children aged < 3 years lived in non-landline households (NCHS/CDC unpublished data).

Secondary research questions include:

- What is coverage bias in this study, and potential coverage bias in other states if the same survey design were used?
- Will use of administrative files to supplement the ACS sample be feasible, and how will this contribute to coverage bias?
- What is non-response bias in this study, overall and at each phase of the survey?
- Are vaccination coverage estimates in Florida from this study equivalent to estimates from the NIS?
- Are response rates for this study equivalent to NIS response rates in Florida?
- How effective is the field follow-up component in reducing coverage and non-response bias?
- What is the estimated cost for the Census Bureau to conduct the NIS in all states using the ACS as the sampling frame?
- What operational advantages and disadvantages would there be if the Census Bureau conducted the NIS using the ACS as the sampling frame?

Further discussion of outcomes and analysis plans of selected research questions follows below.

Evaluating frame coverage bias.
We will create overall estimates of the NIS frame coverage as a by-product of the weighting, as is done for the Current Population Survey and other surveys. The weighted NIS population totals will be compared with independent population estimates. The final step in the weighting will be to adjust the weights so that NIS estimates agree with those independent estimates.

To evaluate frame coverage bias based on the current NIS design, we will compare vaccination coverage estimates for children in landline households with the entire sample of children with adequate data from vaccination providers.

Using an expected effective sample size of 450 with adequate provider data, split into 315 landline and 135 non-landline children, and assuming that 315 households could have been contacted using the usual NIS sampling design and that 135 could not have been contacted, and assuming that the coverage among those that could have been contacted is 80%, the power for detecting a 10% difference using a test with significance level 0.05 is 80%. Assuming that the coverage among those that could be contacted is 90% (probably a more plausible assumption for most of the individual childhood vaccines) the power for detecting a 7% difference is 82%.

Evaluating non-response bias. Use of the ACS as a sampling frame provides a unique and rich set of information to assess non-response bias. The ACS includes several variables that are associated with vaccination coverage and included on the NIS, including race/ethnicity, level of

income and education of adults in the household, and health insurance status. Other variables available on ACS but not on NIS may also be associated with vaccination coverage and can be evaluated (housing characteristics, employment status). The characteristics of responders and non-responders to each phase of the survey will be compared. A simulation model will also be constructed to estimate phase-specific and overall non-response bias. Multiple imputation will be used to estimate the vaccination status of non-responders, which then allows comparisons of vaccination status between responders and non-responders. For estimation of overall non-response bias, we expect about 600 children each in response and non-response groups. Bias will be estimated before and after weighting adjustments. This approach will also be used to evaluate non-coverage bias in the current NIS design, by comparing actual/imputed vaccination coverage estimates for children in landline households with estimates based on the entire sample.

Comparison with NIS vaccination coverage estimates. To test the null hypothesis that the vaccination coverage rate for Florida from this study is the same as the coverage rate for the NIS (assumed true rate of 80%), with n=630, design effect 1.4 (effective n=450), power to detect a significant difference is 86% if the estimated percent is 74% and power is 78% if the estimated percent is 85%. Because of differences in sampling frames and follow-up procedures between surveys, interpretation of the difference in vaccination coverage rates will be of limited value. A secondary analysis will also compare vaccination coverage for the subset of respondents with landline telephones.

Evaluating response rates. Evaluation of potential frame coverage and non-response bias will be more informative for decision-making on future NIS design than evaluation of response rates. Response rates do not necessarily correlate with bias, and it is possible that improvements in frame coverage could be offset by increases in non-response bias. Household response rates from a landline RDD survey that screens for age-eligible households are not comparable to household response rates from a list sample of eligible households. However, we will evaluate response rates at all phases of this study for operational purposes. We will focus particularly on response rates related to the provider component of the survey, given concerns about lowered provider response rates associated with need for providers to obtain Special Sworn Status (SSS). Research based on NIS data has shown that non-response to the provider phase is likely missing at random after control for sociodemographic factors (Smith PJ, Marsh LC. Evaluating assumptions of weighting class methods for partial response using a selection model. Stat Med 2008;27(22):4569-80). This will be re-evaluated given the additional SSS step needed for this study. We will compare several provider-related response rates between this study and the NIS in Florida, including: proportion of respondents completing the interview through Section C that give consent to contact vaccination providers; proportion of respondents giving consent for whom adequate vaccination data is reported by vaccination providers; proportion of immunization history questionnaires mailed to providers that are returned with adequate information; and proportion of children for whom the interview is completed through Section C with adequate provider data (unconditional adequacy rate). The unconditional adequacy rate in the NIS is 70%. Among the 440 cases allocated to sample in each strata, we will assume that 30% will not yield a completed interview. Among the remaining 308 per stratum (x3=924 total), the power to detect a difference from the NIS rate is 90% if the unconditional adequacy rate from this study is 65%. Power will be higher to detect larger differences.

Costs of full-scale NIS. The Census Bureau has estimated the cost of conducting the NIS using the ACS as the sampling frame. Findings from this study will be used to revise the assumptions made in the cost model.

Question 2. Needs and Uses

The NIS is the largest survey ever conducted to assess vaccination coverage of young children and adolescents in the U.S. and is used to measure and assess changes in vaccination coverage levels over time. Also, the NIS helps track progress towards public health immunization goals. The purpose of this evaluation study is to determine if using the ACS as the frame from which to select the NIS sample will result in improvements to the survey, in terms of providing a more complete sampling frame, increasing response rates, and decreasing data collection costs. The evaluation study will be kept as closely as possible to the current NIS to allow comparisons, but plans are to incorporate innovations that could be implemented eventually as part of a full production survey. With the overall goal of improving response rates and coverage, possible experiments could include offering incentives to all sampled households or using different versions of the advance letter or screener to encourage participation.

The NIS is an important tool for measuring vaccination coverage levels for the nation; however, there are limitations and challenges that the current NIS faces. The NIS evaluation study provides the CDC with the opportunity to explore some possible changes to the survey methodology in an attempt to assess new options and refine current methods. One major design change is in the sample selection. The current NIS sample is selected by landline RDD, whereas the sample for the NIS Evaluation Study is a targeted sample of age-eligible respondents drawn from the ACS sample. Using the ACS as the NIS sampling frame provides a rich source of data for non-respondents and allows for more powerful weighting adjustments. Furthermore, the NIS RDD sample is limited to households with landline telephone service. However, the Evaluation Study sample will not only include households with landline service but also non-landline households (wireless service only) and households with no phone service. The information collected from the latter two groups will assist the CDC in assessing the potential bias in the current NIS estimates from the exclusion of these households. However, the success of the evaluation is contingent on the Census Bureau's ability to draw sufficient sample from the ACS for state and local area estimates.

The current NIS covers 56 core areas, including the 50 states and 6 substate areas. The states and substate likely to exhaust the ACS sample are: Delaware, District of Columbia, Philadelphia County, PA, Rhode Island, Vermont, and Wyoming. There is the potential that the NIS may exhaust the ACS sample in additional areas, depending on which additional substate areas NIS

plans to report vaccination rates for in 2012 and beyond. The Census Bureau's plan, however, is not to exhaust the ACS sample, so that the ACS could be used for other studies.

Information quality is an integral part of the pre-dissemination review of information disseminated by the Census Bureau (fully described in the Census Bureau's Information Quality

Guidelines). Information quality is also integral to information collections conducted by the Census Bureau, and is incorporated into the clearance process required by the Paperwork Reduction Act."

Question 3. Use of Information Technology

Respondents are households, with age-eligible children, and vaccination providers. Data collection for the NIS will use a multi-mode approach. First, computer-assisted telephone interviewing (CATI) will be conducted with households with age-eligible children (19-35 months) to collect information on the vaccinations received for each age-eligible child, as well as information on vaccination providers. Second, in-person follow-up interviews with a subsample of non-responders, including households with no telephone service, will be conducted. Due to constraints in time and resources, the follow-up interviews for the evaluation study will be conducted using paper-and-pencil interviewing methods. If the results from the evaluation study prove beneficial, in-person follow-up interviews for the national survey will be conducted using computer-assisted personal interviewing (CAPI) methods, whereby field representatives (FRs) collect the data from respondents using laptop computers. Third, vaccination providers will be contacted through the use of a paper mail-out/mail-back process. Providers will submit information on vaccinations administered and the dates the vaccinations were administered for each child 19 through 35 months of age. Only providers of age-eligible children whose parent or guardian participated in the telephone or paper follow-up survey and who gave consent to follow-up with the provider will be contacted. The provider information on the type of vaccine, the number of vaccinations, and the dates of vaccination will be used to estimate vaccination coverage levels; the information obtained from the parent or guardian will be used to evaluate the completeness of the provider-reported information.

For the NIS Evaluation Study, there are no plans at this time to explore offering providers with a secure and private way to use the Internet for reporting data via an electronic survey questionnaire. An independent study is under consideration to assess the willingness and capability of providers to submit data electronically, as well as the overall impact an electronic collection would have on burden, costs, and the timeliness in reporting the data. If the results of this independent study suggest that a secured online information collection would reduce respondent burden, decrease costs, and improve the timeliness and quality of data, then consideration will be given for adopting this means of collection for the national NIS.

Question 4. Efforts to Identify Duplication

As the current NIS will continue in production as a nationwide RDD survey during the time the NIS Evaluation Study is conducted, there will be duplication in the survey content between the two data collections. Duplication cannot be avoided as the current NIS data collection cannot be used or modified for the NIS Evaluation Study. The current NIS uses list assisted RDD sampling methodology, selecting a random sample of landline telephone numbers that contain at least one directory-listed telephone number. As a result, the sample is restricted to households with landline telephone service. An important feature of the sample for the NIS Evaluation Study is that it will not only be comprised of households with landline telephone service, but also

households with wireless only service and no telephone service. The information collected from households in the latter two groups is critical for it will enable the CDC to assess whether or not there is any bias in the current NIS estimates from the exclusion of these households. Furthermore, the duplication of the survey content is essential so that comparisons of the aggregated data results can be made to ensure that the quality of the data collected is maintained and the results are reliable. Also, the study will provide insight as to whether or not conducting the NIS as a non-RDD survey is cost effective and results in improvements in survey coverage and response rates.

Additionally, there is potential for households and providers to be selected for both surveys, as the RDD NIS will have sample cases in Florida, which is also the test site for the NIS Evaluation Study, at the time the evaluation study is conducted. To minimize duplication of sample cases selected, an option considered for implementation is a cross-reference check of telephone numbers between the two surveys. Any household selected for the NIS Evaluation Study whose telephone number matches the quarterly RDD NIS sample will be removed from the NIS Evaluation Study and not contacted to participate. For households that are inadvertently contacted for both surveys, the survey instrument for the NIS Evaluation Study will be designed to allow the interview to be terminated at the outset of the interview.

Question 5. Minimizing Burden

Small businesses or other small entities are not asked to report information.

Question 6. Consequences of Less Frequent Collection

The NIS Evaluation Study is a one-time undertaking to explore how collaborating with the Census Bureau and using the ACS as the sampling frame for selecting eligible households could result in improvements to the survey and reduce data collection costs. A private contractor currently conducts this survey as an RDD landline telephone survey for the CDC. Using the ACS as the sampling frame for the NIS will result in including households not only with landline service, but also non-landline households (wireless service only) and households with no phone service. The information collected from the latter two groups will assist the CDC in assessing any potential bias in the current NIS estimates from the exclusion of these households. Furthermore, without results to evaluate, the CDC will have no basis for launching the national survey with the Census Bureau as the data collection agent. Also, valuable information would be lost on whether changes to the sample design resulted in improvements in survey coverage and response rates.

Question 7. Special Circumstances

There are no special circumstances that would cause the information collection to be conducted in a manner not consistent with OMB guidelines set forth in 5 CFR 1320.9.

Questions 8. Consultations Outside the Agency

Staff from the Census Bureau and the CDC cooperated in defining the objectives and requirements of the NIS Evaluation Study, developing a sampling plan, and identifying the survey questions to be administered. The principal consultants outside the Census Bureau included Mr. Larry Wilkinson, Mr. James Singleton, Ms. Karen Wooten, and Dr. Phil Smith from the National Center for Immunization and Respiratory Diseases (NCIRD/CDC), and Ms. Marcie Cynamon from the National Center for Health Statistics (NCHS/CDC). Individual consultants from the Census Bureau included Ms. Cheryl Landman, Ms. Marilyn Monahan, Ms. Andrea Piani, Dr. Patrick Flanagan, Mr. Thomas Moore, and Dr. Kimball Jonas.

A notice was published in the *Federal Register* on October 2, 2008, Vol. 73, No. 192, page 57320, inviting public comments on plans to submit this request. We received one comment generally opposing the collection of the data and one comment suggesting ways to refine the evaluation study.

Summary of Comment: The Census Bureau should not get involved in the collection of immunization data as such an undertaking is the responsibility of the Department of Health and a duplication of effort.

Response: The CDC, a major operating component of the Department of Health and Human Services, requests that the Census Bureau conduct an evaluation of an alternative methodology for collecting childhood vaccination data. This project is a test of that methodology only, not an additional data collection activity. As the nation's largest statistical agency, the Census Bureau conducts numerous surveys and special studies on an ongoing, periodic, or one-time basis for other government agencies. It serves as the leading source of quality data about the nation's people and economy. It also protects the confidentiality of information in all of its activities - from data collection to the delivery of statistical products. Conducting this special study on childhood immunization coverage will enable the CDC to assess whether or not changes in the survey methodology will result in improvements to the current survey, along with a better understanding of the overall adaptability and flexibility of all systems involved in this effort. Furthermore, if the outcome of this project shows improvements to the current NIS, the CDC will be able to consider these results, along with various other factors, in making a decision about the future conduct of the NIS. One option could be having the Census Bureau serve as the only data collection agent for the NIS, which ultimately could result in savings of taxpayer dollars.

Statistics on vaccination levels are vital to ensure that children in the United States are being properly immunized to protect them from all of the diseases that have been, at one time or another, a serious threat to them. Most of these diseases are now at their lowest levels in history, due to immunization. Ultimately, by monitoring immunization coverage levels across the country, the CDC is able to assess the extent to which the immunization goals of the Childhood Immunization Initiative are being reached, and the success of the VFC entitlement programs. It also provides vital information on what portions of the target population are not receiving the required immunizations, which could potentially lead to the re-emergence of many serious diseases. Continuation of this program is of vital importance.

Summary of Comment: The federal government should take into consideration the following

factors in designing the NIS-ACS Evaluation Study, and in deciding the future methodology and mechanism for conducting the National Immunization Survey: scope of the NIS-ACS Evaluation Study; burden on survey respondents; impact of use of the ACS sampling frame as the future NIS mechanism on other related surveys; and timeliness and accessibility of NIS data.

Response:

Scope of the NIS-ACS Evaluation Study

The CDC will make decisions on future NIS methodology and mechanisms based on a comprehensive assessment of factors, including: data validity (e.g. continued viability of landline RDD frames); comparability of estimates over time and across states and other immunization grant areas; operational flexibility and timeliness; overall cost-effectiveness including impact on non-immunization surveys that utilize the NIS sample frame; and ability to meet national and state immunization program needs. Information to be used in these decisions will be based in part on quantitative and qualitative findings from the NIS-ACS Evaluation Study, as well as findings from other studies. Decisions on the future of the NIS will need to carefully weigh the advantages and disadvantages of available options, and it is likely that trade-offs will need to be made for any option chosen.

Because of funding constraints, it is not possible to conduct an evaluation of use of the ACS as the NIS sampling frame that replicates all aspects of the current NIS methodology. For example, only one state (Florida) will be included in the NIS-ACS Evaluation Study, with three sub-state sampling strata (Miami-Dade County, Duval County, and remaining areas of Florida). There are known variations in response rates across current NIS sampling areas, so results from Florida may not necessarily reflect what would be experienced if the study were conducted in all states. The plan to sample in three different areas of Florida will provide assessment across different population subgroups (e.g. race/ethnicity, urban vs. rural, types of vaccination providers). It will not be feasible to conduct an evaluation of the ACS sampling frame in all states, so if the NIS were to be conducted in the future using the ACS as the sample frame, initial sample planning assumptions would need to be made based on current NIS planning assumptions combined with findings from the NIS-ACS Evaluation Study. Adjustments in the sampling might need to be made over time to meet sample objectives. To provide the most valid comparison of response rates with other studies, the NIS-ACS Evaluation Study will incorporate the ACS response rates into the calculation of final study response rates.

An evaluation by the Census Bureau has identified several states for which the available ACS sample will not be sufficient to meet the needs of the NIS. If assumptions about response rates fall below expectations, further areas will have inadequate ACS sample availability. In response, the Census Bureau plans to use data from an information resellers (IR) file to identify households in the areas with limited ACS sample. Concurrence from the Social Security Administration has been granted to match these households to the SSA's Numident file. Date of birth information from the Numident file will be used to flag households with children of the correct age who are living in the sample area (per the IR file household/address). Flagged addresses will be compared with the pre-selected cases from the ACS sample. This supplemental sampling approach could

also be used for sampling of other sub-state areas of interest identified by state immunization grantees, an option provided by the current NIS. An evaluation of the usefulness of this alternative sample frame will also be conducted.

The use of the ACS as a sample frame raises other sampling considerations, including the definition of the target population. The current NIS weights to the U.S. population of children aged 19-35 months as of the middle of the data collection year. The actual sample consists of children born over a span of three annual birth cohorts. There will be an approximate seven month lag between rostering of household participants in the ACS until the household is eligible for recontact for the NIS-ACS Evaluation Study. Thus, age-eligible households that move into the sampling area during this lag period would not be reachable by the study and the definition of the eligible target population adjusted accordingly. The NIS-ACS Evaluation Study will include a protocol for tracking and locating movers. The process of tracking and locating movers will be evaluated.

Findings from other studies will be assessed in making decisions about the future methodology and mechanism for conducting the NIS. These include evaluation of potential bias in NIS estimates because of exclusion of non-landline households, evaluation of approaches to supplement the landline frame with a sampling frame that includes non-landline households, and evaluation of new sampling frames that include landline and non-landline households. Studies to evaluate potential bias include a simulation model of non-response at each stage of the NIS that synthesized available data related to non-coverage and non-response bias, and analysis of key health indicators by telephone status (landline vs. non-landline) based on the NHIS. Results from these studies so far do not provide evidence of significant bias in NIS estimates. However, these studies do not provide direct evidence for, or against, bias. More definitive results may be obtained from a follow-up with vaccination providers of children in households participating in the NHIS, initiated October 2008.

Even if there is direct evidence of low levels of bias in NIS estimates generated from a landline sampling frame, the continued increase in children living in non-landline houses and relatively low household response rates raise questions about the continued credibility of the survey and need for continual communication of complex concepts to convince data users of survey validity. CDC is working with the current NIS contractor, National Opinion Research Center (NORC) to evaluate dual frame designs that add a cell phone sampling frame or sample from an Immunization Information System (IIS). However, findings so far indicate much lower response rates for cell phone as compared to landline frames, at much greater expense. Further research is being conducted to evaluate representativeness of cell phone respondents. Use of IIS to supplement landline frames is potentially cost-effective since age of children is known, but household contact information is not standard in all IIS, not sufficient even in more well developed IIS, and logistics and cost of dealing with an independent IIS in each state needs further evaluation for feasibility. CDC will also be conducting research in 2009 with NORC to evaluate the feasibility of using an address-based sampling frame to conduct the NIS. Findings from these research studies will be available and utilized in decisions about the future of the NIS.

Burden on survey respondents

Any follow-on survey using the ACS as a sampling frame creates additional burden on these households. ACS respondents are informed that they may be contacted in the future for other surveys, and a household may only be selected for ACS once every five years. Participation in follow-on surveys is voluntary.

The ACS frame is intended to provide a cost effective way to identify rare and difficult to reach populations, including young children, for federally funded research. In 2006 the ACS had a sample size of over 2 million households, and obtained approximately 1.5 million interviews, in the 50 states and the District of Columbia. The 32,000 NIS households needed for full implementation of the NIS is 1.5 percent of the ACS sample and 2.2 percent of the number of ACS interviews. The policy on using the ACS as a frame for reimbursable follow-on surveys can be found in Attachment A.

To maintain confidentiality under the Census Bureau's Title 13 authority, only persons with Special Sworn Status can know the identity of the children who are participating in this survey. Section 23c of Title 13 in the United States Code provides authority for the Census Bureau to swear in people to assist the Census Bureau in performing its duty. For the NIS Evaluation Study, the Census Bureau will ask staff in the providers' offices to complete an Immunization History Questionnaire for each child participating the survey. The medical providers and support staff who will receive or be privy to information about the individual child(ren) must complete and submit an Immunization Survey Special Sworn Status form before the Census Bureau can mail the child(ren)'s identifying information. A list of steps for the medical staff to follow to maintain confidentiality under Title 13 will be included with the initial packet sent to providers and in follow-up packets that contain personal identifiable information. To help minimize the additional burden, the forms will be preprinted with the name and address of the provider's practice.

Under the Privacy Rule, patients have a right to an accounting of disclosures that have been made of their identifiable information for public health and research purposes. The Census Bureau will supply the medical providers and support staff with all of the necessary documentation they will need to account for the NIS Evaluation Study disclosures. The accounting notices provided will generally state that the medical records were accessed by the CDC.

The Privacy Rule does not require a notation in each medical record that has been accessed by public health authorities, as long as the information required under the Privacy Rule is included in the accounting for disclosure. The Health and Human Services Office of Civil Rights does not recommend placing this information in each medical record.

<u>Impact of use of the ACS sampling frame as the future NIS mechanism on other related surveys</u>
With the recent recommendation of three new vaccines for adolescents, including the human papillomavirus vaccine, the CDC initiated the NIS-Teen survey in 2006. The NIS-Teen was conducted as national surveys in the fourth quarters of 2006 and 2007, then expanded to a state-level survey starting in 2008. The NIS-Teen uses the NIS sampling frame to identify households with children aged 13-17 years, and follows similar methods as for 19-35 month old children to

collect and assess vaccination coverage. Although the NIS-ACS Evaluation Study will not include the teen component, the NIS-Teen would be included if the CDC decided to use the ACS as the NIS sampling frame in the future. Also included would be topical immunization-related modules added to the end of the NIS household survey. Recent modules implemented on the NIS include questions on parental concerns about vaccination.

To capitalize on the extensive household screening necessary to reach NIS targets for households with children aged 19-35 months, the NCHS/CDC, initiated the State and Local Area Integrated Telephone Survey (SLAITS). SLAITS has been used in recent years to conduct large, state-level surveys of children, including the National Survey of Children's Health, the National Survey of Children with Special Health Care Needs, and the National Survey of Adoptive Parents. This mechanism has provided a cost-effective platform for these important health surveys.

SLAITS was created to make efficient use of the sampling frame developed for the NIS. Should that frame no longer be available, NCHS would consider other frame options including but not limited to the ACS. Each option would have strengths and weaknesses related to cost, coverage, timing, access, and response rates.

Unlinking of the NIS and other non-immunization surveys would not allow cross-cutting research that linked immunizations to other factors not collected by the NIS (e.g., vaccination status of children with special health care needs).

With each loss there is a benefit and with each benefit, a loss. Separating the NIS from SLAITS does end the limited ability to analyze the overlapping population in the health context but linkage to the ACS and operating under the aegis of Title 13 opens other doors.

The long-term viability of landline RDD frames to conduct such studies is questionable, and sponsors of SLAITS surveys should be evaluating options for conducting their surveys independent of the NIS sampling frame. SLAITS surveys typically have lower response rates than NIS surveys because of the "do not harm" principle that requires NIS surveys to be conducted first (e.g., advance letters to households mention the immunization study but not specifically other SLAITS surveys). In some instances, SLAITS surveys have required supplementation of the NIS RDD sample frame to meet sample size targets in some states. With addition of the NIS-Teen component to the NIS at the state level in 2008, the available sample for SLAITS has been reduced.

Timeliness and accessibility of NIS data

The NIS is conducted based on quarterly samples and primary results for a calendar year of data collection are available within six months after the end of the data collection year. A summary report is published by summer or fall by CDC with key results, an extensive set of tables and maps are posted online simultaneous with publication of the report, and a public use file meeting disclosure review requirements is released. It is expected that the Census Bureau would provide this information on the same timeline, if the NIS uses the ACS with supplemental sampling sources as its sampling frame.

Currently, CDC staff publish extensively using the confidential NIS data, with direct access from CDC offices. If the NIS were conducted using the ACS as it sampling frame, the data would be protected under the authority of Title 13, which would require establishment of a Census Bureau Research Data Center in Atlanta. CDC staff would need to obtain Special Sworn Status to access the data, perform data analysis within the secure environment of the Research Data Center, and have results and tabulations to be accessed outside the Research Data Center or published cleared after disclosure review by Census Bureau staff. For the NIS-ACS Evaluation study, CDC staff will access the data from the Research Data Center located at Census Bureau headquarters in Suitland, MD.

CDC has initiated discussions with local universities in the Atlanta area about creating a consortium to apply for establishment of a Research Data Center. The Research Data Center or a satellite office could be established in a location convenient to CDC staff with primary responsibility for analyzing the NIS data. The end-result would likely cause some delays in publishing data or responding to ad hoc requests from CDC leadership or outside partners. And, while there may be delays initially as with any new system, once the logistics are worked through, the timing should improve.

The Census Bureau has cultivated effective partnerships with organizations with important administrative records that may benefit the NIS. Collaborations with the Social Security Administration and the Centers for Medicare and Medicaid Services allow access to a number of administrative records files. Innovative applications of administrative records, such as the development and implementation of record linkage techniques may improve data collection by aiding in targeting age-eligible children and using existing data sets to the maximum extent possible.

Question 9. Paying Respondents

Although payment or gifts to respondents are not provided in return for participation in the survey at this time, we may include the use of incentives as an experiment. Should we develop a plan for the use of incentives, we will submit this plan separately for OMB.

Question 10. Assurance of Confidentiality

All information collected about individuals or households is confidential by law Title 13, United States Code, Section 9. Only Census Bureau employees or Special Sworn Status employees sworn to preserve this confidentiality may see the survey responses. In a letter signed by the Director of the Census Bureau, sent to all participants in the survey, respondents are informed of this law and assured that it requires the Census Bureau to keep all information provided by the respondent confidential. The letter also informs respondents that this is a voluntary survey. Furthermore, in addition to the legal authority and voluntary nature of the survey, the letter informs respondents of the public reporting burden for this collection of information, the principal purposes for collecting the information, and the various uses for the data after it is collected which satisfies the requirements of the Privacy Act of 1974.

To maintain confidentiality under the Census Bureau's Title 13 authority, only persons with Special Sworn Status can know the identity of the children who are participating in this survey. Section 23c of Title 13 in the United States Code provides authority for the Census Bureau to swear in people to assist the Census Bureau in performing its duty. For the NIS Evaluation Study, the Census Bureau will ask staff in the providers' offices to complete an Immunization History Questionnaire for each child participating the survey. The medical providers and support staff who will receive or be privy to information about the individual child(ren) must complete and submit an Immunization Survey Special Sworn Status form before the Census Bureau can mail the child(ren)'s identifying information. A list of steps for the medical staff to follow to maintain confidentiality under Title 13 will be included with the initial packet sent to providers and in follow-up packets that contain personal identifiable information.

The Immunization Survey Special Sworn Status form the medical providers and their support staff will sign to uphold Title 13 confidentiality of the children who are participating in this survey is currently in draft form. The Legal and Policy offices at the Census Bureau are in the process of revising the language in Part C – Oath of Nondisclosure to bring clarity to the meaning of the oath. This form and the Explanation of the Immunization Special Sworn Status document will be updated once a decision is reached on the alternative language. The final versions of these forms will be submitted to OMB as a non-substantive change.

Question 11. Justification for Sensitive Questions

Questions relating to immunizations administered, which will be asked in this survey, may be considered private or of a sensitive nature. Asking these questions is necessary in order to monitor rates of vaccination among children in the United States. Other questions asked that could be considered sensitive in nature include family income and family participation in the Women, Infants, and Children (WIC) program, a special nutrition and health program. Income is important in analyzing the immunization information collected as it helps in learning whether persons in one socioeconomic group continue to use medical services more or less than those in another group. Also, it is important to know whether or not children are enrolled in WIC in order to evaluate program success in improving vaccination coverage for low-income and minority children, compared to their counterparts. For these questions, and for any other questions asked in the survey, respondents have the option of refusing to answer.

Question 12: Estimate of Hour Burden

Data collection for the household component of the NIS Evaluation Study will be conducted within a 1-month (31 day) period. A total of approximately 1,307 households with age-eligible children (19-35 months) will be asked the NIS Questionnaire to determine how many of the 1,320 sample children are receiving all of the recommended childhood vaccinations. Approximately 1 percent of the households will be administered only the screening portion of the questionnaire, which is designed to filter out those households that do not have age-eligible children living or staying at the household at the time of the interview. We estimate the average length of the NIS interview for these households will be two minutes. The residual of this group of respondents are those households who have age-eligible children. We estimate the average

length of the interview for these households will be a total of 28 minutes, which includes two minutes for the screener portion of the interview. The majority of these households, approximately 99 percent, will have only one age-eligible child for which collection of immunization information is needed. The estimated length of the interview for these households is 28 minutes. For the remaining households, those with more than one age-eligible child, the estimated length of the interview is 35 minutes.

Respondents will be asked to respond to this survey only once during the one-month interview period. Total respondent burden is approximately 616 hours.

	Interviewed (Screener – no eligible child)	Interviewed (Only 1 age-eligible child)	Interviewed (More than 1 age-eligible child)	TOTAL
No. of respondents (Households)	13	1,294	13	1,320
No. of responses	1	1	1	1
Total responses	13	1,294	13	1,185
Est. Number of hours per response	.03	.47	.58	1,320
Est. Total hours of respondent	0.4	608.2	7.5	616

Data collection for the provider verification component of the NIS Evaluation Study will be conducted over a 5-month period. Approximately 1,661 health care providers (doctors/clinics) in the state of Florida could potentially be asked to provide child vaccination history information by completing the Immunization History Questionnaire. The purpose of the provider record check is to obtain complete, detailed and accurate vaccination dates and types of vaccinations received by children aged 19 to 35 months. Studies have shown that parental recall of childhood vaccines is not sufficiently accurate. Also, not all parents retain vaccination records, and these records may not be up-to-date. For this reason, the NIS was initiated in 1994 with a provider record check component to replace the U.S. Immunization Survey, which utilized the Current Population Survey sampling frame and relied on parental report of child vaccination. Information on parental-reported vaccination (by recall or from parent-held vaccination records) will be used in the determination of adequacy of the provider-reported information. Only children with adequate provider data will be used for estimation of vaccination coverage, while information for other children will be used in development of survey weights. Approximately 23 percent of the sample children will have more than one immunization provider who will be asked to respond to this survey during the 5-month period for the Provider Component. Therefore, we estimate that 1,661 providers will be contacted. Total provider respondent burden is approximately 980 hours. The Immunization Survey Special Sworn Status form is estimated to take 10 minutes to complete, while the Immunization History Questionnaire is estimated to take 15 minutes for each child.

	Special Sworn Status	Interviews (Immunization History Questionnaires)	Total
No. of respondents (Providers)	1,661	1,661	1,661
No. of responses	2	1	
Total responses	3,322	1,661	4,983
Est. Number of hours per response	.17	.25	
Est. Total hours of respondent	565	415	980

The cost of the office staff's time to respond is estimated to be $21,378.70. This amount is calculated by multiplying half of the total annual burden hours 490 by the current hourly wage rate of $13.59 for a medical office manager, and the other half of the total annual burden hours by the hourly wage rate of $30.04 for a registered nurse.

Question 13: Estimate of Cost Burden

There are no costs to respondents other than their time to respond. The information requested from providers is of the type and scope normally included in medical records and no special hardware or accounting software or system is necessary to provide answers to this information collection. Therefore, respondents are not expected to incur any capital and start-up costs or system maintenance costs in responding. Further, purchasing of outside accounting or information collection services, if performed by the respondent, is part of usual and customary business practices and not specifically required for the collection of this information.

Question 14: Cost to the Federal Government

The estimated cost to the Federal Government for the planning, implementation, and processing of the NIS Evaluation Study is $2,666,337. The CDC of the U.S. Department of Health and Human Services bears all costs of the survey.

Question 15. Reason for Change in Burden

The increase in burden hours is attributable to the information collection being submitted as new.

Question 16. Project Schedul
e

In September 2008, the project development activities for the NIS Evaluation Study began and will continue through May 2009. This includes activities such as developing an overall project

plan, selecting a sample of households from the ACS with age-eligible children (19-35 months), and developing a myriad of data collection materials (survey instrument/questionnaire, respondent letters, interviewing manual, and interviewer training materials, and so forth).

Focus group sessions with physicians/health care providers will be conducted. The focus groups will be conducted in early 2009.

Data collection activities (CATI interviewing) will begin in June 2009 with the mail-out of an introductory letter to potential respondents. Actual collection of the data will begin in July 2009 and will continue for one month (31 days).

The field follow-up interviewing operations, which for the evaluation study will be conducted through the use of the paper-and-pencil interviewing methods, will be completed in mid-September 2009.

The immunization provider component will begin in July 2009 and will continue through mid-December 2009. A data file of the unedited results of the evaluation study will be provided to the CDC by the end of January 2010. The CDC will evaluate the data from the study and provide a final decision by August 2010 as to whether or not to move forward with the Census Bureau in launching the NIS. No data estimates will be published based on the results of the evaluation study.

Question 17. Request to Not Display Expiration Date

The OMB number will be displayed on all public-use forms, including electronic instruments, used to collect information from the public. Form BC-1759(P) is the Special Sworn Status form that providers will be asked to fill out and sign before receiving confidential information, including children's names and birthdates. As part of the Special Sworn Status operation we will provide a cover sheet that will be affixed to the SSS Form. This cover sheet will provide additional explanation of the form along with instructions for filling it out. We will place the OMB expiration date on this cover page. We are concerned the presence of an expiration date on the BC-1759(P) may cause individuals confusion as to when their Special Sworn Status expires. By signing the form BC-1759(P), an individual is sworn to maintain the confidentiality of the data as a lifelong responsibility, without exception or expiration. Including the expiration date on the actual Special Sworn Status form may lead some who sign it to believe that their Special Sworn Status has an expiration date. Including the expiration date on the cover sheet affixed to the Special Sworn Status form may help to avoid misarticulating the intent of Special Sworn Status as a lifelong commitment and legal responsibility.

Question 18. Exceptions to the Certification

There are no exceptions to Certification for Paperwork Reduction Act Submissions. Collection is

consistent with the guidelines in 5 CFR 1320.9.