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

## Part B - Collections of Information Employing Statistical Methods

Question 1. Universe and Respondent Selection

The potential universe for the household component of the NIS Evaluation Study includes households located in Florida, with children who will be aged 19-35 months at the time of interview. The three specific areas of interest are Florida's Miami-Dade County, Duval County, and the balance of Florida. The total sample will be divided equally among these two counties and Florida-Rest of State. The primary sampling frame for the NIS Evaluation Study is the ACS.

Several design considerations led to the decision to focus this evaluation on one state rather than a national sample. To improve response rates and test the feasibility of in-person follow-up, a localized sample was needed that could be covered by one regional field office. A more comprehensive approach with a multiple state sample was not possible given available funds. Florida specifically was chosen because a large proportion (5.4%) of the U.S. population of children aged 19-35 months resides in Florida (4$^{th}$ largest state for this population behind CA, NY and TX), Florida has a diverse racial/ethnic population, and the field operation in Florida could accommodate the timing and scope of this evaluation study.

Three areas within Florida were chosen to increase statewide sample size and to include an area (Duval County) for which the available ACS sample was insufficient and would need to be supplemented by an alternate sample frame. This will allow an evaluation of use of this alternate frame. Study questions can be evaluated across the three areas to provide information on the possible variations that would be expected if the NIS were conducted using the ACS sampling frame in full-scale production. The particular areas within Florida (Dade County, Duval County, rest of FL) were chosen based on past NIS sampling, which has stratified on one or both of these areas. Also, these three areas differ in terms of poverty level, racial/ethnic distribution, proportion of children vaccinated by public providers, and urbanicity (NIS 2006 results, http://www2a.cdc.gov/nip/coverage/nis/nis_iap.asp?fmt=d&rpt=tab33_dem_iap&qtr=Q1/2006-Q4/2006 ). In 2009, the NIS continues to stratify the sample by these three areas in Florida but will have adequate sample size only for statewide estimates.

The ACS uses the Master Address File (MAF), which contains a listing of all living quarters in the country. The MAF was initially developed by matching three files: the U.S. Postal Service "Delivery Sequence File" (DSF); the 1990 Decennial Census "Address Control File" (ACF); and the Census Bureau's "Topologically Integrated Geographic Encoding and Referencing" (TIGER) database. The MAF is updated biannually using the most current DSF, along with information obtained from other census surveys and Census Bureau sponsored field listing operations in targeted areas.

As the available sample of ACS households with children aged 19-35 months in Duval County is not enough to reach the sample target of 440 cases for the evaluation study and barely enough in Miami-Dade County, an Information Resellers (IR) file will be used to supplement the actual sample in Florida with IR cases. The Census Bureau will use data from the IR file to identify households in Duval Country and match those households to the SSA's Numident file. Date of birth information from the Numident is 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 then be compared with the pre-selected cases from the ACS sample and unduplicated.

The IR file used for this study contains 132.8 million housing units, and of those units 1.1 percent have incomplete addresses. Agreement between the geocoded IR records and the MAF is 95.3 percent. The IR file is missing some units in multi-unit dwellings; its coverage is better at the basic-street-address level. In addition to address and telephone contact information, the file contains household demographics; housing tenure; and modeled income, asset, and liability categorical data. Certain data from the IR file have been deemed unusable. Tabulations of the Child Present variable on the IR file did not compare favorably with expectations based on other Census data. Children's ages are provided; we are evaluating the quality of the data, conditional on the validity of the child present flag. The distribution of phone types has also raised concerns. Mobile phones are listed in the phone type variable, however the fill rate is very low. The Census Bureau will continue to evaluate the coverage and quality of variables from the IR file.

According to the National Center for Health Statistics there were 4,317,119 live domestic (50 states and DC) births in 2007 and 1,837,806 domestic births between and including August and December of 2006 for a total of 6,154,925. The Numident file used (cut early March 2008) shows 6,103,324 SSN registrations for domestic born children during that time period. If we neglect infant mortality prior to the opportunity for SSN registration, this suggests that among the domestic born for the target birth date interval upwards of 99% of U.S. born children are captured in the Numident file. Since data on immigration is less precise or available, it is unclear to what degree foreign born children are captured on Numident, but as tax advantages (as well as program access and accounting advantages) accrue to parents of newborns who acquire SSNs, we believe that coverage of foreign born children (of legal residents) is also nearly complete.

The Census Bureau receives quarterly updates for the Numident and processes the data once per year. The time sensitivity of the Numident data is quite low since the file was used to identify households with children of the target age range – and not to locate these children geographically Locating the parents in the household was performed using the IR file, which was two months out-of-date at the time of this operation: we used a December 2008 file in February of 2009.

Overall response rate expectations for the NIS Evaluation Study are based on an expected attrition rate from initial sample to person interview and an estimated response rate during the provider follow-up component. The expected attrition rate from the initial sample to completed person interview is approximately 27 percent, based on findings from another study done for the National Epidemiologic Survey of Alcohol and Related Conditions (NESARC) that used the ACS as a sampling frame. This produces an estimated 319 cases from an original sample of 440, for provider follow-up in each of the three areas of interest. Since the impact of the Special Sworn Status requirements on the response to the provider follow-up portion of the study are

unknown at this time, we are estimating a range of response between 70 – 80%, yielding 223 – 256 completed cases respectively. The minimum number of completed cases required by CDC to reach statistical conclusions is 210.

NIS sample sizes are based on achieving a desired level of precision of survey estimates rather than statistical power considerations. Assuming a vaccination coverage rate of 80% and a design effect of 1.4 in the NIS, approximately 210 cases with adequate provider data will be required to obtain vaccination coverage estimates with a coefficient of variation of 0.04 or 4%. The usual NIS area-specific effective (assuming design effect of 1) sample size target is set at 180, which yields a coefficient of variation of 0.075 or 7.5% for a prevalence of 50%. Area-specific samples sizes for the evaluation study were designed to be similar to the current NIS.

Question 2. Procedures for Collecting Information

The NIS Evaluation Study is designed to measure the immunization coverage for the target population - the non-institutional resident population aged 19-35 months in Florida's Miami-Dade and Duval counties, and the balance of Florida. The list used to reach the target population is the addresses of all living quarters in these areas compiled from the ACS.

**SAMPLING**

*Overview and Description of Universe*
The sample for the NIS Evaluation Study will consist of 1,320 Florida households with children aged 19-35 months in July 2009: 440 such households in Miami-Dade County, 440 in Duval County, and 440 in the balance of Florida. (Throughout this section, "the balance of Florida" will mean all of Florida except Miami-Dade and Duval Counties, regardless of context.)

For Miami-Dade County and the balance of Florida, the sample universe will consist of all retired ACS households in those areas that reported a child who will be between 19 and 35 months old in July 2009. ACS cases in sample from August 2006 through December 2008, inclusive, that had children born between August 2006 and December 2007, inclusive, were eligible for the NIS evaluation study.

For Duval County, the primary component of the sample universe will consist of all retired ACS households in those areas that reported a child who will be between 19 and 35 months old in July 2009 with additional sample drawn from an IR file.

The interviews will first be attempted by telephone with calls to households. The interviewers making the calls will be working from one or more of the Census Bureau's three centralized telephone facilities. Census Bureau interviewers will ask questions about the immunization history of the children aged 19-35 months, and will request contact information for the child's health care provider and permission to request the children's immunization records from the provider.

*Statistical Methodology for Stratification and Sample Selection*
There will be three geographical strata in the NIS Evaluation Study: Miami-Dade County, Duval

County, and the balance of Florida. Within the Miami-Dade County and the balance of Florida strata, sample will be selected systematically with probability proportional to the product of two ACS weights: baseweights and factor for probability of selection for personal visit follow-up. In Duval County, all of the eligible ACS sample will be selected, and additional sample will be selected from the IR file.

*Estimation Procedures*
For the Miami-Dade County and the balance of Florida strata, the estimation procedure will, for the most part, follow the usual statistical principles used in other surveys. The final weight for each case will be the product of the inverse of the selection probability (accounting for selection to the ACS and selection into the NIS Evaluation Study), a weight adjustment to account for noninterviews, and a final-stage weighting factor to bring sample estimates into agreement with independent population estimates by race and ethnicity of householder.

The Duval County estimation procedure will follow the same model, but will differ due to the inclusion in the sample of records from the IR file. For ACS only cases, the weight will be the inverse of prob(in ACS)*prob(sel for NIS). For dual frame cases, this is part of the weight, but prob(sel for NIS) =1. By including an unduplication effort between ACS and and IR frame, the base weight will be the inverse of: prob(in ACS)*prob(sel for NIS) + prob(sel from IR) - prob(both).

*Degree of Accuracy Needed For the Purpose Described in the Justification*
The CDC has determined that a minimum of 210 completed interviews with adequate health care provider data on immunizations are needed to reach statistical conclusions of any value. Based on the Census Bureau's past interview completion rates with follow-on surveys to the ACS, and the NIS' rates in obtaining provider data once an interview is completed, it was determined that a minimum sample size of 400 would be necessary to reliably obtain 210 completed interviews with provider data. A reserve sample of 40 cases has been added to each of the specific areas in Florida.

*Unusual Problems Requiring Specialized Sampling Procedures*
The Census Bureau expects that retired ACS sample will provide fewer than 300 eligible cases in Duval County. This will require sampling from the IR file.

## DATA COLLECTION

The NIS Evaluation Study uses a two-stage process for collecting information. First, households with age-eligible children (19-35 months) are contacted, either by telephone or in person, and the interviewer collects information on the vaccinations received by all age-eligible children. Second, health-care providers serving the cohort of children surveyed are contacted by mail.

The interview for the household component of the survey consists of multiple parts. About 10 days before the sample household is interviewed, an advance letter is mailed to the household in an effort to increase participation and to emphasize the legitimacy of the survey. A brochure may also be included in the advance letter mailing to help with participation. Once the household is

contacted for an interview, the interview begins with a set of screening questions designed to verify that the household has age-eligible children 19-35 months and to identify the respondent (parent/guardian) most knowledgeable about the child's vaccination status. If a knowledgeable person is not available to complete the interview, a time to call back is arranged. When a knowledgeable respondent is available, the interview proceeds to the immunization questions at which time the instrument prompts the respondent to locate the child's written vaccination records (shot card) to enhance the accuracy of the reported data. If a shot card is available, the interviewer asks the respondent to report the number and dates on which the child received the recommended vaccinations. The respondent is also asked to report any additional vaccinations received by the child, but not recorded on the shot card. If a shot card is not available, the interviewer asks the respondent to recall from memory the number of shots, but not the dates, for each of the specific vaccinations of interest. Upon completion of the immunization questions, the interview proceeds to the section of the instrument that collects demographics about the sampled child(ren), their current residence, and their residence at birth. The interview then proceeds to the provider information and consent section. In this section, the interviewer collects information on health care providers who have provided vaccinations for the sample child(ren). Information collected includes the health care provider(s) name, address, and telephone number. Verbal consent to contact the named provider(s) is also requested from the respondent. To help overcome language barriers a Spanish version of the immunization questions will be available for the interviews to use.

A field follow-up operation is planned for a subsample of nonresponders from the telephone operation. Approximately 20 percent of households will receive visits from FRs to participate in the NIS Evaluation Study. If the respondents agree to participate, a paper version of the questionnaire is administered. The paper questionnaire follows the same content of the CATI questionnaire. Due to time and resource constraints, it was not possible to develop a CAPI questionnaire with the necessary control systems. Since in most instances the field follow-up interviews will be conducted face-to-face with the respondents, the parents/guardians will be asked to sign the permission form. A Spanish translation of the advance letters, permission form, and items booklet will be available to help overcome Spanish language barriers.

In the second stage of data collection, all health-care providers serving the cohort of children surveyed and for whom consent to contact was received by the parent/guardian, are mailed a packet of materials. The initial mail-out of survey materials consists of a letter explaining the survey, the importance of their participation, and the need for each person who will have access to the data provided by the Census Bureau and/or who will be completing the data collection forms to complete, sign, and return an affidavit of non-disclosure form included in the packet. Once the provider returns the signed affidavit form, a second packet of materials, including a cover letter, is mailed requesting the vaccination history for each child whose vaccination information was gathered from parents. Health care providers are queried on the type and the level of detail of the vaccination records for each child, the dates and types of vaccinations administered, the date of each child's first visit to that provider regardless of reason, the date of the child's most recent visit to that provider regardless of reason, and the type of care the provider gave to the child. Other information collected from the health care provider includes a description of their facility (private, public, hospital-based, and so forth), their position within the facility, the child's date of birth, according to their records, and whether they report any of the

child's immunizations to a local or state registry. In lieu of completing the vaccination history section of the questionnaire, providers can attach a copy of the child's vaccination record to the questionnaire. After the provider information is collected, the responses are combined with information obtained from the households to render estimates of vaccination coverage levels more accurately.

Question 3. Methods to Maximize Response

Several steps are taken to encourage response and to maximize response rates:

- An advance introductory letter is mailed to sample households from the Director of the Census Bureau and the Director of the National Center for Immunization and Respiratory Diseases explaining the authority for and purposes of the survey to the household before the interviewer's contact.

- A Spanish translation of the household CATI questionnaire, the advance letter, and the permission form will be available to help overcome language barriers. In addition, the telephone centers and the regional offices have a staff of interviewers who are able to translate the questionnaire into other languages as well.

- For personal visit interviews with households, FRs carry cards and portfolios identifying them as Census Bureau employees.

- The Census Bureau trains the interviewers to obtain respondent cooperation and instructs them to make repeated attempts to contact respondents and complete all interviews.

- Potential respondents are assured that their answers will be held in confidence and used only for statistical purposes.

- Senior FRs and supervisors may be called in to convert refusals.

- Survey performance guidelines are established in an effort to maximize response rates. These guidelines are used by the regional offices and telephone centers as examples of how they might measure performance.

- As part of interviewer initial training, interviewers are trained in ways they can persuade respondents to participate as well as strategies to use to avoid refusals. Furthermore, the office staff makes every effort to help interviewers reduce their noninterviews by suggesting ways to obtain an interview, and by making sure that sample units reported as noninterviews are in fact noninterviews. Also, survey procedures permit sending a letter to a reluctant respondent as soon as a new refusal is reported by the interviewer to encourage their participation and to reiterate the importance of the survey and their response.

    - Focus Groups will be conducted with medical providers and/or their support staff to review the Special Sworn Status process. Results from these focus

groups may identify other potential means to improve response rates.

- The Special Sworn Status forms to be completed by the medical providers and/or their support staff will be preprinted with the practice name and address to help minimize burden.

- The Census Bureau will prepare the HIPAA Accountings of Disclosure for the providers to keep for compliance with the Privacy Rule.

- Telephone follow-ups are planned for providers we are unable to contact via the mailout/mailback operations.

- Providers may submit the IHQs by fax if this method is more convenient than submitting by mail.

Question 4. Tests of Procedures or Methods

The survey questions administered for the NIS Evaluation Study will be the same as those administered currently for the ongoing NIS. While the survey content will not change and require additional testing, plans are to conduct extensive testing of the automated survey instrument and its interaction with the various control systems as these will be newly developed for the survey. Testing includes *full instrument test* of all parts of the instrument, including the systematic checking of instrument output; one or more *systems tests* of all control systems that will be used for production; a *user's test* in which interviewers review the instrument with input and conduct mock interviews; and a *verification test* to ensure that all changes/problems reported in systems test(s) are corrected.

Additionally, four focus group sessions with providers (physicians and office staff) will be conducted. The objective of the focus group sessions will be three-fold. The first objective is to evaluate the Special Sworn Status (SSS) affidavit of non-disclosure form that providers will be required to complete to determine if participants consider the SSS form an obstacle in getting provider cooperation. Each person who could potentially complete an Immunization History Questionnaire for a respondent in the NIS Evaluation Study will be required to complete an SSS form prior to the Census Bureau releasing the name(s) the child(ren) (Title 13 information) to the provider. This is a new requirement for the NIS, as the sample is drawn from the ACS, a Title 13 survey. There is concern that this new requirement will result in an increase in provider non-response.

The second objective for conducting focus group sessions is to evaluate the cover letter that will accompany the SSS form to determine if the letter is motivational, persuasive, and address benefits of participating. A well-designed letter must be positive, motivational, and understood in order to be effective in gaining respondent cooperation.

The third objective of the focus group session is to explore with the participants whether or not giving incentives to providers would help secure participation particularly if the SSS form emerges as an issue. Giving incentives to providers has not been explored in the past for the

NIS.

Question 5. Contacts for Statistical Aspects and Data Collection

The Census Bureau will collect all the information. Mr. Thomas F. Moore III, of the Demographic Statistical Methods Division of the Census Bureau provided consultation on the statistical and methodological aspects of the NIS Evaluation Study. Mr. Moore can be reached by telephone on 301-763-5992. Ms. Andrea Piani heads the Health Surveys Branch of the Demographic Surveys Division, which manages and coordinates the work for the NIS Evaluation Study. Ms. Piani can be reached by telephone on 301-763-5379.

Attachments to the Supporting Statement include the following:

A. ACS Policy
B. Director's Advance Letter for Households – ACS Sample (7317-100A)
C. Director's Advance Letter for Households – Alternative Sampling Frame (7317-100B)
D. Advance Letter Informational Brochure (7317-ALB)
E. Informational Refusal Letter (7317-IRL)
F. Information Collection Instrument Items Booklet (7317-IB)
G. Information Collection Instrument Items Booklet – Spanish (7317-IBS)
H. Immunization Survey Paper Questionnaire (7317-PPQ)
I. Director's Advance Letter for Households – ACS Sample - Spanish (7317-100AS)
J. Director's Advance Letter for Households – Alternative Sampling Frame – Spanish (7317-100BS)
K. Permission to Contact Immunization Provider - English (7317-110E)
L. Permission to Contact Immunization Provider – Spanish (7317-110S)
M. Director's Special Sworn Status Cover Letter for Providers (7317-SSSCL)
N. Immunization Study Special Sworn Status Form (BC-1759 (P))
O. Explanation of the Immunization Study Special Sworn Status (7317-SSSII)
P. Frequently Asked Questions about HIPAA and the NIS (7317-FAQ)
Q. 2007 Morbidity and Mortality Weekly Report (7317-MMWR)
R. Special Sworn Status Reminder Postcard (7317-SSSP)
S. Director's Special Sworn Status Remail Letter for Providers (7317-SSSRL)
T. Director's Immunization Cover Letter for Providers (7317-IMMCL)
U. Immunization History Questionnaire (7317-IHQ)
V. HIPAA Accounting of Disclosure (7317-DHA)
W. Immunization Reminder Postcard (7317-IMMP)
X. Director's Immunization Remail Letter for Providers (7317-IMMRL)
Y. HIPAA Accounting of Disclosure – Individual Child (7317-DHAC)
Z. Immunization History Questionnaire Sample for Special Sworn Status Packet (7317-IHQFG)