Supporting Statement for Office of Management and Budget Review and Approval of

Asthma Education Study

Part A

April 2012

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A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a new information collection. OMB approval is requested for one year.

The Department of Health and Human Services is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially to those who are least able to help themselves. Their authority has been derived from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), reports that at least 24.6 million Americans currently suffer with asthma, with 12 million experiencing an asthma "attack" in 2009. 17.5 million non-institutionalized adults have asthma. In addition, 7.1 million children in this country have the disorder. Asthma accounts for 17 million health care visits and more than 3,400 deaths per year[1]. Aside from a small number of cases linked to occupational exposures, the causes of asthma remain unknown, and there exists no cure. In the absence of a means to eliminate the disorder, treatment to minimize the frequency and intensity of asthmatic attacks is of paramount importance. Several tools are available, including the use of corticosteroids and control of exposure to allergens and irritants, collectively known as "triggers." Thus, treatment of asthma is important and patients must take action at appropriate times. From this, it follows that the education provided by health care providers to asthmatic patients forms a critical link in efforts to control asthma. CDC and the National Institutes of Health recommend the use of written asthma action plans (Attachment 10) to guide patient self-management of the disorder.

Anecdotal evidence suggests that there is substantial variability in the use of available tools for developing written asthma action plans. Similarly, patient education appears to vary in type and amount. Some causes of this are suspected: billing codes for asthma education are not universally present, and the degree of health literacy among patients varies and is likely not universally sufficient. Nevertheless, in large part, the factors influencing asthma education by health care providers are unknown. To help address this situation, the Air Pollution and Respiratory Health Branch of CDC wishes to conduct a study to identify barriers to, and facilitators of, asthma education among health care providers consistent with National Asthma Education and Prevention Program (NAEPP)/ National Heart, Lung, and Blood Institute *Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma.*[2]

The Air Pollution and Respiratory Health Branch of the CDC National Center for Environmental Health leads CDC's campaign against environmental-related respiratory illnesses, including asthma, and studies indoor and outdoor air pollution. They play a critical role in CDC's effort to identify barriers to, and facilitators of, asthma education

among health care providers. Based on the authority and mission of HHS/CDC, it is appropriate and essential for CDC's Air Pollution and Respiratory Health Branch to conduct a study to help address these aforementioned issues.

At least 24.6 million Americans currently suffer with asthma, with 12 million experiencing an asthma "attack" in 2009, costing the nation $56 billion and individuals on average over $3,200 annually in direct and indirect costs[3]. Improved self-management education, consistent with the NIH/NAEPP guidelines, for enhancing education of persons with asthma in the areas of correct medication adherence and avoidance of environmental triggers of asthma attacks, is central to reducing the health and financial burden on individuals and the nation. This research is an important step in improving the education individuals with asthma, (or parents of children with asthma), receive at their initial diagnostic encounter with the medical system. As such, it is expected to improve proper medication adherence and avoidance of environmental triggers of an asthma attack and in turn to be of use to the government in reducing both the medical and financial burden of asthma on the nation. In this aspect this research is directly in line with both the mission of the CDC National Asthma Control Program, its funder, which seeks to achieve reductions in deaths and hospitalizations and increases in self-management education for individuals with asthma and that Program's Government Performance and Results Act Performance Measure: "Increase the proportion of those with current asthma who report they have received self–management training for asthma in populations served by CDC-funded state asthma control programs." The research project is also in alignment with *Healthy People 2020* objectives including reducing asthma deaths (objective RD-1), reducing hospitalizations for asthma (objective RD -2), reducing hospital emergency department visits for asthma (objective RD -3), reducing activity limitations among persons with asthma (objective RD -4), reducing the proportion of persons with asthma who miss school or work days (objective RD -5), increasing the proportion of persons with asthma who receive formal patient education (objective RD -6), and increasing the proportion of persons with asthma who receive appropriate asthma care according to the NAEPP guidelines (objective RD -7).

Previous research in this field has not focused on the specific question this project examines, "How can the initial asthma diagnostic encounter provide more effective self-management education?" The overall objective of this study is additionally to explore practices, barriers, and facilitators regarding provisions of control education by physicians and nurses to people diagnosed with asthma. Babey, Meng and Jones[4] and Johnson et al.[5] find SES, literacy, race/ethnicity, and other influencers of effective self-management education, but offer only generalized recommendations of how to mitigate this situation. Flores et al.[6] and Howell[7] identify the need for better education of parents of children with asthma, identifying trigger avoidance and medication adherence, along with follow-up care as major factors, thus anticipating the NIH guidelines. They also note the importance of parental attitudes regarding the preventability of asthma attacks and consequent need for hospitalization or ED care. While this provides guidance to the proposed study, it does not obviate the need for it. Davis et al.[8] identify, among Canadian physicians, specific concerns regarding physician financial incentives for self-management education, and an array of complaints from other health professionals

(pharmacists, respiratory therapists) as well as patients regarding poor education they had received, particularly as it relates to medication. Again, this finding is instructive for the proposed study. Adams et al.[9] and Cicutto, Llewellyn-Thomas, and Geerts[10] associate increased patient participation in their own care with better asthma management, a factor to be examined in the proposed study. Other researchers note the importance of being aware of patients' health literacy capabilities[11], the role of systemic change in improving patient-clinician relationships and consequently self-management[12] and other factors that are associated with our research question to varying degrees and that will be examined in the study, though not as a primary focus.

Privacy Impact Assessment

Data will be collected through one-on-one interviews with physicians and through focus groups with nurses at a commercial market research facility using a moderator guide. An overview of the data collection effort is as follows. For this study, CDC will obtain the services of the Oak Ridge Institute for Science and Education (ORISE) to assist in implementing the data collection system efforts. The data collection effort will not involve any Web-based collection efforts or refer respondents to any websites. Therefore there is no risk of "cookies" being placed on respondents' computers. This effort includes no websites with content directed at children less than 13 years of age as well.

Overview of the Data Collection System

The following data collection system steps will be implemented by CDC/ORISE:

- ORISE will recruit physicians and nurses for the interviews and focus group sessions
- Data will be collected through one-on-one interviews with physicians and through focus groups with nurses
- Prior to participating in the study, each prospective participant will receive an information sheet from ORISE explaining sponsorship of the study, their rights as a participant, risks and benefits of participating, and who to contact for more information
- An interviewer provided by ORISE will conduct a guided discussion with participants at a commercial market research facility
- Using a moderator guide (one for the physicians' interviews and one for the nurse focus group sessions) the interviewer will focus on exploring practices, barriers, and facilitators regarding provisions of control education to people diagnosed with asthma and exploring the practices, barriers, and facilitators to routine development and use of written asthma action plans
- Observers from CDC and ORISE may observe the sessions and take notes of the information being collected in preparation for drafting the findings of the study
- ORISE will audio record the sessions to use if there are questions about the information received from the sessions

- No identifying information will be included in the notes, the tape, or in the informed consent process
- ORISE will produce a draft report of the findings which will be delivered to CDC along with one set of audio recordings
- CDC, with assistance from ORISE, will use notes, recordings, and the draft report to analyze the focus groups and interviews thematically, to develop a final report reflecting the depth and detail of participants' input in such a way as to maximize utility for development of reports to partners and development of educational materials and messages.
- ORISE will retain one set of audio recordings and at least one copy of the report. ORISE will retain their records and audio recordings for 3 years, then burn, shred, or otherwise destroy them. ORISE will destroy the hardcopies of the collected materials using a shredder at a secured ORISE building by an ORISE staff member under the supervision of project team member.
- Any records or audio recording that CDC received will be maintained up to 3 years and then disposed of according to appropriate government regulations
- The final report will continue to be available as a record of the results of the findings

Items of Information to be Collected

No information in Individual Identifiable Format (IIF) is being collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The data collection effort will not involve any Web-based collection efforts or refer respondents to any websites. Therefore there is no risk of "cookies" being placed on respondents' computers. This effort includes no websites with content directed at children less than 13 years of age as well.

2. Purpose and Use of Information Collection

This will be the first opportunity for CDC to evaluate barriers to, and facilitators of, asthma education among health care providers. If the study were not conducted, CDC would not be able to reach out to health care providers caring for patients with asthma in a manner that best facilitates improvement of asthma self-management education and mitigates the health and economic burdens of asthma on the public. The overall objective of this study is to:

- Explore practices, barriers, and facilitators regarding provisions of control education to people diagnosed with asthma
- Explore the practices, barriers, and facilitators to routine development and use of HHS written asthma action plans (Attachment 10).

The target audiences for the current efforts are primary care physicians who routinely provide an initial diagnosis of asthma and nurses who routinely provide asthma education to patients. All participants (physicians/nurses) will:

- Be at least 18 years of age
- Be comfortable conversing in English
- Not have anyone in their household working in advertising, public relations, the media, federal government, or pharmaceutical industry

Specifically, physicians will be selected for the study based on the following:

- Report routinely providing an initial diagnosis of asthma to patients
- Be a primary care physician, defined as a member of one of the following specialties:
  - Pediatrics
  - Family Practice
  - Internal Medicine
  - General Practice
- Report working in a private practice
- Be board certified in one of the specialties noted above
- Report spending at least 50% of their professional time in direct contact with patients

Specifically, nurses will be selected to participate in the study based on the following:

- Report routinely providing asthma education to patients
- Report being a Registered Nurse
- Report working in a private practice
- Report spending at least 50% of their professional time in direct contact with patients

Overall, the study will:

- Probe physicians and nurses for their opinions and practices to address specifically asthma-related issues
- Support the goals of the CDC's National Center for Environmental Health to increase knowledge, as well as develop, implement, and evaluate policies and programs to prevent and control diseases/disorders such as asthma
- Directly support CDC's efforts in developing and providing accurate, helpful asthma-related educational information for health care providers and patients in the future

Interviews with physicians and nurses will be conducted in three regions of the country (U.S. Census Bureau identified regions) based on the following criteria:

- New York, New York
  - A northeastern state where recent policy change[13] provides a billing code for asthma education for Medicaid patients
- Houston, Texas
  - A southern city with a history of air-quality issues[14]

- Seattle, Washington
    - A Northwestern city commonly known to have a cool, damp climate[15] conducive to the growth of mold, an important and common trigger of asthma attacks

Potential participants will be recruited by market research firms using proprietary databases and screening instruments (Attachments 3 and 4) developed by ORISE and CDC. The firms include Schlesinger Associates (http://www.schlesingerassociates.com/) for New York, Opinions Unlimited (http://www.opinions-unlimited.com/) for Houston, and Fieldwork Seattle (http://fieldwork.com/Facility/Home.aspx?FacilityID=35) for Seattle.

Recruiting of physicians and nurses will be overseen by the Oak Ridge Institute for Science and Education (ORISE; http://orise.orau.gov/), the supporting contractor for the initiative. ORISE is a Department of Energy institute that focuses on scientific initiatives to research health risks from occupational hazards, assess environmental cleanup, respond to radiation medical emergencies, support national security and emergency preparedness, and educate the next generation of scientists. ORISE also provides support to other government initiatives, including areas related to safety and health research. ORISE has a long history of collecting and analyzing research data for the Department of Health and Human Services, including their agencies such as the Centers for Disease and Control Prevention and the National Institute for Occupation Safety and Health.

For this initiative, ORISE will screen potential interviewees (Attachments 3 and 4), schedule interviews, provide directions, and otherwise make arrangements for participation. ORISE will also provide facilities, moderating services, and a draft report.

Physician Interviews
A total of eight physician interview sessions will be conducted in each city and three cities will be represented in the study for a total of 24 physicians participating in the study. Physicians will be interviewed individually in each city identified (New York City, Houston, and Seattle).

For each individual interview, the participants will assemble at a commercial market research facility. Prior to participating in the study, each prospective participant will receive an information sheet explaining sponsorship of the study, their rights as a participant, risks and benefits of participating, and who to contact for more information (Attachment 7). Participants can keep or discard the information as they choose. A representative from ORISE will address any questions regarding the study before the interview/focus group begins. Physicians asked to participate in focus group sessions will receive a token of appreciation each not to exceed $75.00 (amount may vary slightly based on local standard market payments).

An interviewer (moderator) will conduct a 30-minute guided discussion with physicians using a Moderator Guide (Attachment 5). The interview will focus on discussions about

specifically asthma-related issues. A CDC representative will be available to answer questions at the completion of each interview.

Nurse Focus Groups
A total of two focus group sessions with four participating nurses for each focus group will be conducted in each city, and three cities will be represented in the study for a total 24 nurses participating in the study. Nurses will participate in the focus groups in each city identified (New York City, Houston, and Seattle).

For each focus group, the participants will assemble at a commercial market research facility. Prior to participating in the study, each prospective participant will receive an information sheet explaining sponsorship of the study, their rights as a participant, risks and benefits of participating, and who to contact for more information (Attachment 8). Participants can keep or discard the information as they choose. A representative from ORISE will address any questions regarding the study before the interview/focus group begins. Nurses asked to participate in focus group sessions will receive a token of appreciation each not to exceed $50.00 (amount may vary slightly based on local standard market payments).

A moderator will conduct a 60-minute guided discussion with nurses using a Moderator Guide (Attachment 6). The interview will focus on discussions about specifically asthma-related issues, including any related to an asthma action plan (Attachment 10). A CDC representative will be available to answer questions at the completion of each focus group.

Up to eight observers from CDC, ORISE, and state and local health departments may observe the individual interviews with physicians and the focus group sessions with nurses from behind one-way mirrors. They will take notes of the information being collected in preparation for drafting the findings of the study. No IIF will be included in the notes.

Privacy Impact Assessment Information

The study is being conducted to evaluate barriers to, and facilitators of, asthma education among health care providers. Overall, the study will probe physicians and nurses for their opinions and practices to address specifically asthma-related issues.

The intended use of the information is to:

- Support the goals of the CDC's National Center for Environmental Health to increase knowledge, as well as develop, implement, and evaluate policies and programs to prevent and control diseases/disorders such as asthma
- Directly support CDC's efforts in developing and providing accurate, helpful asthma-related educational information for health care providers and patients in the future

The proposed data collection will have little or no effect on the participant's privacy.

No individually identifiable information (IIF) is needed nor will be collected by either CDC or ORISE.

3. Use of Improved Information Technology and Burden Reduction

Focus groups and in-depth interviews provide an efficient, cost-effective, and relatively inexpensive method to reliably elicit ideas, knowledge, and other important factors in the target audiences' consideration of the issue at hand. This can be accomplished while providing the opportunity to investigate the reasoning, information-bases, and emotional aspects of responses in a supportive, deliberative environment. Focus groups and in-depth interviews are both established qualitative methods in both the public and private sectors for the exploration of the relevance, comprehensibility, credibility, and effectiveness of messages.

An audio recording of the interviews and focus groups will be made but will only be used if there are questions about the information received from the session (interview/focus group meeting). There is no need for a transcript or information to be entered into a data system. It is anticipated the bulk of the information will be obtained from the observers' notes and discussions with the moderator/interviewer of the focus groups and individual interviews.

4. Efforts to Identify Duplication and Use of Similar Information

The current data collection will not duplicate any existing or past CDC work or the work of other agencies. The overall objective of this study is to:

- Explore practices, barriers, and facilitators regarding the provision of control education to people diagnosed with asthma
- Explore the practices, barriers, and facilitators to routine development and application of asthma self-management education

A professionally trained ORISE librarian searched relevant literature, using the PubMed database, for any studies similar to this CDC proposed study. None were found that closely match these potential research efforts with health care providers (physicians/nurses). During the literature search, information was located concerning:

- Studies on barriers to providers to adopt the NAEPP guidelines but very little on addressing provider barriers to specifically providing education and asthma action plans since the ERP-3 guidelines were released in 2007.
- A study[16] that focused on determining whether the provision of a written asthma self-management plan increases adherence and improves outcome. The study did not focus on providers' barriers to providing education and written plans (Published in 2004). The CDC study does not duplicate this study.
- Studies about whether education and action plans improved outcomes. The CDC study does not duplicate those studies.

- Studies on what patients think the barriers are for this area. The CDC study will focus on what physicians and nurses think are the barriers and do not duplicate those studies.
- Studies that concluded that communication between the provider and patients needs to be improved but normally was short on in-depth details on corrective actions to take. The CDC study is seeking information specifically related to barriers to overcome from the perspective of the health care worker in today's rapidly changing health care climate. The CDC study does not duplicate those studies.
- Studies comparing asthma education through the emergency department (ED) instead of primary care. The CDC study does not duplicate those studies.
- A demand for more research on asthma self-managed education, especially for adolescents. An article[17] by Sharma notes:

  > "Asthma self-management education is strongly recommended for all patients by national asthma guidelines due to its proven effectiveness in improving asthma outcomes….Future research is needed to further identify the most important components of asthma education, the optimal duration and intensity of interventions, and their cost-effectiveness. In addition, given the relative of prior research involving adolescents, efforts should be made to evaluate asthma education interventions specifically targeted to that population."

This CDC proposed study should aid in addressing this research recommendation by Dr. Sharma and provide guidance on asthma self-managed education for both adults and adolescents.

5. Impact on Small Businesses or Other Small Entities

The participants for this study will be physicians and nurses. Although these health care workers may work for small businesses, the burden on small businesses will be minimized due to the limited time commitment and small number of personnel interviewed. They will be asked to participate during non-working hours.

6. Consequences of Collecting Information Less Frequently

Data will be collected one time only. This study is an initiative of the Air Pollution and Respiratory Health Branch of the CDC National Center for Environmental Health that leads CDC's campaign against environmental-related respiratory illnesses, including asthma, and studies indoor and outdoor air pollution. This study is being undertaken to identify barriers to, and facilitators of, asthma education among health care providers. It is appropriate and essential for CDC's Air Pollution and Respiratory Health Branch to conduct a study to help address these aforementioned issues. Close to 25 million Americans currently suffer with asthma, with 12 million experiencing an asthma "attack" in 2009, costing the nation $56 billion and individuals on average over $3,200 annually in direct and indirect costs[3]. Improved self-management education, consistent with the NAEPP/NIH guidelines for enhancing education of persons with asthma in the areas of

correct medication adherence and avoidance of environmental triggers of asthma attacks, is central to reducing the health burden and financial burden on individuals and the nation.

The interviews and focus group evaluations comprising this study will be conducted one time.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances involved in this study. This request fully complies with the regulation 5CFR1320.5.

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

A. Federal Register Notice:

A copy of the 60-day notice in the Federal Register soliciting comments on the proposed study is attached (Attachment 2). Published November 5, 2010 (Volume 75, Number 214, pages 68358-68359)

One public comment was received but no substantive comment on the protocol was included.

B. Consultations:

The following professionals/consultants contributed to the development of the Asthma Education Study being proposed in the first quarter of calendar year 2011:

Dr. Mark Herring
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Dr. Mark Herring was consulted on the process and materials to be used for the interviews and focus group sessions. Dr. Herring anticipates personally conducting the interviews and moderating the sessions. Dr. Herring has a doctorate in Counseling Psychology with doctoral-level training in experimental design, group process, and behavioral research. He has over 25 years experience in market research and works regularly on public health issues. He has had experience in the completion of qualitative research projects for the Centers for Disease Control and Prevention on

many topics, including bioterrorism, willingness of first responders to be vaccinated for smallpox, and strategies for encouraging high-risk groups to receive the flu vaccine annually. He has written several articles for national health care and market research publications. Dr. Herring's skills and knowledge in continuously conducting interviews, moderating focus group sessions, and analyzing data collected from the health care workforce in the Unites States would be difficult to match within CDC. His body of knowledge will help to ensure that the study includes the most up-to-date scientific-based research and evaluation knowledge.
The ORISE Project Manager consulted with Dr. Mark Herring in the first quarter of 2011 through phone calls during the development of the processes and materials to be used for the data collection efforts.

Dr. Herring assisted CDC in the design of the data collection instruments (Attachments 5 and 6), and will assist in the collection and analysis of the data.

Kelli Martin
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Ms. Martin has a Master of Public Health and is a Certified Health Education Specialist for Oak Ridge Institute for Science and Education. She has worked in the health education field for approximately 5 years. She has conducted quantitative and qualitative research, analysis, and program evaluation for the Centers for Disease Control and Prevention, National Library of Medicine, and the National Institute for Occupational Safety and Health. Ms. Martin has experience with facilitating and moderating numerous focus groups and key informant interviews. Project areas include diabetes, occupational safety and health, vaccine safety, immunizations, smoking and health media literacy, refugee health, and media analysis. Ms. Martin conducted the testing of the Moderator Guides and accompanying materials for physician interviews and nurse focus group sessions. The Moderator Guide – Nurse Group (Attachment 6) was tested with two Occupational Health Register Nurses at the Oak Ridge Associated Universities (ORAU) who have responsibilities for managing two Occupational Health Offices that are available to over 1,200 people within ORAU. The Interview Guide – Physician (Attachment 5) was tested with one physician. Through the pilot testing for both participant types, the times required to complete the interviews and focus group meetings were determined. The purpose of the testing for interviews and focus group session materials was to determine the clarity, time, and opinion of participants about the materials used. None of the participants in the pilot testing process will be part of the proposed study. Ms. Martin has exceptional interviewing skills that have been used in the past with the health care provider population using a moderator guide. These professional skills include staying focused on collecting the information and asking appropriate follow-up

probing questions based on the participant's responses during the interview. This skill is normally acquired through on-going research and evaluation efforts which most CDC staff would not be involved in on a daily basis.
Ms. Martin assisted CDC in the design of the data collection instruments (Attachments 5 and 6). In the first quarter of 2011, Ms. Martin conducted the testing of the Moderator and Interview Guides and accompanying materials to be used in the data collection efforts. Results of the testing were provided through phone conversations with the ORISE Project Manager and in-person to the ORISE Group Manager.

Deborah McFalls
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Ms. McFalls contributed to the interview and focus group session format and content. She has conducted research in health and safety studies for the past 10 years for the Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Institute for Occupational Safety and Health. She is the Group Manager of the Health and Safety Research and Evaluation Group at the Oak Ridge Institute for Science and Education where she has worked for 19 years. Ms. McFalls assisted CDC in the design of the data collection instruments (Attachments 5 and 6). Ms. McFalls managed the process to test the Moderator and Interview Guides and accompanying materials for the physician interviews and nurse focus group sessions. Ms. McFalls' depth of skills and knowledge in developing/revising moderator's guides ensures that the interview materials will be on target for the task needs.

Dr. Richard Tardif
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Dr. Richard Tardif contributed to the evaluation instrument design format, layout, and content. He is a Senior Scientist at the Oak Ridge Institute for Science and Education (ORISE) with 25 years of experience in risk communication, stakeholder involvement, and training. Dr. Tardif established and currently manages several ORISE health communication efforts in environmental and public health. He is responsible for designing, conducting, and evaluating some of ORISE's most prominent health education and risk communication efforts in the areas of exercise

planning, audience research, communication science, public health preparedness, training development, and evaluation. He has also moderated, facilitated, or served as an instructor for numerous training, workshop, exercise, and focus group activities. Some of his recent projects have addressed health care worker immunization practices, rotavirus vaccine, smallpox, the Strategic National Stockpile, Environmental Public Health Tracking, severe acute respiratory syndrome, emergency communication for bioterrorism events, pandemic influenza preparedness, and factors influencing adherence to public health directives. Dr. Tardif's management skills and knowledge in continuously conducting interviews, moderating focus group sessions, and analyzing data collected from the health care workforce would be difficult to match within CDC. Having both Dr. Herring and Dr. Tardif supporting the study ensures that the study would not be delayed if one of the two were not available for some unforeseen reason.
Dr. Tardif assisted CDC in the design of the data collection instruments (Attachments 5 and 6), and will assist in the collection and analysis of the data.

9. Explanation of Any Payment or Gift to Respondents

Incentives are permitted in research as a way to facilitate participation and to compensate subjects for potential burdens of research participation, such as time, inconvenience, travel, etc. As noted on the Johns Hopkins Medicine Research web site (www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/remuneration.html) "Remuneration for participation in research should be reasonable and the amount paid should be comparable to other research projects involving similar time, effort, and inconvenience."

It is standard practice to provide a token of appreciation for interview and focus group participants for their time:

- Physicians asked to participate in an interview will receive a token of appreciation each not to exceed $75.00 (amount may vary slightly based on local standard market payments). . The sum will compensate them for their time and expenses such as gas, parking cost, etc. involved in the activity.
- Nurses asked to participate in focus group sessions will receive a token of appreciation each not to exceed $50.00 (amount may vary slightly based on local standard market payments). The sum will compensate them for their time and expenses such as gas, parking cost, etc. involved in the activity.

The token of appreciation will be described at the time of recruitment; it is anticipated that this token will facilitate participation in the focus groups and interview sessions. An "Information for Participants" handout (Attachments 7 and 8) will be provided to all participants prior to the start of each focus group or interview. Included in the handout will be information noting that they will receive a token of appreciation for participating but will be free to leave at any time without losing the token of appreciation or other penalty.

10. Assurance of Confidentiality Provided to Respondents

Safeguarding responses from unauthorized disclosure will be improved by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants.

Data are being collected from physicians and nurses. CDC has deemed it unnecessary for this agency to have access to information about the participants in the study. Under this policy, the support contractor, ORISE, will:

- Maintain no identifiers connecting any data collected to any particular participant
- Provide no personal identifiers to CDC or others. Firms that conduct recruiting and host the sessions will be required to not provide personal identifiers to ORISE or CDC.
- Retain one set of audio recordings and at least one copy of any report it produces
- Develop a report in an agreed-upon format summarizing the responses provided by participants; the report will contain no personal identifiers
- Deliver the report and one set of audio recordings to CDC
- Only retain records and audio recordings for 3 years, then burn, shred, or otherwise destroy them

Any records or audio recording that CDC receives will be maintained up to 3 years and then disposed of according to approved record schedules. The formal report and any scholarly publications reporting the study findings will continue to be available as a record of the results of the finding.

<u>IRB Approval</u>

ORISE submitted an application to conduct research on human subjects to their Institutional Review Board (IRB) and was notified that this research was found to be an exempted category of research involving human subjects. CDC submitted an application for a determination of whether the project was research on human subjects to their IRB along with a copy of the ORISE IRB's findings and received agreement with the ORISE findings (Attachment 9).

The support contractor, ORISE, submitted an application to conduct this research study to the Oak Ridge Site-Wide Institutional Review Board (IRB). The Oak Ridge Site-Wide IRB determined on March 14, 2011 that the study is exempt from IRB review according to federal regulations as outlined in 45 CFR 46.101(b)(2) (Attachment 9).

<u>Privacy Impact Assessment Information</u>

A. This submission has been reviewed by the Information Collection Review Office, who determined that the Privacy Act does not apply.

B. While participants' names and contact information will be collected as part of the screening process, this information will be destroyed and discarded as soon as the interview or focus group session takes place.

The interview and focus group session observers' notes will be housed in a password protected folder at ORISE in their electronic file system that will only be available to ORISE project team members. ORISE will audio record the sessions to use if there are questions about the information received from the sessions. Participants will be informed of audio taping before sessions begin and given the option not to participate in the session. No IIF will be included on the tape. ORISE will retain one set of audio recordings and at least one copy of the report produced that will be locked in a secure cabinet at ORISE with access available only to project staff members. ORISE will deliver the report and one set of audio recordings to CDC that has no IIF. CDC will house the audio tapes in a secured, locked cabinet at CDC, accessible only by the CDC Project Officer. Upon completion of analysis, any audio tape will be destroyed. Analyzed data will be aggregated and not reported by subject or available by subject.

C. The potential participants will be told orally during the participant screening process about the intended use of the information collected. The consent to participate will be orally obtained through the screening process. An "Information for Participants" handout (Attachments 7 and 8) will be provided to all participants prior to the start of each interview or focus group session that explains sponsorship of the study, their rights as a participant, risks and benefits of participating, and who to contact for more information. Among the information on the handout will be a section about safeguarding information that notes the following:

> "We will keep the information you give us private to the extent allowed by law. Your name will not be used in the final report. No statement you make will be linked to you by name. We plan that only members of the research staff will be allowed to look at the records. When we present this study or publish its results, your name or other facts that point to you will not be shown or be used."

Participants can keep or discard the information as they choose. A representative from ORISE will address any questions regarding the study before the interview/focus group begins.

D. Included in the "Information for Participants" handout will be a section about voluntary nature of their response that notes the following:

> "Please remember that even if you choose to participate, you are not required to answer any questions that may make you feel uncomfortable."

No IIF is being collected.

11. Justification for Sensitive Questions

No questions will be asked that are of a personal or sensitive nature. The data collection process does not contain any personal questions regarding health status, lifestyle, sexual practices, religious beliefs, or other potentially sensitive issues commonly considered to be private. Participants will be asked questions about the following during the participant screening process:

- Age: All participants will be told they must be at least 18 years of age, but no age will be recorded
- Language: All participants will be comfortable conversing in English
- Employment/ Education: Physicians will meet the following criteria:
    - Provide initial diagnosis of asthma to 12 or more patients per year (average in a typical year)
    - Report spending at least 50% of their professional time in direct contact with patients
    - Be defined as a member of one of the following specialties:
        - Pediatrics
        - Family Practice
        - Internal Medicine
        - General Practice
    - Be board certified in their specialty
    - Work in a private practice

  Nurses will meet the following criteria:
    - Provide asthma treatment and control education after the patient's initial diagnosis of asthma to 12 or more patients per year (average in a typical year)
    - Work in a private practice
    - Be a Registered Nurse
- Gender: For information purposes only – not a selection criteria
- Race: For information purposes only – not a selection criteria
- Other: None of the participants will have family members in their household working in advertising, public relations, the media, federal government, or pharmaceutical industry

12. Estimate of Annualized Burden Hours and Costs

The target audiences for the study are physicians and nurses. A total of three U.S. cities will be visited.

Data will be collected from 24 physicians through an individual in-depth 30-mintue interview. Up to eight physicians will be selected for individual 30-minute interviews per city. Administration of the screening instrument is expected to take 5 minutes for each physician. Up to 48 physicians in total will be screened.

Data from 24 nurses will be collected by means of a 60-minute focus group session. Up to four participants will be recruited for each focus group for a total of two focus groups per city. Administration of the screening instrument is expected to take 5 minutes for each nurse. Up to 48 nurses in total will be screened.

The pilot test with one physician indicated that the interview will require approximately 30 minutes to complete. The pilot test with two nurses indicated that the focus group sessions will require approximately 60 minutes to complete. The interview and focus group format/materials are designed so participants can focus quickly on addressing questions and reviewing materials easily, moving from one exercise to the next.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Physician and Nurse	Screener	48	1	5/60	4
Physician	Interview	24	1	30/60	12
Nurse	Focus Group	24	1	1	24
Total					**40 hours**

Estimated Annualized Burden Costs*

Type of Respondent	Total Burden Hours	Hourly Wage Rate[18]	Total Respondent Costs
Physician—screener only	2	$81.03	$162.06
Nurse—screener only	2	$31.99	$63.98
Physician	12	$81.03	$972.36
Nurse	24	$31.99	$767.76
Total	**40**		**$1966.16**

US Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm#29-0000 accessed 5 May 2011.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

The interviews or focus group sessions have no capital, operating, maintenance, or other costs to the physicians or nurses or their employers.

14. Annualized Cost to the Federal Government

This baseline study will be conducted by ORISE under an Interagency Agreement with CDC. ORISE has participated in the development of the study plan, including the Moderator Guides, Screening Instruments, and Participant Information Forms; finalization of materials for testing; and pilot testing the materials to be used during the

interviews and focus group sessions. ORISE will also be responsible for conducting the focus group sessions and the interviews, analyzing the data, and developing reports of the results. The total estimated cost for support from ORISE is $98,800, which also includes the tokens of appreciation to physicians and nurses.

The cost for the federal employees involved is for evaluation planning, oversight, data analysis, and report writing. The government employee costs are as follows:

- 100 hours of a GS-14-6 ($56.48 fully loaded hourly rate)
  - 100 hours x $56.48 = $5,648
- Employee Travel cost of $1,500

The estimated total cost of the project to the government is $105,948 (total ORISE cost = $98,800 and Federal cost = $7,148). This includes the cost for the data collection by ORISE, as well as the federal cost for the federal employees involved in the initiative. The total time period from the beginning of the planning of the project until the completion of the project is approximately 3 years. Therefore, the annualized cost of the project to the government is $35,316.

15. Explanation for Program Changes or Adjustments

This is a new data collection submission.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results for this information collection.

A. Project Time Schedule:

Project Activity	Time Schedule
Recruit physicians from New York, New York; Houston, Texas; and Seattle, Washington for interviews.	1 to 2 months after OMB approval
Recruit nurses from New York, New York; Houston, Texas; and Seattle, Washington for focus group sessions.	1 to 2 months after OMB approval
Arrange for locations (market research facilities) where interviews and focus group sessions will be held.	1 to 2 months after OMB approval
Arrange for a moderator(s)/interviewer(s) for the interviews and focus group sessions.	1 to 2 months after OMB approval
Travel to New York, New York; Houston, Texas; and Seattle, Washington for interviews and focus group sessions.	2 to 3 months after OMB approval
Develop a report summarizing the responses provided by physicians and nurses.	4 to 8 months after OMB approval

B. Analysis and Publication Plan:

A report of the findings will be compiled for public health partners through deliberations based on the observations and notes of CDC and ORISE observers, as well as the moderator. Statistical analysis will neither be necessary nor appropriate for these data. Audio recordings will be reviewed as necessary if additional information or clarification is needed.

The results will be combined from the different locations; a comparison of the results from the different locations may also be required. It is anticipated a final report of the study will include:

- Executive Summary
- Introduction
- Findings and Comments
- Conclusion and Recommendations
- Appendices

Wherever appropriate, a graph or table will display information from related analyses of the results.

The results of the study will assist CDC in developing and providing accurate, helpful asthma-related educational information for health care providers and patients in the future.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no exceptions to certification.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification.