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

Asthma Education Study

Part B

November 17, 2011

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B. Collections of Information Employing Statistical Methods

B. 1. Respondent Universe and Sampling Methods

No statistical methods will be used to select participants. Participants will be selected based on the following criteria:

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.

- All participants will be at least 18 years of age
- All participants will be comfortable conversing in English
- Physicians will be board certified in their specialty; work in a private practice; 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; and be defined as a member of one of the following specialties: Pediatrics, Family Practice, Internal Medicine, or General Practice. Nurses will work in a private practice; be a Registered Nurse; and 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)
- Individuals will be excluded if they have family members in their household working in advertising, public relations, the media, federal government, or pharmaceutical industry.

B. 2. Procedures for the Collection of Information

This is a qualitative study using focus groups and in-depth interviews administered by a trained interviewer. Dr. Mark Herring, who will moderate the interviews and focus groups, has 27 years' experience in moderating such interviews and group. He was integrally involved in the development of the moderator's guide and the interview guide. He will continue to be involved in preparation for data collection. A practice session will occur immediately before data collection commences, and discussions immediately following initial interviews and groups will help refine further data collection.

Focus groups and in-depth interviews are both established qualitative methods in both the public and private sectors to explore the relevance, comprehensibility, credibility, and effectiveness of messages. "Qualitative data," Patton notes¹⁹, "consist of detailed descriptions of situations, events, people, interactions, and observed behaviors" of the sort most useful for design of education and communication messages and approaches. Such data do not fit predetermined, standardized—*i.e.*, quantitative—categories by design, in order to provide the greater depth and detail inherently needed for educational design of the type this study is intended to support. Both ORISE and CDC have used this technique numerous times with success.

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

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

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.

B. 3. Methods to Maximize Response Rates and Deal with Nonresponse

Given the financial constraints of this study, screening will continue only until the target of 100% of participants is achieved. Therefore, considerations of nonresponse rates are not applicable.

B. 4. Tests of Procedures or Methods to be Undertaken

Focus groups and in-depth interviews are both proven and established methods in both the public and private sectors to explore the relevance, comprehensibility, credibility, and effectiveness of messages. Both ORISE and CDC have used this technique numerous times²⁰ to study an array of public health topics including: barriers and facilitators to vaccinations for childhood, adolescent, and adult immunization; pandemic influenza preparedness; bioterrorism preparedness; and testing of public service announcements regarding carbon monoxide poisoning. For example, in the last decade ORISE and CDC have conducted more than 10 studies on various aspects of influenza immunization alone. The instruments (Attachments 5 and 6) used in this study were reviewed and tested for clarity and validity by ORISE and CDC.

B. 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Following standard qualitative research practice²¹, no statistical methods will be used to select participants and there is no plan to publish this information for statistical use. ORISE will audio record the sessions and provide a summary report, based on observations of the sessions made by ORISE and CDC and notes taken by ORISE and CDC. Given the financial constraints of this study, analysis will be limited to recording-based and notes-based analysis conducted collaboratively by CDC and ORISE. This will include development of an abridged transcript containing comments directly related to the topic at hand plus the moderator/interviewer's oral summary immediately given at the conclusion of each session. In addition to this debriefing session, field notes taken by both ORISE and CDC will contribute to the analysis, and the recordings will be used to verify the conclusions and inferences drawn by CDC and ORISE.

The following consultants contributed to the development of the study:

Dr. Mark Herring Company President Mark Herring Associates, Inc. 2150 Diamond Rock Road Malvern, PA 19355-9528

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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 Health Education Specialist Project Manager Oak Ridge Institute for Science and Education/Oak Ridge Associated Universities P.O. Box 117 Oak Ridge, TN 37831-0117

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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 inperson 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.

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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.

Mr. Damon, principal CDC investigator, is responsible for receiving and approving all contract deliverables, including collection and analysis of the data. He designed the protocol and will lead in the collection and analysis of the data.