Formative Research on Lung Cancer Screening

Request for OMB Approval

Supporting Statement Part A

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Attachments

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) seeks OMB approval to conduct a formative research study about lung cancer screening practices. Information will be collected from health care consumers and physicians over a two-year period. Authorization for CDC to conduct the study is provided under Section 301 of the Public Health Service Act (42 U.S.C. 241) (See Attachment A).

Lung cancer is the second most common type of cancer in the United States after skin cancer (National Cancer Institute [NCI], 2005a). It is also the leading cause of cancer death among both sexes, accounting for more deaths each year than breast, prostate, and colon cancers combined (American Cancer Society [ACS], 2008). During 2007, there will be about 213,380 new cases of lung cancer (114,760 among men and 98,620 among women) (ACS, 2008). The one-year survival rate for lung cancer is approximately 40% and has not improved in the past 10 years (ACS, 2008). The five-year relative survival rate for all stages of lung cancer combined is only 15% (ACS, 2008). Early diagnosis at a localized stage (i.e., Stage I or II) significantly improves the five-year survival rate to about 49%, but only 16% of cases are detected early (ACS, 2008).

There is currently much debate within the health care community about the value of lung cancer screening. Traditionally, the tests used to screen patients with lung conditions included chest x-rays (CXR), computed tomography (CT) scans, and sputum cytology. The potential benefit of these tests is that they may lead to early detection of lung cancers, thus providing an earlier opportunity for treatment. However, efforts aimed at early detection of lung cancer with these tests have yet to demonstrate a reduction in mortality, and uncertainty in interpretation of results from existing studies has led to conflicting positions regarding the value of certain screening tests, especially among populations at risk (e.g., smokers) (Humphrey et al., 2004; Smith and Glynn, 2000; Fontana et al., 1991; Marcus et al., 2000; Kubik and Polak, 1986; Melamed et al., 1984; Frost et al., 1984). In addition, the invasive nature of diagnostic testing and the possibility of a high number of false-positive tests in certain populations raise concerns about the potential for significant harms from screening (Humphrey et al., 2004). The competing harms and benefits associated with these tests and their failure to detect lung cancer early enough to improve survival rates have raised questions about their efficacy (NCI, 2005b). Studies are underway to test more recent screening technology, including NCI's National Lung Screening Trial (NLST). In the meantime, the U.S. Preventive Services Task Force (USPSTF) reports that the evidence is insufficient to recommend for or

against screening asymptomatic persons for lung cancer with either low-dose computerized tomography (LDCT), CXR, sputum cytology, or a combination of these tests (USPSTF, 2006). While the scientific community works to resolve these issues and conduct research on new screening and diagnostic tools, an important interim step is to gain an understanding of health care consumer experiences and physician practices in the area of lung cancer screening and testing.

Little is known about the prevalence of lung cancer screening among health care consumers at risk for lung cancer. In addition, the scientific literature is limited on health care consumers' knowledge, attitudes, and experiences and physicians' attitudes and practices related to lung cancer screening and testing. Factors involved in better understanding consumers' knowledge and use of available screening tests for lung cancer have yet to be explored.

The Centers for Disease Control and Prevention (CDC) thus recognizes the need for formative research to explore health care consumers' and physicians' experiences with lung cancer screening tests in order to better plan for future research and program efforts. Therefore, CDC proposes a formative research study to fill this knowledge gap by using qualitative methodologies to help answer the following key research questions: (1) What are physicians' attitudes and practices in relation to use and utility of cancer screening guidelines? (2) What are health care consumers' and physicians' attitudes toward and experiences with screening tests in general, and with lung cancer screening in particular? (3) What processes do physicians go through to identify candidates for lung cancer testing? (4) What do physicians tell their patients about lung cancer screening tests? (5) What are health care consumers' general perceptions of lung cancer screening tests?

Privacy Impact Assessment

The proposed study involves a minimum amount of information in identifiable form (IIF). Respondents will be recruited from existing record systems. The data collection contractor, RTI International (RTI), will have access to respondents' names, telephone numbers, and recruitment screening information in order to schedule their participation in focus group (FG) discussions and telephone interviews. However, the IIF used for recruitment and scheduling purposes will not be linkable to the response data collected subsequently. Participation in the study is voluntary and does not involve the collection of highly sensitive information.

Overview of the Data Collection System

The research study will be conducted over a two-year period. The proposed formative research study will involve the collection of information from health care consumers located in four cities in different quadrants of the United States and primary care physicians across the country. The health care consumer component will consist of a total of 16 in-person focus groups (FGs) conducted over the two year study period (i.e., 8 FGs per year) with individuals at high risk of developing lung cancer (i.e., long-term heavy smokers ages 40-70). Depending on what is learned during these discussions, a limited number of FG respondents may be asked to participate in individual in-depth interviews (IDIs) that will be conducted by telephone. Information will also be collected through 8 telephone FG discussions conducted over the two year study period (i.e., 4 FGs per year) involving primary care physicians. After completion of the project, all electronic files (notes, documents, reports) will be archived on RTI's shared drive.

Items of Information to be Collected

Health care consumer participants will be screened on smoking history. In-person FGs with the health care consumers will explore their knowledge, beliefs and experiences relating to health screening in general, and lung cancer screening specifically. The IDIs will provide additional detailed information on specific experiences with lung cancer screening and testing, such as experience with spiral CT, and health care consumers' understanding of the advantages and disadvantages of various tests.

The physician FGs will explore physician attitudes and practices in relation to lung cancer screening and testing. These FGs will be conducted by telephone.

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

The proposed research does not involve the collection of information through websites, or any website content directed at children under 13 years of age.

A.2 Purpose and Use of Information Collection

The information from this project supports the Healthy People 2010 goals for cancer and health communication: 1) to reduce the number of new cancer cases as well as the illness, disability, and death caused by cancer and 2) to use communication strategically to improve health. At this time, little is known about the prevalence of lung cancer screening among high-risk individuals or their actual experiences with lung cancer screening. The information to be collected may be used as a basis for

developing more effective educational and screening interventions and for determining future research needs.

Privacy Impact Assessment Information

This submission has been reviewed by CDC's Information Collection Review Office (ICRO) and it was determined that the Privacy Act does not apply. Physicians will be recruited from a pre-existing record system (AMA Master File). Primary care physicians will be selected from the AMA Master File record system. Health care consumers will be recruited from pre-existing record systems maintained by professional focus group facilities. As part of business operations, focus group facilities register individuals who are interested in participating in different types of focus groups. The registration process is completely voluntary. As part of the registration process, individuals provide basic demographic information and more specific information about different behaviors, including smoking. For the health care consumer focus groups, focus group facilities will contact individuals registered with their facility who are over age 18 and who are smokers.

Information about the identity of the health care consumer participants and physician participants will not be connected to response data. Potentially sensitive information collected as part of the recruitment screener will not be maintained. Although the contractor, RTI International, will have temporary access to identifiable information for recruitment and scheduling purposes, this information will be destroyed once the FGs and IDIs are complete.

In regard to the IDIs, if a health care consumer discloses during the FG that he or she has been screened for lung cancer by CT scan, an observer of the FG will place a check mark on the individual's informed consent form (Attachment D1). At the end of the informed consent form for health care consumers (Attachment D1), permission is requested to contact the individual after the FG for a telephone interview if necessary. The participant can either decline or agree. Those who agree provide a signature as permission and provide a telephone number. Those persons who were identified during the FG as having been screened for lung cancer using CT scan technology (identified by a check mark on their informed consent form) and who agreed to be follow-up (permission provided on their informed consent) will be contacted for an IDI. As detailed below, identifying information of participants will not be associated with any data collected.

Privacy safeguards for FGs and IDIs will include removing all participants' identifying information from data collected (i.e., study transcripts, notes). Audio recordings will be destroyed after the transcription is complete. All paper files (e.g., informed consent forms) will be stored and locked in a project file cabinet at RTI, which will be accessible only to select project staff. The informed consent forms will be the only

forms maintained with the participants' names. As described, however, individual names will not be linked to any data collected. All electronic project files (e.g., digital audio recordings, written transcriptions) will be stored at RTI on a limited-access project share drive on RTI's secure network servers; only project staff who have been authorized by the project director can access the share drive. Five years after project completion, all electronic files (e.g., notes, documents, data) will be archived on RTI's project share drive for five years and then deleted permanently. Any paper files will be destroyed.

A.3 Use of Improved Information Technology and Burden Reduction

The proposed formative research project is based on qualitative methods, such as semi-structured interviews and group discussions, rather than electronic information collection procedures.

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

A review of the literature reveals there are no existing data collection efforts, no comparable studies, and no available data to address the research questions proposed by this study. Literature is limited on health care consumers' knowledge, attitudes, and experiences and physicians' attitudes and practices related to lung cancer screening and testing. As a result, the proposed data collection effort is distinct from previous studies identified in the literature. CDC recognizes the need for formative research to explore health care consumers' and physicians' experiences with lung cancer screening and testing in order to better plan for future research efforts and to inform public health practice. This project seeks to fill the current knowledge gap.

A.5 Impact on Small Businesses or Other Small Entities

The physician component of this study will involve physicians who may represent small business or other small entities. Potential physician participants will be mailed Physician Recruitment Materials (Attachment G1) explaining the study. The materials will instruct those who are interested in participating to complete and return the Informed Consent for Physicians Form (Attachment G2) and the Physician Response Form (Attachment F). Physicians who are not interested in participating will not be required to respond in any way and may simply discard the materials. Physician participation in this voluntary study does not involve travel, record-keeping or

preparation for the FG discussions, and is not expected to have an impact on small business.

A.6 Consequences of Collecting the Information Less Frequently

Reducing the respondent burden below the estimated levels (that is, reducing the number of FGs or number of participants per group) would diminish the utility of the study and compromise the findings. It is methodologically desirable to have multiple groups in a variety of geographic sites. This type of collection activity follows standard qualitative research methodology (Patton, 1990).

For the health care consumer component of this project, we will conduct one-time, in-person FGs. Eight FGs of 9 participants each will be conducted each year of the two-year study. As needed, one-time, follow-up IDIs with health care consumers will be conducted by telephone to explore and understand their knowledge and beliefs about lung cancer screening and testing. The study design allows for a total of 8 IDIs each year of the two-year study.

In the physician component, we will conduct one-time, telephone FGs with selected practicing primary care physicians. Four FGs of 6 participants each will be conducted each year of the two-year study.

Because each data collection method will be implemented only once, it is not possible to reduce the frequency of data collection. The exception is the second data collection effort with a small subset of health care consumers for follow-up IDIs. Participation in the IDIs is voluntary and will only be conducted if individuals are identified through the focus groups who have been screened for lung cancer with a CT scan.

There are no legal obstacles to reducing the burden.

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

These data are collected in a manner consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances contained within this application.

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

The notice in the *Federal Register* (Vol. 73, No. 150, August 4, 2008, p. 45225-45226) soliciting comments is shown in Attachment B1. One public comment was received in response to this notice and a response was provided (Attachment B2).

For this project, the project team consulted with key stakeholders (listed in Table A.8-1) with experience in the field of cancer, preventive screening and shared decision making, particularly health care consumer and physician preferences, in order to gather input on the evaluation design, research questions, and survey instruments.

Table .8-1. Consultants Outside the Agency

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A.9 Explanation of Any Payment or Gift to Respondents

The payment or monetary incentive for respondents is intended to encourage participation and to achieve a strong response rate. Numerous empirical studies have shown that payments can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000). Compensation for focus group participation is customary and recognizes the burden to respondents involved in this type of information collection format. Therefore, FG participants in the health care consumer groups will receive $75 at the conclusion of the group discussion. Participants in the follow-up IDIs will receive an additional $25 check in the mail after their telephone interview.

Similarly, to support recruitment and an adequate response rate, physicians will receive a $175 check in the mail after the telephone FG. Physicians are among the most difficult populations to reach. The amount of the incentive for physicians was determined based upon the burden to the respondents, taking into account that the respondents are physicians, the length of the focus group, and our previous experience conducting focus groups and interviews with this audience. Physicians are highly paid and their time is at a premium. They receive frequent requests from numerous entities for their time for varying activities such as participation in interviews or listening to pharmaceutical sales representatives. As a result, they often decline their participation. Our experience has shown that providing an incentive less than $175 does not appear sufficiently attractive to physicians. This is especially true given that a higher number of physicians are now paid on a fee-for-service basis and may be reluctant to leave their office for an interview or focus group. For example, if a physician sees a minimum of four patients an hour, each with an average billing rate of $50, this equates to a physician hourly rate of $200 without leaving the office. Suggested standard incentives range from $200 to $250 for physicians (Slaughter, et al., 1999). This amount is consistent with quotes we have received from focus group facilities for recruiting primary care physicians (personal communication, January 18, 2007). However, incentive amounts may be dependent upon a physician's training and expertise as well as their geographic location. For this study, we will be recruiting general practitioners and not specialists. In addition, we are not requiring physicians to go to a physical location to participate in the group, but requesting their participation in focus groups by telephone conference call. Participants will receive their incentive payment in the mail shortly after completing their participation in the focus group/interview.

A.10 Assurance of Confidentiality Provided to Respondents

The research team will collect qualitative data from two audiences, health care consumers at high risk for lung cancer and practicing primary care physicians. CDC has contracted with RTI International (RTI) to conduct a series of eight, in-person FGs per year and, as needed, up to eight telephone IDIs per year with health care consumers to explore their knowledge and beliefs about health screening in general and, more specifically, about lung cancer screening and testing. RTI will also conduct 4 telephone FGs per year with a small sample of practicing primary care physicians. Through these FGs, RTI will collect information about physicians' attitudes and practices in relation to lung cancer screening and testing. The proposed study has been reviewed and approved by the CDC IRB (Attachment H, IRB Approval Letter).

Privacy Impact Assessment Information

A. This submission has been reviewed by CDC's Information Collection Review Office, which determined that the Privacy Act does not apply. Although respondents' names and telephone numbers will be used for recruitment and scheduling purposes, the identifying information is obtained from previously established record systems and will not be linked to the response data collected for the proposed research study. Health care consumers who participate in focus group discussions will be recruited from existing data bases maintained by professional focus group facilities. Physicians will be recruited from a pre-existing record system (AMA Master File).

B. Privacy safeguards will be implemented to ensure that participants' identifying information will not be connected to the response data collected during focus group discussions and interviews (i.e., study transcripts, notes). Potentially sensitive information collected as part of the screening and recruitment process for health care consumers will not be maintained. Similarly, information about the identity of physician respondents will not be connected to response data. Although the contractor, RTI International, will have temporary access to identifiable information for recruitment and scheduling purposes, response data will not be recorded in a manner that is linkable to respondent identifiers. Each interview respondent or FG participant will be assigned a unique identifier that will be used to track and store data. Audio recordings of focus group discussions will be destroyed after the transcription is complete.

   Notes and transcripts of the FGs and IDIs will be maintained electronically at RTI. Again, all notes and transcripts will be stripped of identifying information. All electronic project files at RTI are stored on a limited-access project shared drive on RTI's secure network servers; only project staff who have been authorized by the project director can access the shared drive. After project completion, all electronic files (e.g., notes, documents, reports) will be archived on RTI's project shared drive. All RTI employees and contractors working on the project who have access to project data are required to sign a confidentiality agreement (Attachment I.)

C. A number of procedures have been put in place to ensure that all respondents are adequately informed about the study and that they consent to participation. The Health Care Consumer Screener (Attachment C) requests the consumer's permission to proceed with screening questions. Those who are eligible and willing to participate in the study provide written consent (Attachment D1, Informed Consent for Health Care Consumers). Physician respondents are informed about the nature of the study through the Physician

Recruitment Materials (Attachment G1) and also provide written consent if they choose to participate (Attachment G2, Informed Consent for Physicians).

D. The proposed data collection is voluntary, and no persons are required to respond to the interviews. In addition, respondents may decline to answer any question. This voluntary aspect of the interviews is clearly stated in the FG introductions and on the informed consent forms.

A.11 Justification for Sensitive Questions

A few questions on the health care consumer screener (e.g., race, ethnicity, history of cancer, see Attachment C) are potentially sensitive to a small portion of respondents, but are not considered highly sensitive. The questions are necessary to recruit respondents who represent a variety of demographic groups and are eligible for the study in terms of health history.

A.12 Estimates of Annualized Burden Hours and Costs

A. Interest and eligibility for participation in the health care consumer component of the study will be evaluated using the Health Care Consumer Screener (Attachment C). Based on the RTI's previous experience in recruiting participants, we estimate that screening burden will average 2 minutes per response and that the response rate for recruitment into the study will be approximately 50%. Each FG will consist of an average of 9 respondents and will last 2 hours. We estimate 8 FGs will be conducted each year. To allow for any last minute changes in availability, 12 health care consumers will be recruited to each FG (i.e., 9 respondents and 3 alternates). Therefore, to ensure participation of 72 respondents for 8 FGs per year (i.e., 8 FG x 9 respondents), a total of 96 health care consumers will be recruited (i.e., 8 FG x 12 respondents). Given the expected 50% response rate, we estimate a total of 192 health care consumers will be screened for participation each year (i.e., 96 respondents x 2). The FG discussions will be led by a professional FG moderator (see Attachment D, Moderator's Guide for Health Care Consumer Focus Groups). The average burden of the FG is estimated at 2 hours.

A limited number of health care consumers (up to 8 per year) will be invited to participate in follow-up, in-depth interviews (IDIs) to be conducted by telephone. The purpose of the IDI is to explore issues and experiences identified during the FG, such as previous experience with lung cancer testing and consumers' understanding of the advantages and disadvantages of various tests, especially spiral CT. By the nature of this research design, the final IDI will depend on the information collected during the FGs. We have developed an in-depth interview guide in anticipation of potential FG

findings (see Attachment E, Guide for In-Depth Interviews with Health Care Consumers). The average burden of the IDI is estimated at one hour.

The burden for the physician component of the study includes a time commitment for completing the Physician Response Form (Attachment F), which is estimated to take 5 minutes per response, and the time commitment for participating in the physician focus group, which is estimated at 1.25 hours (see Attachment G, Moderator's Guide for Physician Focus Groups). We estimate that 4 focus groups will be conducted each year. Each physician focus group will consist of 6 respondents, however, to allow for last-minute changes in availability, 8 physicians will be recruited to each FG (i.e., 6 respondents and 2 alternates). This reflects a total of 32 physicians recruited annually for the physician FG. Again assuming a 50% response rate, we anticipate screening a total of 64 physicians per year with the Physician Response Form.

Information will be collected in two consecutive years. The total estimated annualized burden hours are 193.4. Table A.12-1 provides a summary of the burden for each study component.

Table A.12-1. Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Health Care Consumers	Health Care Consumer Screener Form	192	1	2/60	6
	Moderator's Guide for Health Care Consumer Focus Groups	72	1	2	144
	Guide for In-Depth Interviews with Health Care Consumers	8	1	1	8
Physicians	Physician Response Form	64	1	5/60	5
	Moderator's Guide for Physician Focus Groups	24	1	1.25	30
				Total	193

B. The total estimated annualized cost to respondents is $5,870, as summarized in Table A.12-2. Average hourly wage rates for both types of respondents were calculated using an estimated 40-hour work week and usual weekly earnings released from the United States Department of Labor, Bureau of Labor Statistics (2006).

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage Rate	Total Cost
Health Care Consumers	Health Care Consumer Screener Form	192	1	2/60	$21.00	$134
	Moderator's Guide for Health Care Consumer Focus Groups	72	1	2	$21.00	$3,024
	Guide for In-Depth Interviews with Health Care Consumers	8	1	1	$21.00	$168
Physicians	Physician Response Form	64	1	5/60	$72.00	$384
	Moderator's Guide for Physician Focus Groups	24	1	1.25	$72.00	$2,160
					Total	$5,870

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

Respondents will incur no capital or maintenance costs to complete this data collection.

A.14 Annualized Cost to the Government

Total costs include work performed by the research contractor, Research Triangle Institute (RTI), and CDC personnel. RTI is funded at an annual cost of $104,433.50 over the two-year period of data collection. RTI will be responsible for recruitment procedures, working with the professional FG moderators and interviewers to collect information, data analysis, and report preparation. CDC personnel costs are estimated at $9,500 annually for 0.10 FTE of an evaluator. Table A.14-1 summarizes the estimated annualized cost to the Federal Government.

Table A.14-1. Estimated Annualized Cost to the Federal Government

	Annualized Cost
CDC Personnel	$9,500
Research Contractor (RTI)	$104,434
Total	$113,934

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

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

Table A.16-1 provides a timeline for the activities scheduled during the period for which this clearance is requested.

Table A.16-1. Project Activity Time Schedule

Project Activity	Date
OMB Clearance Process	**12 months**
Health care consumer component	
Identify facilities for health care consumer FGs: Cities 1-4	**While awaiting OMB approval**
Reserve facilities for health care consumer FGs: Cities 1-4	**Within 1 month following OMB approval**
Recruit health care consumers for health care consumer FGs: City 1	**Within 3 months following OMB approval**
Attend and conduct health care consumer FGs and IDIs: City 1	**Within 4 months following OMB approval**
Recruit health care consumers for health care consumer FGs: City 2	**Within 6 months following OMB approval**
Attend and conduct health care consumer FGs and IDIs: City 2	**Within 8 months following OMB approval**
Recruit health care consumers for health care consumer FGs: City 3	**Within 12 months following OMB approval**
Attend and conduct health care consumer FGs and IDIs: City 3	**Within 13 months following OMB approval**
Recruit health care consumers for health care consumer FGs: City 4	**Within 14 months following OMB approval**
Attend and conduct health care consumer FGs and IDIs: City 4	**Within 15 months following OMB approval**
Analyze health care consumer FG and IDI data: Cities 1-4	**Within 20 months following OMB approval**
Draft final report	**Within 23 months following OMB**

	approval
Submit final report and technical documentation	**Within 24 months following OMB approval**
Physician component	
Select dates and reserve executive teleconference service	**Within 6 month following OMB approval**
Purchase AMA list of eligible physicians	**Within 6 months following OMB approval**
Recruit physicians for FGs (i.e., send recruitment packets) **Set up executive conference service**	**Within 8 months following OMB approval**
Conduct physician FGs	**Within 16 months following OMB approval**
Analyze physician FG data	**Within 20 months following OMB approval**
Draft final report	**Within 23 months following OMB approval**
Submit final report and technical documentation	**Within 24 months following OMB approval**

Health Care Consumer Component

For the health care consumer component, analysis of FG data will start immediately after completion of data collection and will be conducted under the supervision of a senior RTI staff member with extensive experience in qualitative research. FG data will be professionally transcribed. RTI will conduct thematic analysis and other varied analytic techniques of the data to understand participants' thoughts about and experiences with lung cancer screening and testing in as rigorous and detailed a manner as possible. Using a common coding scheme, two RTI project staff will review and independently code the data using the qualitative data analysis software N*Vivo.

If IDIs are warranted, data from the IDIs will be entered into an electronic data matrix by the RTI note taker during the IDI. Using a separate coding scheme and codebook, the two RTI coders will analyze the data in the matrices and summarize the data in a final report.

Physician Component

The analysis of physician data will start immediately after completion of data collection and will be conducted under the supervision of a senior staff member with extensive experience in qualitative research. FG data will be professionally transcribed, and thematic analysis will be conducted by two RTI coders. Depending on the amount of data collected, the team of coders will review the data from all FGs

independently using either N*Vivo or a data matrix analysis approach. Once the data have been coded, they will be summarized in a final report.

In addition to the final reports, results of both of the study components will be prepared for scientific publication. The manuscripts for publication will report critical findings from this study, inform future research and program efforts, and assist in filling a gap in the literature on lung cancer screening behaviors and practices among health care consumers and physicians.

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

This research project does plan to display the expiration date for OMB approval for the information collected and does not seek a waiver.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These data are collected in a manner consistent with the certification statement identified in Item 19 “Certification for Paperwork Reduction Act Submissions” of OMB Form 83-I. No exceptions are being sought.

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