Exploratory Research with People Living with Lung Cancer

Request for OMB Approval

Supporting Statement Part A

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Lung cancer is the most common cancer and the leading cause of cancer-related mortality in the world (Ganti and Mulshine 2005). In 2008, the American Cancer Society estimates over 215,000 Americans will be diagnosed with lung cancer and over 160,000 will die from the disease (ACS 2008).

With a low survival rate for individuals with lung cancer, health care researchers have focused less on understanding the health and social needs of individuals affected by lung cancer compared with other cancers (Krishnasamy and Wilkie 1997, Sarna et al. 2002). Further, most of the current research that has focused on the experience and psychosocial needs of individuals with lung cancer has been done in European countries.

With a diagnosis of lung cancer, one can expect to deal with physical challenges, including receiving adequate pain and symptom management and provision of adequate palliative care. There are also important psychological issues to address with lung cancer. Several studies have focused on increased risk for depression among individuals diagnosed with lung cancer (Hughes 1985, Montazeri et al. 1998, Hopwood and Stephens 2000). Others (Salander and Henriksson 2005) have examined communicative needs of patients and the extent to which providers are meeting these needs.

Lung cancer can also be socially debilitating; often people with lung cancer are shut out from normal everyday activities because of physical limitations. Likewise, questions are just starting to be asked about the experience of people living with lung cancer in terms of the stigma, victim blaming, and discrimination relating to smoking behaviors. Other issues include the economic challenges that lung cancer can present and receiving appropriate spiritual support.

Another area of deficit for individuals with lung cancer is receiving adequate information on their disease. In examining the information needs of lung cancer survivors, Hill et al. (2003), in an article in the European Journal of Cancer Care, describe the results of a brief survey used to identify the information needs of 80 lung cancer patients shortly after diagnosis. In this study, patients reported that less than half of their information needs were met during their care. In particular, patients' psychosocial needs were the least likely to have been addressed. Similarly, a recent British study (Gore et al. 2000), in reporting the findings of a study of health care needs of patients with chronic obstructive pulmonary disease and non-small cell lung cancer, concluded that patients in both groups reported a lack of information from professionals regarding diagnosis, prognosis, and social support.

With a significant number of Americans affected by lung cancer—people who will face many, if not all, of the challenges of individuals diagnosed with other cancers—there is a need to address this gap in knowledge on the experiences of living with lung cancer and improve our understanding of the challenges and needs of individuals with lung cancer. As Gridelli et al. (2001) point out, with limited progress in the lung cancer survival rate, there is a critical need to understand the effects of treatment to improve quality of life for lung cancer patients.

Overall, there is a need for research to better understand the experiences of individuals living with lung cancer in order to meet their psychosocial needs. Additionally, the Centers for Disease Control and Prevention and the Lance Armstrong Foundation have developed a *National Action Plan* to address survivorship issues (CDC 2004). This plan includes the following objectives:

- Preventing secondary cancers and recurrence of cancer whenever possible
- Promoting appropriate disease management following diagnosis and treatment to ensure the maximum number of years of healthy life for cancer survivors
- Minimizing preventable pain, disability, and psychosocial distress for those living with, through, and beyond cancer
- Assisting cancer survivors in accessing family, peer, community support, and other resources they need for coping with their disease

In particular, the proposed research will explore issues related to 1) individuals' diagnosis process, 2) their experiences of stigma and victim blaming once diagnosed with lung cancer, and 3) their opportunities for counseling and support services.

Authorization for CDC to collect such information to formatively evaluate lung cancer screening practices among health care consumers' and physicians' is provided under Section 301 of the Public Health Service Act (42 U.S.C. 241) (See **Attachment 1**). We are seeking a one-year clearance request from the Office of Management and Budget.

Privacy Impact Assessment

This is a new research study. It has not previously been assessed for privacy impact.

Overview of the Data Collection System

The proposed formative research will use in-depth telephone interviews to learn information health needs of people living with lung cancer. Telephone interviews are suited to the descriptive requirements of the proposed research; they allow flexible, in-depth exploration of individual perceptions and experiences. We will recruit 27 individuals who have been diagnosed with lung cancer, with nine of the participants being current smokers, nine of the participants being former smokers, and nine of the participants being individuals who have never smoked. Study participants will be recruited from a convenience sample of individuals receiving care at pulmonary, thoracic surgery, and oncology medical practices and clinics associated with two clinic sites in different U.S. cities. Individuals will be screened and enrolled in the study on a rolling basis.

Items of Information to be Collected

The study is primarily designed to collect information about respondents' experiences and feelings relating to the diagnosis of lung cancer. Information about smoking status (current, former, never) will be collected for screening purposes. Secondarily, to support the recruitment and interview scheduling process, we will also collect the following identifiable information: *Name, Date of Birth, Mailing Address*, and *Phone Number*, however, the IIF will not be stored with the response data from the in-depth interviews.

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

No websites will be used in this study and there is no website content directed at children under 13 years of age.

A.2 Purpose and Use of the Information Collection

The information collected from this project supports the Healthy People 2010 goals for cancer and health communications: 1) to use communication strategically to improve health. At this time, little is known about the experiences of persons diagnosed with lung cancer. Data collected through this project will help address current knowledge gaps about the experiences of individuals living with lung cancer, particularly those related to their diagnosis process, experiences of stigma and victim blaming, and opportunities for counseling and support services. This information will be used to determine the need for

future research and to develop interventions related to this topic. The information collected through this study is important to improving the health and well-being of individuals with lung cancer by improving the services and resources potentially available to them.

Privacy Impact Assessment Information

Respondents will be recruited from clinic sites with existing record systems. Clinic staff who have access to patient information as part of their regular duties will identify potentially eligible patients and refer those who are interested to Research Triangle Institute International (RTI), the contracting organization that will manage the study on behalf of CDC. Patients will give explicit consent for referral and further contact. Potentially sensitive information (diagnosis of lung cancer) collected as part of the recruitment screener will not be maintained. The principal items of information to be collected are not sensitive. Although the contractor, RTI International, will have temporary access to information in identifiable form (IIF) for recruitment and scheduling purposes, this information will be destroyed once the interviews are complete, and will not be connected to response data. Respondent privacy will be safeguarded through controls on physical records (use of locked cabinets for paper documents, which will be destroyed on a schedule maintained by the contractor), controls on electronic data systems (limited staff access to shared drive, and separation of IIF from response data), and administrative measures (contractor employees will sign non-disclosure agreements).

A.3 Use of Improved Information Technology and Burden Reduction

The proposed formative research project is based on qualitative methods, rather than electronic information collection procedures. However, the study design includes a number of conveniences to accommodate respondents and promote their participation. In particular, we propose the use of in-depth interviews via the telephone, thus reducing travel requirements. Telephone calls will be conducted via a toll-free conference line. When possible and upon consent from the participant, we will audio tape the telephone interviews to capture all information and assist with preparation of reports.

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

In order to identify duplication and use of similar information, we conducted an extensive review of the literature by examining several large periodical journal databases. In addition to reviewing published information, we searched for “gray” literature by exploring the Internet. We also searched the internet using several Internet search engines, including Google, Yahoo, AltaVista, Medline, and Science Direct. We were unable to find duplication or the use of similar information. There is no other study that duplicates our proposed efforts.

A.5 Impact on Small Businesses or Other Small Entities

This study does not have impact on small businesses or other small entities. We will schedule all interviews at the convenience of the participant and we will not impact the participant's employer.

A.6 Consequences of Collecting the Information Less Frequently

Reducing the respondent burden below the estimated levels (that is, reducing the number of interviews) would diminish the utility of the study and compromise the findings. It is methodologically desirable to have multiple persons in the segmented groups (e.g., current smokers, former smokers, never smoked). This type of collection activity follows standard qualitative research methodology (Patton, 1990).

This is a one-time data collection effort (i.e., a one-time study conducted with survivors of lung cancer and does not require periodic collection of data). The present study will provide the primary data needed to help the CDC develop an understanding of the needs of lung cancer survivors. If we do not conduct this formative research, we would not be able to know the needs of this population. Additionally, CDC would not have the information needed to create targeted educational campaigns that addressed their needs. Our formative research process includes gaining an understanding of a target audience's perceived needs, benefits sought, and barriers of concern.

There are no legal obstacles to reduce 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 CRF 1320.5 (d)(2). 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

A.8.a. A 60-Day *Federal Register* notice that was published on Monday, August 4, 2008 (Volume 73, Number 150, pages 45224-45225) solicited comments on Exploratory Research with People Living with Lung Cancer (**Attachment 2A**). Two responses were received from one organization: a request for additional information, and a letter of support. A summary of public comments and CDC's response are included in **Attachment 2B**.

A.8.b. The CDC study team collaborated with RTI International staff (contractor) on the study design, screening instruments, and interview guides. RTI staff are trained and experienced in formative research. CDC recognizes the importance of gaining valuable insights directly from members of the target audience and from organizations and

individuals who work with them in the community. Consultation with individuals and related activities occurred and are listed below. No major problems were identified that could not be resolved.

We consulted with the following individuals at various times throughout 2006-2007 for development of campaign concepts, messages, and materials (see **Table A.8-1**). We will continue consultation as needed.

Table A.8-1. Individuals Consulted During the Development Research Project

Centers for Disease Control and Prevention Division of Cancer Prevention and Control National Center for Chronic Disease Prevention and Health Promotion 4770 Buford Highway NE, MS-K52 Atlanta, GA 30341-3724		
Linda Pederson, PhD Office on Smoking and Health National Center for Chronic Disease Prevention and Health Promotion 4770 Buford Hwy NE, MS-K50 Atlanta, GA 30341-3717	Scientific Advisor	Phone: (770) 488-5476 E-mail: lip9@cdc.gov
RTI International 3040 Cornwallis Road P.O. Box 12194 Research Triangle Park, NC 27709-2194		
Julia Kish Doto, PhD	Project Leader	Phone: (202) 974-7850 Fax: (202) 728-2095 E-mail: jkdoto@rti.org
Lauren McCormack, PhD	Scientific Advisor	Phone: (919) 541-6277 Fax: (919) 990-8454 E-mail: lmac@rti.org
Jon Poehlman, PhD	Senior Analyst	Phone: (919) 541-7068 Fax: (919) 541-7384 E-mail: jpoehlman@rti.org

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 information collection format. Therefore, interview participants will receive $50 at the conclusion of the group discussion.

A.10 Assurance of Confidentiality Provided to Respondents

The primary purpose of the research is to collect information about respondents' experiences and feelings associated with the diagnosis with lung cancer. Respondents who have never smoked will be recruited, along with current smokers and former smokers. Potentially sensitive information collected as part of the screening process will not be maintained. Although the contractor, RTI International, will have temporary access to information in identifiable form (IIF) for recruitment and scheduling purposes, response data collected during in-depth telephone interviews will not be recorded in a manner that is linkable to respondent identifiers.

This data collection has received institutional review board (IRB) approval from the CDC Human Research Protection Office (protocol #5326, expiration 3/12/09). The CDC, RTI, and its clinical partners' IRB approvals are included as **Attachment 3**. IRB approvals will be renewed annually as needed.

Privacy Impact Assessment Information

A. Privacy Act Determination

Staff in the CDC Information Collection Request Office have reviewed this submission and have determined that the Privacy Act does not apply. Although respondents' names and telephone numbers (IIF) will be used for recruitment and interview scheduling purposes, the identifying information is available from previously established record systems in the clinics that serve as recruitment sites (but will be verified by respondents during the consent process to ensure accuracy). Identifying information will not be linked to the response data collected for the proposed research study.

B. Safeguards

Privacy safeguards will include removing all participants' identifying information from data collected (i.e., study transcripts, notes). Audio tapes will be destroyed after the transcription is complete. Each respondent will be assigned a unique identifier that will be used to track and store data. Notes and transcripts from the interviews will be stored and locked in a secure project file cabinet at RTI, which will be accessible only to select project staff. 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 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.

C. Consent

Two clinics will serve as recruitment sites. Clinic staff who have access to patient information as part of their routine duties will identify potentially eligible patients and refer those who are interested in participating to study staff employed by RTI, the data collection contractor. Patients who are interested in study participation will provide consent for further contact by the contractor as well as consent for enrollment in the study. The Scott and White clinic has specific HIPAA-related consent requirements for referral and release of patient contact information.

D. Voluntary Nature of Response

Participation in the proposed research is entirely voluntary. In addition, respondents may decline to answer any question. The voluntary nature of the interviews is clearly stated as part of the interview introductions and in the informed consent forms.

A.11 Justification for Sensitive Questions

One question on the health care consumer screener (i.e., date of diagnosis of lung cancer) is potentially sensitive to a small portion of respondents, however, the question is necessary to recruit respondents who are eligible for the study in terms of health history. Participants are given a *Recruitment Flyer* (**Attachment4**) that explains the study.

A.12 Estimates of Annualized Burden Hours and Costs

A. Two clinic sites will assist in recruiting patients for the study. Interest for participation in the study will be evaluated by a clinic staff member. If a patient meets the initial study criteria, the staff member will describe the study and invite their participation, assisted by speaking points provided in the *Recruitment Flyer* (**Attachment 4**) and a Study Invitation script included in the *Instructions for Clinic Staff* (**Attachment 5**). Patients who agree to further contact, in order to learn more about the study and to be assessed for eligibility, will complete the *Contact Information Form* (**Attachment 6**). The burden for completion of this form was calculated at 8 minutes including documentation of *Consent for Contact*. Timings were conducted during the instrument development process to determine the overall burden per respondent. We estimate that clinic staff will initiate the Study Invitation discussion with approximately 250 patients in order to identify 88 patients who are potentially eligible and agree to further contact, however, no information will be collected from patients who do not express initial interest in participating.

Each recruitment site will provide approximately half (44) of the total number of respondents (88) who consent to further contact and screening. Participants who are recruited from the Scott and White clinic will complete one additional form: the Scott and

White Consent Form (**Attachment 7**). This form is required by the site's Institutional Review Board to satisfy their requirements pertaining to the Health Insurance Portability and Accountability Act (HIPAA).

RTI staff will conduct screening via telephone. We estimate that RTI will be able to reach 66 of the 88 respondents (75%) who consented to further contact and screening. Eligibility will be assessed through questions contained in the *Screening Form* (**Attachment 8**). Based on timings conducted during the instrument development process, administration of the *Screening Form* is estimated to take 10 minutes. Of those screened, we anticipate that 50% will be eligible and willing to participate in the study. Therefore, 33 patients (50% of 66) will be scheduled for an interview and will complete the *Informed Consent Form* (**Attachment 9**). RTI staff will mail two copies of the Informed Consent Form to each patient who is scheduled for an interview, with instructions to return one signed form to RTI (via fax or mail) in advance of the scheduled interview date, and to retain one copy for their personal records.

Of the 33 respondents scheduled for in-depth interviews, we assume that 6 will cancel for various reasons, therefore, 27 will actually participate. A professional interviewer with the RTI study team will conduct the interviews by telephone (see **Attachment 10,** *In-Depth Interview Guide*). The purpose of the interview is to explore issues related to the patients' diagnosis process, experiences of stigma and victim blaming, and opportunities for counseling and support services.

Information will be collected over a one year period. The total estimated annualized burden hours are 50, as summarized in Table A.12-1.

Table A.12-1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
People Living with Lung Cancer	Contact Information Form and Consent for Contact	88	1	8/60	12
	Screening Form	66	1	10/60	11
	In-depth Interview Guide	27	1	1	27
				Total	50

B. In calculating the annualized estimated cost to respondents, we used the May 2007 average U.S. hourly wage of $ 19.56. We used the mean hourly wage for all occupations in the United States according to the Department of Labor, Bureau of Labor Statistics - May, 2007 (BLS, 2008) (available online at: http://www.bls.gov/oes/current/oes_nat.htm#b00-0000). Actual hourly wage rates will vary by education, work experience and other factors. The estimated annual cost to participants for the time burden for collections of information is $978. Table 1.12-2 provides a summary of the estimated annualized cost to respondents.

Table A.12-2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden Hours	Average Hourly Wage Rate	Total Cost
People Living with Lung Cancer	Contact Information Form and Consent for Contact	88	1	12	$19.56	$235
	Screening Form	66	1	11	$19.56	$215
	In-depth Interview Guide	27	1	27	$19.56	$528
		TOTAL				$978

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

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than their time to participate. There are no start-up, capital, or maintenance costs to complete this data collection. We do not require any additional record keeping.

A.14 Annualized Cost to the Government

The total annualized cost for this study is estimated to be $108,934. 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. RTI will be responsible for recruitment procedures, facilitating interviews to collect information, data analysis and report preparation. CDC personnel costs are estimated at $4,500 for a 0.05 FTE of an evaluator. Table A.14-1 summarizes the estimated annualized cost to the Federal Government.

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

	Annualized Cost
CDC Personnel	$4,500
Research Contractor (RTI)	$104,434
Total	$108,934

A.15 Explanation for Program Changes or Adjustments

This is a new, one-time information 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

Activity	Time Schedule
Begin recruitment	1 month after OMB approval
Begin Data Collection	2 months after OMB approval
Complete Data Collection	6 months after OMB approval
Analyze Data	6 months after OMB approval
Deliver Draft Final Report	10 months after OMB approval
Deliver Final Report	12 months after OMB approval

Analysis of the interview data will begin 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. Interview data will be professionally transcribed. RTI will conduct thematic analysis of the data to understand participants' thoughts about and experiences with their diagnosis of lung cancer. Using a common coding scheme, RTI staff will review and code the data using qualitative data analysis software. Once data are coded and further analyzed, they will be summarized in a final report.

In addition to a final report, results of will be prepared for scientific publication. The manuscripts for publication will report critical findings from this study, inform future research efforts, and assist in filling a gap in the literature on the experiences of lung cancer patients.

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

This research project will 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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