Exploratory Research with People Living with Lung Cancer

Request for OMB Approval

Supporting Statement Part B

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

This is a descriptive and exploratory qualitative research project. Statistical methods will not be used to select respondents. The purpose of this study is to conduct formative research (individual telephone interviews) that will be used by the CDC to develop an understanding of the perceptions and experiences of individuals with lung cancer. This information will be used to determine the need for future research and to develop interventions related to this topic.

Activities will be conducted over a one-year period. We will recruit a convenience sample of 27 individuals living with lung cancer. These individuals will be recruited from various medical clinics (internal medicine, pulmonary oncology, thoracic surgery) associated with two clinical sites in the United States (see **Table B.1-1.**) Participating clinical sites include:

Table B.1-1. Clinical Sites

Clinical Site:	Location:	Contact:
Moses Cone Hospital, Greensboro AHEC	Greensboro, North Carolina	Dr. Samuel Cyket, MD Director of the Internal Medicine Residency Program
Scott and White Clinic	Temple, Texas	Dr. Carl Boethel, MD

At each of the two clinical sites, clinical staff will invite patients who are presenting for care related to lung cancer to learn more about the study and to complete a basic screening on study recruitment criteria. If potential participants meet the initial screening criteria and consent to further contact, a study coordinator from Research Triangle Institute International (RTI) will contact them by telephone for a full eligibility screening. If an individual completes the full screening and is eligible, he or she will be invited to participate in the study. An informed consent form will be mailed to them, which is to be signed and returned by mail or fax.

In order to obtain the target number of respondents (n=27), we estimate contacting approximately 250 patients in the clinical setting at the two participating clinical sites. We are assuming that 35% of patients (n=88) that are approached will accept the invitation for further screening and provide contact information so that the study team can call them by telephone and conduct a screening for eligibility. We anticipate that we will reach 75% of those who provided contact information (n=66) to participate in a full telephone eligibility

screening. Assuming a 50% eligibility rate, 33 patients will be scheduled to participate in a one-hour telephone interview. We also estimate that 6 of the patients scheduled will cancel for various reasons and that 27 will actually participate in the telephone interview.

The following presents the inclusion and exclusion criteria for the study:

Inclusion Criteria

- Diagnosed with lung cancer
- At least six months since first diagnosis
- Between the ages of 30 and 80

Exclusion Criteria

- Not able to complete an interview in English
- Cannot complete an hour interview in 1-2 sessions
- Participating in a cancer-related research study

Further, to the extent possible, we will stratify the sample of lung cancer survivors on their smoking status prior to their diagnosis of lung cancer. In the screening process for the interviews, we will assess their smoking behaviors at time of diagnosis and assign them to one of three categories- *Smoker, Former Smoker*, and *Never Smoked*. In recruiting for the interviews, our goal is to include 9 individual from each of these categories in the overall sample of 27 participants.

Statistical power is not applicable because this is a qualitative study. The results are not generalizable to the general population.

B.2 Procedures for the Collection of Information

Recruitment will begin at least four weeks before the interviews are scheduled. RTI will keep CDC apprised of the recruitment progress and will make any necessary adjustments during the recruitment process. We will begin recruitment for the interviews within a month of receiving OMB clearance and anticipate recruiting for about 3 months' time.

All recruiting will be conducted using a convenience sample drawn from our two participating clinical sites. RTI has developed a three-step process for conducting recruiting for the study that includes: 1) Clinical Screening, 2) Full Study Screening, and 3) Scheduling.

Step One – Initial Eligibility Screening at Clinical Sites: Two clinical sites are participating in the study to assist with patient recruitment. A local recruiting coordinator from RTI will provide training and supervision to the clinical staff about study eligibility criteria and recruitment procedures. Clinic staff will identify potential participants for the study based on their knowledge of the lung cancer patients attending their clinics. Guided by the *Instructions for Clinic Staff* (**Attachment 5**), clinic staff will approach potential participants to provide an introduction to the study and provide them a *Patient Flyer* (**Attachment 4**) with written information about the study.

For interested patients, the clinic staff will ask them to complete a *Living with Lung Cancer Contact Information Form* (**Attachment 6**) and request their permission for the local research coordinator or their designated assistant to contact them. The clinical staff will inform the patient that participation is voluntary and that they are free to say no to participation at any time. In addition, clinical staff will provide a telephone number so that potential participants can independently contact the local study coordinator or RTI research staff about participation or to ask questions about the study. Patients recruited from the Scott and White site will also be required to complete a *Scott and White Consent Form* (**Attachment 7**).

The basic steps in the *Clinical Screening* process are:

1. Identify individuals potentially eligible for the study based on their diagnosis of lung cancer, time since first diagnosis, age, and history of smoking, using the *Instructions for Contact Form*;

2. Provide eligible participants with an introduction to the study, its sponsors, and objectives;

3. Offer potential participants a *Patient Flyer* that tells more about the study and provides contact information;

4. For patients interested in participating, request patient permission to be contacted for further eligibility screening and collect personal contact information using the *Living with Lung Cancer Contact Information Form* (**Attachment 6**). Patients recruited from the Scott and White site will also be required to complete a *Scott and White Consent Form* (**Attachment 7**).

The *Living with Lung Cancer Contact Information Form* is the only location where personal information (e.g., telephone numbers, email address) about potential participants is

recorded. After initial eligibility screening, clinical staff will telephone their local RTI study coordinator and provide the contact information recorded in the *Living with Lung Cancer Contact Information Form* and *Consent for Contact*. This page of the form with identifiable contact information will be separated and stored in a locked file cabinet until it can be personally collected by the local RTI study coordinator at each site and destroyed. For individuals who decline to participate, no information will be recorded. Clinical staff at each of the clinical sites will receive training on the recruiting procedures, including confidentiality practices, from the local RTI study coordinator.

Step Two- Full Study Eligibility Screening: The local RTI study coordinator at each site, after receiving contact information from clinical staff, will contact potential study participants for further screening. Using the *Screening Form* (**Attachment 8**), the study coordinator will review and confirm the initial eligibility questions with each patient and determine his or her insurance status. Further questions relating to an individual's history of smoking will be asked in order to segment individuals into one of the study's three audience segments (smokers, former smokers, and never smoked).

If a participant is eligible and interested in participating after the screening, the study coordinator will relay the screening information, including contact information, to research staff at RTI via telephone. RTI will record all contact and patient information on an RTI record sheet. At the conclusion of this process, the local RTI study coordinator will store the full study screener in a locked file cabinet located in a secured building at their site.

Step Three – Interview Scheduling: After RTI receives information about an eligible participant, RTI will contact that individual to schedule an interview at a convenient time for the participant. Reminder letters/e-mails and the *Informed Consent Form* (**Attachment 9**) will be sent to potential participants prior to the interview**.** The consent form can either be faxed or returned in a postage paid envelop to RTI. Confirmation calls will also be made 1–2 days prior to the interview to assure that all recruits are confirmed.

All interviews will be completed within one year. The interviews will be conducted over the telephone using the *In-depth Interview Guide* (**Attachment 10**). Each interview will last for one hour. In addition to the interviewer, an additional RTI staff member and CDC staff members may listen in to the interview.

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

The following procedures will be used to maximize cooperation and to achieve the desired participation rates:

- Reminder letters/e-mails will be sent with call-in information for the telephone interview and reminder phone calls placed 1-2 days prior to the scheduled interview. Participants will not be contacted again after the interview is over.

- Provision of honoraria to participants (please see Section A-9 for more information about the honoraria).

B.4 Tests of Procedures or Methods to Be Undertaken

To estimate the burden for administering the screening questionnaire, two different project team members were consulted. The project team members conducted mock screening interviews and provided affirmative responses to most or all questions that branched to further follow-up questions. In this way, the burden estimate most closely resembles a maximum average burden, since almost all screening questions were presented in the interview. In addition, the project team members deliberately read each item at a slow rate of speed. The project team members estimated the maximum average for each of the screening instruments as follows:

Contact Information Form (contact information only)	5 min
Living with Lung Cancer Consent for Contact	3 min
Screening Form	10 min

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

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