

8. PROCEDURES TO ASSESS CONTAMINATION

8.1 Overview

As part of the Lung Screening Study, a portion of enrolled participants with negative findings on the screening examination will be re-contacted to assess the extent to which participants received screening examinations outside of this study. With respect to chest X-ray and spiral CT, such outside examinations constitute contamination. Contamination will be measured by the Health Assessment Questionnaire (HAQ) (Appendix 8-1). Around May 1, 2001, SC staff will mail the HAQ to a random selection of 60 participants (360 total) that had negative screening results with no abnormalities, along with a cover letter that explains the purpose of the questionnaire. Each SC should administer the HAQ to 40 participants who had a negative chest X-ray screening exam with no abnormalities and 20 participants who had a negative spiral CT screening exam with no abnormalities. NCI may request additional sampling from other categories of negative results to ascertain follow-up in them. The HAQ will assess the extent to which study participants received either spiral CT examinations (for participants allocated to the chest X-ray group) or chest X-ray examinations (for participants allocated to the Spiral CT group) outside of those screens administered through the Lung Screening Study. Detailed procedures for the administration and processing of these forms are presented in the following sections.

8.2 Timeframe

All contamination assessment activities for the Lung Screening Study will be done from mid-April 2001 to the end of June 2001. Activities are scheduled according to this timetable.

- **April 2001** – The CC will randomly select the 360 enrolled study participants who will be asked to complete the HAQ and will send HAQs, pre-labeled with the PID number, the SC name and address, and the screening examination date to the appropriate SC.
- **May 1, 2001** – The SCs will mail packets containing the labeled HAQs along with a cover letter and postage-paid return envelope to selected study participants.
- **May 22, 2001** – The SCs will begin contacting non-responding study participants by telephone to administer the HAQ.

- **June 30, 2001** – The SCs will forward the last completed HAQs or completed Missing Data Forms to the CC. All attempts to contact non-respondents and all data retrieval must be completed.

8.3 Methods for Administration of the Health Assessment Questionnaire (HAQ)

Both the CC and each SC share the responsibilities for completing tasks associated with the contamination assessment. Due to the short period of time planned for this activity, it is important that the CC and SCs have staff and materials available to meet the stated deadlines. The responsibilities of the CC and SCs are described in the sections that follow.

8.3.1 CC Responsibilities

During the month of April 2001, the CC is responsible for the random selection of 360 study participants from those with negative screening examination results with no abnormalities. Once the selection is completed, the CC will print an HAQ that includes the PID number, the SC name and address, and the screening examination date for each selected participant. The CC will distribute the HAQs to the appropriate SC along with a list of the randomly selected PIDs from that SC. In addition, the CC will provide blank questionnaires without PID labels or screening examination dates to each SC for re-mailing or telephone administration to non-respondents. All materials will be sent to the SCs by mid-April so that the mailings can be completed by May 1, 2001. The CC is also responsible for receipting and performing data entry on completed HAQs transmitted weekly during the data collection period in May and June.

8.3.2 SC Responsibilities

Upon receiving the pre-labeled HAQs from the CC, the SC will prepare the packets for the mailing to the selected participants. The SC will include the following items:

- An HAQ form with a PID, SC name and address and screening examination date printed on it,
- A cover letter on SC letterhead, and
- A postage-paid return envelope with first-class postage.

On May 1, 2001, the HAQ packets will be mailed from the SCs to the selected participants with a cover letter explaining the purpose and timeframe of the HAQ. These packets should be mailed first-class. A sample cover letter is provided in Appendix 8-3. If the SC wishes to use a letter that differs from the sample, it must be approved by the NCI prior to its use in the study.

The HAQ should be completed and returned by mail to the SC. The SCs are responsible for obtaining completed questionnaire information on all of the randomly selected study participants. Participants not responding to the mailed questionnaire within three weeks of mailing (non-respondents) will be called in an attempt to administer the HAQ by telephone. It will be the responsibility of the SC staff to attach a PID label and record the screening examination date on the CC-supplied blank questionnaires used for telephone administration. Specifications for completion of the HAQ are provided in Appendix 8-2.

8.4 Receipt, Editing and Data Retrieval for the HAQ

When a completed HAQ is received by mail, SC staff will review it for legibility, completeness and consistency. If the SC receives a HAQ with any missing, unclear, or inconsistent information, the participant should be contacted by telephone to obtain the information. If a participant does not return a completed HAQ within 3 weeks of the initial mailing, s/he should be contacted by telephone to administer the HAQ.

Successfully contacting study participants by telephone requires making calls at times when the individuals are available to provide the information, which often means evening and weekend calls. Guidelines for conducting telephone follow-up are given below:

- Make at least five attempts to contact a participant by telephone.
- Place each call on a different day of the week, Monday through Friday.
- If necessary, place two additional calls, one on Saturday and one on Sunday.
- Separate first and last calls by at least one week.
- Make calls at different times each day: morning, afternoon, and evening.

The SC may wish to use call records to track SC efforts in telephone data collection. A Sample Call Record is provided in Appendix 8-4.

8.5 Documenting Non-Response to the HAQ

If an HAQ form has not been completed for a selected participant by June 30, 2001, the SC staff will complete an MDF in place of the HAQ (See Chapter 9). It is expected that an HAQ or an MDF will be on file at the SC for each participant sent an HAQ by June 30, 2001.

8.6 Tracking, Reporting, and Monitoring HAQ Collection Activities

Each SC will track the collection of HAQ forms from their group of randomly selected study participants, in order to document whether all expected forms have been collected. Each SC will have a system, manual or automated, for tracking the steps involved in the collection and transmittal of HAQ forms. This system will include at a minimum a tracking record for each participant randomly selected for the health assessment.

SCs will transmit completed original HAQs and MDFs to the CC on a weekly basis. From these transmitted forms, the CC will produce the Summary Data Receipt Report (Appendix 9-23) which will provide each SC with a list of the HAQs and MDFs that have been receipted. If the HAQ or an MDF for the HAQ was not receipted, it will be shown as pending. This report will allow for the monitoring of receipted, missing, and pending HAQs by the SC and the CC during the contamination assessment period. SC staff should use this report to ensure that CC records for the collection of HAQs match those at the SC.

8.7 Transmittal of the HAQ to the CC

The SC is responsible for shipping HAQs and MDFs to the CC on a weekly basis. In preparation for shipping, the SC should photocopy the HAQs and MDFs and separate them by form type. Participant identifiers and any personal notes should be removed from the HAQs. The forms, with the PIDs included, should be mailed to the CC each week and listed on the Forms Transmittal Log (see Section 9.7).

The photocopy of the completed HAQ or MDF should be filed in the participant's study file at the SC. If a situation arises in which an MDF must be deleted from the central records, the SC should notify the CC of the necessary deletion, but keep the hardcopy MDF in the participant's folder. For example, this situation could occur if the actual study form is received or found, or if the MDF was completed in error. SC staff should document on the MDF why the form was deleted from the central records and initial and date the form.

Appendices for Chapter 8

- 8-1 Health Assessment Questionnaire (HAQ)
- 8-2 Specifications for Completion of the Health Assessment Questionnaire (HAQ)
- 8-3 Sample Cover Letter for the Health Assessment Questionnaire (HAQ)
- 8-4 Sample Call Record