7. FOLLOW-UP OF A POSITIVE SCREEN

7.1 Overview of Diagnostic Evaluation Procedures

Each Screening Center (SC) will implement procedures to follow-up all participants who have a positive screening result that is suspicious for cancer whether from a spiral CT scan or chest X-ray. Criteria used to classify an abnormal examination result as a "Positive Screen" were previously discussed in Chapters 4 and 5 of this manual. Standardized procedures will ensure that the SCs collect diagnostic evaluation including cancer diagnosis information for every positive screen. This information is to be obtained in a timely manner following the screening visit. The goal of diagnostic follow-up is to document the diagnostic evaluation process for all participants for whom a positive screen is obtained by collecting and abstracting medical records related to the follow-up of the positive screen, and to confirm whether or not a cancer was diagnosed. Certified Medical Record Abstractors from each SC will review the participant's medical records and abstract all diagnostic information regarding follow-up of the positive screen onto the Diagnostic Evaluation Form (DE).

This chapter will present procedures for the collection and abstraction of the diagnostic information by SCs and tracking of medical record acquisition. Quality assurance measures for medical record abstraction are discussed. In addition, this chapter describes the DE Form and the letter to request medical records.

7.2 Timeframe for Collection of Medical Records

Medical records documenting diagnostic evaluation and staging procedures should be collected for all positive screens. Records should be collected on all procedures occurring on or before the date of conclusive diagnosis (including staging) or on or before May 1, 2001, whichever comes first. Records may be collected through May 31, 2001.

Medical records documenting complications of diagnostic evaluations or staging procedures performed on or before May 1, 2001 should also be collected. These records should be collected for complications that occur up to two months after the date of diagnosis or May 31, 2001, whichever comes first.

Although short, this time period is thought to be adequate for acquisition of the patient's medical records if SCs are both thorough and diligent in their contacts. The SC should conduct a review of all cases with pending medical record requests in early May. This review will allow adequate time to re-send requests for medical records either not received from an earlier request or inadvertently not requested earlier. If, despite SC efforts to encourage a participant to seek medical attention for a positive screen, the participant does not initiate follow-up of the screen for several months, the SC must still adhere to the timeline set forth above for acquisition of medical records.

7.3 Procedures for Contacting Physicians and Hospitals

Approximately 4 weeks after the contact with the participant confirming a follow-up appointment, the SC will contact the physician and/or hospital in writing to request the release of the patient's medical records to determine what diagnostic tests have been performed.

All information regarding diagnostic procedures, including outcomes, should be obtained from a physician or hospital, not from the participant. In the rare cases where neither written nor verbal documentation of the diagnostic procedure performed can be obtained from a physician or hospital, the SC may accept information from the participant.

If the SC refers a participant internally after a positive screen, the records relating to the internal referral should be collected. If the internal referral physician does not recommend additional follow-up but the participant undergoes additional diagnostic evaluation, both the internal referral and the additional follow-up should be collected.

The following list enumerates the contact procedures for obtaining the participant's medical records by mail.

1. The SC will initiate diagnostic follow-up procedures four weeks after the screening visit by contacting the participant to determine the status of follow-up.

2. The SC will confirm the physician's name and office/hospital address and establish a contact person at the office/Medical Records Department prior to mailing the letter requesting medical records.

3. A letter requesting the release of medical records, along with a signed Medical Record Authorization Form (Appendix 3-3), will be sent to each physician/hospital named by the participant.

4. The SC will re-contact the participant to obtain a more recent Medical Record Authorization Form, if needed.

5. The SC will check on the status of the request within 3 to 5 business days after the mailing.

6. If necessary, the SC will make additional requests for information regarding diagnostic procedures related to positive screen in order to obtain the complete history of the participant's follow-up.

7.4 Letter To Request Medical Records

The CC will provide the SCs with a sample letter (Appendix 7-1) to request the participant's medical records. This letter should be adapted by the SC, copied onto SC letterhead, and signed by the Principal Investigator at the SC. The participant's date of birth and the date of the screening visit are included in the letter to assist the physician/hospital in locating the correct medical records for the participant named in the letter. The letter requests the physician/hospital to send photocopies of the patient's medical records dated from the time of the screening visit to the present. The initial request for medical records will be sent about 2 months after the screening exam. This request may need to be sent to multiple physicians and/or hospitals concurrently. In addition, some physicians and/or hospitals may require multiple requests before the complete records are provided. Because it may not be possible to request the complete record, certain key parts have been identified that are needed to complete the DE form. These include (for each admission):

1. Admission history for diagnosis
2. History and physical
3. Discharge summary for all hospitalizations related to diagnosis
4. Operative Reports
5. Radiology Reports
6. Pathology Reports
7. Lab Reports
8. Progress notes and reports of diagnostic work-up

The letter should also contain the SC Coordinator's name and a phone number in case there are questions.

The SC must enclose a copy of the participant's Medical Record Authorization Form (Appendix 3-3) along with the letter. The authorization form should also be on SC letterhead and the copy must be legible. The original authorization form will be kept in the participant's file at the SC. In some instances the physician/hospital may not accept the Medical Record Authorization Form as sufficient for release of the records. Additional authorization may need to be requested from the participant or the participant's next of kin. In addition, some institutions require that the authorization be recent (within 6 months, for example) or that they receive the original. And, in some cases, hospitals or insurance plans may require the medical release in a specific format. In some of these special situations the participant may need to be re-contacted by the SC to obtain a new release form.

7.4.1 Collection of Medical Records

As noted previously, SCs should encourage participants to seek medical attention in a timely fashion following a positive screen. A DE form will always be completed for participants who have a positive screening exam, even if cancer was not diagnosed. The collection of medical records to complete the DE form may involve any or all of the following: contacting physicians and hospitals to determine the status of screening follow-up; the collection of medical records documenting the participant's cancer status; and in the case of cancer diagnosis, obtaining diagnostic evaluation and staging information, including the pathology report.

In some cases, the SC may be charged a fee for obtaining copies of medical record documentation. Since the Lung Screening Study is federally funded research, the SC may be able to obtain a waiver of fees from some institutions.

All medical records collected should be labeled with the PID and kept in the participant's study file.

7.4.2 Tracking Medical Record Acquisition

Each SC is responsible for tracking the medical records collection process, that is, to track the requests to participants for signed medical records release forms and to physicians and hospitals for copies of the medical records. The tracking may be done manually using methods such as tickler files, or using an automated system. The SC Coordinator will determine the tracking method.

7.5 Abstraction of the Medical Records

The Diagnostic Evaluation Form (DE) (Appendix 7-2) has been developed to facilitate standardized documentation of information concerning diagnostic evaluation and cancer confirmation, including pathology, histology, and staging evaluation. The item-by-item specifications for completing the DE form can be found in Appendix 7-3. A trained and approved medical record abstractor will abstract information regarding diagnostic evaluation and cancer confirmation. A certified nosologist (medical coder) is required for coding cancer and non-cancer diagnoses. Qualifications and certification requirements for the medical record abstractor and the study nosologist are discussed in Section 7.7.

The first step in abstracting the medical records is to confirm that they are for the correct participant by placing them in date order and reviewing them carefully. A PID label may be attached to each page. Each document should be reviewed for legibility and completeness. Consistency of information between documents should be checked and, if necessary, the physician or hospital should be contacted to resolve any problems or inconsistencies. In addition, if the records are not complete, the diagnosing physician or hospital may need to be re-contacted for additional information.

The next step of the abstraction process is to document all diagnostic procedures on the DE form. If a cancer was diagnosed, information from the record about the diagnosis of the cancer should be abstracted onto the DE form. In cases where follow-up of a positive screen revealed no cancer, information about the diagnostic evaluation and the non-malignant diagnosis will also be abstracted.

Diagnostic evaluation information is recorded in the three sections of the DE form. These sections are described below.

Part A: Diagnostic Evaluation and Staging - This section is used to document procedures performed for diagnostic evaluation and staging, the medical complications of the diagnostic evaluation and staging, and the final result of the diagnostic evaluation.

Part B: Diagnosis Information for Any Condition Other Than Primary Lung Cancer - This section is used to record the diagnosis of any abnormality other than primary lung cancer. Only those conditions listed on page 11 of the specifications (Appendix 7-2) should be recorded.

Part C: Primary Lung Cancer Diagnosis Information - This section is used to document the source of the primary lung cancer confirmation, the date and description of the primary lung cancer diagnosis, the ICD-O-2 code, the histologic classification, and TNM staging. It also requests that the histopathology or cytopathology report that supports the diagnosis be photocopied and attached.

In the case of a confirmed cancer, diagnostic evaluation information should be collected within the study timeframe laid out in Section 7.2. All staging information related to the initial diagnosis should be collected, even if a staging procedure was performed after the date of the initial diagnosis. Staging procedures that are recorded should correspond to the TNM or stage of disease classifications recorded in Part C of the DE form. Staging information on cancer recurrence should not be collected.

In conducting medical record abstractions for lung cancer, the SC may encounter some special situations:

- **When no follow-up procedures were performed based on a SC internal referral (for chest X-ray or spiral CT) or a physician's decision that follow-up of a positive screening examination was not necessary.** In such cases, the SC should complete a DE form and document the result of the diagnostic evaluation as "No Malignancy." The SC must also document that the case was an internal referral or must record verbatim what the physician stated (whether written or verbal) regarding follow-up and the date the physician made the statement. In the situation where only a participant's report can be obtained that his/her physician decided not to conduct follow-up on a positive screening exam, this information should be collected. Refer to the specifications for the DE form for specific instructions for completing the form in such situations.

- **When the participant begins diagnostic evaluation but then decides (against the recommendation of his physician) not to continue**: In such cases, the SC should complete a DE form and document the result of the diagnostic evaluation as "No information available" and provide an explanation of the situation. Refer to the specifications for the DE form for specific instructions for completing the form in such situations.

7.6 Missing Data Form

In some cases, the SC will not be able to complete a DE form. The following are the conditions under which a Missing Data Form (MDF) should be completed (refer to Chapter 9 for additional information on the completion and transmittal of the MDF to the CC):

- If the participant states that s/he plans to follow-up but does not obtain diagnostic follow-up or the participant refuses to obtain diagnostic follow-up for a positive screen during the course of the study, an MDF should be completed. Code 01 (Refused Procedure/Activities) should be recorded on the MDF;

If the participant explicitly states that s/he refuses to follow-up, the MDF can be completed at the time of refusal. Otherwise, the MDF can be completed when the SC determines the lack of action on the participant's part indicates that s/he will not be obtaining diagnostic follow-up;

- When the participant had no follow-up for a positive lung screen due to other, more critical illnesses. Code 01 (Refused Procedure/Activity) should be recorded on the MDF;

- When the SC is unable to locate the participant to determine whether or not s/he had follow-up for a positive screen. Code 02 (Can't locate) should be recorded on the MDF;

- When the SC is unable to locate the participant to obtain consent to collect medical records. Code 02 (Can't locate) should be recorded on the MDF;

- When the participant dies before seeking follow-up for a lung positive screen. Code 03 (Deceased) should be recorded on the MDF;

- When the medical records necessary for the completion of the DE are not available (i.e., records are lost, institutional refusal, foreign or non-local institution). Code 04 (Records Could Not Be Obtained) should be recorded on the MDF; and

- When a participant refuses to sign a Medical Record Authorization Form for the SC to obtain medical records to document diagnostic follow-up procedures. Code 04 (Records Could Not Be Obtained) should be recorded on the MDF.

A MDF should not be completed in place of the DE form if the SC or the participant consults a physician for follow-up and the physician indicates, based on the screening exam result and/or a review of the participant's medical record, that no follow-up is necessary (see page 7-6). In this situation, a DE form should be completed as described in the form completion specifications (Appendix 7-3).

7.7 Quality Assurance of Medical Record Abstraction

Each abstractor and nosologist will be required to submit qualifications, training, and certification to the CC for review. The Record of Experience, Credentials, and Training (ECT) form (See Chapter 9) must be completed and sent to the CC for each abstractor and nosologist to document the abstractor's and nosologist's qualifications to perform competently for the Lung Screening Study. The CC will review the ECTs. If the qualifications meet the CC criteria, the CC will recommend approval to NCI. If the qualifications do not match requirements, the CC will request an exception approval from NCI if appropriate.

The medical record abstractor should have knowledge of medical record terminology, anatomy, physiology and concepts of disease in addition to basic medical coding instruction. The abstractor must also have a minimum of 2 years on-the-job experience abstracting medical records. The nosologist should also possess at least one of the following credentials from each list for ICD-9-CM and ICD-O-2 coding.

For ICD-9-CM coding (in order of desirability):

a. Certified Coding Specialist (CCS) - This individual has obtained sufficient coding expertise either through education, experience, or a combination of the two to pass an advanced coding exam and become certified.

b. Registered Health Information Technician (RHIT) - A RHIT has at least an Associate's degree in Medical Record Science and has passed an accreditation exam. This individual must meet RHIT continuing education requirements to maintain accreditation.

c. Registered Health Information Administrator (RHIA) - A RHIA has at least a Bachelor's degree in Medical Record Science and has passed a registration exam. This individual must meet RHIA continuing education requirements to maintain registration. If a person is a RHIA and is currently doing medical coding, then he/she may be qualified to conduct medical coding. If, however, a RHIA is doing supervisory work, then he/she may not be up-to-date on medical coding.

For ICD-O-2 coding and TNM staging:

a. Certified Tumor Registrar (CTR or CTR-eligible) - A CTR is an individual who has passed the Certification Examination for Cancer Registrars, which is offered by the National Board for Certification of Registrars (NBCR). To maintain a certified status, a CTR must meet current continuing education requirements of the National Cancer Registrars Association (NCRA). To be eligible to take the Certification Examination, an individual must meet one of the following requirements as of the test date:

   i) Two years full-time equivalent experience in the cancer registry field.

   ii) Successful completion of a college level curriculum in cancer data management/cancer registry, and a work experience component composed of 120 hours in a CTR staffed computerized cancer registry or 240 hours in a non-CTR staffed computerized cancer registry.

   iii) One year full-time equivalent experience in the cancer registry field and successful completion of college level curriculum in medical records, nursing, or other allied health field.

iv) One year full-time equivalent experience in the cancer registry field and credentialed or licensed status in a recognized allied health field as determined by NBCR.

The staff person in charge of medical record abstraction at the CC will facilitate regular communication between the SCs and NCI on medical record abstraction issues and problem resolution as well as coordinate training. This person at each SC will assist the CC in monitoring internal quality assurance at their SC and provide input for resolution of medical record abstraction issues.

Each SC will send copies of medical records for a 10% random sample of all participants for whom medical records were collected to the CC for re-abstraction. All participant identifiers must be removed. This process will be concurrent with medical record abstraction. Medical record abstractors at the CC, who are also trained in study protocol, will abstract this sample of medical records. The results will be compared and reported to the SCs and NCI.

7.8 Tracking, Reporting and Monitoring Medical Record Abstraction Activities

Medical record abstract forms should be manually edited at the SC. See Chapter 9 for information regarding editing of forms. After a form has undergone a manual edit, it will immediately be sent to the CC for data entry. Completed abstracts will be filed in a participant folder maintained at the CC. In addition, a copy of the abstract and all medical records received at the SC should be filed in the participant's folder or, if required, copied, with the copy retained and the original returned to the physician or institution from which they were requested.

An Expected Forms Report (Appendix 9-19) will be produced by the CC and will list all participants and all delinquent, incomplete or outstanding forms for each participant. This report, generated weekly, may be used by the SC Coordinator to track the completion of the medical record abstract forms. All CC-generated monitoring reports are described in Section 9.10.

Appendices for Chapter 7

7-1 Letter to Request Medical Records

7-2 Diagnostic Evaluation (DE) Form

7-3 Specifications for the Diagnostic Evaluation Form