6. REPORTING RESULTS OF SCREENING TESTS

6.1 Overview of Results Reporting

The SC is responsible for reporting the results of screening tests to the participant, to the participant's primary care physician, and to the CC. The participant and primary care physician will be notified of all screening results. All results will be reported to the participant and his/her physician of choice within 3 weeks of the screening visit. Abnormal results that are suspicious of malignancy (positive screens) may also result in the participant being referred to a specialist of his/her choice. The SC is also responsible for reporting the results of follow-up of positive screens to the CC. A participant with abnormal findings that are not suspicious of malignancy will be referred according to the standard practices of the SC.

This chapter details the procedures for providing notification to participants and physicians, including creating cover letters, providing test results reports, making referrals when necessary, and tracking, reporting, and monitoring notification tasks.

6.2 Identifying the Appropriate Physician for Notification

Prior to the screening examination, each participant will be asked to provide the name, address, and telephone number of his/her primary care physician on the Participant Contact Form (PCF) (see Chapter 3). Regardless of the result of the screening procedure, the SC will send the participant's test results to this physician. During the screening visit, the SC staff should confirm with the participant that the physician listed on the PCF is the appropriate physician to whom results should be sent, and that the name and address are correct. If a participant does not have a physician listed on the PCF, the SC Coordinator should work with the participant to identify a primary care physician, to whom the screening results will be sent.

In the event of a positive screen, the participant will be contacted by telephone. Additionally, the results will be sent to both the participant and the identified primary care physician. The SC should urge participants to see their primary care physician and discuss whether there is a need to see a recognized specialist for further evaluation of their test results. If requested by the participant, the SC Coordinator will provide a list from which he/she may choose a specialist to receive the findings of the examination.

In the event of a negative screen with abnormal findings (those with significant abnormalities requiring further evaluation, and those with minor abnormalities), the results will be sent to both the participant and the primary care physician. In addition, results will be sent to a specialist if requested by the participant. The SC's current standard of care will be used to determine whether a referral to a specialist will be made.

6.3 Notifying Participants and Physicians

The SC will report results in writing to the participant and to the participant's physician of choice within three weeks of the screening visit. Positive screens will also be reported to participants by telephone. If the participant is unavailable by telephone, results will be sent via certified mail. Positive screens may be reported to physicians by telephone, FAX, or certified mail. Negative screens with abnormalities will be reported to the participant and his/her physician according to standard radiologic practice at the SC.

6.3.1 Notification Documents for Reporting Results of the Screening Examinations

The SC will report all findings of the screening examinations. Results and findings will be sent to participants and physicians with a cover letter (see section 6.3.2 below). The SC may choose to incorporate results and findings into the cover letter, may attach a copy of the SCT or XRY2 exam form, may attach a copy of the radiologist's dictated report, or may produce a customized report of results and findings. The combination of documents sent must reflect the result and all findings of the examination. In the case of positive screens, the SC may provide the participant with a copy of the screening exam image, upon his/her request, to take to his/her follow-up examination. If an internal referral is obtained, then the findings of the internal referral must also be reported to the participant and the participant's primary care physician.

6.3.2 Cover Letters for Reporting Results of the Screening Examinations

Screening test results will be sent to participants and physicians with a separate cover letter. Each SC is responsible for drafting its own cover letters using SC letterhead. However, the letters must include the elements described below.

The participant letter must include:

- A disclaimer stating that the examination was a screening examination, not a comprehensive examination;
- A statement providing the overall result of the screening examination (such as a "positive screen with abnormalities suggestive of malignancies," a "negative screen with significant abnormal findings requiring further evaluation," a "negative screen with minor abnormalities," a "negative screen with identification of a small, smooth, non-calcified nodule," a "negative screen with no abnormalities," or an "inadequate screen") with reference to any attached supplemental report for further details;
- A statement urging the participant to see his/her primary care physician and talk with him/her about whether the participant should see a recognized specialist for further evaluation of test results in the case of positive screening test results;
- A statement recommending that the participant see his/her primary care physician to discuss his/her examination results in the case of a negative screen with significant abnormalities or a negative screen with small, smooth, non-calcified nodules;
- A statement that the results have been sent to his/her primary care physician; and
- The SC telephone number and the SC Coordinator's and Principal Investigator's names for any questions or concerns the participant may have.

The physician letter must include:

- A statement that the Lung Screening Study is a NCI-sponsored scientific study designed to evaluate screening tests for lung cancer;
- The name and date of birth of the participant whose results are being reported;
- The date of the screening examination;
- A disclaimer stating that the examination was a screening examination, not a comprehensive examination;
- A statement providing the overall result of the screening examination (such as a "positive screen with abnormalities suggestive of malignancies," a "negative screen with significant abnormal findings requiring further evaluation," a "negative screen with minor abnormalities," a "negative screen with identification of a small, smooth, non-calcified nodule," a "negative screen with no abnormalities," or an "inadequate screen") with reference to any attached supplemental report for further details;
- A statement indicating that the participant was urged to seek medical attention from a recognized specialist in the case of positive screening test results;

- A statement indicating that the participant received a recommendation to discuss his/her examination results with his/her primary care physician in the case of a negative screen with significant abnormalities or a negative screen with small, smooth, non-calcified nodules.

- A statement encouraging the physician to see the participant for diagnostic follow-up of positive screening tests;

- A statement inviting the physician to contact the SC for more information regarding the diagnosis and treatment of lung cancer; and

- The SC telephone number and the SC Coordinator's and Principal Investigator's names for any questions or concerns the physician may have.

Sample participant result letters for each general result type (positive screen, a negative screen with significant abnormalities, a negative screen with minor abnormalities, a negative screen with smooth, non-calcified nodules/masses $\leq$ 3mm, a negative screen with no abnormalities, or an inadequate screen) are presented as Appendices 6-1 through 6-6. Sample physician result letters for each result type are presented as Appendices 6-7 through 6-12. Notification letters must be approved by NCI prior to use at the SC. A copy of the notification letter should be kept in the participant's study file.

6.4 Making Referrals for Positive Examinations

All participants with a positive screen must be encouraged to speak with their primary care physicians regarding whether they need to see a specialist. Each SC is responsible for referring participants to appropriate medical professionals in accordance with standard practice at the SC. Participants with negative screening results but one or more significant abnormalities may also be referred for follow-up at the discretion of the SC. In some cases, the SC may wish to refer a participant to a medical professional associated with the SC for a review of a positive result (internal referral).

6.4.1 Internal Referrals for Positive Screening Exams

Internal referrals for a positive screening examination involve the review of a positive screen in conjunction with any previous images by a SC physician or other qualified individual affiliated with the SC. In most cases, an internal referral entails a review of the examination data by the physician, and not an actual clinical examination of the participant. If the internal referral physician determines that further follow-up is necessary, the participant will then be referred "externally" to a physician of his/her choice. If an internal referral indicates that an abnormality is stable and there has been no change, the SC is not required to refer the participant externally, but the SC must report the results of the study

examination and the internal referral to the participant and to the participant's physician of choice. If the participant requests an additional referral, the SC must refer the participant externally.

Internal referrals are allowed according to standard radiologic practice at the SC. However, the result of the internal referral will not change the result of the initial screening examination. Additionally, the SC must state the result of the initial study examination as well as the result of the internal referral when reporting screening test results to the participant and the primary care physician. Reporting the results of internal referrals must be done via an addition to the screening exam results letter or report created by the SC, or by some other type of written communication.

Internal referrals represent the first step in the follow-up of a positive screen. The result of an internal referral resulting from a positive screen must be documented on a Diagnostic Evaluation Form (see Chapter 7), and not on a screening examination form. If there is a subsequent external referral for the positive screen, it should also be documented on the same Diagnostic Evaluation Form.

6.5 Correcting an Erroneous Results Report

If it is discovered that erroneous results were sent to the participant or his/her physician, the correct results must be reported, regardless of the type of error (underestimate or overestimate of seriousness). The manner and timing of this reporting should be handled on a case by case basis at the discretion of the SC. In addition to reporting the correct results, the SC should also report this error to the CC as a protocol violation, as described in Chapter 9.

If the error was found after the materials were sent to the CC, the SC should report this immediately to the CC so that any erroneous materials will not be processed. The SC should resend the correct materials and keep the incorrect materials as a record, identifying them as incorrect. The correct results should be reported with an explanation of the circumstances to the participant and his/her physician (as necessary).

Errors in notification may also be identified through quality control checks performed by the CC. Some of these efforts are described in Section 6.8. If errors are found through these checks, the SC will be notified to perform data retrieval to correct any errors. Details regarding data retrieval procedures and follow-up are also described in Chapter 9.

6.6 Reporting Weekly Log of Mailed Result Letters to the Coordinating Center

The SC Coordinator will report details on the results letters sent to the participant and his/her primary care physician to the CC on a weekly basis using the Weekly Log of Mailed Result Letters. The Weekly Log of Mailed Result Letters must list the detail about results letters sent during the immediate past reporting week from Friday to Thursday. An example of this log can be found in Appendix 6-13. Information to report includes PID, date of screening exam, visit number, type of screening exam, result, and dates of letters sent to the participant and physician(s). The specifications for completing this log can be found in Appendix 6-14.

Copies of screening exam forms, dictated radiologist reports and other materials should not be sent to the CC. The log should be sent via Fed Ex to the CC on a weekly basis at the same time as the weekly forms transmittal shipment to the CC. The details regarding the Fed Ex shipment are provided in Chapter 9.

6.7 Ensuring Diagnostic Work-up for Positive Screens and Small, Smooth, Non-calcified Nodules

The SC Coordinator is responsible for ensuring that a participant will follow-up with his/her physician in the case of a positive screen or a negative screen that reveals a small, smooth, non-calcified nodule. The SC will perform this by contacting the participant within 4 weeks after the initial screening examination to determine whether a follow-up examination has been scheduled with his/her primary physician or a specialist. If follow-up has not yet been scheduled, the SC will contact the participant 4 weeks later (8 weeks after the screening examination) to determine whether a follow-up appointment has been scheduled with his/her primary care physician or a specialist. The SC will report on the follow-up of these participants to the CC on a weekly basis using the Follow-Up Log. This log must list information about telephone calls placed during the immediate past reporting week; from Friday to Thursday. A copy of this log can be found in Appendix 6-15. The information to report includes PID, date contacted, whether this is the first or second telephone call placed to obtain follow-up information, and status of follow-up. The specifications for completing this log can be found in Appendix 6-16. -Approximately 4 weeks after contact with the participant confirming a follow-up appointment, the SC will contact the physician and/or hospital to obtain information regarding diagnostic tests (to be abstracted and recorded on a Diagnostic Evaluation Form – See Chapter 7). This follow-up can be performed through telephone contact and/or written correspondence.

6.8 Tracking, Reporting, and Monitoring Notification Activities

The SC Coordinator will track the mailings of written notifications of positive screening examination results to ensure that written notifications are sent within 3 weeks after the screening examination, and to confirm that the written notifications have been received by the participant, and by the participant's physician of choice. The SC Coordinator should keep all documentation concerning the certified mailings, including the original certified mail receipt with postmark, as well as any return receipt cards signed by the addressee that are returned to the SC. If no receipt card has been received after 2 weeks of the postmark of the mailing to a participant or physician, the SC Coordinator will follow-up to determine if s/he received the notification and to resend the notification if confirmed by the participant or physician that it was not received.

The SC will send the listing of all notification letters sent during the study week (Friday to Thursday) to the CC as described in section 6.7. The CC will log these letters as sent by the SC and generate weekly reports for each SC. These reports will be posted on ~~a~~ the CC Web site to assist in monitoring notification activities and identifying any problems with notification procedures. These reports include:

- Screening Exam Results Report by SC (Appendix 9-18): This is a two-part report that shows the results of the screening exams and whether or not the results were sent. Part 1 shows completed exams with results pending or notification letters not sent. Part 2 shows completed exams with results reported and notification letters sent. This report is available to each SC individually and to the CC and NCI.

- Expected Forms Report by SC (Appendix 9-19): For each participant, this report shows the data collection forms that are expected, but have not yet been receipted. The report may be generated by form type or by PID. This report is available to each SC individually and to the CC and NCI.

In addition to these reports, the CC will perform quality assurance on some of the notification activities, including checks to ensure that there is no discrepancy in results reporting between the screening exam form and the listings of results notification letters sent.

Appendices for Chapter 6

6-1 through 6-6	Sample Results Letters to Participants
6-7 through 6-12	Sample Results Letters to Physicians
6-13	Weekly Log of Mailed Result Letters
6-14	Specifications for the Weekly Log of Mailed Result Letters
6-15	Follow-Up Log
6-16	Specifications for the Follow-Up Log