National Emphysema Treatment Trial

# NETT

# Limited Access Database Documentation

June 2006

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#### NETT Limited Access Database Documentation Dataset Specifications

- 1. These are the limited access master data files for NETT as of the October, 2004 TR Master Database. Mortality is up to date through 30 September 2004.
- 2. Data files and this documentation are included on the CD. Data files are:

Other files included on the CD are: limaccdoc.pdf (this documentation).

3. Data file format: SAS transport files

#### General Comments on Database

**Introduction:** The NETT Limited Access Database is derived from the October 2004 version of the NETT Master Database. The Limited Access Database includes data collected in the main trial and the Cardiovascular Substudy, the Exercise ABG Substudy, and the Lung Mechanics Substudy, as well as data generated by the IAC from the chest CT scans collected in NETT.

Data for randomized patients and data for non randomized patients are included in the Database.

The Database includes data collected under the original contract period, data collected under the initial extension (data collection in 2003), and data collected in the mailed quality of life followup (January through June 2004). Vital status is up to date through 30 September 2004.

The NETT data are too voluminous to provide one record per patient with all NETT data included. What we have provided are files for specific data forms or for types of data. A SAS Proc Contents listing is provided for each file. In the case of files that correspond to specific NETT forms, early form revisions have been coded to the most recent revision of the form; copies of the most recent revision of a form are included with this documentation. Form revisions may result in blank items for some items if the item in question was not included on the earlier form version.

The MEDID variable in the valids.tpt file identifies whether a patient is randomized or not, and if randomized, it identifies the randomly assigned treatment (MEDID=blank if non randomized, =1 if assigned to medical treatment, =2 or 3 if assigned to LVRS [2= median sternotomy, 3=VATS]).

**File formats, variable names, and variable formats:** All files are SAS 6.12 files in SAS transport file format. Each variable on each file has an associated SAS label, except in the case of the files received from the IAC. Variables which are in direct correspondence to a form item (and so in direct correspondence to the response categories on the form) are named ffxiii where ffx is the form abbreviation and revision number and iii is the item number. For example, variable aa309 is item 9 on revision 3 of form AA.

**Deletions to protect patient confidentiality:** The Limited Access Database does not include these items of information, even though they were collected on NETT forms: Clinic, date of birth, zip code of residence, height, weight, HIC number, social security number, type of health insurance, data in response to Other (specify) items, data in response to administrative information sections on forms (staff PIN, date and time of next appointment, form review date), death certificate data, satellite information, and comment fields. Race/ethnicity responses have been pooled to be Caucasian (white) or other. Age at start of screening is provided on the EB form, but age 51 or less is coded as 00 and age 80 or greater is coded as 99. Adverse event forms are not included in the Database.

**Dates:** All dates have been converted to the number of days before or after the randomization date, if the patient was randomized (so for randomized patients, date of randomization [variable name ENROLLDT] = 0). For non randomized patients, all dates have been converted to the number of days after the date screening started (so for non randomized patients, date screening started [variable name ELIGDT] = 0).

**Patient ID number and clinic identifiers:** Every record includes a recoded ID number for the patient the record refers to. The variable corresponding to the recoded patient ID number (variable name NEWNETT) is a 5 character alphabetic text string.

**Visit codes:** NETT visit codes are s1, s2, s3, rz, n, f01, f02, f04, f06, f08, f10, f12, f15, f18, f21, f24, f27, f30, f33, f36, f39, f42, f45, f48, f51, f54, f57, and f60. For visits with code fxx, xx is the number of months from randomization. Visit codes s1and s2 refer to pre rehabilitation, pre randomization

General Comments on Database (cont'd)

visits. A patient has a visit s2 if the visit was needed to obtain certain measurements that were within 42 days of the start of rehab. A patient has a visit rz if the visit was needed to obtain certain measurements that were within 21 days of randomization. Hence, not all patients will have s2 visits and not all patients will have rz visits for measurement data.

The rz visit code was also used for four randomization phase forms: the XZ form (which documents randomization to treatment), the RP form (which documents the perfusion scan done prior to randomization), and the XS and XP surgery data forms. The n visit code was used for forms that are not associated with a particular visit. The n visit code was also used for the quality of life forms collected during the second extension of NETT followup (mailed collection of quality of life forms in the first six months of 2004).

**Decimal points have not been keyed for numeric data items.** Variables that are in direct correspondence with a form item remain in the format that they were keyed in – ie, character data and without a decimal point. The user must transform the keyed value into numeric data as needed (eg, you must divide by 10, 100, or other appropriate denominator depending on the format of the item on the NETT form). If there is no denominator (ie, the item was recorded in a whole number format), then add 0 to a numeric item to transform the data from character to numeric. If the variable name is not in the format ffxiii, then the variable most likely has already been put into analysis-ready format.

**Pre rehab and post rehab baseline values:** When identifying the pre rehab baseline value for a specific procedure, the records for the specific procedure being analyzed need to be checked for s1 and s2 values, and the later visit constitutes the pre rehab baseline; similarly, when identifying the post rehab baseline for a specific procedure, the records for the specific procedure being analyzed need to be checked for s3 and rz values, and the later visit constitutes the post rehab baseline. If the patient has both s1 and s2 values for a measurement, the s2 value is used as the pre rehab value. If a patient has both s3 and rz values for a measurement, the rz value is used as the post rehab value. Note that only measurements that were out of these time windows were repeated – a patient could have a mix of s1 and s2 values serve as the pre rehab baseline values (eg, s1 spirometry might have been within 42 days of starting rehab, while the s1 exercise test was out of that window, requiring the exercise test, but not spirometry, be repeated at s2; in this case the s2 exercise test value serves as the pre rehab baseline exercise value and the s1 spirometry values serve as the pre rehab baseline spirometry values).

In general, the baseline from which change from baseline to followup is calculated is the post rehab, pre randomization value.

**Visit dates:** The procedures for a NETT visit could be spread over several days so long as all dates were within the time window for the visit. The time windows for the NETT visits (ideal, opening date, closing date; enrolldt=randomization date) are:

f01 (enrolldt+30, ideal-14, ideal+14) f02 (enrolldt+61, ideal-14, ideal+14) f04 (enrolldt+122, ideal-14, ideal+14) f06 (enrolldt+183, enrolldt+92, enrolldt+274; at least 90 days after randomization) f08 (enrolldt+244, ideal-14, ideal+14) f10 (enrolldt+304, ideal-14, ideal+14) f12 (enrolldt+365, enrolldt+275, enrolldt+547; at least 90 days after f06)

General Comments on Database (cont'd)

f15 (enrolldt+457, ideal-14, ideal+14) f18 (enrolldt+548, ideal-14, ideal+14) f21 (enrolldt+639, ideal-14, ideal+14) f24 (enrolldt+730, enrolldt+548, enrolldt+913; at least 183 days after f12) f27 (enrolldt+822, ideal-14, ideal+14) f30 (enrolldt+913, ideal-14, ideal+14) f33 (enrolldt+1004, ideal-14, ideal+14) f36 (enrolldt+1096, enrolldt+914, enrolldt+1278; at least 183 days after f24) f39 (enrolldt+1187, ideal-14, ideal+14) f42 (enrolldt+1278, ideal-14, ideal+14) f45 (enrolldt+1370, ideal-14, ideal+14) f48 (enrolldt+1461, enrolldt+1279, enrolldt+1644; at least 183 days after f36) f51 (enrolldt+1552, ideal-14, ideal+14) f54 (enrolldt+1644, ideal-14, ideal+14) f57 (enrolldt+1735, ideal-14, ideal+14) f60 (enrolldt+1826, enrolldt+1645, enrolldt+2009; at least 183 days after f48)

A standard month consists of 30.4375 days and a standard year consists of 365.25 days. The ideal date for a visit is the anniversary of the randomization date.

**NETT phases and changes in protocol that resulted in changes in forms required at visits:** Data collection on NETT patients began in October, 1997. NETT randomizations began in January, 1998 and ended in July 2002. The original contract phase of patient followup ended on 31 December 2002. NETT was granted a one year extension of followup which allowed followup to be extended from 1 January 2003 through 31 December 2003. NETT was then granted a six months extension of followup for collection by mail of quality of life forms (31 December 2003 through 30 June 2004). Data from all three of these calendar periods of followup are included in this database.

During the original contract period, patients were seen in person for visits f06, f12, f24, f36, f48, and f60. The other fxx visits were telephone visits. A listing of the forms used at each visit is included with this documentation. Starting with the extension year (1 January 2003 through 31 December 2003), only visits f06, f24, f36, and f60 were done in person; the same sets of forms were completed at these visits as were completed during the original phase. During the extension year, visits f12 and f48 were done by telephone and included only the Interim History (IH) form. The telephone visits (f01, f02, f04, f08, f10, f15, f18, f21, f27, f30, f33, f39, f42, f45, f51, f54, f57) and the telephone visit (AT) form were not completed during the extension year. Analyses that include the extension period (1 January 2003 through 31 December 2003) cannot assume that missing procedure data for visit f12 and f48 are missing due to physical inability of the patient to attend the visit – the procedures were not required to be done at f12 and f48 during 2003.

During the period of mailed quality of life followup (31 December 2003 through 30 June 2004), only forms QF, QG, QS, and QW were completed. Each patient was asked to complete the forms once during this period and completion could occur at any time during this period. The quality of life forms completed by mail as part of this extension period use visit code n. If you want to analyze the mailed quality of life forms, select QF, QG, QS, and QW forms with visit code n. Another way to use these forms is to map the forms into fxx visit windows and retain those that do not map into an already occupied visit window (ie, a visit for which the form was completed during the one year extension followup).

General Comments on Database (cont'd)

**Change in 6 minute walk testing protocol:** Day 2 six minute walks were eliminated on 24 May 1999.

**Vital status:** Vital status can be determined by checking the VITSTAT variable in the valids.tpt file. DEATHDT is also included in the valids.tpt, but be aware that we did not have a date of death for every non randomized patient reported as deceased. Every randomized patient reported as deceased does have a known date of death. Thus for non randomized patients, VITSTAT and DEAHTDT are not in 1-1 correspondence, but the two variables are in 1-1 correspondence for randomized patients.

**Cautions when dealing with data for non randomized patients:** Non randomized patients have incomplete data entry. Every non randomized patient has an EB and an EH form. Non randomized patients who started rehabilitation are also required to have an ER form. No other forms were required for non randomized patients, but other forms keyed for non randomized patients have been retained in the database.

**Subgroup status:** Five subgroups with differential outcomes by treatment group were identified during the course of NETT: high risk, upper lobe predominant emphysema and low exercise, upper lobe predominant emphysema and high exercise, non upper lobe predominant emphysema and low exercise, and non upper lobe predominant emphysema and high exercise. The subnejm.tpt file indicates subgroup membership for each patient randomized in NETT.

**Substudy participation:** Data from three substudies conducted in NETT (Cardiovascular, Exercise ABG, and Lung Mechanics) are included in this database. The substudy.tpt file indicates substudy participation for each patient (randomized and non randomized) who participated in at least one of these substudies.

**IAC data:** The raw IAC data are provided in 12 files: 4 relating to the right lung (rcore.tpt, rpeel.tpt, rver2.tpt, and rhole.tpt), 4 relating to the left lung (lcore.tpt, lpeel.tpt, lver2.tpt, and lhole.tpt), and 4 relating to the whole lung (wcore.tpt, wpeel.tpt, wver2.tpt, and whole.tpt). Within each right lung and left lung file, there are variables relating to the upper, middle, and lower sections of the lung (the variables start with u, m, and l, respectively), as well as variables that relate to the entire (right or left) lung.

Within the core, peel, and ver2 files, there are a series of variables of the form bexxx (eg, be960, be950, etc); each represents the number of voxels below the xxx threshold (Hounsfield cutoff value). There are also a series of variables of the form aexxx (eg, ae50, ae100, etc); each represents the number of voxels above the xxx threshold.

You can calculate % emphysema for the whole lung, the right lung, the right upper lung, the right upper lung core, the right upper lung peel, etc. The basic calculation is bexxx/totvx. NETT investigators have had long discussions about which Hounsfield cutoff value to use. Some felt that the cutoff value should be specific to the slice thickness used in the scan. Slice thickness (slicethi) is specified in each file and varies from 2.47 to 10.5; you can use -950 for < 5 mm, -930 for 5-7.5 mm, -910 for > 7.5 mm. Since the 75<sup>th</sup> percentile of slice thickness is around 5, this amounts to using -950 for most scans.

For a specific Hounsfield cutoff, core + peel = ver2.

The hole files have a series of "alpha" variables, each corresponding to a specific Hounsfield cutoff

General Comments on Database (cont'd)

value. Alpha\_1 corresponds to -950, alpha\_2 corresponds to -930, and alpha\_3 through alpha\_6 correspond to -910, -890, -870 and -850, respectively.

For the xxx Hounsfield cutoff, % emphysema is calculated by:

Whole lung: bexxx (from wver2 file) / totvx (from wver2 file) Whole core: bexxx (from wcore file) / totvx (from wcore file) Whole peel: bexxx (from wpeel file) / totvx (from wpeel file)

Difference in % emphysema, upper lung - lower lung, is calculated by

(UpperR + UpperL)-(LowerR + LowerL)

Using -950 as the cutoff, the formula is:

[ube950 (from rver2) + ube950 (from lver2)]/[utotvx (from rver2)+utotvx (from lver2)] -

[lbe950 (from rver2) + lbe950 (from lver2)]/[ltotvx (from rver2)+ltotvx (from lver2)]

Difference in alpha, upper lung - lower lung, is calculated by

(UpperR + UpperL)-(LowerR + LowerL)

Using -950 as the cutoff, the formula is:

[ualpha 1 (from rhole)+ualpha 1 (from lhole)] - [lalpha 1 (from rhole)+lalpha 1 (from lhole)]

Two possible definitions of upper lobe predominant by IAC parameters are:

- (1) Upper lobe predominant if difference in alpha, upper lower, < 0Not upper lobe predominant if difference in alpha, upper - lower,  $\ge 0$
- (2) Upper lobe predominant if different in % emphysema, upper lower, > 0Not upper lobe predominant if difference in % emphysema, upper - lower,  $\le 0$

A file with calculated IAC parameters (iacparam.tpt) is provided, as well as the 12 raw data files. The parameters in iacparam.tpt relate to the -950 and -960 thresholds.

There are a large number of additional variables included in the IAC data files. These are described in general in the IAC Scan Analysis Variables listing included later in this documentation. Many of these interrelate the locations of emphysematous voxels with regional centroids (whole lung; upper, middle, lower lung; left and right lungs).

#### Specific Comments on Database

**aa.tpt:** All AA forms in AA3 format. Item 10, the specify data in items 27 and 29, and items 30-34 have been deleted. Every randomized patient has an AA form.

**ab.tpt:** All AB forms in AB2 format. Items 10 and 20-24 have been deleted. The AB form was not required if the patient did not complete any post randomization rehabilitation (this event should be documented in ue\_noreh.tpt).

**at.tpt:** All AT forms in AT3 format. The specify data in items 7, 23, 36, and 27 have been deleted. Items 28-36 have been deleted. Note that this form was completed regardless of the success of the interview. That is, the completed AT form can document an interview with the patient, an interview with someone who knows the whereabouts of the patient, and an interview that could not be completed because the patient was unavailable and no one with knowledge of the patient was available for interview. Thus a count of AT forms does not give a count of completed telephone interviews – the contents of the AT form need to be examined to determine which kind of interview the form documents.

**bu.tpt:** All BU forms in BU2 format. Alpha 1 anti-trypsin data are available at s1. A1AT concentration (item 16) has been converted to mg/dl (concentrations in mg/ml were multiplied by 100 and concentrations in  $\mu$ M were multiplied by 7.5); the new variable name is A1ATCONC. Item 17 has been recoded to A1ATPTYP. The specify data in item 22 have been deleted. Items 23-27 have been deleted.

**dr.tpt:** All DR forms in DR2 format. The specify data in item 8 have been deleted. Items 9-12 have been deleted. A death report form was to be completed for any registered NETT patient who was reported to be deceased. Hence, this file includes death report forms for randomized and non randomized patients. To identify all deceased NETT patients, use the vitstat variable in the valids.tpt file.

**eb.tpt:** All EB forms in EB2 format. Item 9 has been deleted, and age (item 10) has been recoded to 00 if age 51 or less and to 99 if age 80 or greater. Item 12 has been dropped (ethnicity coded as white or other is available in the valids.tpt file). Specify data in items 16, 23, 27, and 29 have been dropped. Items 15, 19, 21, 28, 31, 55-58, 60-67 have been deleted.

**eh.tpt:** All EH forms in EH3 format. Specify data in Items 8, 14 and 24 have been deleted. Items 25-29 have been deleted. Every patient who has an EB form has an EH form. The EH form contains the spirometry and lung function values and CT scan scores for the ineligible patients who did not initiate rehab, if those values were available (the patient could have been found to be ineligible before any of those procedures were done, or after only some of those procedures were done). Also, these values are not available for patients who were found to be ineligible after initiating rehab and who had Form ER completed (because those patients appeared to be eligible as of completion of Form EH).

**er.tpt:** All ER forms in ER3 format. Specify data in items 10, 14, 15, 16, and 28 have been deleted. Items 29-35 have been deleted. Every patient who started rehab has an ER form, but not every patient who started rehab went on to randomization.

**es.tpt:** This is the Exercise ABG Substudy record for the cycle ergometry exercise test. Every patient has an EW form (the main trial record for the cycle ergometry exercise test), regardless of participation in the Exercise ABG Substudy; for those who participated in the Exercise ABG Substudy, the ES form includes the data unique to the Exercise ABG Substudy. If you want all of a patient's exercise test data, you need to use the union of the ES and EW forms (match the records on

Specific Comments on Database (cont'd)

NETT ID number and visit code). Borg scores that did not match the allowed values (0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10) have been rounded to the nearest value on the scale. Items 11-15 have been deleted.

**ew.tpt:** All EW forms in EW1 format. If the protocol was not followed for the exercise test, maximum work was considered to be missing. If the patient completed the 5 minute rest phase and the 3 minutes of unloaded pedaling, but could not do any loaded pedaling, maximum work was considered to be 0 watts. The MAXWK variable in the ew.tpt file has been coded according to this algorithm. In April 1998, the ramp rate options for the NETT exercise test were changed from 4 and 8 watts/minute to 5 and 10 watts/minute. Item 10 is coded as: 1=4 watts/min, 2=8 watts/min, 3=5 watts/min, 4=10 watts/min. Borg scores that did not match the allowed values (0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10) have been rounded to the nearest value on the scale. Specify data in items 13, 15, 18, 19, and 21 have been deleted. Items 7 and 22-26 have been deleted.

**ga.tpt:** All GA forms in GA1 format. Items 7 and 9-12 have been deleted. Item 7 was deleted since some clinic IRBs did not require additional consent for the extension year.

**hb.tpt:** All HB forms in HB3 format. Specify data in items 10, 23, 24, 26, 27, 29, 31, 34, 35, and 43 have been deleted. Items 17 and 46-48 have been deleted.

**hf.tpt:** All HF forms in HF4 format. Specify data in items 9, 29, 32, and 33 have been deleted. Items 34-39 have been deleted. Versions 2 and 3 of the HF form did not include a sign for measured systolic RV pressure (item 26b on version 4 of the HF form).

**hi.tpt:** All HI forms in HI3 format. Specify data in items 11, 20, 26, 27, 28, 30, 31, 38, and 39 have been deleted. Items 12, 23, 33, 35, and 40-44 have been deleted.

**iacparam.tpt:** This file includes a few parameters calculated from the raw data in the 12 IAC files. See the PROC CONTENTS listing for the specific parameters provided.

**inelig.tpt:** This file is a synthesis of the data on EH and ER forms relating to reasons why patients were ineligible for NETT. This file was created by the Coordinating Center based on the EH and ER data and possibly data from other forms and correspondence or conversations with clinic staff about the specific patient. This is the Coordinating Center's best effort to classify why a specific patient was not eligible in NETT. Patients can be ineligible for more than one reason.

ja.tpt: All JA forms in JA1 format. Specify data in item7 were deleted. Items 13-15 were deleted.

**lcore.tpt:** IAC file relating to digitized CT scans. Core file for the left lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**Ihole.tpt:** IAC file relating to digitized CT scans. Holes file for the left lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

Specific Comments on Database (cont'd)

**lpeel.tpt:** IAC file relating to digitized CT scans. Peel file for the left lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**lver2rz.tpt:** IAC file relating to digitized CT scans. Ver2 file for the left lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**mm.tpt:** All MM forms in MM3 format. In May 1999, the protocol was changed to not require a Day 2.6 minute walk. If the record dates from the period when both Day 1 and Day 2 walks were required, the record has variable mm207=1 or mm207=2. If mm207 is blank, the test is from the period when the Day 2 walk was not required. This change in protocol was implemented while patients were in the midst of testing – for example, a patient can have Day 1 and Day 2 walks for visit s1 and just a single walk for visit s2. In general, when working with the pre randomization data, you need to identify a patient's record for each visit and then identify which visit to use and some patients will have one record per visit and some will have two records. In the NEJM papers, when both Day 1 and Day2 walks were available for analysis, we used the longest walk for the visit. Walk distances have been converted to feet. Borg scores that did not match the allowed values (0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10) have been rounded to the nearest value on the scale. Specify data in items 19 and 21 have been deleted. Items 13 and 22-26 have been deleted.

**mo.tpt:** All MO forms in MO3 format. Borg scores that did not match the allowed values (0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10) have been rounded to the nearest value on the scale. Specify data in items 10, 12, 17, 18, 19, 24, and 32 have been deleted. Items 7 and 35-39 have been deleted.

**mv.tpt:** All MV forms in MV4 format. Note that during the extension year (ie, 2003), the only form required for f12 and f48 was the HI form. Thus, during the extension year, f12 and f48 may be completed or may be missed completely; they cannot be incomplete. During the original contract period (ie, before 31 Dec 2002), MV forms were not required for visits whose window opened in 2002 and closed in 2003. However, visits that were started before 31 Dec 2002 had to be fully accounted for. MV forms were not completed during the second extension of followup (mailed quality of life questionnaires) – we have no information regarding why living patients who did not complete questionnaires did not do so. Specify data in items 8, 9, 11, 12, and 13 were deleted. Items 14-16 were deleted.

**pe.tpt:** All PE forms in PE2 format. Height and weight have been deleted (items 8-11). Specify data in items 17, 18, 19, 20, 22, 24, 25, 27, 28, 29, and 30 have been deleted. Items 31-35 have been deleted.

pm.tpt: All PM forms in PM3 format. Items 30-34 have been deleted.

**pulmfunc.tpt:** This file is based on the PF forms. Lung function values on Form PF have been reformatted as numeric data, predicted values have been calculated for FVC,  $FEV_1$ , TLC, RV, and  $D_LCO$ , and percent of predicted values have been calculated. All  $D_LCO$  values are uncorrected for hemoglobin.  $D_LCO$  values from all clinics except NJC are uncorrected for altitude; all  $D_LCO$  values

Specific Comments on Database (cont'd)

from NJC have been corrected for altitude. Predicted values were calculated using the prediction equations of Crapo and Morris:

- Crapo RO, Morris AH, Gardner RM: Reference spirometric values using techniques and equipment that meet ATS recommendations. Am Rev Resp Dis 1981;123:659-664.
- Crapo RO, Morris AH, Clayton PD, Nixon CR: Lung volumes in healthy nonsmoking adults. Bulleton Europeen de Physiopathologie Resiratoire 1982;18:419-425.
- Crapo RO and Morris AH: Standardized single breath normal values for carbon monoxide diffusing capacity. Am Rev Resp Dis 1981;123:185-189.

Predicted values are specified to 2 decimal places except for  $D_LCO$ , which is specified to 1 decimal place. Percent of predicted is rounded to the nearest integer. All respiratory mouth pressures have been converted to cmH<sub>2</sub>O.

**qb.tpt:** All QB forms (Beck Depression Inventory) in QB2 format. Items 9-13 have been deleted. Note that the responses to individual items were not keyed.

**qe.tpt:** All QE forms (Self Evaluation Questionnaire) in QE2 format. Items 8-10 have been deleted. Note that the responses to individual items were not keyed.

**qf.tpt:** All QF forms (SF- 36) in QF2 format. Individual item responses are provided, as well as the 8 Sherbourne-Hayes subscale scores, the 8 Ware subscale scores, and the Ware PCS and MCS summary scores. Users should realize that the PCS and MCS scores are calculated from Ware subscale scores, not Sherbourne-Hayes subscale scores. Items 7-9 have been deleted. Item 21 was never keyed.

**qg.tpt:** All QG forms (St George's Respiratory Questionnaire) in QG2 format. Individual item responses are provided, as well as the total score and the symptoms, activities, and impacts subscale scores. Items 7-9 have been deleted. Item 60 was never keyed.

**qs.tpt:** All QS forms (UCSD Shortness of Breath Questionnaire) in QS2 format. Individual item responses are provided as well as the total score. Items 7-9 have been deleted. Item 34 was never keyed.

**qw.tpt:** All QW forms in QW2 format. Individual item responses are provided as well as the average daily score. The records in this file correspond 1-1 with actual completed QW forms. If you are doing an analysis where you want to assign dead participants a score of 0, you need to create QW records for these patient-visits. Specify data in item 52 have been deleted. Items 7-9 and 70 have been deleted. Item 10 was never keyed.

**rc.tpt:** All RC forms in RC2 format. Other specify data in item 11 have been deleted. Items 12-17 have been deleted. The baseline record includes a variable HETEROBL which corresponds to the heterogeneous/non heterogeneous (homogeneous) characterization used in the high risk subgroup paper (NEJM 2001;345:1075-83) and a variable UPLOBBL which corresponds to the upper lobe predominant/non upper lobe predominant characterization used in the primary outcome paper (NEJM 2003;348:2059-73). Heterogeneity was assessed from the CT scan zone scores provided by the radiologist on the RC form. A patient was considered to have heterogeneous emphysema if the

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Specific Comments on Database (cont'd)

maximum difference in zone scores for either the right or left side was at least 2. All other score combinations were considered non heterogenous (homogeneous is the term used in the paper). The upper lobe characterization was a qualitative characterization of the cranio-caudal distribution of emphysema by the radiologist recorded on the RC form. Any characterization other than upper lobe predominant was considered non upper lobe. There are more records in rc.tpt than there are CT scans in the IAC files. Not every non randomized patient had RC keyed and not every scan that was taken for a randomized patient was transmitted to the IAC and some transmitted scans were not analyzable by the IAC.

**rcore.tpt:** IAC file relating to digitized CT scans. Core file for the right lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**resid.tpt:** Residence over time data compiled from EB, HI, and AT forms and coded to the categories used in the NEJM primary outcome paper (private home, nursing home or rehab facility, or acute care hospital).

**rhole.tpt:** IAC file relating to digitized CT scans. Holes file for the right lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**rp.tpt:** All RP forms in RP2 format. Items 9-13 have been deleted. Perfusion ratio (prat) is calculated as the ratio of the sum of the % perfusion in the upper zones of both lungs to the sum of the % perfusion in the middle and lower zones of both lungs ((rp208al+rp208ar)/(rp208bl+rp208br+rp208cl+rp208cr)). Note that the 6 percent perfusion values had to sum to 100%. All prat values were rounded to the nearest hundredth (x.xx).

**rpeel.tpt:** IAC file relating to digitized CT scans. Peel file for the right lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**rr.tpt:** All RR forms in RR2 format. Specify data in item 8 have been deleted. Items 9-13 have been deleted.

**rver2.tpt:** IAC file relating to digitized CT scans. Ver2 file for the right lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

Specific Comments on Database (cont'd)

**subnejm.tpt:** One record per randomized patient indicating status with respect to the high risk subgroup and the 4 subgroups of non high risk patients discussed in the NETT primary outcome paper.

**substudy.tpt:** One record per randomized patient participating in at least one of the 3 substudies. Indicates participation status in the ABG Exercise Substudy, Cardiovascular Substudy, and Lung Mechanics Substudy.

**tmto.tpt:** All TM forms in TM1 format and all TO forms in TM1 format. TO forms have been combined with the TM forms (the TO variables have been mapped to the corresponding TM variables). The original form is evident by the value of the form variable. Also, TM209 and TM210 are missing if the original form was TO. The TM form was used for visits s1, f24, and f48 while the TO form was used for visits f12, f36, and f60. Specify data in item 10 have been deleted. Items 11-15 have been deleted.

**ue\_admit.tpt:** Includes a record for each known admission of a patient to a medical institution other than an acute care hospital reported on Form UE (ie, yes to item 35 on Form UE). Record is composed of items 7 and 37-39 on form UE.

**ue\_exreh.tpt:** Includes a record for each prescription of extra rehab for a patient (patients may have more than one record; ie, yes to item 19 on Form UE). Record is composed of items 7 and 20, 22, 25, 27, 30, and 32 on form UE.

**ue\_lvr14.tpt:** Includes a record for each patient assigned to LVRS who had LVRS more than 14 days after randomization (ie, yes to item 13 on Form UE). Record is composed of items 14-16 on form UE (but specify information from items 15 and 16 have been deleted).

**ue\_nnett.tpt:** Includes a record for each patient known to have received LVRS outside of NETT (ie, yes to item 40 on Form UE). Record is composed of items 41-45 on form UE (with specify information from item 41 deleted).

**ue\_noreh.tpt:** Includes a record for each randomized patient who did not complete any rehab sessions after randomization (ie, no to item 17 on Form UE). Record is composed of NEWNETT only.

**ue\_ref.tpt:** Includes a record for each patient randomized to LVRS who refused LVRS after randomization or who was refused LVRS after randomization (ie, yes to item 9 or 11 on Form UE). Record is composed of items 9-10 on form UE (with specify information from item 10 deleted).

**ue\_trns.tpt:** Includes a record for each patient known to have received a lung transplant during NETT followup (ie, yes to item 47 on Form UE). Record is composed of items 48 and 49 on form UE.

**valids.tpt:** ID, demographic, and treatment assignment information are included in this file. Note that MEDID=1 corresponds to assignment to medical treatment, MEDID=2 corresponds to assignment to median sternotomy, and MEDID=3 corresponds to assignment to VATS. The ethnicity variable included in this file has been recoded to w (Caucasian) or o (other). Vital status is included in this file (vitstat =1 if dead, blank=alive).

Specific Comments on Database (cont'd)

**vc.tpt:** If you wish to match the vc.tpt records to data from another file, match on ID number and visit code. Another caution: the data entry program for form VC accepted whatever was keyed for item 19 (mean pulmonary arterial end expiratory pressure) and item 20 (mean pulmonary arterial end inspiratory pressure) since some clinics recorded the calculated value and some clinics recorded the readout from the "mean" switch. To be consistent, calculate item 19 as (item 15+(2 x item 17))/3 and item 20 as (item 16+(2 x item 18))/3.

**wcore.tpt:** IAC file relating to digitized CT scans. Core file for the whole lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**whole.tpt:** IAC file relating to digitized CT scans. Holes file for the whole lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**wpeel.tpt:** IAC file relating to digitized CT scans. Peel file for the whole lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**wver2.tpt:** IAC file relating to digitized CT scans. Ver2 file for the whole lung. If you match this file to the rc.tpt file (on ID number and visit code), be aware that non randomized patients may not have an RC form keyed and that CT scans were not sent to the IAC for every RC form keyed for each randomized patient (ie, this file will not be in 1-1 correspondence with the RC file and the discrepancies may be of two kinds).

**xp.tpt:** All XP forms in XP3 format. The questions about air leak on the original version of XP (XP2) were constructed so that duration of air leak in the 30 day post operative period was recorded only if there was an air leak and this information was not specific for right or left side. Data from XP2 have been mapped to the XP3 questions as best as possible, but the mapping did not allow much use of data from XP2. Using the XP3 questions about airleak (items 9-14) will exclude many patients who had XP2 completed from the analysis. Two new variables were created to help deal with this problem: (1) ALDURE or maximum days with air leak on either side and (2) ALDYNE or air leak, yes/no, in the 30 day post operative period. Specify data from items 11, 14, 29, and 32 have been deleted. Items 36 and 37 and 42-46 have been deleted.

**xs.tpt:** All XS forms in XS3 format. Version 2 of the XS form (form=xs2) did not ask about number of VATS incisions and length of longest VATS incision by side; instead this version asked about total number of incisions and length of the longest incision. So as not to lose all information about number of incisions and length of the longest incision from these forms, two new variables were created: TOTNINC (total number of incisions, ie, number of incisions on the Right side + number of incisions on the Left side) and MAXINCL (length of the longest incision on either the Right or Left side). Similarly, version 2 of the XS form did not ask about air leak at closure by side, but asked this for both sides pooled, using the same grading scheme as used on XS3 in item 28. Therefore,

Specific Comments on Database (cont'd)

AIRLKCLE was created; AIRLKCLE is the maximum airleak code for either side; the codes have been converted from character to numeric. Specify data from items 8, 11, 15, 19, 20, 21, 22, 24, 25, 31, 34, and 41 have been deleted. Items 42 and 48-53 have been deleted.

**xz.tpt:** All XZ forms in XZ2 format. Specify data from items 10 and 12 have been deleted. Items 14-18 have been deleted.

#### IAC Scan Analysis Variables

For each of the 58 variables listed in the table below we will be generating parameters for the Whole lung (W), Right lung (R), Left lung (L), Right Upper (RU), Right Middle (RM), Right Lower (RL), Left Upper (LU), Left Middle (LM), and Left Lower (LL) lung sections. The lung sector prefixes will precede each of the 47 different Variable names to yield a total of 423 parameters (9x47) for each patient. (I.e. "RUairV", "WRb920" etc.)

VarID	Variable	VarFullName	Description
1	HistoID		
2	H*CreateTS	Histogram Created	Date and Time the histogram program was ran
3	ptid	NETT ID + Scan Date	Unique identifier for each scan processed.
4	NETTID	NETT ID	
5	ScanDateU	Scan Date	
6	SliceThickness	Slice Thickness	
7	Intercept	Value given in dicom header	This value is used to convert a voxel value into houndsfield units.
8	VxSize	Voxel Size	
	EntityVer	Module version	The histogram program version number used to create the data.
10	TotVx	Total pixels	Total number of voxels within a region.
11	be960	Below -960	Number of voxels below -960 houndsfield units within a region.
12	be950	Below -950	Number of voxels below -950 houndsfield units within a region.
13	be940	Below -940	Number of voxels below -940 houndsfield units within a region.
14	be930	Below -930	Number of voxels below -930 houndsfield units within a region.
15	be920	Below -920	Number of voxels below -920 houndsfield units within a region.
16	be910	Below -910	Number of voxels below -910 houndsfield units within a region.
17	be900	Below -900	Number of voxels below -900 houndsfield units within a region.
18	be890	Below -890	Number of voxels below -890 houndsfield units within a region.
19	be870	Below -870	Number of voxels below –870 houndsfield units within a region.
	be850	Below -850	Number of voxels below –850 houndsfield units within a region.
		Below -830	Number of voxels below –830 houndsfield units within a region.
22	be810	Below –810	Number of voxels below –810 houndsfield units within a region.
1	be660	Below –660	Number of voxels below –660 houndsfield units within a region.
24	be640	Below -640	Number of voxels below –640 houndsfield units within a region.
	be620	Below –620	Number of voxels below –620 houndsfield units within a region.
	be600	Below -600	Number of voxels below –600 houndsfield units within a region.
	ae50	Above -50	Number of voxels above -50 houndsfield units within a region.
	ae100	Above -100	Number of voxels above -100 houndsfield units within a region.
1	ae150	Above -150	Number of voxels above -150 houndsfield units within a region.
	ae200	Above -200	Number of voxels above -200 houndsfield units within a region.
	ae250	Above -250	Number of voxels above -250 houndsfield units within a region.
	mean	Mean	Mean
	med	Median	Median
34		Standard Deviation	Standard Deviation
	skew	Skewness	Skewness
	kurt	Kurtosis	Kurtosis
	fwhm	Full-width Half-max	The difference between the values of points at which the height of the histogram is half the maximum height
	airV	Air Volume	Volune of Region that is Air (in milliliters)
	tisV	Tissue Volume	Volume of Region that is Tissue and Blood (not Air) (in milliliters)
40	totV	Total Volume	Total Volume of Region (in cubic milliliters)

41	knee	Knee	**For Knee and Ankle Variables see text below
42	kSlp	Knee Slope	
43	kInt	Knee Intercept	
44	ankl	Ankle	
45	aSlp	Ankle Slope	
46	aInt	Ankle Intercept	
47	cCutoff	Default is -910	Users puts in value for calculating the cut off range for the emphysema measurement.
48	cVm	Mean of Centroid Vectors	Mean distance of emphysematous voxels from centroid of volume of lung being evaluated
49	cVsd	Standard Deviation of Centroid Vectors	St Dev of distance of emphysematous voxels from centroid of volume of lung being evaluated
50	cVXm	Mean of X-component of Centroid	Mean distance of emphysematous voxels from centroid of volume of lung being evaluated (X dimension: + = left, - = right)
51	cVXsd	StDev of X-component of Centroid	St Dev of distance of emphysematous voxels from centroid of volume of lung being evaluated (X dimension)
52	cVYm	Mean of Y-component of Centroid	Mean distance of emphysematous voxels from centroid of volume of lung being evaluated (Y dimension: + = ventral, - = dorsal)
53	cVYsd	StDev of Y-component of Centroid	St Dev of distance of emphysematous voxels from centroid of volume of lung being evaluated (Y dimension)
54	cVZm	Mean of Z-component of Centroid	Mean distance of emphysematous voxels from centroid of volume of lung being evaluated (Z dimension: + = apical, - = basal)
55	cVZsd	StDev of Z-component of Centroid	St Dev of distance of emphysematous voxels from centroid of volume of lung being evaluated (Z dimension)
56	HU10	Houndsfield Units at 10%	Hu value below which 10% of the voxels fall
57	HU15	Houndsfield Units at 15%	Hu value below which 15% of the voxels fall
58	HU20	Houndsfield Units at 20%	Hu value below which 20% of the voxels fall
59	NomAir	Nominal Air	The nominal air value in a CT scan. Only in Whole lung tables.
60	ActAir	Actual Air	The actual air value in the CT scan. Only in Whole lung tables.
61	NomBT	Nominal Blood	The nominal blood tissue value in a CT scan. Only in Whole lung tables.
62	ActBT	Actual Blood	The actual blood tissue value in the CT scan. Only in Whole lung tables.

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#### \*\*Definitions of "Knee" and "Ankle" Variables

The points of inflection of the cumulative histogram of pixel densities would be the two points for which the histogram would be at it highest positive slope and steepest negative slope (second derivative equal to zero). The highest positive slope is the ankle and the highest negative slope is the knee. 1. If we take all the cumulative histogram values below the ankle and keep only the middle third of these values: the "slope of ankle" is the slope of a

line fitted to these middle points; and the "intercept of ankle" is the intercept of the line fitted to these middle points.

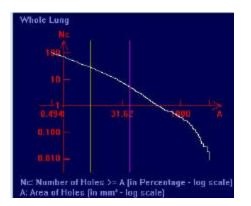
2. If we take the values that lie between the two points of inflection (ankle and knee) and throw out the highest and lowest thirds: The "slope of the knee" is the line fitted to these middle points, and the "intercept of the knee" is the intercept of the line fitted to these middle points.

#### The Holes tables:

For each of the 27 variables listed in the table below we will be generating parameters for the Whole lung (W), Right lung (R), Left lung (L), Right Upper (RU), Right Middle (RM), Right Lower (RL), Left Upper (LU), Left Middle (LM), and Left Lower (LL) lung sector prefixes will precede each of the 18 different Variable names to yield a total of 72 parameters (4x18) for each patient. (I.e. "RUCutoff\_1", "LLCutoff\_1" etc.)

VarID	Variable	VarFullName	Description
1	HoleID		
2	HWCreateTS	Hole Created	Date and Time the hole program was ran
3	ptid	The NETT ID + Scan Date	Unique identifier for each scan processed.
4	NETTID	NETT ID	
5	ScanDateU	Scan Date	
6	SliceThickness	Slice Thickness	
7	Intercept	Value given in dicom header	This value is used to convert a voxel value into houndsfield units.
8	VxSize	Voxel Size	
9	EntityVer	Module version	The hole program version number used to create the data.
10	Cutoff_1	-950 HU	Voxel value below -950 used to determine the hole (the area of emphysema).
11	Alpha_1	Slope	The x axis is the log of the hole size and the y axis is the log of the percentage of the $\#$ of holes > & = to hole size.
12	C1_1	Y Intercept	
13	Cutoff_2	-930 HU	Voxel value below -930 used to determine the hole (the area of emphysema).
14	Alpha_2	Slope	The x axis is the log of the hole size and the y axis is the log of the percentage of the $\#$ of holes > & = to hole size.
15	C1_2	Y Intercept	
16	Cutoff_3	-910 HU	Voxel value below -910 used to determine the hole (the area of emphysema).
17	Alpha_3	Slope	The x axis is the log of the hole size and the y axis is the log of the percentage of the $\#$ of holes > & = to hole size.
18	C1_3	Y Intercept	
19	Cutoff_4	-890 HU	Voxel value below -890 used to determine the hole (the area of emphysema).
20	Alpha_4	Slope	The x axis is the log of the hole size and the y axis is the log of the percentage of the $\#$ of holes > & = to hole size.
21	C1_4	Y Intercept	
22	Cutoff_5	-870 HU	Voxel value below -870 used to determine the hole (the area of emphysema).
23	Alpha_5	Slope	The x axis is the log of the hole size and the y axis is the log of the percentage of the $\#$ of holes > & = to hole size.
24	C1_5	Y Intercept	
25	Cutoff_6	-850 HU	Voxel value below -850 used to determine the hole (the area of emphysema).
26	Alpha_6	Slope	The x axis is the log of the hole size and the y axis is the log of the percentage of the $\#$ of holes > & = to hole size.
27	C1_6	Y Intercept	

For the graph of the hole measurements we use the equation  $\log N = -alpha(\log a) + C1$ , where N is defined as the percentage number of holes. C1 is the y intercept on the graph and alpha is the slope of the graph.



#### Computed tomography (CT).

**CT Part 1:** This imaging series is designed for the detection of pulmonary nodules, which may represent bronchogenic carcinoma in this high-risk patient population. No spirometric control of respiration is proposed due to the complexity of assuring consistency across all centers.

Volumetric Helical/Spiral CT				
Patient position: supine				
Collimation: 5-8 mm collimation				
Pitch: 1.7:1				
Reconstruction interval: 50% overlap (ex. 4 mm recon. interval for 8 mm collimation)				
Reconstruction algorithm: Standard (also include Lung, if possible)				
120 to 140 kVp				
FOV: outer ribs at widest dimension thorax				
Scan direction: lung apex to base (cranial to caudal)				
Suspended full inspiration (TLC)				
Breathing instructions: 3-4 hyperventilatory breaths prior to scan				
If patient can breath hold for entire scan, do in one breath; otherwise, scan in 2 breath-holds dividing the lungs in half from apex to top of the diaphragm, overlapping by 1 cm				
No intravenous contrast (unless indicated by specific chest radiographic abnormalities)				
Photography: film 12-20 on 1; lung windows at width 1500, level -600 to -750 May photograph every other reconstructed image				

CT Part 2. This imaging series will be used for scoring emphysema severity and bronchiectasis.

HRCT-Suspended Full Inspiration (TLC)			
1 mm collimation			
10 mm (1 cm) intervals			
High spatial frequency (bone) reconstruction			
Field of view to encompass lung only			
mAs: minimum 200 (greater in large patients)			
Scan apex to base			
Allow sufficient pauses between breath holds			
Photography: Film 12 on 1; window width 1500, level -600 to -750			

**CT Part 3:** This imaging series may be helpful in accentuating the attenuation differences between normal lung and emphysema.

HRCT-Suspended End Expiration (FRC)				
1 to 1.5 mm collimation				
20 mm (2 cm) intervals (minimum)				
High spatial frequency (bone) reconstruction				
Field of view to encompass lung only				
mAs: minimum 200 (greater in large patients)				
Scan apex to base				
Allow sufficient pauses between breath holds				
Photography: optional Film 12 on 1; window width 1500, level -600 to -750				

#### **Emphysema scores**

- Each lung is divided into 3 zones and each zone is given a score 0-4 (integer scores only)
  - 0: Normal (no destruction)
  - 1: Mild (1-25% destruction)
  - 2: Moderate (26-50% destruction)
  - 3: Marked (51-75% destruction)
  - 4: Severe (> 75% destruction)
- The zones are:
  - Upper:Lung apex to the top of the aortic archMiddle:Aortic arch to the right inferior pulmonary veinLower:Right inferior pulmonary vein to the most caudal extent to the lungs
- Emphysema is characterized as:

Heterogenous: Maximum difference on at least 1 side is  $\ge 2$ Moderate to marked homogeneous: All 2s or a combination of 2s and 3s but not all 3s Marked to severe homogeneous: All 3s or a combination of 3s and 4s but not all 4s or a combination of 2s, 3s, and 4s such that the maximum difference on each side is  $\le 1$ Other: Any other combination of scores

Perfusion Scan Protocol			
Radiopharmaceutical	Technetium 99m macroaggregated albumin (99m Tc MAA)		
Dose	3 or 4 mCi (dose of 6 mCi for patients over 100 kg) acceptable)		
Number of Particles/Dose	100,000–500,000		
Energy Peak	140 keV — 20% symmetric window		
Position During Injection Supine (patient may be erect or reclining if he/she cannot lie f Inject slowly over 5–10 respiratory cycles. Do not draw blood the syringe.			
Collimator	Parallel hole, low energy, all purpose		
Position During Imaging	Erect (supine if patient cannot cooperate)		
Projections	Anterior, posterior, both laterals, both posterior obliques, both anterior obliques		
Number of Counts/Image	600,000 - 750,000 for posterior, anterior, and all obliques; 500,000 - 600,000 for lateral view with best perfusion, same time for other lateral; 1,000,000 counts/image for all views is also acceptable		
Scintillation Camera	Wide field of view		
Computer	All images will be stored on a computer for further analysis		

#### Perfusion scintigraphy (Q scan).

Perfusion scans are evaluated quantitatively and qualitatively for areas of abnormal (decreased or absent) perfusion. The evaluation results are recorded on the Perfusion Scan (RP) form.

**Quantitative analysis.** Quantitative analysis will include only anterior and posterior views of the lungs and will be based on geometric areas of interest assigned.

- 1. Determine the boundaries of the lungs by careful inspection of the images on the monitor.
- 2. Construct a rectangle abutting the outermost margins in the superior, inferior, medial, and lateral aspects of lungs.
- 3. Divide the rectangle into 3 equal zones (upper, middle, and lower) by assigning 2 horizontal lines within the rectangle; make certain that rectangles reconstructed on anterior and posterior views are similarly positioned with respect to the lung they encompass and are superimposable.
- 4. Geometric mean counts in each zone will be measured by multiplying the number of counts and calculating the square root of this product.
- 5. Calculate percent perfusion to each zone based on geometric mean counts as follows:

percent perfusion =	geometric mean of zone counts	x 100
	geometric mean of counts in both lungs	

6. Record the percent perfusion for each of the 6 zones on the Perfusion Scan (RP) form. The sum of the percent perfusion over the 6 zones should be 100%.

**Qualitative scoring.** Each lung is divided into three zones of equal height, for a total of six zones. For each zone, score the homogeneity of perfusion using the following scheme:

- A = homogeneous perfusion
- B = mildly heterogeneous perfusion
- C = moderate to severe heterogeneity of perfusion

Visit/ Phase	Form abbr	Form title	Procedures to be done (at NETT clinic)
0		c prior to NETT testing	
s1	EB	Brief Screen for Eligibility	Interview; complete before initiating any NETT testing
Screer	ing and p	ore rehab assessments	
s1	PE	Physical Examination	Physical exam
	BU	Blood and Urine Analyses	Hematology, serum chem, A1AT, cotinine, urinanalysis
	HB	Baseline History	Interview
		Pulmonary Function Summary	Spiro, lung vols, D <sub>L</sub> CO, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV
	RC	CT Scan Report	CT scan evaluation
	RR	Chest Radiograph Summary	Chest X-ray evaluation
	HF	Heart Function Summary	Resting EKG, echo, dobutamine-radionuclide cardiac scan, right heart cath and/or cardiologist consult if needed, timing of cath and consult at clinic discretion so long as done pre- randomization
	MO	Oxygen Titration	Resting and walking oxygen titrations
	MM	6 Minute Walk Test	6 minute walk
	EW	Exercise Test	Maximum exercise test
	QF	MOS SF-36	Questionnaire
	QG	St George's Respiratory Quest.	Questionnaire
	QS	Shortness-of-Breath Quest.	Questionnaire
	QW	Quality of Well-Being Scale	Questionnaire
	ES	Exercise substudy	Only if in substudy
	PM	Mechanics substudy	Only if in substudy
	VC	Cardiovascular substudy	Only if in substudy
Rehah	Eval for	ns	
sl	QB	Beck Depression Inventory	Questionnaire
51	<b>Q</b> Ē	Self-Evaluation Questionnaire	Questionnaire
	ŤΜ	Trail Making Test	Test
Dro ro	hah range	at assassments (reneat any dance > 1	2 days previous to start of Core Rehab)
s2	PE	Physical Examination	Physical exam
32	HI	Interim History	Interview
	PF(PW)	Pulmonary Function Summary	Spiro, lung vols, $D_LCO$ , $PI_{max}/PE_{max}$ , resting ABG, MVV
	MO	Oxygen Titration	Resting and walking oxygen titrations $P_{\text{max}}$
	MM	6 Minute Walk Test	6 minute walk
	EW	Exercise Test	Maximum exercise test
	QF	MOS SF-36	Questionnaire
	OG	St George's Respiratory Quest.	Questionnaire
	òs	Shortness-of-Breath Quest.	Questionnaire
	ÒŴ	Quality of Well-Being Scale	Questionnaire
	QS QW ES	Exercise substudy	Only if in substudy
Eligihi	ility check	-	

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Eligibility check s2 EH/SH Pre Rehab Elig Check

Visit/ Phase	Form abbr	Form title	Procedures to be done (at NETT clinic)					
Post-r	ehab asse	essments						
s3	PE	Physical Examination	Physical exam					
	BU	Blood and Urine Analyses	Cotinine for non nicotine users					
	HI	Interim History	Interview					
	PF/PW	Pulmonary Function Summary	Spiro, lung vols, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV					
	MO	Oxygen Titration	Resting and walking oxygen titrations					
	MM	6 Minute Walk Test	6 minute walk					
	EW	Exercise Test	Maximum exercise test					
	QF	MOS SF-36	Questionnaire					
	QG	St George's Respiratory Quest.	Questionnaire					
	QS	Shortness-of-Breath Quest.	Questionnaire					
	QW	Quality of Well-Being Scale	Questionnaire					
	AA	Core and Cont Rehab Summary	Summary of Core and Cont Rehab participation					
	ES	Exercise substudy	Only if in substudy					
Post re	ehab repe	eat assessments (repeat any done mo	ore than 21 days prior to randomization)					
ŕΖ	PE	Physical Examination	Physical exam					
	HI	Interim History	Interview					
	PF/PW	Pulmonary Function Summary	Spiro, lung vols, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV					
	MO	Oxygen Titration	Resting and walking oxygen titrations					
	MM	6 Minute Walk Test	6 minute walk					
	EW	Exercise Test	Maximum exercise test					
	QF	MOS SF-36	Questionnaire					
	QG	St George's Respiratory Quest.	Questionnaire					
	QS	Shortness-of-Breath Quest.	Questionnaire					
	QW ES	Quality of Well-Being Scale Exercise substudy	Questionnaire Only if in substudy					
	LS	Exercise substudy	Only II III Substudy					
		done for randomization						
ŕΖ	RP	Perfusion Scan	Perfusion scan					
Rando	mization							
rz	ER/SZ	Final Eligibility Review	None					
	XZ	Documentation of Randomization	Randomization					
	XS	Surgery Summary Report	Summarize events of surgery day					
	XP	Post-Operative Summary Report	Summarize 30 day events					
	AB	Post Randomizaton Rehab Summ.	Summarize attendance in 8 wks post RZ rehab					
Follow	Followup (note that telephone visits were not done during 2003)							
f01	ÀŤ	Reg Sched Telephone Contact	Interview					
f02	AT	Reg Sched Telephone Contact	Interview					
f04	AT	Reg Sched Telephone Contact	Interview					

Visit/ Phase	Form abbr	Form title	Procedures to be done (at NETT clinic)
f06	PE HI PF/PW RC RR HF MO MM EW QF QG QS QW ES VC	Physical Examination Interim History Pulmonary Function Summary CT Scan Report Chest Radiograph Summary Heart Function Summary Oxygen Titration 6 Minute Walk Test Exercise Test MOS SF-36 St George's Respiratory Quest. Shortness-of-Breath Quest. Quality of Well-Being Scale Exercise substudy Cardiovascular substudy	Physical exam Interview Spiro, lung vols, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV CT scan Chest x-ray Echocardiogram Resting and walking oxygen titrations 6 minute walk Maximum exercise test Questionnaire Questionnaire Questionnaire Questionnaire Only if in substudy Only if in substudy
f08	AT	Reg Sched Telephone Contact	Interview
f10	AT	Reg Sched Telephone Contact	Interview
f12	PE BU HI PF/PW MO MM EW QF QG QS QW TO ES	Physical Examination Blood and Urine Analyses Interim History Pulmonary Function Summary Oxygen Titration 6 Minute Walk Test Exercise Test MOS SF-36 St George's Respiratory Quest. Shortness-of-Breath Quest. Quality of Well-Being Scale Alternate Trail Making Test Exercise substudy	Physical exam Hematology, serum chem, urinanalysis Interview Spiro, lung vols, $D_LCO$ , $PI_{max}/PE_{max}$ , resting ABG, MVV Resting and walking oxygen titrations 6 minute walk Maximum exercise test Questionnaire Questionnaire Questionnaire Test Only if in substudy
	HI only	during 2003	
f15	AT	Reg Sched Telephone Contact	Interview
f18	AT	Reg Sched Telephone Contact	Interview
f21	AT	Reg Sched Telephone Contact	Interview

Visit/ Phase	Form abbr	Form title	Procedures to be done (at NETT clinic)
f24	PE BU HI PF/PW MO MM EW QF QG QS QW TM ES	Physical Examination Blood and Urine Analyses Interim History Pulmonary Function Summary Oxygen Titration 6 Minute Walk Test Exercise Test MOS SF-36 St George's Respiratory Quest. Shortness-of-Breath Quest. Quality of Well-Being Scale Trail Making Test Exercise substudy	Physical exam Hematology, serum chem, urinanalysis Interview Spiro, lung vols, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV Resting and walking oxygen titrations 6 minute walk Maximum exercise test Questionnaire Questionnaire Questionnaire Test Only if in substudy
f27	AT	Reg Sched Telephone Contact	Interview
f30	AT	Reg Sched Telephone Contact	Interview
f33	AT	Reg Sched Telephone Contact	Interview
f36	PE BU HI PF/PW RC RR EW QF QG QS QW TO ES	Physical Examination Blood and Urine Analyses Interim History Pulmonary Function Summary CT Scan Report Chest Radiograph Summary Exercise Test MOS SF-36 St George's Respiratory Quest. Shortness-of-Breath Quest. Quality of Well-Being Scale Alternate Trail Making Test Exercise substudy	Physical exam Hematology, serum chem, urinanalysis Interview Spiro, lung vols, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV CT scan Chest x-ray Maximum exercise test Questionnaire Questionnaire Questionnaire Test Only if in substudy
f39	AT	Reg Sched Telephone Contact	Interview
f42	AT	Reg Sched Telephone Contact	Interview
f45	AT	Reg Sched Telephone Contact	Interview

Visit/ Phase	Form abbr	Form title	Procedures to be done (at NETT clinic)
f48	PE BU HI PF/PW EW QF QG QS QW TM ES PM HI only	Physical Examination Blood and Urine Analyses Interim History Pulmonary Function Summary Exercise Test MOS SF-36 St George's Respiratory Quest. Shortness-of-Breath Quest. Quality of Well-Being Scale Trail Making Test Exercise substudy Mechanics substudy during 2003	Physical exam Hematology, serum chem, urinanalysis Interview Spiro, lung vols, PI <sub>max</sub> /PE <sub>max</sub> , resting ABG, MVV Maximum exercise test Questionnaire Questionnaire Questionnaire Questionnaire Test Only if in substudy Only if in substudy
f51	AT	Reg Sched Telephone Contact	Interview
f54	AT	Reg Sched Telephone Contact	Interview
f57	AT	Reg Sched Telephone Contact	Interview
f60	PE BU HI PF/PW EW QF QG QS QW TO ES	Physical Examination Blood and Urine Analyses Interim History Pulmonary Function Summary Exercise Test MOS SF-36 St George's Respiratory Quest. Shortness-of-Breath Quest. Quality of Well-Being Scale Alternate Trail Making Test Exercise substudy	Physical exam Hematology, serum chem, urinanalysis Interview Spiro, lung vols, $PI_{max}/PE_{max}$ , resting ABG, MVV Maximum exercise test Questionnaire Questionnaire Questionnaire Questionnaire Test Only if in substudy

Note: Forms SH, SZ, and PW were worksheets and were not keyed forms.

Title	Accession No.
National Emphysema Treatment Trial (NETT) Protocol (21 Jun 1999)	PB2001-102646
National Emphysema Treatment Trial (NETT) Manual of Operations, Part 1: Patient Procedures (29 Nov 2000)	PB2001-102647
National Emphysema Treatment Trial (NETT) Forms, Charts, and Flash Cards Book (13 Feb 2001)	PB2001-103545

#### NETT documents available from the National Technical Information Service

#### **NTIS Contact Information**:

National Technical Information Service 5285 Port Royal Road Springfield, VA 22161 888-584-8332 (phone) www.ntis.gov 1. **National Emphysema Treatment Trial Research Group**: Rationale and design of the National Emphysema Treatment Trial (NETT): A prospective randomized trial of lung volume reduction surgery. J Thorac Cardiovasc Surg, 118:518-28, **1999**.

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- 24. **DeCamp MM et al for the National Emphysema Treatment Trial Research Group.** Patient and surgical factors influencing air leak. <u>Annals of Thoracic Surgery</u> (in press)
- 25. **Naunheim K et al for the National Emphysema Treatment Trial Research Group.** Longterm follow-up of patients receiving LVRS versus medical therapy for severe emphysema. <u>Annals of Thoracic Surgery</u> (in press)
- 26. **Chatila Wet al for the National Emphysema Treatment Trial Research Group.** Advanced emphysema in African Americans compared with Caucasians: Do differences exist? <u>Chest (in press)</u>
- 27. **Martinez FJ et al for the National Emphysema Treatment Trial Research Group.** Predictors of mortality in severe emphysema. <u>Am J Respir Crit Care Med</u> (in press)

AA - Form AA Core and Continued Rehabilitation Summary (rev 3)

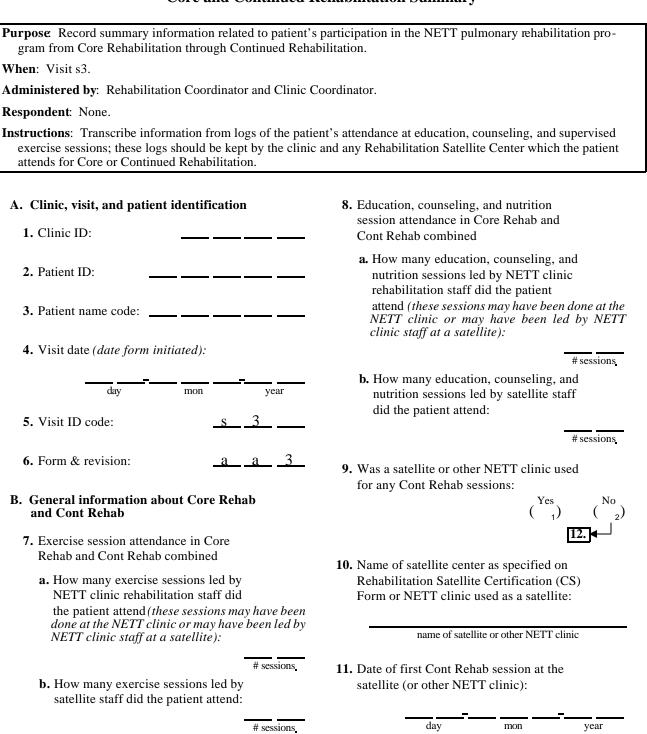
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Obsei	ons:				1439	
Variables:						90

Maniah la			Manialala	
Variable Name	Variable Label	Туре	Variable Length	Format
Name	Variable laber	турс	Deligen	rormac
aa309	9 Was satellite used for any sessions?	Char	1	
aa311	#11 cnvrtd to #days from RZ/scr strt	Num	8	
aa313	13 Number of days from item 12a to 12b	Char	2	
aa314	14 Count in item 13 is 40-70?	Char	1	
aa315	#15 cnvrtd to #days from RZ/scr strt	Num	8	
aa320	#20 cnvrtd to #days from RZ/scr strt	Num	8	
aa321	#21 cnvrtd to #days from RZ/scr strt	Num	8	
aa322	#22 cnvrtd to #days from RZ/scr strt	Num	8	
aa323	#23 cnvrtd to #days from RZ/scr strt	Num	8	
aa324 aa328	#24 cnvrtd to #days from RZ/scr strt	Num Num	8 8	
aa329	#28 cnvrtd to #days from RZ/scr strt 29 Reason to declare patient ineligible	Char	1	
aa307a	7a Number of sessions at NETT clinic	Char	2	
aa307b	7b Number of sessions at satellite cent	Char	2	
aa308a	8a Number of sessions led by NETT staff	Char	2	
aa308b	8b Number of sessions led by satellite	Char	2	
aa312a	#12a cnvrtd to #days from RZ/scr strt	Num	8	
aa312b	#12b cnvrtd to #days from RZ/scr strt	Num	8	
aa316a	#16a cnvrtd to #days from RZ/scr strt	Num	8	
aa316b	#16b cnvrtd to #days from RZ/scr strt	Num	8	
aa316c	#16c cnvrtd to #days from RZ/scr strt	Num	8	
aa316d	#16d cnvrtd to #days from RZ/scr strt	Num	8	
aa317a	#17a cnvrtd to #days from RZ/scr strt	Num	8	
aa317b	#17b cnvrtd to #days from RZ/scr strt	Num	8	
aa317c	#17c cnvrtd to #days from RZ/scr strt	Num	8	
aa317d aa318a	#17d cnvrtd to #days from RZ/scr strt	Num	8	
aa318a aa318b	<pre>#18a cnvrtd to #days from RZ/scr strt #18b cnvrtd to #days from RZ/scr strt</pre>	Num Num	8 8	
aa318c	#18b chvitd to #days from RZ/scr strt	Num	8	
aa318d	#18d cnvrtd to #days from RZ/scr strt	Num	8	
aa319a	#19a cnvrtd to #days from RZ/scr strt	Num	8	
aa319b	#19b cnvrtd to #days from RZ/scr strt	Num	8	
aa319c	#19c cnvrtd to #days from RZ/scr strt	Num	8	
aa319d	#19d cnvrtd to #days from RZ/scr strt	Num	8	
aa325a	25a Number of exercise sessions complete	Char	2	
aa325b	25b At least 12 exercise sessions comple	Char	1	
aa325c	#25c cnvrtd to #days from RZ/scr strt	Num	8	
aa325d	#25d cnvrtd to #days from RZ/scr strt	Num	8	
aa325e	#25e cnvrtd to #days from RZ/scr strt	Num	8	
aa325f	#25f cnvrtd to #days from RZ/scr strt	Num	8	
aa325g aa325h	#25g cnvrtd to #days from RZ/scr strt	Num Num	8 8	
aa325i	#25h cnvrtd to #days from RZ/scr strt #25i cnvrtd to #days from RZ/scr strt	Num	8	
aa325j	#25j cnvrtd to #days from RZ/scr strt	Num	8	
aa325k	#25k cnvrtd to #days from RZ/scr strt	Num	8	
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aa325n	#25n cnvrtd to #days from RZ/scr strt	Num	8	
aa325o	#25o cnvrtd to #days from RZ/scr strt	Num	8	
aa325p	#25p cnvrtd to #days from RZ/scr strt	Num	8	
aa325q	#25q cnvrtd to #days from RZ/scr strt	Num	8	
aa325r	#25r cnvrtd to #days from RZ/scr strt	Num	8	
aa326a	26a Number of pyschosocial sessions done	Char	2	
aa326b	26b At least 12 pyschosocial sessions do	Char	1	
aa326c	#26c cnvrtd to #days from RZ/scr strt	Num	8	
aa326d aa326e	#26d cnvrtd to #days from RZ/scr strt	Num	8 8	
aa326f	#26e cnvrtd to #days from RZ/scr strt #26f cnvrtd to #days from RZ/scr strt	Num Num	8	
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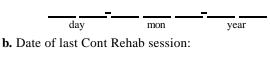
AA - Form AA Core and Continued Rehabilitation Summary (rev 3)

Date file o Observation Variables:	created: 12 May 2006 ns: 1439 90			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
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aa326q	#26q cnvrtd to #days from RZ/scr strt	Num	8	
aa326r	#26r cnvrtd to #days from RZ/scr strt	Num	8	
aa327a	27a Emphysema education	Char	1	
aa327b	27b Medications education	Char	1	
aa327c	27c Collaborative self-management educat	Char	1	
aa327d	27d Oxygen therapy education	Char	1	
aa327e	27e Breathing training	Char	1	
aa327f	27f Secretion clearance and management	Char	1	
aa327q	27g Stress management	Char	1	
aa327ĥ	27h Nutrition education	Char	1	
aa327i	27i Travel and environmental issues	Char	1	
aa327j	27j Sexuality and COPD	Char	1	
aa327k	27k Energy conservation and ADL	Char	1	
aa3271	271 Advanced directives	Char	1	
aa327m	27m 1st other topic	Char	1	
aa327n	27n 2nd other topic	Char	1	
aa327o	27o 3rd other topic	Char	1	
aa327p	27p 4th other topic	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days from RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

#### **Core and Continued Rehabilitation Summary**

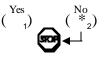


- **12.** Duration of Core and Cont Rehab
  - **a.** Date of initial Core Rehab session:





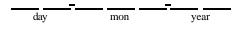
- **13.** Number of days from date in item 12a through date in item 12b (*count the date in item 12a as Day #1; count forward to the date in item 12b; record the number for the date in item 12b in this item*):
- **14.** Is the number in item 13 at least 40 and no greater than 70:



(\*Core and Cont Rehab must last at least 40 days and no longer than 70 days. The patient is ineligible for NETT. Complete this form but do not key it; skip to Section H. Note the reason for ineligibility on Form ER.)

# C. Visit with NETT physician to review results of screening

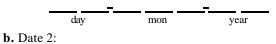
**15.** Date of visit with NETT physician:

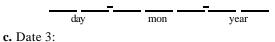


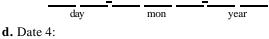
#### D. Core Rehab summary

**16.** Dates of lower extremity endurance sessions:

**a.** Date 1:

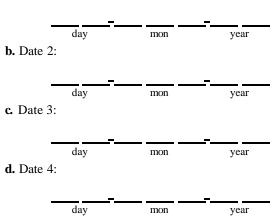






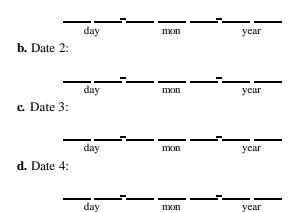


- **17.** Dates of upper extremity endurance sessions:
  - **a.** Date 1:



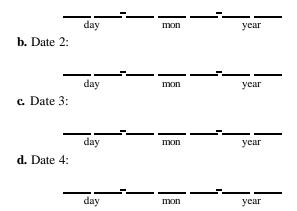
Patient ID:

- 18. Dates of flexibility sessions:
  - **a.** Date 1:



**19.** Dates of strength training sessions:

**a.** Date 1:



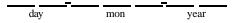
Patient ID:

38

**20.** Date of pulmonary rehabilitation education session:



**21.** Date of medication plan education session:



**22.** Date of NETT education session:



**23.** Date of oxygen use education session (*enter n if patient does not use oxygen and did not have this session*):

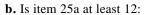


**24.** Date of psychosocial counseling session:



#### E. Cont Rehab exercise sessions

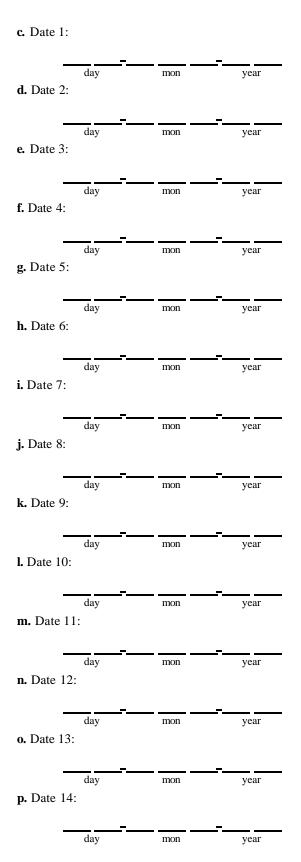
- 25. Exercise sessions
  - **a.** How many exercise sessions did the patient complete in Cont Rehab:

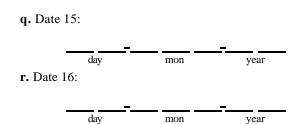




# sessions

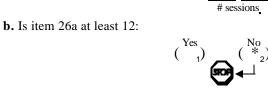
(\*At least 12 exercise sessions must be completed in Cont Rehab. Have the patient complete additional Cont Rehab sessions if time remains within the 70 day window. Otherwise, the patient is inelegible for NETT and you must skip to Section H and note the reason for ineligibility on Form ER.)





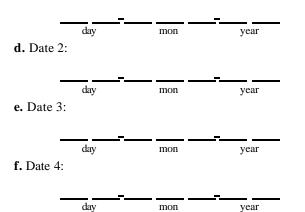
#### F. Additional education/psychosocial sessions in Core and Cont Rehab

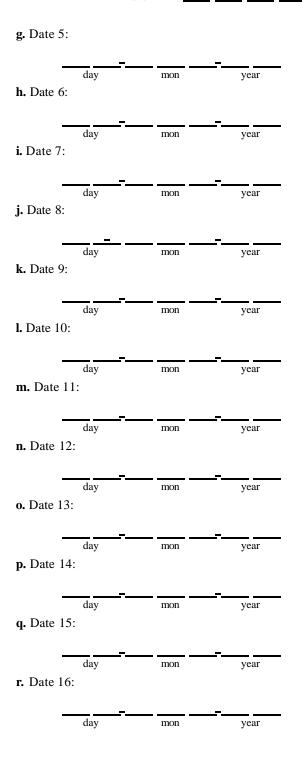
- **26.** Additional education/psychosocial sessions
  - **a.** In addition to the required Core Rehab education/psychosocial sessions specified in items 20-24, how many education/psychosocial sessions did the patient complete in Core and/or Cont Rehab:



(\*At least 12 education/psychosocial sessions, additional to the sessions in items 20-24 must be completed in Core and/or Cont Rehab. If the patient has not completed at least 12 additional education/pyschosocial sessions, have the patient complete additional education sessions if time remains within the 70 day window. Otherwise, the patient is ineligible for NETT and you must skip to Section H and note the reason for ineligibility on Form ER.)

**c.** Date 1:



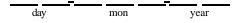


**27.** Topics of additional education/psychosocial sessions (check all that patient attended) a. Anatomy, physiology, pathophysiology of COPD and emphysema: 1) ( 1) **b.** Medications: 1) c. Collaborative self-management: **d.** Oxygen therapy: 1) 1) e. Breathing training: 1) ( f. Secretion clearance and management: 1) **g.** Stress management: ( **h.** Nutrition: 1) 1) i. Travel and environmental issues: **j.** Sexuality and COPD: 1) ( **k.** Energy conservation and ADL: 1) **I.** Advanced directives: <sub>1</sub>) 1) **m.** 1st other topic (*specify*): (

_	specify		
<b>n.</b> 2	2nd other topic (specify):	(	1)
			•
	specify		
0.3	Brd other topic ( <i>specify</i> ):	(	1)
			17
-	specify		
n 4	4th other topic ( <i>specify</i> ):	(	,)
ь.	the other topic (specify).	(	1)

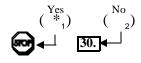
specify

**28.** Date of nutrition visit (*enter n if patient did not need this session*):



# G. Eligibility check

**29.** Is there any reason to declare the patient ineligible based on performance in Core Rehab and/or Cont Rehab:



#### specify reason for ineligibility

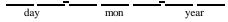
Patient ID:

(\*Complete this form but do not key it; note the reason for ineligibility on Form ER.)

#### H. Administrative information

**30.** Rehabilitation Coordinator PIN: \_\_\_\_\_

- **31.** Rehabilitation Coordinator signature:
- **32.** Clinic Coordinator PIN:
- **33.** Clinic Coordinator signature:
- **34.** Date form reviewed:



AB - Form AB Post Randomization Rehabilitation Summary (rev 2)

Date	file	created:	12	May	2006
Obsei	rvatio	ons:			1113
Varia	ables	:			32

Variable			Variable	
Name	Variable Label	Туре	Length	Format
- 1- 0.0.0		Class.	1	
ab209	9 Satellite center used for rehab	Char	1 7	
ab211	#11 cnvrtd to #days from RZ/scr strt	Char	7	
ab212	#12 cnvrtd to #days from RZ/scr strt	Char	7	
ab213	#13 cnvrtd to #days from RZ/scr strt	Char		
ab207a	7a No. of sessions at NETT clinic	Char	2	
ab207b	7b No. of exercise sessions at satellit	Char	2	
ab208a	8a No. of education sessions at NETT cl	Char	2	
ab208b	8b No. of education sessions at satelli	Char	2	
ab214a	#14a cnvrtd to #days from RZ/scr strt	Char	7	
ab214b	#14b cnvrtd to #days from RZ/scr strt	Char	7	
ab215a	#15a cnvrtd to #days from RZ/scr strt	Char	7	
ab215b	#15b cnvrtd to #days from RZ/scr strt	Char	7	
ab216a	#16c cnvrtd to #days from RZ/scr strt	Char	7	
ab216b	#16b cnvrtd to #days from RZ/scr strt	Char	7	
ab217a	#17a cnvrtd to #days from RZ/scr strt	Char	7	
ab217b	#17b cnvrtd to #days from RZ/scr strt	Char	7	
ab218a	#18a cnvrtd to #days from RZ/scr strt	Char	7	
ab218b	18b Date 1: type of session	Char	1	
ab218c	#18c cnvrtd to #days from RZ/scr strt	Char	7	
ab218d	18d Date 2: type of session	Char	1	
ab219a	#19a cnvrtd to #days from RZ/scr strt	Char	7	
ab219b	#19b cnvrtd to #days from RZ/scr strt	Char	7	
ab219c	#19c cnvrtd to #days from RZ/scr strt	Char	7	
ab219d	#19d cnvrtd to #days from RZ/scr strt	Char	7	
ab219e	#19e cnvrtd to #days from RZ/scr strt	Char	7	
ab219f	#19f cnvrtd to #days from RZ/scr strt	Char	7	
ab219g	#19g cnvrtd to #days from RZ/scr strt	Char	7	
ab219h	#19h cnvrtd to #days from RZ/scr strt	Char	7	
form	Form abreviation and revision number	Char	4	
formdate	item 4 cnvrtd to #days from RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

**Purpose** Record summary information related to the patient's participation in the NETT pulmonary rehabilitation program in the 8 weeks of Consolidation and Continued Consolidation Rehabilitation.

When: Use visit ID code rz; complete after patient completes post randomization rehabilitation.

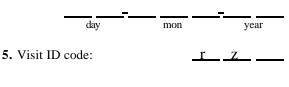
Administered by: NETT clinic rehabilitation staff, Rehabilitation Coordinator, or Clinic Coordinator.

#### Respondent: None.

**Instructions**: Transcribe information from the logs of exercise and education/counseling sessions completed for the patient by the NETT clinic and any Rehabilitation Satellite Center which the patient attended. Ideally, the patient will complete post randomization rehabilitation as specified by protocol (2 days of Consolidation Rehabilitation followed by 8 weeks of Continued Consolidation Rehabilitation, 1 session per week). Report sessions as they occur regardless of whether the timing goes according to protocol. If the patient has not completed all Consolidation and Continued Consolidation Rehabilitation sessions by the close of the patient's f06 visit window, complete this form reporting the Consolidation or Continued Rehabilitation sessions completed. Put m's in for sessions not done. Report prescription of extra rehabilitation sessions on the Unusual Event (UE) form. If the patient did not complete **any** Consolidation or Continued Consolidation Rehabilitation sessions, do not complete this form; complete the Unusual Event (UE) form instead.

#### A. Clinic, visit, and patient identification

- 1. Clinic ID:
- 2. Patient ID:
- 3. Patient name code:
- **4.** Visit date (*date form initiated*):



6. Form & revision:  $\underline{a} \ \underline{b} \ \underline{2}$ 

#### **B.** General information for Consolidation and Continued Consolidation Rehabilitation

- 7. Exercise session attendance in Consolidation and Continued Consolidation Rehabilitation combined
  - a. How many exercise sessions led by NETT clinic rehabilitation staff did the patient attend (these sessions may have been done at the NETT clinic or may have been led by NETT clinic staff at a satellite):

# sessions

**b.** How many exercise sessions led by satellite staff did the patient attend:

# sessions

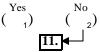
- 8. Education, counseling, and nutrition session attendance in Consolidation and Continued Consolidation Rehabilitation combined
  - **a.** How many education, counseling, and nutrition sessions led by NETT clinic rehabilitation staff did the patient attend (*these sessions may have been done at the NETT clinic or may have been led by NETT clinic staff at a satellite*):

# sessions

**b.** How many education, counseling, and nutrition sessions led by satellite staff did the patient attend:

# sessions

**9.** Was a satellite or other NETT clinic used for any Continued Consolidation Rehabilitation sessions:



 Name of satellite center as specified on Rehabilitation Satellite Certification (CS) Form or other NETT clinic used as a satellite:

satellite name or other NETT clinic

**11.** Date of initial Consolidation Rehabilitation session:

day mon year

**12.** Date of last Continued Consolidation Rehabilitation session:

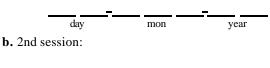
day	mon	У	ear

#### C. Consolidation Rehabilitation summary

**13.** Date of visit with NETT clinic physician:



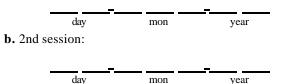
- **14.** Dates of upper extremity exercise sessions:
  - **a.** 1st session:





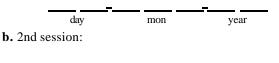
**15.** Dates of lower extremity exercise sessions:

**a.** 1st session:



**16.** Dates of flexibility exercise sessions:

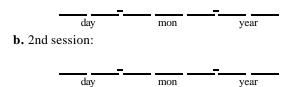
**a.** 1st session:





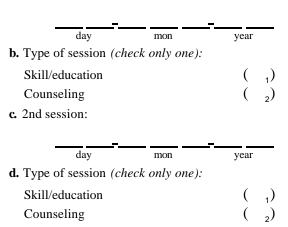
17. Dates of strengthening exercise sessions:

**a.** 1st session:



Patient ID:

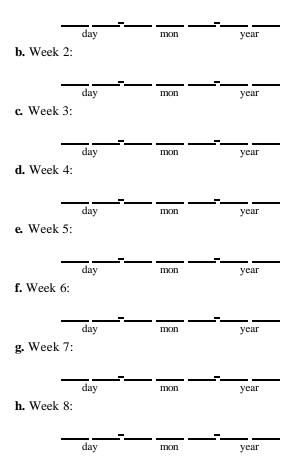
- \_
- **18.** Dates of required education/counseling sessions:
  - **a.** 1st session:



# **D.** Continued Consolidation Rehabilitation summary

**19.** Dates of supervised exercise sessions (*patient* should have 1 supervised session per week for 8 weeks; if the patient's sessions do not occur on a weekly schedule, fill in the dates of sessions as they occur):

**a.** Week 1:



## E. Administrative information

20. Rehabilitation Coordinator PIN: \_\_\_\_\_

**21.** Rehabilitation Coordinator signature:

**22.** Clinic Coordinator PIN:

**23.** Clinic Coordinator signature:

**24.** Date form reviewed:

day mon year

\_ \_\_\_\_

AT - Form AT Regularly Scheduled Telephone Contact (rev 3)

Date	file	created:	12	May	2006
Obsei	rvatio	ons:			11068
Varia	ables:	:			37

Variable Name	Variable Label	Type	Variable Length	Format
			-	
at307	7 Current residence	Char	1	
at308	8 Spoke with patient	Char	1	
at316	16 No. overnight hospital stays in past	Char	2	
at317	17 No. overnights in rehab hosp in past	Char	2	
at318	18 No. ER visits in past month	Char	2	
at319	19 No. visits to MD in past month	Char	2	
at320	20 No. visits at home by health profess	Char	2	
at321	21 No. visits at home by health care wo	Char	2	
at322	22 No. visits at home by health equipme	Char	2	
at323	23 Other visits with health care worker	Char	1	
at324	24 Illness caused family to restrict ac	Char	1	
at325	25 No. hrs family cared for patient in	Char	3	
at312a	12a Any endurance exercise past 7 days	Char	1	
at312b	12b Number of times exercised in past we	Char	2	
at312c	12c Length of exercise session (min)	Char	2	
at313a	13a Any flexibility exercise past 7 days	Char	1	
at313b	13b Times did flexibility exercise past	Char	2	
at314a	14a Upper extremity exercise in past 7 d	Char	1	
at314b	14b Times did upper extrem exercise past	Char	2	
at315a	15a Strength exercise in past 7 days	Char	1	
at315b	15b Times did strength exercise in past	Char	2	
at326a	26a Spoke with patient	Char	1	
at326b	26b Spoke with spouse	Char	1	
at326c	26c Spoke with other family member	Char	1	
at326d	26d Spoke with caregiver (non-family)	Char	1	
at326e	26e Spoke with staff at institution	Char	1	
at326f	26f Spoke with other	Char	1	
at326q	26g Spoke with no one about patient	Char	1	
at327a	27a Patient too sick	Char	1	
at327b	27b Patient refused	Char	1	
at327c	27c Patient temporarily away	Char	1	
at327d	27d Missed time window	Char	1	
at327e	27e Other	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	item 4 cnvrtd to #days from RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
VIUIC	SI, SZ, SS, IZ, II, IXX WHELE XX MOD IIOM NZ	CHUL	5	

46

**Purpose** To record information about regularly scheduled post randomization followup telephone contacts. When: Visits f01, f02, f04, f08, f10, f15, f18, f21, f27, f30, f33, f39, f42, f45, f51, f54, and f57. Administered by: NETT clinic rehabilitation staff, Rehabilitation Coordinator or Clinic Coordinator. Respondent: Patient. Instructions: Use this form to report the status of followup telephone contacts at the scheduled contact times. Complete this form whether or not you speak with the patient. If you could not locate the patient or anyone knowledgeable about the patient's whereabouts or if you did not try to contact the patient during the time window for the contact, enter the last permissable date in the time window for the contact in item 4. Specify residence in item 7 only if you know the patient's whereabouts during the time window for the contact. A. Clinic, visit, and patient identification C. General interview (ask these questions and record the responses in general, but do not key items 9-11) 1. Clinic ID: 9. How are you doing: 2. Patient ID: **3.** Patient name code: 4. Visit date (date of telephone contact; date window closed if contact was missed): day mon year **10.** Do you have any problems: Yes 5. Visit ID code: **11.** Suggested plan: 3 **6.** Form & revision: **B.** Current residence of patient 7. Patient's current residence (check only one): Private home, apartment, or condominium <sub>1</sub>) Retirement home 2) Nursing home 3) Rehabilitation facility <sub>4</sub>) Acute care hospital 5) Other (specify): <sub>6</sub>) Could not locate patient or anyone with knowledge of patient's whereabouts 7) 32. 8. Were you able to speak with the patient within the time window for the telephone contact: (Yes No 26.

- 12. Lower extremity endurance exercise
  - **a.** In the 7 days prior to this phone call did you do any lower extremity endurance exercise (such as walking or cycling):

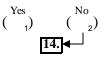
$$(Yes \ 1) \ (Yes \ 2)$$

**b.** On how many days did you do lower extremity endurance exercise:

# days

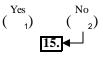
**c.** On average, how many minutes long was your lower extremity endurance exercise session:

- 13. Flexibility (stretching) exercise
  - **a.** In the 7 days prior to this phone call did you do any flexibility (stretching) exercise:



**b.** On how many days did you do flexibility (stretching) exercise:

- 14. Upper extremity endurance exercise
  - **a.** In the 7 days prior to this phone call did you do any upper extremity endurance exercise:



**b.** On how many days did you do upper extremity endurance exercise:

# days

- **15.** Strength training exercise
  - **a.** In the 7 days prior to this phone call did you do any strength training exercise (such as therabands, free weights):

Patient ID:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

**b.** On how many days did you do strength training exercise:

#	days

- **E. Healthcare utilization interview** (these questions relate to all medical care, not just care for emphysema)
- **16.** In the past month, how many nights have you stayed overnight in a hospital or other acute care facility *(include nights for NETT LVRS):*

# nights

**17.** In the past month, how many nights have you stayed overnight in a rehabilitation hospital, nursing home, or other nonacute care facility:

# nights\_

18. In the past month, how many times have you been seen at an emergency room (department), triage area, or urgent care facility:

# times

**19.** In the past month, how many times have you visited a physician, physician's assistant, or nurse in their office or have you visited an outpatient clinic for any reason (exclude hospital stays, visits to nonacute care facilities, and emergency room, triage area or urgent care area visits; exclude NETT screening, followup, and rehab visits; by followup visits, we mean the regularly scheduled NETT in person followup visits, eg, f06, f12, f24, etc):

# times

- **20.** In the past month, how many times has a health care professional (eg, home health agency nurse, physical therapist, occupational therapist) visited you in your residence:
  - # times
- **21.** In the past month, how many times has a health care service worker (eg, aide, attendant) come to your residence for health reasons:

# times

**22.** In the past month, how many times has a health equipment technician or respiratory therapist come to your residence to adjust, service, or care for some item of health care equipment used by you:

# times

**23.** In the past month, did you have any other visits with health care workers other than those just mentioned (*exclude NETT screening, followup, and rehab visits; by followup visits, we mean the regularly scheduled NETT in person followup visits, eg, f06, f12, f24, etc.):* 

Yes

If yes, please describe:

#### F. Other contacts about patient

**26.** With whom did you speak when trying to complete the interview with the patient (*check* "patient" if you were able to interview the patient within the time window for the telephone contact; otherwise check all that apply)

a. Patient:	(	_1)
	30.◀	Ţ
<b>b.</b> Spouse:	(	1)
<b>c.</b> Other family member:	(	1)
<b>d.</b> Caregiver (non family):	(	1)
<b>e.</b> Staff at institution where patient is	,	
staying:	(	1)
f. Other (specify):	(	1)

- g. Did not speak with anyone about patient within the time window: ( 1)
- **27.** Why weren't you able to speak to the patient (*check all that apply*)

<b>a.</b> Patient too sick:	(	1)
<b>b.</b> Patient refused:	(	1)
<b>c.</b> Patient temporarily away:	(	1)
<b>d.</b> Missed time window:	(	1)
e. Other (specify):	(	1)

**28.** What is the patient's situation:

**24.** In the past month, has your illness required any family members or friends to restrict their work or social activities (*include efforts to help you participate in NETT*):

$$\frac{\text{Yes}}{1} \qquad (\frac{\text{No}}{2})$$

(

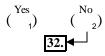
**25.** About how many hours in the past week have family members or friends spent in helping with your care (*include efforts to help you participate in NETT*):

# hours

**29.** When might the patient be available for interview:

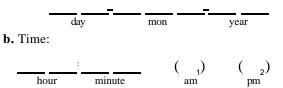
# G. Next telephone contact

**30.** Was the next telephone contact scheduled:



31. Date and time of next telephone contact

a. Date:



## H. Administrative information

- **32.** Interviewer name (*please print*):
- **33.** Interviewer signature:

**34.** Clinic Coordinator PIN:

- **35.** Clinic Coordinator signature:
- **36.** Date form reviewed:

-

BU - Form BU Blood and Urine Analysis (rev 2)

Date file created: 13 May 2006 Observations: 5340 Variables: 31

Variable			Variable	
Name	Variable Label	Type	Length	Format
		71 -	- 2	
alatconc	Concentration level (mg/dL)	Num	8	
alatptyp	Phenotype	Char	4	
bu207	7 Blood collected for hematology	Char	1	
bu208	#8 cnvrtd to # of days frm RZ/scr strt	Num	8	
bu211	11 Blood collected for plasma cotinine	Char	1	
bu212	#12 cnvrtd to # days frm RZ/scr strt	Num	8	
bu213	13 Plasma cotinine (ng/ml)	Char	3	
bu214	14 Blood collected for A1AT testing	Char	1	
bu215	#15 cnvrtd to # of days frm RZ/scr strt	Num	8	
bu218	18 Urine collected for analysis	Char	1	
bu219	<pre>#19 cnvrtd to # of days frm RZ/scr strt</pre>	Num	8	
bu221	21 s1 or s3 visit?	Char	1	
bu222	22 Patient ineligibleblood/urine	Char	1	
bu209a	9a WBC	Char	3	
bu209b	9b Hemoglobin (g/dL)	Char	3	
bu209c	9c Platelets (10**9/L)	Char	4	
bu210a	10a Creatinine	Char	1	
bu210b	10b Total protein	Char	1	
bu210c	10c Albumin	Char	1	
bu210d	10d Glucose	Char	1	
bu210e	10e AST (SGOT)	Char	1	
bu210f	10f Alk phos	Char	1	
bu210g	10g Total bilirubin	Char	1	
bu220a	20a Glucose	Char	1	
bu220b	20b Protein	Char	1	
bu220c	20c pH	Char	3	
bu220d	20d Specific gravity	Char	4	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to No. of days from RZ	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

51

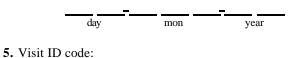
When: Visits s1, s3, f12, f24, f36, f48, and f60.Administered by: Study Physician and Clinic Coordinator.Respondent: None.

**Purpose** To record results of blood and urine analyses.

**Instructions**: Hematology, serum chemistry, plasma cotinine (if patient is not using nicotine), and urinalysis results should be obtained at s1 before clearing the patient for beginning Core Rehabilitation. Plasma cotinine should be repeated at s3 (if patient is not using nicotine). Alpha-1 antitrypsin deficiency testing is done at s1 only. Hematology, serum chemistry and urinalysis should be completed at f12, f24, f36, f48, and f60. All relevant lab reports should be marked with the patient's ID number and name code and stapled to the back of this form. If your lab reports values electronically, print a copy of the report, mark it with the patient's ID number and name code, and staple it to the back of this form. If the patient is found to be ineligible, complete this form but do not key it. The reason for the ineligibility will be noted on Form EH or Form ER.



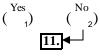
- 1. Clinic ID:
- 2. Patient ID:
- 3. Patient name code: \_\_\_\_\_
- **4.** Visit date (*date form is initiated*):



**6.** Form & revision:

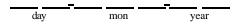
# B. Blood and urine analyses

7. Was blood collected for hematology and serum chemistry (*s1*, *f12*, *f24*, *f36*, *f48*, *f60 visits*):



<u>b u 2</u>

**8.** Date of blood collection:



9. Hematology results:

a. WBC:

 $10^{9}/L \text{ or } 10^{3}/\mu L \text{ or } 10^{3}/\text{mm}^{3}$ 

**b.** Hemoglobin:

g/dL

 $10^9$ /L or  $10^3$ / µL or  $10^3$ /mm

**c.** Platelets:

	Normal	Abnormal	
a. Creatinine:	( <sub>1</sub> )	( <sub>2</sub> )	
<b>b.</b> Total protein:	( <sub>1</sub> )	( <sub>2</sub> )	
<b>c.</b> Albumin:	( <sub>1</sub> )	( <sub>2</sub> )	
<b>d.</b> Glucose:	( <sub>1</sub> )	( <sub>2</sub> )	
e. AST (SGOT):	( <sub>1</sub> )	( <sub>2</sub> )	
f. Alk phos:	( <sub>1</sub> )	( <sub>2</sub> )	
g. Total bilirubin:	( <sub>1</sub> )	( <sub>2</sub> )	

**11.** Was blood collected for plasma cotinine analysis (*s1 and s3 visits, only for patients not using nicotine*):



**12.** Date of blood collection:

**10.** Serum chemistry results:



**13.** Reported plasma cotinine:

(Note: Code 00.0 if lab reports "negative" or "none detected"; if plasma cotinine is greater than 13.7 ng/ml and patient is not using nicotine, the patient is ineligible for NETT.)



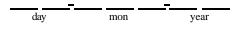
**14.** Was blood collected for alpha-1 antitrypsin deficiency testing (*s1 visit only*):



- **15.** Date of blood collection:
- day mon year 16. Concentration: a. Level: **b.** Units: 1) mg/dL ( mg/ml ( 2) 3) μΜ **17.** Phenotype (check only one) ZZ 1) 2) MZ 3) MM
  - MM $\begin{pmatrix} & & \\ & & \end{pmatrix}$ SS $\begin{pmatrix} & & \\ & & \end{pmatrix}$ SZ $\begin{pmatrix} & & \\ & & \end{pmatrix}$ Null $\begin{pmatrix} & & \\ & & \theta \end{pmatrix}$ Other (specify): $\begin{pmatrix} & & \\ & & & \end{pmatrix}$

specify phenotype

- **18.** Was urine collected for analysis (*s1*, *f12*, *f24*, *f36*, *f48*, *f60 visits*):
  - $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$
- **19.** Date of urine collection:



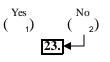
**20.** Urinalysis results:

	No	Normal		Abnormal	
a. Glucose:	(	1)	(	<sub>2</sub> )	
<b>b.</b> Protein:	(	1)	(	<sub>2</sub> )	
<b>c.</b> pH:			•		

d. Specific gravity: \_\_\_\_\_

# C. Check on eligibility

**21.** Is this the s1 or s3 visit:



If yes, specify reason:

for NETT:

#### specify reason

Patient ID:

**22.** Do any of the blood or urine analyses cause you to declare the patient ineligible

(\*Complete this form but do not key it; note the reason for ineligibility on Form EH or Form ER.)

## C. Administrative information

- **23.** Study Physician PIN:
- 24. Study Physician signature:
- **25.** Clinic Coordinator PIN:
- **26.** Clinic Coordinator signature:
- 27. Date form reviewed:

day mon year

DR - Form DR Death Report Form (rev 2)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			536
Varia	ables:	:			14

Variable			Variable	
Name	Variable Label	Туре	Length	Format
1 0 0 7		~1	_	
dr207	#7 cnvrtd to No. of days frm RZ/scr strt	Char	/	
dr208a	8a Patient's family	Char	1	
dr208b	8b Friend	Char	1	
dr208c	8c Health care provider or NETT staff	Char	1	
dr208d	8d Newspaper	Char	1	
dr208e	8d Funeral parlor/home	Char	1	
dr208f	8f Medical record	Char	1	
dr208g	8g Medical examiner	Char	1	
dr208h	8h Coroner	Char	1	
dr208i	8i Other	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to No. of days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	



54

**Purpose** To record the report of a patient's death.

When: As soon as clinic is notified of a patient's death.

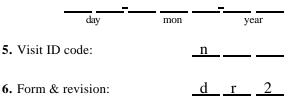
Administered by: Clinic Coordinator.

Respondent: None.

**Instructions**: Complete this form whenever the clinic is informed of a patient's death. After completing this form request the death certificate from the State Vital Records office. Do not request the certificate from the patient's family. When this form is added to the database, a report will print after the second keying. Fax the report to the Coordinating Center. If date of death is edited subsequently, a revised report will print and that report should also be faxed to the Coordinating Center.

A.	Clinic,	visit,	and	patient	identification
----	---------	--------	-----	---------	----------------

- 1. Clinic ID:
- **2.** Patient ID:
- 3. Patient name code: \_\_\_\_\_
- **4.** Visit date (*date this form is initiated*):



## **B.** Death information

7. Date of death:

day mon year

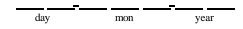
- **8.** Source of death report (*check all that apply*):
- **a.** Patient's family: ( \_) **b.** Friend: <sub>1</sub>) **c.** Health care provider or NETT staff: 1) ,) **d.** Newspaper: **e.** Funeral parlor/home: ( 1) **f.** Medical record: 1) g. Medical examiner: 1) **h.** Coroner: 1) 1) i. Other (*specify*):

other source

city/state/province/country

12. Date form reviewed:

9. Place of death:



*NOTE:* If a report prints upon completion of keying, fax the report to the Coordinating Center.

EB - Form EB Brief Screen for Eligibility (rev 2)

Date file created: 13 May 2006 Observations: 3775 Variables: 52

Variable			Variable	Dermet
Name	Variable Label	Туре	Length	Format
eb207	7 Patient suitable for the trial	Char	1	
eb208	8 Consent form signed?	Char	1	
eb210	#10: age<=51=00, age>=80=99	Char	2	
eb211	11 Gender	Char	1	
eb213	13 Retired or disabled?	Char	1	
eb214	#14: retirement age <=40 coded as 00	Char	2	
eb216	16 Reason for retiring	Char	1	
eb217	17 Currently disabled	Char	1	
eb218	18 Disabled due to emphysema?	Char	1	
eb220	20 Currently employed	Char	1	
eb222	22 Hours per week at work	Char	2	
eb223	23 Occupational group	Char	1	
eb224	24 Marital status	Char	1	
eb225	25 Educational level	Char	1	
eb226	26 Economic status	Char	1	
eb230	30 Participated in pulm rehab program	Char	1	
eb232	32 Duration of program (weeks)	Char	3	
eb233	33 Ever smoked cigarettes	Char	1	
eb234	34 Smoked cigarettes in past 120 days	Char	1	
eb235	35 Smoked cigarettes regularly	Char	1	
eb236	36 Age started smoking regularly	Char	2	
eb237	37 Age stopped smoking (years)	Char	2	
eb238	38 Avg no. cigarettes/day smoked	Char	3	
eb239	39 Inhaled the cigarette smoke	Char	1	
eb240	40 Ever smoked cigars/cigarillos	Char	1	
eb241	41 Smoked cigars in past 120 days	Char	1	
eb242	42 Smoked cigars regularly	Char	1	
eb243	43 Age started smoking cigars	Char	2	
eb244	44 Age stopped smoking cigars	Char	2	
eb245	45 Avg no cigars smoked per day	Char	3	
eb246	46 Inhaled the cigar smoke	Char	1	
eb247	47 Ever smoked a pipe	Char	1	
eb248	48 Smoked a pipe in past 120 days	Char	1	
eb249	49 Smoked a pipe regularly	Char	1	
eb250	50 Age started smoking a pipe	Char	2	
eb251	51 Age stopped smoking a pipe	Char	2	
eb252	52 Avg no oz smoked per week	Char	3	
eb253	53 Inhaled the pipe smoke	Char	1	
eb254	54 Currently use nicotine products	Char	1	
eb259	59 BMI (kg/m**2)	Char	3	
eb229a	29a Staff at the center	Char	1	
eb229b	29b Mailing from this center	Char	1	
eb229c	29c Staff at another center	Char	1	
eb229d	29d Newspaper	Char	1	
eb229e	29e Radio	Char	1	
eb229f	29f Television	Char	1	
eb229g	29g Friend	Char	1	
eb229h	29h Other	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
	,,,,,,,	onur	9	

Purpose: To assign Patient ID number and obtain consent for diagnostic testing and entry into registry.

# When: Visit s1.

Administered by: Study Physician (pulmonary physician or thoracic surgeon) and Clinic Coordinator.

Respondent: Patient and Clinic Coordinator.

A. Clinic, visit, and patient identification

**Instructions**: This form may be started after the study physician has reviewed the materials from the referring physician (eg, spirometry, chest x-ray, EKG, history) and has concluded that the patient's history is consistent with emphysema and that the patient may be suitable for NETT or when the patient arrives for the initial visit. If a STOP condition is checked, do not complete the remainder of this form and do not assign an ID number; the patient is ineligible for NETT. File the partially completed form in the file for ineligible patients. If the patient remains eligible after completion of the form and the patient has signed the Consent for Screening and Patient Registry, proceed with diagnostic testing. A report will print when this form is keyed to the database or subsequently is edited. A page of lung function predicted values for the patient will also print. Fax the report to the Coordinating Center.

1. Clinic ID:		9. Date of birth:
2. Patient ID:		d
3. Patient name code:		10. Age at last bi
4. Visit date <i>(date this f</i>	form is initiated):	11. Gender: Male
day	mon year	Female
5. Visit ID code:	<u>s</u> <u>1</u>	12. Racial/ethnic check only or
6. Form & revision:	<u>e b 2</u>	White (not Hi

# **B.** Consent

7. After reviewing the existing records (spirometry, chest x-ray, EKG, and/or history) does the study physician feel that the patient may be suitable for the trial:

Y	es	N	0
(	) _	_ (	2)
	STC	)	

8. Has the patient signed the Consent for Screening and Patient Registry:

# day mon year ast birthday: vears <sub>1</sub>) ethnic group (show patient Flash Card #1; nly one): White (not Hispanic) <sub>1</sub>) African American (not Hispanic) ,) Hispanic 3) ₄) Asian or Pacific Islander <sub>5</sub>) American Indian or Alaskan Native

specify

13. Are you retired:

14. At what age did you retire:

Other (specify)

C. Information about patient

<sub>6</sub>)

56

( ) keved

15. What was your occupation at retirement:

specify occupation16. What was your main reason for retiring (show respondent Flash Card #2; check only one):

Eligible to retire due to age or length of<br/>employment(Disability due to illness(Other (specify)(3)

specify

**17.** Are you currently disabled:

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$ 

18. Is your disability due to emphysema:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

**19.** What was your occupation before you became disabled:

specify occupation

20. Are you currently employed:

 $\begin{pmatrix} Yes \\ 1 \end{pmatrix} \begin{pmatrix} No \\ 2 \end{pmatrix}$ 

21. What is your current occupation:

specify occupation

**22.** About how many hours do you work each week:

# hours

Patient ID:

<ul> <li>23. Which of the following occupational groups best characterizes your occupational history (show respondent #3; check only one):</li> </ul>	
Laborer	( <sub>1</sub> )
Clerical	( <sub>2</sub> )
Professional	( 3)
Homemaker	( 4)
Other (specify):	( <sub>5</sub> )

#### specify

24. Marital status (show respondent Flash Card #4; check only one):

(	_)
(	2)
(	3)
(	<sub>4</sub> )
(	<sub>5</sub> )
	( ( ( (

**25.** Highest educational level achieved (show respondent Flash Card #5; check only one):

Did not complete high school	(	1)
Completed high school	(	2)
Some college or post high school education or training	(	3)
Bachelor's degree or higher	(	<sub>4</sub> )

26. To help us characterize the economic status of our study population, please indicate which category best describes the combined annual income before taxes, of all members of your household for last year (show respondent Flash Card #6; check only one):
Less than \$15,000 (1)
\$15,000 - \$29,999 (2)
\$30,000 - \$49,999 (3)

\$50,000 or more

(

27.	What best describes your current residence (show respondent Flash Card #7 check only one):	, ,	
	Private home, apartment, or condominium	(	) 1/
	Retirement home	(	2
	Nursing home	(	3
	Rehabilitation facility	(	4
	Acute care hospital	(	5/
	Other (specify)	(	6,

specify

28. What is your current zipcode:

<b>29.</b> How did you find out about the NETT <i>that apply</i> ):	(check	all
a. Staff at this center	(	1)
<b>b.</b> Mailing from this center	(	1)
<b>c.</b> Staff at another medical center or		
office	(	1)
d. Newspaper	(	1)
e. Radio	(	1)
f. Television	(	1)
g. Friend	(	1)
h. Other (specify)	(	,)

specify

**30.** Have you ever participated in a pulmonary rehabilitation program:

Yes No 1) ( \_\_) 33.

31. Month and year you started the program (guess if uncertain)

a. Month:

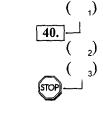
b. Year:

#### D. Tobacco smoking history (ATS-DLD)

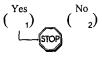
33. Have you ever smoked cigarettes:

Never

In the past but not any more Currently smoke cigarettes



34. Have you smoked any cigarettes in the past 4 months:



**35.** Did you smoke cigarettes regularly ("No" means less than 20 packs of cigarettes or 12 oz of tobacco in a lifetime or less than 1 cigarette a day for one year):

 $\binom{\text{Yes}}{1}$ 40.

**36.** How old were you when you first started regular cigarette smoking:

years

years

- 37. How old were you when you (last) stopped smoking cigarettes:
- **38.** On the average of the entire time you smoked cigarettes, how many cigarettes did you smoke per day:

cigarettes/day

39. Did you inhale the cigarette smoke:

Not at all	(	,)
Slightly	(	2) 2
Moderately	(	3)
Deeply	(	4)

**40.** Have you ever smoked cigars or cigarillos:

Never

In the past but not any more

Currently smoke cigars or cigarillos

41. Have you smoked any cigars or cigarillos in the past 4 months:

**42.** Did you smoke cigars or cigarillos regularly ("Yes" means more than 1 cigar a week for a year):

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

years

years

- **43.** How old were you when you first started regular cigar or cigarillo smoking:
- 44. How old were you when you (last) stopped smoking cigars or cigarillos:
- **45.** On the average of the entire time you smoked cigars or cigarillos, how many cigars or cigarillos did you smoke per day:

cigars/cigarillos/day

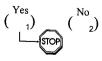
- 46. Did you inhale the cigar/cigarillo smoke:
  - Not at all( 1)Slightly( 2)Moderately( 3)Deeply( 4)

47. Have you ever smoked a pipe:

Never

In the past but not any more Currently smoke a pipe

**48.** Have you smoked a pipe in the last 4 months:



- Patient ID:
- 49. Did you smoke a pipe regularly (Yes means more than 12 oz tobacco in a lifetime):



- **50.** How old were you when you first started to smoke a pipe regularly:
- 51. How old were you when you (last) stopped smoking a pipe:

years

years

**52.** On the average of the entire time you smoked a pipe, how much pipe tobacco did you smoke per week (a standard pouch of tobacco contains 1 1/2 oz):

oz/week

53. Did you inhale the pipe smoke:

Not at all	(	,)
Slightly	Ć	2)
Moderately	Ć	$\binom{2}{3}$
Deeply	Ì	3) ₄)

54. Are you currently using nicotine products (eg, gum, patch):

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

# E. Measurements

- 55. Units of height measurement performed:
  - Inches ( 1) Centimeters ( 2)

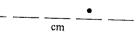
56. Height

a. Height in inches:



58b.

**b.** Height in centimeters (measured directly or item 56a \* 2.54):



57. Units of weight measurment performed:

Pounds

1)

- 58. Weight
  - a. Weight in pounds:

\_\_\_\_\_ •\_\_\_\_\_

**b.** Weight in kilograms (measured directly or item 58a/2.2046):

**59.** Body mass index, BMI (kg/m<sup>2</sup>; weight/[(ht/100)<sup>2</sup>]; use a calculator):

kg/m<sup>2</sup>

(Note: If BMI > 31.1 (males) or > 32.3 (females) at time of randomization, patient is ineligible for NETT. Clinic staff will need to judge whether patient should continue with screening or stop.)

#### F. ID assignment

(If a STOP condition was checked in Section B or D, the patient is ineligible and a Patient ID should not be assigned. Otherwise, assign an ID by following the directions in the item below.)

**60.** Place ID label below and enter Patient ID in item 2, and in the upper right hand corner of pages 2-5.



#### G. Insurance information

The following information is necessary so that payment can be made to the institution by the patient's insurance company for NETT testing. Some of this information will also be used to search public databases for vital status information. This information will be transmitted to the Coordinating Center.

- 61. Patient's social security number:
- **62.** Insurance claim data

a. Insurance company to be billed for NETT procedures:		
Medicare	(	1)
Kaiser Permanente Northeast	(	2)
Other (specify)	(	3)

specify

 b. Patient's claim number for insurance company named in item 62a (NOTE: HIC # is 9 digits plus 1 or more alphabetic characters)

Note, patient can not be enrolled unless an insurance claim number is provided.

If patient is eligible and the Consent for Screening and Registry has been signed, order diagnostic tests and examinations.

#### H. Administrative information

**63.** Study Physician PIN:

64. Study Physician signature:

**65.** Clinic Coordinator PIN:

66. Clinic Coordinator signature:

**67.** Date form reviewed:

day mon year

NOTE: Fax the report to the Coordinating Center.

EH - Form EH Pre Rehabilitation Eligibility Check (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			3775
Varia	ables:	:			74

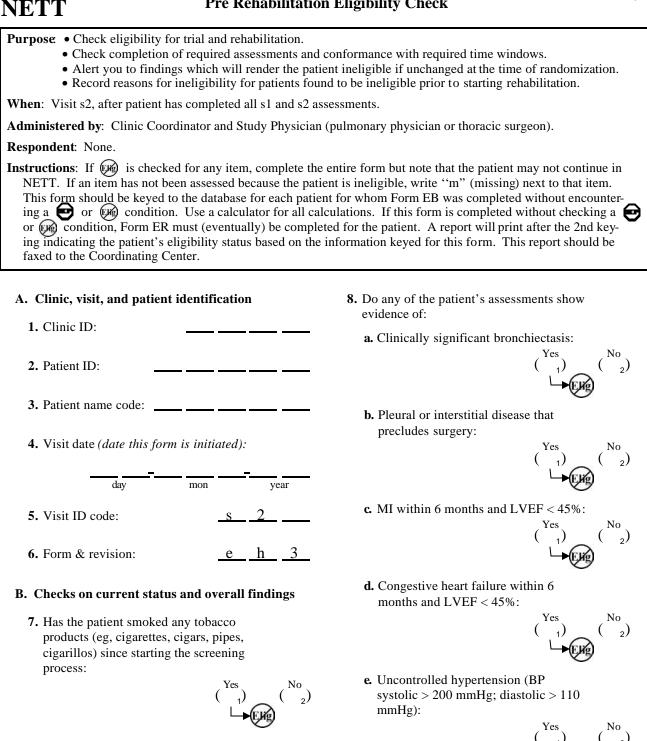
Variable			Variable	
Name	Variable Label	Туре	Length	Format
eh307	7 Smoked any tobacco products since S1	Char	1	
eh310	#10 cnvrtd to #days frm RZ/scr strt	Char	7	
eh311	#11 cnvrtd to #days frm RZ/scr strt	Char	7	
eh312	#12 cnvrtd to #days frm RZ/scr strt	Char	7	
eh313	#13 cnvrtd to #days frm RZ/scr strt	Char	7	
eh315	15 Run task or do worksheet?	Char	1	
eh316	#16 cnvrtd to #days frm RZ/scr strt	Char	7	
eh317	17 Task: any stops?	Char	1	
eh318	18 SH worksheet: any stops?	Char	1	
eh320	20 Consent for rehabilitation signed	Char	1	
eh321	#21 cnvrtd to #days frm RZ/scr strt	Char	7	
eh308a	8a Clinically significant bronchiectasi	Char	1	
eh308b	8b Pleural/interstitial disease	Char	1	
eh308c	8c MI within 6 months and LVEF<45%	Char	1	
eh308d	8d Congestive HF within 6 mos & LVEF<45	Char	1	
eh308e	8e Uncontrolled hypertension	Char	1	
eh308f	8f Resting bradycardia (<50 b/min)	Char	1	
eh308g	8g Frequent multifocal PVCs	Char	1	
eh308h	8h Complex ventricular arrhythmia	Char	1	
eh308i	8i Sustanined SVT	Char	1	
eh308j	8j Other cardiac dysrhythmia	Char	1	
eh308k	8k History of exercise related syncope	Char	1	
eh3081	81 Previous sternotomy/lobectomy	Char	1	
eh308m	8m Previous lung volume reduction surge	Char	1	
eh308n	8n Pulmonary nodule surgery	Char	1	
eh308o	80 Giant bulla	Char	1	
eh308p	8p Systemic disease/neoplasia affecting	Char	1	
eh308q	8q Dx/condition which may impair cooper	Char	1	
eh308r	8r Unstable angina	Char	1	
eh309a	9a Bilateral emphysema on CT scan	Char	1	
eh309b	9b Diffuse emphysema unsuitable for LVR	Char	1	
eh319a	19a No checked for item 17	Char	1	
eh319b	19b No checked for item 18	Char	1	
eh319c	19c Yes checked for item 17	Char	1	
eh319d	19d Yes checked for item 18	Char	1	
eh319e	19e Ineligible checked in items 7-14	Char	1	
eh319f	19f None of the above	Char	1	
eh322a	22a Pre BD FEV1 (liters)	Char	3	
eh322b	22b Post BD FEV1 (liters)	Char	3	
eh322c	22c DLCO (ml/min/mmHg)	Char	3	
eh322d	22d Post BD TLC (liters)	Char	4	
eh322e	22e Post BD RV (liters)	Char	4	
eh322f	22f PaCO2 on room air (mmHg)	Char	2	
eh322g	22g PaO2 on room air (mmHg)	Char	3	
eh323al	23a Emphysema severity score:L upper zon	Char	1	
eh323ar	23a Emphysema severity score:R upper zon	Char	1	
eh323bl	23b Emphysema severity score:L middle zo	Char	1	
eh323br	23b Emphysema severity score:R middle zo	Char	1	
eh323cl	23c Emphysema severity score:L lower zon	Char	1	
eh323cr	23c Emphysema severity score:R lower zon	Char	1	
eh324a	24a PFT a/o CT scan ineligibility	Char	1	
eh324b	24b Items 7-14 ineligibility	Char	1	
eh324c	24c Cotinine>13.7 ng/ml & not using nico	Char	1	
eh324d	24d Carboxyhemoglobin>2.5% & using nicot	Char	1	
eh324e	24e Other blood/urine exclusion 24f BMI>31.1(male) or >32.3(female)	Char	1	
eh324f		Char	1 1	
eh324g	24g Unplanned weight loss>10% usual weig	Char Char	1	
eh324h	24h Excessive daily sputum	CIIdI	1	

EH - Form EH Pre Rehabilitation Eligibility Check (rev 3)

Date	file	created:	13	8 May	2006
Obsei	rvatio	ons:			3775
Varia	ables:	:			74

Variable Name	Variable Label	Туре	Variable Length	Format
eh324i	24i Unstable on <=20 mg prednisone	Char	1	
eh324j	24j Exclusionary medical condition from	Char	1	
eh324k	24k Exclusionary medical condition from	Char	1	
eh3241	241 Exclusionary condition from cardiac	Char	1	
eh324m	24m Cardiologist exclusion	Char	1	
eh324n	24n Could not complete 6-minute walk tes	Char	1	
eh324o	24o Other reason from 6-minute walk test	Char	1	
eh324p	24p Could not complete 3-min unloaded pe	Char	1	
eh324q	24q Other reason based on exercise test	Char	1	
eh324r	24r Trail Making Test exclusion	Char	1	
eh324s	24s Time window exclusion	Char	1	
eh324t	24t Other reason for exclusion	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

63



**f.** Resting bradycardia (< 50 beats/min):



g. Frequent multifocal PVCs:

**h.** Complex ventricular arrhythmia:



i. Sustained SVT:



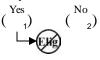
**j.** Other cardiac dysrhythmia which may pose risk to patient during exercise:



**k.** History of exercise related syncope:



**l.** Previous sternotomy or lobectomy:



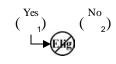
**m.** Previous laser or lung volume reduction surgery:



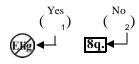
n. Pulmonary nodule requiring surgery:



**o.** Giant bulla:



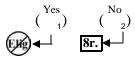
**p.** Any systemic disease or neoplasia that is expected to compromise survival over duration of the trial:



If Yes, specify:

specify

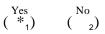
**q.** Any disease or condition which may impair cooperation with exercise tests, therapy, or followup (*eg, renal insufficiency, uncontrolled diabetes, cancer*):



If Yes, specify:

specify

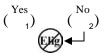
**r.** Unstable angina:



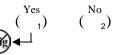
(\*Patient must be evaluated by a cardiologist prior to randomization.)

## C. Check on CT scan eligibility criteria

- 9. CT scan assessment
  - **a.** Does the CT scan show evidence of bilateral emphysema suitable for LVRS:



**b.** Does the CT scan show evidence of diffuse emphysema judged unsuitable for LVRS:



- **D.** Check on completion of Rehab Eval assessments (these evaluations must be completed prior to starting Core Rehabilitation)
- **10.** Date of physician (clinic physician or rehab physician) visit:



**11.** Date of exercise evaluation:



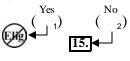
**12.** Date of skill/education evaluation:



13. Date of psychosocial evaluation:



14. Should the patient be excluded from enrollment based on any findings from the Rehab Eval assessments (*items 10-13; enter m if Rehab Eval was not done*):



If Yes, specify:

specify reason for ineligibility

# E. Date, numeric, and form specific checks and summary check on eligibility

Instructions: You may:

(1) Complete the Pre Rehabilitation Eligibility Check Worksheet (Form SH) and do the date, numeric, and form checks by hand.

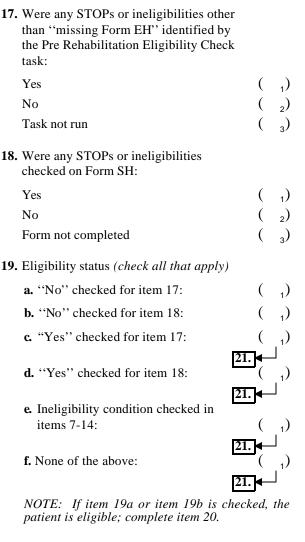
(2) Key the s1/s2 Forms HB, PE, PF, BU, HF, RC, RR, MO, MM, EW/ES, QB, QE, TM, QF, QG, QS, and QW and run the Pre Rehabilitation Eligibility Check task on your clinic data system.

(3) Do neither of (1) or (2) because you already know the patient is ineligible.

You must do(1) or(2) in order to clear the patient for rehabilitation. You must do(2) prior to randomization.

**15.** Do you want to evaluate eligibility (ie, run the Pre Rehabilitation Eligibility Check task or complete Form SH) (*check "No" if you know the patient is ineligible*):

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$ 



Patient ID:

Rehabilitation session (you must specify a date in

item 16; eligibility cannot be evaluated if a date is

mon

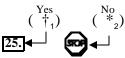
year

**16.** Anticipated date for first Core

day

not specified):

**20.** Has the patient signed the Consent for Pulmonary Rehabilitation:



(*†The patient is cleared to start NETT rehabilitation; skip to item 25.*)

(\*The Consent for Pulmonary Rehabilitation must be signed prior to starting Core Rehabilitation.)

# F. Selected baseline data and reasons for ineligibility for ineligible patients

NOTE: Complete this section for ineligible patients <u>ONLY</u>.

**21.** Date of s1/s2 Form PF:

day	mon	year

**22.** Pulmonary function values (*complete as many of these values from s1/s2 Form PF as you can; enter "m" for any that were not done*)

<b>a.</b> Pre BD FEV <sub>1</sub> :	• liters-BTPS
<b>b.</b> Post BD FEV 1:	• liters-BTPS
<b>c.</b> DLCO:	ml/min/mmHg STPD
<b>d.</b> Post BD TLC:	liters-BTPS
e. Post BD RV:	liters-BTPS
<b>f.</b> PaCO <sub>2</sub> on room ai	r:mmHg
<b>g.</b> PaO <sub>2</sub> on room air	mmHg

**23.** Emphysema severity scores (complete as many of these values from Form RC as you can; enter "m" for any that were not done)

	Right	Left
<b>a.</b> Upper zone:	(0-4)	(0-4)
<b>b.</b> Middle zone:	(0-4)	(0-4)
<b>c.</b> Lower zone:	(0-4)	(0-4)

# **24.** Reasons for ineligibility (*check all that apply*)

	p (j)	
<b>a.</b> Numeric PFT, ABG, and/or FEV <sub>1</sub> subgroup ineligibility:	(	1)
<b>b.</b> Reason covered in items 7-14:	(	1)
<b>c.</b> Cotinine > 13.7 ng/ml and patient is not using nicotine products:	(	1)
<b>d.</b> Carboxyhemoglobin > 2.5% and patient is using nicotine products:	(	1)
<b>e.</b> Excluded on the basis of other blood or urine analysis results:	(	1)
<b>f.</b> BMI > 31.1 (male) or 32.3 (female) and judgment is that patient would be excluded on this basis at randomization:	(	1)
<b>g.</b> Unplanned weight loss > 10% usual weight in the 3 months prior to interview:	(	)
<b>h.</b> Excessive daily sputum:	(	1)
<ul> <li>i. Patient is not stable on ≤ 20 mg prednisone (or equivalent) daily and judgment is that patient would be excluded on this basis at randomization:</li> </ul>	(	1) 1)
<b>j.</b> History indicates evidence of exclusionary medical condition:	(	1)
<b>k.</b> Physical exam indicates evidence of exclusionary medical condition:	(	1)
<b>l.</b> Cardiac function test (ECG, echo, dobutamine-radionuclide scan, right heart cath) indicates evidence of exclusionary condition:	(	1)
<b>m.</b> Cardiologist did not clear patient for randomization:	(	1)
<b>n.</b> Patient could not complete the six minute walk test:	(	1)
<b>o.</b> Other reason for exclusion based on six minute walk test:	(	1)
<b>p.</b> Patient could not complete 3 minutes unloaded pedaling:	(	1)
<b>q.</b> Other reason for exclusion based on exercise test:	(	1)
<b>r.</b> Excluded based on performance on Trail Making Test:	(	1)

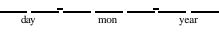
<b>s.</b> Tests are outside time window and clinic chose not to repeat tests:	(	1)
t. Other reason not yet covered on this form (eg, refused consent):	(	1)
specify reason for ineligibility		
G. Administrative information		
25. Study physician PIN:		

**26.** Study physician signature:

**27.** Clinic Coordinator PIN:

**28.** Clinic Coordinator signature:

**29.** Date form reviewed:



NOTE: When this form is keyed, a report will print after the second keying indicating the patients's eligibility status. Fax the report to the Coordinating Center immediately.

ER - Form ER Final Eligibility Review (rev 3)

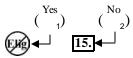
Date	file	created:	13	May	2006
Obsei	rvatio	ons:			1799
Varia	ables:	:			44

Variable		_	Variable	
Name	Variable Label	Туре	Length	Format
er220	20 Any reason patient is ineligible?	Char	1	
er221	21 Any reason patient is ineligible?	Char	1	
er307	7 Patient smoked any tobacco products	Char	1	
er308	8 BMI>31.1(men) or BMI>32.3(women)	Char	1	
er309	9 Patient stable on <= 20mg prednisone	Char	1	
er310	10 Any reason to exclude patient	Char	1	
er311	#11 cnvrtd to #days frm RZ/scr strt	Char	7	
er312	#12 cnvrtd to #days frm RZ/scr strt	Char	7	
er313	#13 cnvrtd to #days frm RZ/scr strt	Char	7	
er314	14 Any reason patient is ineligible?	Char	1	
er315	15 Surgeon judges patient ineligible	Char	1	
er316	16 Pulm MD judges patient ineligible	Char	1	
er317	17 Randomization task/worksheet done	Char	1	
er318	#18 cnvrtd to #days frm RZ/scr strt	Char	7	
er319	19 STOPS on Randomization task	Char	1	
er320	20 STOPS on Form SZ	Char	1	
er322	22 Signed Consent for Randomization?	Char	1	
er323	23 Surgery can be done within 14 days?	Char	1	
er324	24 Clinic in contact with patient?	Char	1	
er325	25 Patient prepared to return to clinic	Char	1	
er326	26 Patient still consents to randomizat	Char	1	
er327	27 Ineligible conditions checked in 22-	Char	1	
er321a	21a NO checked for item 19	Char	1	
er321b	21b NO checked for item 20	Char	1	
er321c	21c YES checked for item 19	Char	1	
er321d	21d YES checked for item 20	Char	1	
er321e	21e Ineligible in items 7-16	Char	1	
er321f	21f None of the above	Char	1	
er328a	28a Ineligible items checked in 7-27	Char	1	
er328b	28b Change in PFT and/or ABG from pre re	Char	1	
er328c	28c Cotinine >13.7 ng/ml, not using nico	Char	1	
er328d	28d Carboxyhemoglobin>2.5%, using nicoti	Char	1	
er328e	28e Rt heart catherization exclusion	Char	1	
er328f	28f Cardiologist exclusion	Char	1	
er328g	28g Walked < 140 meter on 6 min walk	Char	1	
er328h	28h Other s3/rz 6 min walk exclusion	Char	1	
er328i	28i Could not complete 3 min unloaded pe	Char	1	
er328j	28j Other exercise test exclusion	Char	1	
er328k	28k s3/rz tests outside time window	Char	1	
er3281	281 Other reason for ineligibilty	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

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NETT **Purpose** To review eligibility just prior to randomization. When: Visit rz. Administered by: Clinic Coordinator, Thoracic Surgeon, and Pulmonary Physician. Respondent: None. Instructions: This form must be completed for each patient who was eligible upon completion of Form EH. Hence it will be completed for patients who proceed to randomization and for patients who were cleared for rehabilitation but became ineligible after that event. A report will print after the 2nd keying indicating the patient's eligibility status based on the information keyed for this form. This report should be faxed to the Coordinating Center. For patients whom you expect to randomize: this form should be completed after post rehabilitation (s3) and randomization assessments have been completed. It must be keyed prior to running the randomization program. The clinic must be able to contact the patient immediately following generation of the random treatment assignment. If the patient signed the Consent for Randomization to Treatment at a previous visit, consent should be affirmed by the patient orally (telephone or in person) prior to generating the randomization. A. Clinic, visit, and patient identification **9.** Is the patient stable on  $\leq 20 \text{ mg}$ prednisone (or its equivalent; see Chart 1. Clinic ID: 1) daily:  $\binom{\text{Yes}}{1}$ 2. Patient ID: **3.** Patient name code: 10. Consider items 8 and 9 on Form EH; based on knowledge of the patient to **4.** Visit date (*date this form is initiated*): date, is there any reason to think that the patient has any of the exclusionary conditions listed in these items: mon vear 5. Visit ID code: <u>r z</u> r 3 **6.** Form & revision: If Yes, specify: specify reason for ineligibility B. Checks on current status and overall findings 7. Has the patient smoked any tobacco C. Check on completion of Rehab Re-evaluation assessments products (eg, cigarettes, cigars, pipes, cigarillos) since starting the screening **11.** Date of clinic physician visit: process for NETT: dav mon vear 12. Date of exercise evaluation: 8. Is BMI > 31.1 kg/m<sup>2</sup> (men) or > 32.3  $kg/m^2$  (women): day mon vear **13.** Date of skill/education evaluation: day mon year

**14.** Is there any reason to declare the patient ineligible based on these assessments *(items 11-13):* 

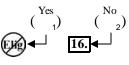


If Yes, specify:

specify reason for ineligibility

# D. Surgeon and pulmonologist approval for randomization

**15.** In your judgement (study surgeon) is there any reason to exclude the patient from randomization:



If Yes, specify reason:

specify reason for ineligibility

specify reason for ineligibility

specify reason for ineligibility

**16.** In your judgement (study pulmonary physician) is there any reason to exclude the patient from randomization:

17.

If Yes, specify reason:

specify reason for ineligibility

specify reason for ineligibility

specify reason for ineligibility

Patient ID:

- E. Date, numeric, and form specific checks and summary check on eligibility

Instructions: You may:

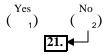
(1) Complete the Final Eligibility Review Worksheet (Form SZ) and do the date, numeric, and form checks by hand.

(2) Key the s3/rz Forms AA, HI, PE, PF, BU (if applicable), RP, MO, MM, EW/ES, QF, QG, QS, and QW and run the check Randomization eligibility task on your clinic data system. The task will run assuming randomization will occur today. The task includes checks on pre rehab data as well -- the checks are cumulative.

(3) Do neither of (1) or (2) because you already know the patient is ineligible.

You must do (2) prior to randomization.

**17.** Will you run the Randomization eligibility check task or complete the Final Eligibility Review Worksheet (Form SZ) (*Check "Yes" if you think the patient is eligible or if you want to evaluate eligibility; check "No" if you know the patient is ineligible):* 



**18.** Anticipated date for randomization:

day	mon	year

**19.** Were any STOPs or ineligibilities other than "missing Form ER" identified by the Randomization eligibility check task:

Yes	(	1)
No	(	2)
Task not run	(	3)

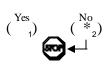
**20.** Were any STOPs or ineligibilities checked on Form SZ:

Yes	(	1)
No	(	2)
Form not completed	(	<sub>2</sub> )

- **21.** Eligibility status (*check all that apply*)
  - **a.** "No" checked for item 19:
  - **b.** "No" checked for item 20:  $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$
  - **c.** "Yes" checked for item 19:
  - d. "Yes" checked for item 20:
  - **e.** Ineligibility condition checked in items 7-16:
- 28. ( 1) 28. ( 1) ( 1) ( 1) ( 1) ( 1)

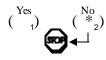
\_\_)

- **f.** None of the above:
- **22.** Has the patient signed the Consent for Randomization to Treatment:



(\*Consent form must be signed prior to randomization.)

**23.** Is the clinic prepared to operate on the patient in the 14 days following the date in item 18 if the patient is randomized to surgery:



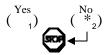
(\*Do not randomize the patient until schedule permits operation within 14 days.)

24. Is the clinic in contact with the patient (ie, patient is present or available by telephone) so that the patient will be informed about the random treatment assignment:



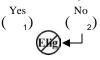
(\*Do not randomize until patient is available.)

- Patient ID:
- **25.** Is the patient prepared to return to the clinic the day of randomization or the day after to begin Consolidation Rehabilitation if assigned to medical treatment:

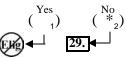


(\*Do not randomize until patient can return as needed.)

**26.** Does the patient still consent to randomization (*ie*, *if patient signed consent previous to the day of randomization, you should ask the patient to orally affirm his/her consent):* 



**27.** Were any ineligible or STOP conditions checked in items 22-26:



(\*Complete Section G, Administrative information. Next step is to key this form and run the Randomization eligibility check task.)

1)

e rehab levels; or FEV <sub>1</sub> p ineligibility:	(	1)	<b>31.</b> Pu
x > 13.7 ng/ml and patient is g nicotine products:	(	1)	<b>32.</b> Pu
hemoglobin > 2.5% and s using nicotine products:	(	1)	
art catheterization indicates of exclusionary condition:	(	1)	<b>33.</b> Cl
gist did not clear patient for zation:	(	1)	<b>34.</b> Cl
e walked on s3/rz Day 1 six walk was < 140 meters (459 ID distance walked on s3/rz x minute walk was < 140 459 feet):	(	1)	<b>35.</b> Da
ason for exclusion based on ninute walk test:		1)	N
ould not complete 3 minutes l pedaling on s3/rz exercise	(	1)	af el Cu
ason for exclusion based on prcise test:		1)	
nore s3/rz tests are outside adow and clinic chose not to est(s):	(	1)	
a(a).	(	1/	

(1)

a. Reason covered in items 7-27:

b. Change in PFT and/or ABG values

National Emphysema Treatment Trial

NOTE: Complete this section for ineligible patients <u>ONLY</u>.

**28.** Reasons for ineligibility (*check all that apply*)

from pre rehab levels; or FEV <sub>1</sub> subgroup ineligibility:	(
<b>c.</b> Cotinine > 13.7 ng/ml and patient is not using nicotine products:	(
<b>d.</b> Carboxyhemoglobin > 2.5% and patient is using nicotine products:	(
e. Right heart catheterization indicates evidence of exclusionary condition:	(
<b>f.</b> Cardiologist did not clear patient for randomization:	(

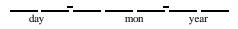
- g. Distance minute w feet) AN Day 2 six meters (4 h. Other rea s3/rz 6 m
- i. Patient co unloaded test:
- j. Other rea s3/rz exe
- **k.** One or m time win repeat test(s): I. Other reason not yet covered on this form (eg, refused randomization): (

specify reason for ineligibility

# G. Administrative information 29. Thoracic surgeon PIN: **30.** Thoracic surgeon signature:

- ulmonary physician PIN:
- ulmonary physician signature:
- linic Coordinator PIN:
- linic Coordinator signature:

ate form reviewed:



NOTE: When this form is keyed, a report will print ifter the second keying indicating the patient's eligibility status. Fax the report to the *Coordinating Center immediately.* 

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4 of 4

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			908
Varia	ables:	:			535

Variable					Variable	
Name	Var	iable La	bel	Туре	Length	Format
					_	
es107	7		ric pressure	Char	3	
es109	9	-	valve dead space (ml)	Char	3	
es108a es108b			ture (degrees) ture (scale)	Char Char	3 1	
es110a1	8b 105	1min:	Testing done 1=yes, 2=no	Char	1	
es110a1 es110a2		2min:	Testing done 1=yes, 2=no	Char	1	
es110a3		3min:	Testing done 1=yes, 2=no	Char	1	
es110a4		4min:	Testing done 1=yes, 2=no	Char	1	
es110a5		5min:	Testing done 1=yes, 2=no	Char	1	
es110a6	10a	6min:	Testing done 1=yes, 2=no	Char	1	
es110a7	10a	7min:	Testing done 1=yes, 2=no	Char	1	
es110a8	10a	8min:	Testing done 1=yes, 2=no	Char	1	
es110a9		9min:	Testing done 1=yes, 2=no	Char	1	
es110a10		10min:	Testing done 1=yes, 2=no	Char	1	
es110a11		11min:	Testing done 1=yes, 2=no	Char	1	
es110a12		12min:	Testing done 1=yes, 2=no	Char	1	
es110a13		13min:	Testing done 1=yes, 2=no	Char	1	
es110a14 es110a15		14min: 15min:	Testing done 1=yes, 2=no Testing done 1=yes, 2=no	Char	1 1	
es110a15		16min:	Testing done 1-yes, 2-no Testing done 1-yes, 2-no	Char Char	1	
es110a10		17min:	Testing done 1-yes, 2-no Testing done 1-yes, 2-no	Char	1	
es110a18		18min:	Testing done 1=yes, 2=no	Char	1	
es110a19		19min:	Testing done 1=yes, 2=no	Char	1	
es110a20		20min:	Testing done 1=yes, 2=no	Char	1	
es110a21	10a	21min:		Char	1	
es110a22	10a	22min:	Testing done 1=yes, 2=no	Char	1	
es110a23	10a	23min:	Testing done 1=yes, 2=no	Char	1	
es110a24	10a	24min:	Testing done 1=yes, 2=no	Char	1	
es110a25		25min:	Testing done 1=yes, 2=no	Char	1	
es110amp			Testing done 1=yes, 2=no	Char	1	
es110amx		Max:	Testing done 1=yes, 2=no	Char	1	
es110aun		~	Testing done 1=yes, 2=no	Char	1	
es110b1		1min:	Sp02 (%)	Char	3 3	
es110b2 es110b3		2min: 3min:	SpO2 (%) SpO2 (%)	Char Char	3	
es110b5		4min:	Sp02 (%)	Char	3	
es110b4		5min:	Sp02 (%)	Char	3	
es110b6		6min:	Sp02 (%)	Char	3	
es110b7		7min:	Sp02 (%)	Char	3	
es110b8	10b	8min:	Sp02 (%)	Char	3	
es110b9	10b	9min:	Sp02 (%)	Char	3	
es110b10	10b	10bin:	SpO2 (%)	Char	3	
es110b11		11min:	SpO2 (응)	Char	3	
es110b12			Sp02 (%)	Char	3	
es110b13			Sp02 (%)	Char	3	
es110b14			Sp02 (%)	Char	3	
es110b15			SpO2 (%)	Char	3	
es110b16			SpO2 (%) SpO2 (%)	Char Char	3 3	
es110b17 es110b18			Sp02 (%)	Char	3	
es110b10			Sp02 (%)	Char	3	
es110b19			Sp02 (%)	Char	3	
es110b21			Sp02 (%)	Char	3	
es110b22			Sp02 (%)	Char	3	
es110b23			SpO2 (%)	Char	3	
es110b24			SpO2 (%)	Char	3	
es110b25			Sp02 (%)	Char	3	
es110c1	10c	1min:	PaO2 (mmHg)	Char	3	

Date	file	created:	13	May	2006
Obsei	cvatio	ons:			908
Varia	ables:	:			535

Variable	Variable La	bol	Tumo	Variable Length	Format
Name	Vallable La	Dei	Туре	Length	Format
es110c2	10c 2min:	PaO2 (mmHg)	Char	3	
es110c3	10c 3min:	PaO2 (mmHg)	Char	3	
es110c4	10c 4min:	PaO2 (mmHg)	Char	3	
es110c5	10c 5min:	PaO2 (mmHg)	Char	3	
es110c6	10c 6min:	PaO2 (mmHg)	Char	3	
es110c7	10c 7min:	PaO2 (mmHg)	Char	3	
es110c8	10c 8min:	PaO2 (mmHg)	Char	3	
es110c9	10c 9min:	PaO2 (mmHg)	Char	3	
es110c10	10c 10cin: 10c 11min:	PaO2 (mmHg)	Char	3	
es110c11 es110c12	10c 12min:	PaO2 (mmHg) PaO2 (mmHg)	Char Char	3 3	
es110c12 es110c13	10c 13min:	PaO2 (mmHg)	Char	3	
es110c14	10c 14min:	PaO2 (mmHq)	Char	3	
es110c15	10c 15min:	PaO2 (mmHg)	Char	3	
es110c16	10c 16min:	PaO2 (mmHq)	Char	3	
es110c17	10c 17min:	PaO2 (mmHg)	Char	3	
es110c18	10c 18min:	PaO2 (mmHg)	Char	3	
es110c19	10c 19min:	PaO2 (mmHg)	Char	3	
es110c20	10c 20min:	PaO2 (mmHg)	Char	3	
es110c21	10c 21min:	PaO2 (mmHg)	Char	3	
es110c22	10c 22min:	PaO2 (mmHg)	Char	3	
es110c23	10c 23min:	PaO2 (mmHg)	Char	3	
es110c24	10c 24min:	PaO2 (mmHg)	Char	3	
es110c25	10c 25min:	PaO2 (mmHg)	Char	3	
es110cmp	10c 5minMP:		Char	3	
es110cmx	10c Max:	PaO2 (mmHg)	Char	3	
es110cun		PaO2 (mmHg)	Char	3	
es110d1	10d 1min:	PaCO2 (mmHg)	Char	2	
es110d2	10d 2min:	PaCO2 (mmHg)	Char	2 2	
es110d3	10d 3min:	PaCO2 (mmHg)	Char		
es110d4 es110d5	10d 4min: 10d 5min:	PaCO2 (mmHg) PaCO2 (mmHg)	Char Char	2 2	
es110d5 es110d6	10d 6min:	PaCO2 (mmHq)	Char	2	
es110d0	10d 7min:	PaCO2 (mmHg)	Char	2	
es110d8	10d 8min:	PaCO2 (mmHq)	Char	2	
es110d9	10d 9min:	PaCO2 (mmHg)	Char	2	
es110d10	10d 10din:	PaCO2 (mmHg)	Char	2	
es110d11	10d 11min:	PaCO2 (mmHq)	Char	2	
es110d12	10d 12min:	PaCO2 (mmHg)	Char	2	
es110d13	10d 13min:	PaCO2 (mmHg)	Char	2	
es110d14	10d 14min:	PaCO2 (mmHg)	Char	2	
es110d15	10d 15min:	PaCO2 (mmHg)	Char	2	
es110d16	10d 16min:	PaCO2 (mmHg)	Char	2	
es110d17	10d 17min:	PaCO2 (mmHg)	Char	2	
es110d18	10d 18min:	PaCO2 (mmHg)	Char	2	
es110d19	10d 19min:	PaCO2 (mmHg)	Char	2	
es110d20	10d 20min:	PaCO2 (mmHg)	Char	2	
es110d21	10d 21min:	PaCO2 (mmHg)	Char	2	
es110d22 es110d23	10d 22min: 10d 23min:	PaCO2 (mmHg)	Char Char	2 2	
es110d23 es110d24	10d 23min: 10d 24min:	PaCO2 (mmHg) PaCO2 (mmHg)	Char	2	
es110d24 es110d25	10d 24min: 10d 25min:	PaCO2 (mmHg) PaCO2 (mmHg)	Char	2	
es110d25 es110dmp	10d 5minMP:	-	Char	2	
es110dmx	10d Max:	PaCO2 (mmHq)	Char	2	
es110dun	10d 3minUp:	. 57	Char	2	
es110e1	10e 1min:	pH	Char	3	
es110e2	10e 2min:	рH	Char	3	
es110e3	10e 3min:	рH	Char	3	

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Variable				Variable	
Variable Name	Variable Lab		Туре	Variable Length	Format
Name	Variable las	Jei -	турс	Deligen	rornac
es110e4	10e 4min:	РН	Char	3	
es110e5	10e 5min:	рН	Char	3	
es110e6	10e 6min:	рН	Char	3	
es110e7	10e 7min:	рН	Char	3	
es110e8	10e 8min:	рН	Char	3	
es110e9	10e 9min:	рН	Char	3	
es110e10	10e 10ein:	рН	Char	3	
es110e11	10e 11min:	рН	Char	3	
es110e12	10e 12min:	рH	Char	3	
es110e13	10e 13min:	рH	Char	3	
es110e14	10e 14min:	рH	Char	3	
es110e15	10e 15min:	рH	Char	3	
es110e16	10e 16min:	рH	Char	3	
es110e17	10e 17min:	рH	Char	3	
es110e18	10e 18min:	рH	Char	3	
es110e19	10e 19min:	рH	Char	3	
es110e20	10e 20min:	рH	Char	3	
es110e21	10e 21min:	pH	Char	3	
es110e22	10e 22min:	рH	Char	3	
es110e23	10e 23min:	рH	Char	3	
es110e24	10e 24min:	рH	Char	3	
es110e25	10e 25min:	рH	Char	3	
es110emp	10e 5minMP:	1	Char	3	
es110emx	10e Max:	PH	Char	3	
es110eun	10e 3minUp:	1	Char	3	
es110f1	10f 1min:	HCO3 (mEq/L)	Char	3	
es110f2	10f 2min:	HCO3 (mEq/L)	Char	3	
es110f3	10f 3min:	HCO3 $(mEq/L)$	Char	3 3	
es110f4 es110f5	10f 4min: 10f 5min:	HCO3 (mEq/L) HCO3 (mEq/L)	Char Char	3	
es11015 es110f6	10f 6min:	HCO3 (mEq/L)	Char	3	
es110f7	10f 7min:	HCO3 (mEq/L)	Char	3	
es110f8	10f 8min:	HCO3 (mEq/L)	Char	3	
es110f9	10f 9min:	HCO3 (mEq/L)	Char	3	
es110f10	10f 10fin:	HCO3 (mEq/L)	Char	3	
es110f11	10f 11min:	HCO3 (mEq/L)	Char	3	
es110f12	10f 12min:	HCO3 (mEq/L)	Char	3	
es110f13	10f 13min:	HCO3 (mEq/L)	Char	3	
es110f14	10f 14min:	HCO3 (mEq/L)	Char	3	
es110f15	10f 15min:	HCO3 (mEq/L)	Char	3	
es110f16	10f 16min:	HCO3 (mEq/L)	Char	3	
es110f17	10f 17min:	HCO3 (mEq/L)	Char	3	
es110f18	10f 18min:	HCO3 (mEq/L)	Char	3	
es110f19	10f 19min:	HCO3 (mEq/L)	Char	3	
es110f20	10f 20min:	HCO3 (mEq/L)	Char	3	
es110f21	10f 21min:	HCO3 (mEq/L)	Char	3	
es110f22	10f 22min:	HCO3 (mEq/L)	Char	3	
es110f23	10f 23min:	HCO3 (mEq/L)	Char	3	
es110f24	10f 24min:	HCO3 (mEq/L)	Char	3	
es110f25	10f 25min:	HCO3 (mEq/L)	Char	3	
es110fmp	10f 5minMP:		Char	3	
es110fmx	10f Max:	HCO3 (mEq/L)	Char	3	
es110fun		HCO3 (mEq/L)	Char	3	
es110g1	10g 1min:	+/- BE	Char	4	
es110g2	10g 2min:	+/- BE	Char	4	
es110g3	10g 3min:	+/- BE	Char	4	
es110g4	10g 4min:	+/- BE	Char	4	
es110g5	10g 5min:	+/- BE	Char	4	

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Variable				Variable	
Name	Variable Lab	bel	Туре	Length	Format
			11	2	
es110g6	10g 6min:	+/- BE	Char	4	
es110g7	10g 7min:	+/- BE	Char	4	
es110g8	10g 8min:	+/- BE	Char	4	
es110g9	10g 9min:	+/- BE	Char	4	
es110g10	10g 10gin:	+/- BE	Char	4	
es110g11	2	+/- BE	Char	4	
es110g12	10g 12min:		Char	4	
es110g13	-	+/- BE	Char	4	
es110g14	10g 14min:		Char	4 4	
es110g15	2	+/- BE +/- BE	Char Char	4	
es110g16 es110g17	10g 17min:		Char	4	
es110g18	-	+/- BE	Char	4	
es110g19	10g 19min:		Char	4	
es110g20		+/- BE	Char	4	
es110g21	10g 21min:		Char	4	
es110g22	10g 22min:		Char	4	
es110g23	10g 23min:		Char	4	
es110q24	10g 24min:		Char	4	
es110g25	10g 25min:	+/- BE	Char	4	
es110gmp	10g 5minMP:	+/- BE	Char	4	
es110gmx	10g Max:	+/- BE	Char	4	
es110gun	10g 3minUp:	+/- BE	Char	4	
es110h1	10h 1min:	SaO2 (%)	Char	3	
es110h2	10h 2min:	SaO2 (%)	Char	3	
es110h3	10h 3min:	SaO2 (응)	Char	3	
es110h4	10h 4min:	SaO2 (%)	Char	3	
es110h5	10h 5min:	SaO2 (%)	Char	3	
es110h6	10h 6min:	SaO2 (%)	Char	3	
es110h7	10h 7min:	SaO2 (%)	Char	3	
es110h8	10h 8min:	SaO2 (%)	Char	3	
es110h9	10h 9min:	SaO2 (%)	Char	3	
es110h10	10h 10hin:	SaO2 (%)	Char	3	
es110h11	10h 11min:	SaO2 (%)	Char	3	
es110h12	10h 12min:	SaO2 (%)	Char	3	
es110h13 es110h14	10h 13min: 10h 14min:	SaO2 (%) SaO2 (%)	Char Char	3 3	
es110h15	10h 15min:	Sa02 (%)	Char	3	
es110h16	10h 16min:	Sa02 (%)	Char	3	
es110h17	10h 17min:	SaO2 (%)	Char	3	
es110h18	10h 18min:	SaO2 (%)	Char	3	
es110h19	10h 19min:	SaO2 (%)	Char	3	
es110h20	10h 20min:	SaO2 (%)	Char	3	
es110h21	10h 21min:	SaO2 (%)	Char	3	
es110h22	10h 22min:	SaO2 (%)	Char	3	
es110h23	10h 23min:	SaO2 (%)	Char	3	
es110h24	10h 24min:	SaO2 (%)	Char	3	
es110h25	10h 25min:	SaO2 (%)	Char	3	
es110hmp	10h 5minMP:	SaO2 (%)	Char	3	
es110hmx	10h Max:	SaO2 (%)	Char	3	
es110hun	10h 3minUp:		Char	3	
es110i1	10i 1min:	FeCO2 (fraction)	Char	4	
es110i2	10i 2min:	FeCO2 (fraction)	Char	4	
es110i3	10i 3min:	FeCO2 (fraction)	Char	4	
es110i4	10i 4min:	FeCO2 (fraction)	Char	4	
es110i5	10i 5min:	FeCO2 (fraction)	Char	4	
es110i6	10i 6min:	FeCO2 (fraction)	Char	4	
es110i7	10i 7min:	FeCO2 (fraction)	Char	4	

		cereise mos subscuty rec	(ICV I)		
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Variables:		535			
Vaniable				Variable	
Variable Name	Variable I	abel	Туре	Length	Format
ivanic	Variable i		TAPC	Deligen	rormae
es110i8	10i 8min:	FeCO2 (fraction)	Char	4	
es110i9	10i 9min:	FeCO2 (fraction)	Char	4	
es110i10		FeCO2 (fraction)	Char	4	
es110i11		FeCO2 (fraction)	Char	4	
es110i12 es110i13		FeCO2 (fraction) FeCO2 (fraction)	Char Char	4 4	
es110113 es110i14		FeCO2 (fraction)	Char	4	
es110i15	10i 15min:		Char	4	
es110i16	10i 16min:		Char	4	
es110i17	10i 17min:	FeCO2 (fraction)	Char	4	
es110i18		FeCO2 (fraction)	Char	4	
es110i19		FeCO2 (fraction)	Char	4	
es110i20 es110i21	10i 20min:	FeCO2 (fraction) FeCO2 (fraction)	Char Char	4	
es110121		FeCO2 (fraction)	Char	4	
es110i23		FeCO2 (fraction)	Char	4	
es110i24		FeCO2 (fraction)	Char	4	
es110i25	10i 25min:	FeCO2 (fraction)	Char	4	
es110imp		P: FeCO2 (fraction)	Char	4	
es110imx	10i Max:	FeCO2 (fraction)	Char	4	
es110iun		: FeCO2 (fraction)	Char	4	
es110j1 es110j2		Ve (BTPS;L/min) Ve (BTPS;L/min)	Char Char	3 3	
es110j2 es110j3		Ve (BIPS, L/min) Ve (BTPS; L/min)	Char	3	
es110j4		Ve (BTPS;L/min)	Char	3	
es110j5		Ve (BTPS;L/min)	Char	3	
es110j6	10j 6min:	Ve (BTPS;L/min)	Char	3	
es110j7		Ve (BTPS;L/min)	Char	3	
es110j8	10j 8min:		Char	3	
es110j9 es110j10	10j 9min: 10j 10jin:		Char Char	3 3	
es110j10	10j 10jin. 10j 11min:		Char	3	
es110j12	10j 12min:		Char	3	
es110j13	10j 13min:		Char	3	
es110j14	10j 14min:	Ve (BTPS;L/min)	Char	3	
es110j15	10j 15min:		Char	3	
es110j16	10j 16min:		Char	3	
es110j17 es110j18	10j 17min:	Ve (BTPS;L/min) Ve (BTPS;L/min)	Char Char	3 3	
es110j18	10j 19min:		Char	3	
es110j20	10j 20min:		Char	3	
es110j21	10j 21min:		Char	3	
es110j22	10j 22min:		Char	3	
es110j23	10j 23min:		Char	3	
es110j24	10j 24min:		Char	3	
es110j25	10j 25min:		Char	3 4	
es110k1 es110k2	10k 1min: 10k 2min:	Vt (BTPS,L) Vt (BTPS,L)	Char Char	4	
es110k2	10k 3min:	Vt (BTPS,L)	Char	4	
es110k4	10k 4min:	Vt (BTPS,L)	Char	4	
es110k5	10k 5min:	Vt (BTPS,L)	Char	4	
es110k6	10k 6min:	Vt (BTPS,L)	Char	4	
es110k7	10k 7min:	Vt (BTPS,L)	Char	4	
es110k8	10k 8min:	Vt (BTPS,L)	Char	4	
es110k9 es110k10	10k 9min: 10k 10min:	Vt (BTPS,L) Vt (BTPS,L)	Char Char	4 4	
es110k10 es110k11	10k 11min:		Char	4	
es110k12	10k 12min:		Char	4	

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Observation	siealeu: IS	908			
Variables:	.13 •	535			
Variable				Variable	
Name	Variable La	abel	Туре	Length	Format
110110	101 10 1		~		
es110k13	10k 13min:	Vt (BTPS,L)	Char	4	
es110k14	10k 14min:	Vt (BTPS,L)	Char	4	
es110k15 es110k16	10k 15min: 12k 16min:	Vt (BTPS,L)	Char Char	4	
es110k10	12k 17min:	Vt (BTPS,L) Vt (BTPS,L)	Char	4	
es110k18	12k 18min:	Vt (BTPS,L)	Char	4	
es110k19	12k 19min:	Vt (BTPS,L)	Char	4	
es110k20	12k 20min:	Vt (BTPS,L)	Char	4	
es110k21	12k 21min:	Vt (BTPS,L)	Char	4	
es110k22	12k 22min:	Vt (BTPS,L)	Char	4	
es110k23	12k 23min:	Vt (BTPS,L)	Char	4	
es110k24	12k 24min:	Vt (BTPS,L)	Char	4	
es110k25	12k 25min:	Vt (BTPS,L)	Char	4	
es11011	101 1min:	V CO2 (STDP;L/min)	Char	4	
es11012	101 2min:	V CO2 (STDP;L/min) V CO2 (STDP;L/min)	Char	4	
es11013 es11014	101 3min: 101 4min:	V CO2 (STDP;L/min) V CO2 (STDP;L/min)	Char Char	4	
es11014	101 5min:	V CO2 (STDP;L/min)	Char	4	
es11015	101 6min:	V CO2 (STDP;L/min)	Char	4	
es11017	101 7min:	V CO2 (STDP;L/min)	Char	4	
es11018	101 8min:	V CO2 (STDP;L/min)	Char	4	
es11019	101 9min:	V CO2 (STDP;L/min)	Char	4	
es110110	101 10min:	V CO2 (STDP;L/min)	Char	4	
es110111	101 11min:	V CO2 (STDP;L/min)	Char	4	
es110112	101 12min:	V CO2 (STDP;L/min)	Char	4	
es110113	101 13min:	V CO2 (STDP;L/min)	Char	4	
es110114	101 14min:	V CO2 (STDP;L/min)	Char	4	
es110115 es110116	101 15min: 101 16min:	V CO2 (STDP;L/min) V CO2 (STDP;L/min)	Char Char	4 4	
es110110 es110117	101 17min:	V CO2 (STDP;L/min) V CO2 (STDP;L/min)	Char	4	
es110118	101 18min:	V CO2 (STDP;L/min)	Char	4	
es110119	101 19min:	V CO2 (STDP;L/min)	Char	4	
es110120	101 20min:	V CO2 (STDP;L/min)	Char	4	
es110121	101 21min:	V CO2 (STDP;L/min)	Char	4	
es110122	101 22min:	V CO2 (STDP;L/min)	Char	4	
es110123	101 23min:	V CO2 (STDP;L/min)	Char	4	
es110124	101 24min:	V CO2 (STDP;L/min)	Char	4	
es110125	101 25min:	V CO2 (STDP;L/min)	Char	4	
es110m1 es110m2	10m 1min: 10m 2min:	VO2 (STDP;L/min) VO2 (STDP;L/min)	Char Char	4	
es110m2	10m 3min:	VO2 (SIDF, L/min) VO2 (STDP;L/min)	Char	4	
es110m4	10m 4min:	VO2 (STDP;L/min)	Char	4	
es110m5	10m 5min:	VO2 (STDP; L/min)	Char	4	
es110m6	10m 6min:	VO2 (STDP;L/min)	Char	4	
es110m7	10m 7min:	VO2 (STDP;L/min)	Char	4	
es110m8	10m 8min:	VO2 (STDP;L/min)	Char	4	
es110m9	10m 9min:	VO2 (STDP;L/min)	Char	4	
es110m10	10m 10min:	VO2 (STDP;L/min)	Char	4	
es110m11	10m 11min:	VO2 (STDP;L/min)	Char	4	
es110m12	10m 12min:	VO2 (STDP;L/min) VO2 (STDP;L/min)	Char	4	
es110m13 es110m14	10m 13min: 10m 14min:	VO2 (STDP;L/min) VO2 (STDP;L/min)	Char Char	4 4	
es110m14 es110m15	10m 14min: 10m 15min:	VO2 (STDP;L/min) VO2 (STDP;L/min)	Char	4	
es110m16	10m 16min:	VO2 (SIDF, L/min) VO2 (STDP;L/min)	Char	4	
es110m17	10m 17min:	VO2 (STDP;L/min)	Char	4	
es110m18	10m 18min:	VO2 (STDP;L/min)	Char	4	
es110m19	10m 19min:	VO2 (STDP;L/min)	Char	4	
es110m20	10m 20min:	VO2 (STDP;L/min)	Char	4	

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Variables:		535			
Variable Name	Variable La	bel	Туре	Variable Length	Format
es110m21	10m 21min:	VO2 (STDP;L/min)	Char	4	
es110m22	10m 22min:	VO2 (STDP; L/min)	Char	4	
es110m23	10m 23min:	VO2 (STDP;L/min)	Char	4	
es110m24	10m 24min:	VO2 (STDP;L/min)	Char	4	
es110m25	10m 25min:	VO2 (STDP;L/min)	Char	4	
es110mmp		VO2 (STDP;L/min)	Char	4	
es110mmx	10m Max:	VO2 (STDP;L/min)	Char	4 4	
es110mun es110n1	10m 3minop: 10n 1min:	VO2 (STDP;L/min) Heart rate (beats/min)	Char Char	4 3	
es110n2	10n 2min:	Heart rate (beats/min)	Char	3	
es110n3	10n 3min:	Heart rate (beats/min)	Char	3	
es110n4	10n 4min:	Heart rate (beats/min)	Char	3	
es110n5	10n 5min:	Heart rate (beats/min)	Char	3	
es110n6	10n 6min:	Heart rate (beats/min)	Char	3	
es110n7	10n 7min:	Heart rate (beats/min)	Char	3	
es110n8	10n 8min:	Heart rate (beats/min)	Char	3	
es110n9	10n 9min:	Heart rate (beats/min)	Char	3	
es110n10	10n 10nin:	Heart rate (beats/min)	Char	3	
es110n11	10n 11min:	Heart rate (beats/min)	Char	3	
es110n12 es110n13	10n 12min: 10n 13min:	Heart rate (beats/min) Heart rate (beats/min)	Char Char	3 3	
es110n14	10n 14min:	Heart rate (beats/min)	Char	3	
es110n15	10n 15min:	Heart rate (beats/min)	Char	3	
es110n16	10n 16min:	Heart rate (beats/min)	Char	3	
es110n17	10n 17min:	Heart rate (beats/min)	Char	3	
es110n18	10n 18min:	Heart rate (beats/min)	Char	3	
es110n19	10n 19min:	Heart rate (beats/min)	Char	3	
es110n20	10n 20min:	Heart rate (beats/min)	Char	3	
es110n21	10n 21min:	Heart rate (beats/min)	Char	3	
es110n22	10n 22min:	Heart rate (beats/min)	Char	3	
es110n23	10n 23min:	Heart rate (beats/min)	Char	3	
es110n24	10n 24min:	Heart rate (beats/min)	Char	3	
es110n25	10n 25min:	Heart rate (beats/min)	Char	3 2	
es110o1 es110o2	10o 1min: 10o 2min:	Respiratory rate Respiratory rate	Char Char	2	
es11002 es11003	100 2min: 100 3min:	Respiratory rate	Char	2	
es11003	100 4min:	Respiratory rate	Char	2	
es110o5	100 5min:	Respiratory rate	Char	2	
es110o6	100 6min:	Respiratory rate	Char	2	
es110o7	10o 7min:	Respiratory rate	Char	2	
es110o8	10o 8min:	Respiratory rate	Char	2	
es110o9	10o 9min:	Respiratory rate	Char	2	
es110o10	10o 10oin:	Respiratory rate	Char	2	
es110o11	100 11min:	Respiratory rate	Char	2	
es110o12	100 12min:	Respiratory rate	Char	2 2	
es110o13 es110o14	10o 13min: 10o 14min:	Respiratory rate Respiratory rate	Char Char	2	
es110014	100 14min: 100 15min:	Respiratory rate	Char	2	
es110015	100 16min:	Respiratory rate	Char	2	
es110o17	100 17min:	Respiratory rate	Char	2	
es110o18	100 18min:	Respiratory rate	Char	2	
es110o19	10o 19min:	Respiratory rate	Char	2	
es110o20	10o 20min:	Respiratory rate	Char	2	
es110o21	10o 21min:	Respiratory rate	Char	2	
es110o22	10o 22min:	Respiratory rate	Char	2	
es110o23	10o 23min:	Respiratory rate	Char	2	
es110o24	100 24min:	Respiratory rate	Char	2	
es110o25	10o 25min:	Respiratory rate	Char	2	

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Variable				Variable	
Variable Name	Variable La	bol	Туре	Variable Length	Format
Maille	Vallable La	idet	туре	Lengen	roimat
es110p1	10p 1min:	SBP (mm Hg)	Char	3	
es110p2	10p 2min:	SBP (mm Hg)	Char	3	
es110p3	10p 3min:	SBP (mm Hg)	Char	3	
es110p4	10p 4min:	SBP (mm Hg)	Char	3	
es110p5	10p 5min:	SBP (mm Hg)	Char	3	
es110p6	10p 6min:	SBP (mm Hg)	Char	3	
es110p7	10p 7min:	SBP (mm Hg)	Char	3	
es110p8	10p 8min:	SBP (mm Hg)	Char	3	
es110p9	10p 9min:	SBP (mm Hg)	Char	3	
es110p10	10p 10pin:	SBP (mm Hg)	Char	3	
es110p11	10p 11min:	SBP (mm Hg)	Char	3	
es110p12	10p 12min:	SBP (mm Hg)	Char	3	
es110p13	10p 13min:	SBP (mm Hg)	Char	3	
es110p14	10p 14min:	SBP (mm Hg)	Char	3	
es110p15	10p 15min:	SBP (mm Hg)	Char	3	
es110p16	10p 16min:	SBP (mm Hg)	Char	3	
es110p17	10p 17min:	SBP (mm Hg)	Char	3	
es110p18	10p 18min:	SBP (mm Hg)	Char	3	
es110p19	10p 19min:	SBP (mm Hg)	Char	3	
es110p20	10p 20min:	SBP (mm Hg)	Char	3	
es110p21	10p 21min:	SBP (mm Hg)	Char	3	
es110p22	10p 22min:	SBP (mm Hg)	Char	3	
es110p23	10p 23min:	SBP (mm Hg)	Char	3	
es110p24	10p 24min:	SBP (mm Hg)	Char	3	
es110p25	10p 25min:	SBP (mm Hg)	Char	3	
es110q1	10q 1min:	DBP (mm Hg)	Char	3	
es110q2	10q 2min:	DBP (mm Hg)	Char	3	
es110q3	10q 3min:	DBP (mm Hg)	Char	3	
es110q4	10q 4min:	DBP (mm Hg)	Char	3	
es110q5	10q 5min:	DBP (mm Hg)	Char	3	
es110q6	10q 6min:	DBP (mm Hg)	Char	3	
es110q7	10q 7min:	DBP (mm Hg)	Char	3	
es110q8	10q 8min:	DBP (mm Hg)	Char	3	
es110q9	10q 9min:	DBP (mm Hg)	Char	3	
es110q10	10q 10qin:	DBP (mm Hg)	Char	3	
es110q11	10q 11min:	DBP (mm Hg)	Char	3	
es110q12	10q 12min:	DBP (mm Hg)	Char	3	
es110q13	10q 13min:	DBP (mm Hg)	Char	3	
es110q14	10q 14min:	DBP (mm Hg)	Char	3	
es110q15	10q 15min:	DBP (mm Hg)	Char	3	
es110q16	10q 16min:	DBP (mm Hg)	Char	3	
es110q17	10q 17min:	DBP (mm Hg)	Char	3	
es110q18	10q 18min:	DBP (mm Hg)	Char	3	
es110q19	10q 19min:	DBP (mm Hg)	Char	3	
es110q20	10q 20min:	DBP (mm Hg)	Char	3	
es110q21	10q 21min:	DBP (mm Hg)	Char	3	
es110q22	10q 22min:	DBP (mm Hg)	Char	3	
es110q23	10q 23min:	DBP (mm Hg)	Char	3	
es110q24	10q 24min:	DBP (mm Hg)	Char	3	
es110q25	10q 25min:	DBP (mm Hg)	Char	3	
es110r1	10r 1min:	Borg (breathlessness)	Char	3	
es110r2	10r 2min:	Borg (breathlessness)	Char	3	
es110r3	10r 3min:	Borg (breathlessness)	Char	3	
esll0r4	10r 4min:	Borg (breathlessness)	Char	3	
es110r5	10r 5min:	Borg (breathlessness)	Char	3	
es110r6	10r 6min:	Borg (breathlessness)	Char	3	
es110r7	10r 7min:	Borg (breathlessness)	Char	3	
es110r8	10r 8min:	Borg (breathlessness)	Char	3	

Date fil	Le created:	13	May	2006
Observat	cions:			908
Variable	es:			535

Variable				-	Variable	_
Name	Variable Lak	bel		Туре	Length	Format
es110r9	10r 9min:	Borg	(breathlessness)	Char	3	
es110r10	10r 10rin:	2	(breathlessness)	Char	3	
es110r11	10r 11min:	2	(breathlessness)	Char	3	
es110r12	10r 12min:	2	(breathlessness)	Char	3	
es110r13	10r 13min:	2	(breathlessness)	Char	3	
es110r14	10r 14min:	2	(breathlessness)	Char	3	
es110r15	10r 15min:	2	(breathlessness)	Char	3	
es110r16	10r 16min:	2	(breathlessness)	Char	3	
es110r17	10r 17min:		(breathlessness)	Char	3	
es110r18	10r 18min:	2	(breathlessness)	Char	3	
es110r19	10r 19min:	2	(breathlessness)	Char	3	
es110r20	10r 20min:	2	(breathlessness)	Char	3	
es110r21	10r 21min:	2	(breathlessness)	Char	3	
es110r22	10r 22min:	2	(breathlessness)	Char	3	
es110r23	101 22min: 10r 23min:	2	(breathlessness)	Char	3	
es110r24	101 24min:	2	(breathlessness)	Char	3	
es110r25	101 24min: 10r 25min:	2	(breathlessness)	Char	3	
es110125	101 25min. 10s 1min:		(leq muscle fatique)	Char	3	
es110s1	10s 2min:		(leg muscle fatigue)	Char	3	
	10s 2min: 10s 3min:		(leg muscle fatigue)	Char	3	
es110s3 es110s4	10s 4min:		(leg muscle fatigue)	Char	3	
			(leg muscle fatigue)		3	
es110s5	10s 5min: 10s 6min:			Char		
es110s6 es110s7			(leg muscle fatigue)	Char	3 3	
	10s 7min:		(leg muscle fatigue)	Char		
es110s8	10s 8min:		(leg muscle fatigue) (leg muscle fatigue)	Char	3 3	
es110s9	10s 9min:	2		Char		
es110s10			(leg muscle fatigue)	Char	3	
es110s11			(leg muscle fatigue)	Char	3	
es110s12	10s 12min:		(leg muscle fatigue)	Char	3	
es110s13	10s 13min:		(leg muscle fatigue)	Char	3	
es110s14	10s 14min:		(leg muscle fatigue)	Char	3	
es110s15		_	(leg muscle fatigue)	Char	3	
es110s16	10s 16min:		(leg muscle fatigue)	Char	3	
es110s17	10s 17min:	_	(leg muscle fatigue)	Char	3	
es110s18	10s 18min:	-	(leg muscle fatigue)	Char	3	
es110s19	10s 19min:		(leg muscle fatigue)	Char	3	
es110s20		_	(leg muscle fatigue)	Char	3	
es110s21			(leg muscle fatigue)	Char	3	
es110s22	10s 22min:	_	(leg muscle fatigue)	Char	3	
es110s23		_	(leg muscle fatigue)	Char	3	
es110s24	10s 24min:		(leg muscle fatigue)	Char	3 3	
es110s25	10s 25min:	_	(leg muscle fatigue)	Char	3	
es110t1	10t 1min:		(watts)	Char	3	
es110t2	10t 2min:		(watts)	Char	3	
es110t3	10t 3min:		(watts)	Char	3	
es110t4	10t 4min:		(watts)	Char	3	
es110t5	10t 5min:		(watts)	Char	3	
es110t6	10t 6min:		(watts)	Char	3	
es110t7	10t 7min:		(watts)	Char	3	
es110t8	10t 8min:		(watts)	Char	3	
es110t9	10t 9min:		(watts)	Char	3	
es110t10	10t 10tin:		(watts)	Char	3	
es110t11	10t 11min:		(watts)	Char	3	
es110t12	10t 12min:		(watts)	Char	3	
es110t13			(watts)	Char	3	
es110t14	10t 14min:		(watts)	Char	3	
es110t15			(watts)	Char	3	
es110t16	10t 16min:	Load	(watts)	Char	3	

Date file o Observation Variables:	created: 13 May 2006 ns: 908 535			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
es110t17	10t 17min: Load (watts)	Char	3	
es110t18	10t 18min: Load (watts)	Char	3	
es110t19	10t 19min: Load (watts)	Char	3	
es110t20	10t 20min: Load (watts)	Char	3	
es110t21	10t 21min: Load (watts)	Char	3	
es110t22	10t 22min: Load (watts)	Char	3	
es110t23	10t 23min: Load (watts)	Char	3	
es110t24	10t 24min: Load (watts)	Char	3	
es110t25	10t 25min: Load (watts)	Char	3	
form	Form abreviation and revision number	Char	4	
formdate	<pre># 4 cnvrtd to #days from RZ/scr strt</pre>	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## Exercise ABG Substudy Testing

_				
	Who 1 Adn Inst	rz (if more than 21 days after the s3 tes <b>ministered by:</b> Substudy staff and Cli <b>tructions:</b> This form supplements for	assessme st), f06, f1 nic Coord m EW for EW for sub	ent no more than 42 days prior to the start of Core Rehabilitation), s3, 12, f24, f36, f48, and f60. rdinator. or recording the additional data required by the Exercise ABG abstudy patients. Form EW is required for all substudy patients.
A.	Cli	nic, visit, and patient identification		
	1.	Clinic ID:		
	2.	Patient ID:		
	3.	Patient name code:		
	4.	Visit date ( <i>date of exercise test</i> ):		  ear
	5.	Visit code:	5	
	6.		S	
B.	Tes	st session		
	7.	Barometric pressure:	mmHg	
	8.	Temperature		
		a. Degrees:		
		b. Scale: °C °F		$\begin{pmatrix} & & 1 \\ & & 2 \end{pmatrix}$
	9.	System (valve) dead space $(V_D)$ :		
			ml	

## C. Test session

#### 10. Data

	Quantity	5 min on mouth- piece	3 min unloade d	1 min	2 min	3 min	4 min	5 min	6 min	7 min	8 min
a. Was testi (key Yes=	ng done? :1, No=2)	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
<b>b.</b> SpO <sub>2</sub> (%)	XXX	N/A	N/A								
<b>c.</b> $PaO_2$ (mm	Hg) XXX										
<b>d.</b> $PaCO_2$ (m	mHg) XX										
<b>e.</b> pH	X.XX										
<b>f.</b> HCO <sub>3</sub> (mE	Eq/L) XX.X										
g. BE	± XX <b>.</b> X										
<b>h.</b> SaO <sub>2</sub> (%)	XX.X										
i. FeCO <sub>2</sub> (fr	action) X.XXX										
<b>j. V</b> e (BTP	S; L/min) XX.X	N/A	N/A								

### 10. Data (cont'd)

	Quantity		5 min on mouth- piece	3 min unloade d	1 min	2 min	3 min	4 min	5 min	6 min	7 min	8 min
k.	Vt (BTPS; L)	x.xxx	N/A	N/A								
1.	<b>♥</b> CO <sub>2</sub> (STPD; L/min)	x.xxx	N/A	N/A								
m.	VO <sub>2</sub> (STPD; L/min)	x.xxx										
n.	Heart rate (beats/min)	XXX	N/A	N/A								
0.	Respiratory rate (breaths/min)	XX	N/A	N/A								
р.	Systolic blood pressure (mmHg)	XXX	N/A	N/A								
q.	Diastolic blood pressure (mmHg)	XXX	N/A	N/A								
r.	Borg (breathlessness)	XX.X	N/A	N/A								
s.	Borg (leg muscle fatigue)	XX.X	N/A	N/A								
t.	Load (watts)	XXX	N/A	N/A								

### 10. Data (cont'd)

	Quantity	9 min	10 min	11 min	12 min	13 min	14 min	15 min	16 min	17 min	18 min
a.		Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
b.	SpO <sub>2</sub> (%) XXX										
c.	PaO <sub>2</sub> (mmHg) XXX										
d.	PaCO <sub>2</sub> (mmHg) XX										
e.	pH X.XX										
f.	HCO <sub>3</sub> (mEq/L) XX.X										
g.	BE ± XX.X										
h.	SaO <sub>2</sub> (%) XX.X										
i.	FeCO <sub>2</sub> (fraction) X.XXX										
j.	<b>V</b> e (BTPS; L/min) XX.X										

#### 10. Data (cont'd)

	Quantity		9 min	10 min	11 min	12 min	13 min	14 min	15 min	16 min	17 min	18 min
k.	Vt (BTPS; L)	X.XXX										
1.	<b>♥</b> CO <sub>2</sub> (STPD; L/min)	X.XXX										
m.	VO <sub>2</sub> (STPD; L/min)	X.XXX										
n.	Heart rate (beats/min)	XXX										
0.	Respiratory rate (breaths/min)	XX										
р.	Systolic blood pressure (mmHg)	XXX										
<b>q.</b>	Diastolic blood pressure (mmHg)	XXX										
r.	Borg (breathlessness)	XX.X										
s.	Borg (leg muscle fatigue)	XX.X										
t.	Load (watts)	XXX										

#### 10. Data (cont'd)

Record values to level of precision indicated at right of column labeled "Quantity".

Quantity	19 min	20 min	21 min	22 min	23 min	24 min	25 min	Maximum
<b>a.</b> Was testing done? (key Yes=1, No=2)	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
<b>b.</b> SpO <sub>2</sub> (%) XXX								N/A
c. PaO <sub>2</sub> (mmHg) XXX								
<b>d.</b> PaCO <sub>2</sub> (mmHg) XX								
e. pH X.XX								
<b>f.</b> HCO <sub>3</sub> (mEq/L) XX.X								
<b>g.</b> BE ± XX.X								
<b>h.</b> SaO <sub>2</sub> (%) XX.X								
i. FeCO <sub>2</sub> (fraction) X.XXX								
j. <b>V</b> e (BTPS; L/min) XX.X								N/A

\_\_\_\_ \_\_\_ \_\_\_

	Quantity	19 min	20 min	21 min	22 min	23 min	24 min	25 min	Maximum
<b>k.</b> Vt (BTPS; L)	X.XXX								N/A
<b>Ⅰ. Ů</b> CO <sub>2</sub> (STPD	y; L/min) X.XXX								N/A
<b>m.</b> VO <sub>2</sub> (STPD; L	/min) X.XXX								
<b>n.</b> Heart rate (be	ats/min) XXX								N/A
o. Respiratory ra	ate (breaths/min) XX								N/A
p. Systolic blood	d pressure (mmHg) XXX								N/A
<b>q.</b> Diastolic bloc	od pressure (mmHg) XXX								N/A
r. Borg (breathl	essness) XX.X								N/A
s. Borg (leg mus	scle fatigue) XX.X								N/A
t. Load (watts)	XXX								N/A

Patient 819 \_\_\_\_ \_\_\_ \_\_\_ \_\_\_

## 90

#### **D.** Administrative information

**11.** Pulmonary Function Coordinator PIN:

**12.** Pulmonary Function Coordinator signature:

**13.** Clinic Coordinator PIN:

**14.** Clinic Coordinator signature:

**15.** Date form reviewed:

-		-
dav	mon	vear
uay	mon	year

- -

- -

- -

EW - Form EW Exercise Testing (rev 1)

Date	file	created:	13	May	2006
Obsei	cvatio	ons:			6292
Varia	ables:	:			64

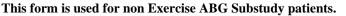
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ew108	8 Initial s1/s2 exercise test session?	Char	1	
ew109	9 Initial s1/s2 post BD MVV (L/min BTP	Char	4	
ew109	10 Ramp rate for exercise test	Char	1	
ew111	11 2+ hours since last meal	Char	1	
ew112	Bronchodilator in past 4 hours	Char	1	
ew113	13 Pulse oximeter manufacturer/model	Char	1	
ew113	14 Pulse oximeter ECG-gated	Char	1	
ew115	15 Pulse oximeter probe site	Char	1	
ew117	17 Staff terminated test before end	Char	1	
ew120	20 Pre-randomization assessment	Char	1	
ew120	21 Exercise test reason for exclusion	Char	1	
ew116a1	16 5 min rest: test completed	Char	1	
ew116a2	16 3 min unloaded: test completed	Char	1	
ew116a3	16 Maximum: test completed	Char	1	
ew116b3	16 Maximum: ramp rate	Char	2	
ew116c1	16 5 min rest: SpO2 (%)	Char	3	
ew116c2	16 3 min unloaded: Sp02 (%)	Char	3	
ew116c3	16 Maximum: SpO2 (%)	Char		
ew116d1	16 5 min rest: Ve (BTPS, L/min)	Char	3 3	
ew116d2		Char	3	
ew116d3	16 3 min unloaded: Ve (BTPS, L/min) 16 Maximum: Ve (BTPS, L/min)	Char	3	
		Char	3	
ew116e1			3	
ew116e2		Char Char	3	
ew116e3	16 Maximum: Vt (BTPS, L)		4	
ew116f1	16 5 min rest: VCO2 (STPD, L/min)	Char	4	
ew116f2	16 3 min unloaded: VCO2 (STPD, L/min)	Char		
ew116f3	16 Maximum: VCO2 (STPD, L/min)	Char	4	
ew116g1	16 5 min rest: heart rate (beats/min)	Char	3 3	
ew116g2	16 3 min unloaded: heart rate (beats/mi	Char	3	
ew116g3	16 Maximum: heart rate (beats/min)	Char		
ew116h1	16 5 min rest: respiratory rate (breath	Char	2 2	
ew116h2	16 3 min unloaded: respiratory rate (br	Char		
ew116h3	16 Maximum: respiratory rate (breaths/m	Char	2	
ew116i1	16 5 min rest: systolic BP (mmHg)	Char	3	
ew116i2	16 3 min unloaded: systolic BP (mmHg)	Char	3	
ew116i3	16 Maximum: systolic BP (mmHg)	Char	3 3	
ew116j1	16 5 min rest: diastolic BP (mmHg)	Char		
ew116j2	16 3 min unloaded: diastolic BP (mmHg)	Char	3 3	
ew116j3	16 Maximum: diastolic BP (mmHg)	Char	3	
ew116k1	16 5 min rest: Borg breathlessness	Char	3	
ew116k2	16 3 min unloaded: Borg breathlessness	Char	3	
ew116k3	16 Maximum: Borg breathlessness	Char	3	
ew11611	16 5 min rest: Borg leg muscle fatigue	Char	3	
ew11612	16 3 min unloaded: Borg leg muscle fati	Char	3	
ew11613	16 Maximum: Borg leg muscle fatigue	Char	3	
ew116n	16 BP measured by transducer or cuff	Char	1	
ew118a	18a Cadence dropped <40 rpm	Char	1	
ew118b	18b Mental confusion	Char	1	
ew118c	18c EKG arrhythmia	Char	1	
ew118d	18d EKG ischemia	Char	1	
ew118e	18e Elevated blood pressure	Char	1	
ew118f	18f Low blood pressure	Char	1	
ew118g	18g Other reason for termination	Char	1	
ew119a	19a Dyspnea or SOB	Char	1	
ew119b	19b Dizziness or lightheadedness	Char	1	
ew119c	19c Chest pain	Char	1	
ew119d	19d Leg fatigue	Char	1	
ew119e	19e Leg cramps or leg pain	Char	1	

EW - Form EW Exercise Testing (rev 1)

Date	file	created:	: 13	May	2006
Obsei	rvatio	ons:			6292
Varia	ables:	:			64

Variable			Variable	
Name	Variable Label	Туре	Length	Format
ew119f	19f Other reason for termination	Char	1	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days from RZ/scr strt	Num	8	
maxwk	Maximum: load (watts)	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## **Exercise Testing**



Purpose: To guide technician in completion of maximum exercise testing and to record data.

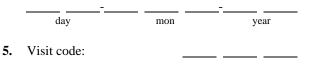
When: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to the start of Core Rehabilitation), s3, rz (if more than 21 days after the s3 test), f06, f12, f18, f24, f36, f48, and f60.

Administered by: PFT laboratory staff, Pulmonary Function Coordinator, and Clinic Coordinator.

**Instructions:** All patients will use supplemental oxygen (FiO<sub>2</sub>=0.3) during exercise testing. **Initial exercise test:** Ramp rate is determined from post BD MVV. **All subsequent exercise tests:** Use the ramp rate used at the initial NETT exercise tests. **All exercise tests:** If patient and staff member terminate the test simultaneously, the staff member's reason for termination takes precedence over the patient's (ie, record only the staff member's reason for termination). Attach report from PFT laboratory.

## A. Clinic, visit, and patient identification

- 1. Clinic ID: \_\_\_\_\_
- 2. Patient ID: \_\_\_\_\_ \_\_\_\_
- 3. Patient name code:
- **4.** Visit date (*date of exercise test*):



- 6. Form and revision: <u>e w 1</u>
- **7.** Lab ID:

Clinic ID Lab ID

- **B.** Information needed before starting test (Complete these items before sending the patient for testing)
  - **8.** Is this the initial (s1/s2) NETT exercise test session:

Yes No (1) ( $*_2$ ) **10.** 

(\*Use the ramp rate used for the initial (s1/s2) exercise test session.)

9. Initial (s1/s2) post bronchodilator MVV:

L/min BTPS

*Note: If post BD MVV ≤ 40.0, ramp=5 watts/min; if post BD MVV > 40.0, ramp=10 watts/min.* 

**10.** Ramp rate for exercise test:

5 watts/min	(	3)
10 watts/min	(	4)

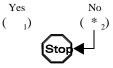
### C. Checks on patient condition

**11.** Has it been at least 2 hours since the patient last ate a meal: Yes No



(\*Wait until it has been at least 2 hours since the patient last ate a meal; then check Yes and proceed with testing.)

**12.** Has the patient taken a short-acting bronchodilator within 4 hours:



(\*Administer short-acting bronchodilator; and then check Yes and proceed with testing after 15 minutes.)

NETT Form EW Revision 1 (11 Jan 99)

**13.** Pulse oximeter manufacturer/model:

Criticare 504 USP	(	1)
Nellcor N200	(	2)
Ohmeda Biox 3740	(	3)
Sensormedic 767501-102	(	<sub>4</sub> )
Other (specify)	(	<sub>5</sub> )

## manufacturer/model

14.	Is pulse oximeter ECG-gate	ed: Yes	No
		$\begin{pmatrix} 1 \\ 1 \end{pmatrix}$	
		(1)	( <sub>2</sub> )
15.	Pulse oximeter probe site:		
	Finger		( <sub>1</sub> )
	Ear		( _2)
	Forehead		$\begin{pmatrix} & 2 \\ & 3 \end{pmatrix}$
	Other ( <i>specify</i> )		( <sub>4</sub> )

probe site

## Instructions (use Form ES if in Exercise ABG substudy):

- Calibrate system with supplemental oxygen in place
- Start patient on oxygen; patient will breath with Venturi mask without mouthpiece or noseclip (31% oxygen)
- Instruct patient on exercise test procedures
- Instruct patient on Borg scale data collection
- Patient rests for 10 minutes in chair
- Transfer patient to cycle; have patient breath on system mouthpiece with noseclip for 5 minutes (FiO<sub>2</sub>=0.3)
- Obtain resting values (next to last 20 second average [regardless of duration of rest period]) administer Borg scale for perceived breathlessness and leg muscle fatigue; remind patient that 0 means no breathlessness (leg muscle fatigue) and 10 means the maximum he/she has ever felt
- Technician assists patient in starting (optional)
- Patient performs unloaded pedaling for 3 minutes; patient may pedal at any cadence between 40-70 rpm
- Obtain values for 3 minutes unloaded pedaling (last 20 second average [regardless of duration of unloaded pedaling]); administer Borg scale for perceived breathlessness and leg muscle fatigue; remind patient that 0 means no breathlessness (leg muscle fatigue) and 10 means the maximum he/she has ever felt

- Start ramped portion of test
- Encourage patient at each minute of exercise
- Patient should indicate when he/she is within one minute of maximal exertion by raising his/her finger
- After patient gives 1 minute signal, encourage in 20 second increments
- Test ends when cadence drops below 40 rpm and does not return, when patient requests end, or when staff member terminates test for safety
- Administer Borg scale for perceived breathlessness and leg muscle fatigue; remind patient that 0 means no breathlessness (leg muscle fatigue) and 10 means the maximum he/she has ever felt
- When test ends, transfer patient to chair and place on appropriate oxygen flow
- Maximal watts on the cycle should be recorded when workload is removed; all other maximal data will be from the final 20 second interval unless the VCO<sub>2</sub> value in the final 20 second interval is an outlier; in that case, choose a representative value of VCO<sub>2</sub> from the last minute and report values from this 20 second interval
- Note: Patient is ineligible if unable to complete 3 minutes of unloaded pedaling

Quantity		5 min rest on mouthpiece/cycle	3 min unloaded	Maximum
Was testing completed? (key Yes=1, 1	No=2)	Yes / No	Yes / No	Yes / No
Ramp rate (circle one)		N/A	N/A	05 or 10
SpO <sub>2</sub> (%)	XXX			
<b>ṫ</b> e (BTPS; L∕min)	XX.X			
Vt (BTPS; L)	X.XX			
$\mathbf{\dot{V}}$ CO <sub>2</sub> (STPD; L/min)	X.XXX			
Heart rate (beats/min)	XXX			
Respiratory rate (breaths/min)	XX			
Systolic blood pressure (mmHg)	XXX			
Diastolic blood pressure (mmHg)	XXX			
Borg (breathlessness)	XX.X			
Borg (leg muscle fatigue)	XX.X			
Load (watts)	XXX	N/A	N/A	
How was blood pressure measured: A	key Transdu	cer=1, Cuff=2	Transducer or	Cuff

## 16. Data

**17.** Did the staff member terminate the test session:

Yes No (1) (2) 19

- **18.** Reason staff member terminated the test session *(check all that apply)* 
  - a. Cadence dropped below 40 rpm and did not return: 1) ( **b.** Mental confusion: ( 1) ( **c.** EKG arrhythmia: 1) ( **d.** EKG ischemia: 1) e. Elevated blood pressure: ( 1) **f.** Low blood pressure: 1) Other (specify): g. 1)

specify

20.

- **19.** Reason patient terminated the test session (*check all that apply*)
  - a. Dyspnea or shortness of breath:( 1)b. Dizziness or lightheadedness:( 1)c. Chest pain:( 1)
  - d.
     Leg fatigue:
     ( 1)

     e.
     Leg cramps or leg pain:
     ( 1)
  - **f.** Other (specify):

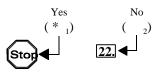
specify

**20.** Is this a pre-randomization assessment:



1)

**21.** Should the patient be excluded based on any findings from the exercise test:



If yes, specify:

specify

(\*The patient is ineligible for NETT; complete Section E, Administrative information.)

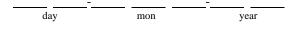
## E. Administrative information

- **22.** Pulmonary Function Coordinator PIN:
- **23.** Pulmonary Function Coordinator signature:

Patient ID:

- 24. Clinic Coordinator PIN:
- **25.** Clinic Coordinator signature:

## **26.** Date form reviewed:



GA - Form GA Enrollment in Extension Year (rev 1)

Date	file	created:	13	May	2006
Obser	vatio	ons:			664
Varia	bles:	:			5

Variable			Variable	
Name	Variable Label	Туре	Length	Format
form formdate ga108 newnett	Form abreviation and revision number #4 converted to #days from RZ/scr strt 8 Visit consented patient consented to New NETT patient ID no.	Char Num Char Char	4 8 2 5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

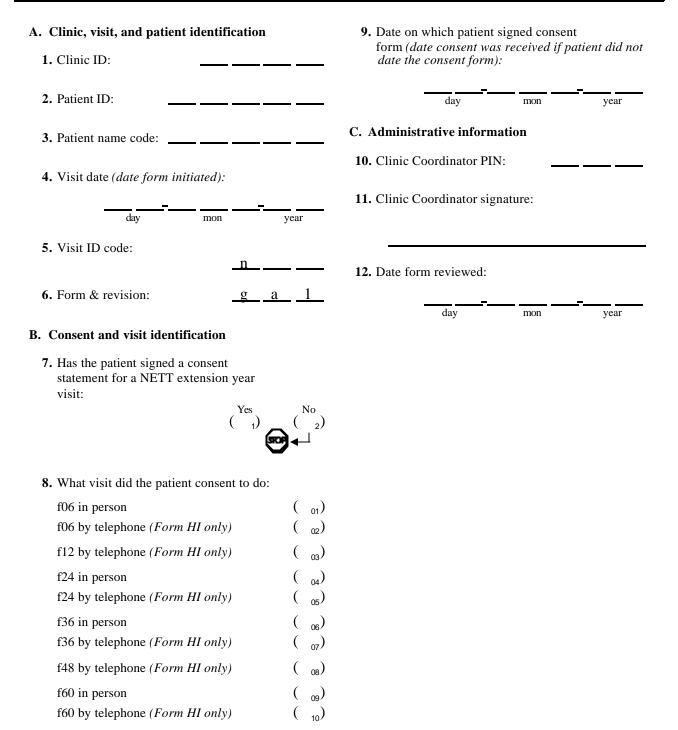
Purpose To document enrollment in extension year of NETT and to identify visit to be completed in extension year.

When: Once consent has been obtained.

Administered by: Clinic Coordinator.

## Respondent: None.

**Instructions**: This form documents enrollment in the extension year. It should be completed once consent has been obtained. It must be keyed before other extension visit forms are keyed since it documents that consent was obtained for the entension year visit. While protocol calls for f06, f24, f36, and f60 to be done in person, some patients may consent only to do these visits by telephone. Hence item 8 allows for telephone visits for f06, f24, f36, and f60.



HB - Form HB Baseline History (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			2325
Varia	ables:	:			82

Variables:		82			
Variable Name	Vari	able Label	Туре	Variable Length	Format
Name	Varia	abie habei	турс	Deligen	rormae
form	Form	abreviation and revision number	Char	4	
formdate	#4 ci	nvrtd to #days from RZ/scr strt	Num	8	
hb307	7	1st degree relatives have emphysema	Char	1	
hb308	8	1st degree relatives have congenita	Char	1	
hb309	9	1st degree relatives have asthma	Char	1	
hb310	10	1st degree relatives have other lun	Char	1	
hb311	11	Sputum clinically significant am	Char	1	
hb312	12	Usual weight (lbs)	Char	3	
hb313	13	10% of usual weight (lbs)	Char	2	
hb314	14	No. lbs lost in past 3 months	Char	3	
hb315	15	Lost >10% of weight in past 3 month	Char	1	
hb316	16	Was weight loss planned?	Char	1	
hb318	18	Weight loss exclusion?	Char	1	
hb319	19	Frequency of alcohol use	Char	1	
hb320	20	Sleep apnea dx in past 12 months	Char	1	
hb321	21	Sleepy during day/working hours	Char	1	
hb322	22	Snore loudly	Char	1	
hb323	23 24	Current oral steroids Current inhaled steroids	Char	1 1	
hb324	24 25		Char	1	
hb325 hb328	23	Current bronchodilators Oxygen used at restnot sleeping	Char Char	1	
hb330	20 30	Oxygen used at restnot steeping Oxygen used on exertion	Char	1	
hb332	32	Oxygen used when sleeping	Char	1	
hb333	33	Oxygen dose used (L/min)	Char	2	
hb336	36	No. nights in hospital in past 3 mo	Char	2	
hb337	37	No. nights in nonacute care in past	Char	2	
hb338	38	No. times seen in ER in past 3 mos	Char	2	
hb339	39	No. times seen MD in office in past	Char	3	
hb340	40	No. times seen health care provider	Char	3	
hb341	41	No. times seen health care worker i	Char	3	
hb342	42	No. times seen health equip tech in	Char	3	
hb343	43	Other medical contacts in past 3mos	Char	1	
hb344	44	Illness restricted family activitie	Char	1	
hb345	45	Hrs in past week of help from famil	Char	3	
hb326a	26a		Char	1	
hb326b	26b	Short-acting sympathomimetics	Char	1	
hb326c	26c	Anticholinergics	Char	1	
hb326d	26d	Oral sympathomimetics	Char	1	
hb326e	26e	Theophylline	Char	1	
hb326f	26f		Char	1	
hb327a	27a	Analgesics	Char	1	
hb327aa		Vitamins	Char	1	
hb327ab		Other type of medication	Char	1	
hb327ac		None	Char	1	
hb327b	27b	Antacids	Char	1	
hb327c	27c		Char	1	
hb327d		Antiarrhythmics	Char	1	
hb327e		Antibiotics	Char	1	
hb327f	27f		Char	1	
hb327g	27g		Char	1	
hb327h	27h 27i		Char	1	
hb327i	27i 27i		Char	1	
hb327j bb327k		Antitussives	Char	1 1	
hb327k	27k 271	Antihypertensives	Char	1	
hb3271 hb327m	271 27m	Aspirin	Char	1	
hb327m	27m 27n	Decongestants Digitalis	Char Char	1	
hb3270	270	Digitalls	Char	1	
1100270	210		Unar	1	

HB - Form HB Baseline History (rev 3)

Date file created: 13 May 2006 Observations: 2325 Variables: 82

Variable				Variable	
Name	Vari	able Label	Туре	Length	Format
hb327p	-	Expectorants	Char	1	
hb327q	-	H2 blockers	Char	1	
hb327r	27r	Hormone replacement	Char	1	
hb327s	27s	Insulin	Char	1	
hb327t	27t	Mucolytics	Char	1	
hb327u	27u	Nasal steroids	Char	1	
hb327v	27v	Nitroglycerine	Char	1	
hb327w	27w	Non steroidal anti-inflammatory	Char	1	
hb327x		Ophthalmic medications	Char	1	
hb327y	27y	Oral beta blockers	Char	1	
hb327z	27z	Sedatvies	Char	1	
hb334a	34a	None	Char	1	
hb334b	34b	Compressed gas (tanks)	Char	1	
hb334c	34c	Liquid	Char	1	
hb334d	34d		Char	1	
hb334e	34e	Other type of oxygen	Char	1	
hb335a	35a	Nasal cannula	Char	1	
hb335b	35b	Oxymizer	Char	1	
hb335c	35c	Pendant	Char	1	
hb335d	35d	Transtracheal	Char	1	
hb335e	35e	Pulse/demand delivery device	Char	1	
hb335f	35f	-	Char	1	
newnett		NETT patient ID no.	Char	5	
visit		2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

National Emphysema Treatment Trial

\_ \_

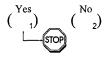
#### - - 12-- - TT2ъ

( ) keyed

101
101

NETT				e History	
Purpose: To collect baseline m	edical history	informa	tion a	bout the patient.	
When: At visit s1.					
Administered by: Clinic Coord	linator.				
Respondent: Patient.					
Instructions: Collect informati complete section J, Administ				ent is found to be ineligible after completin ot key this form.	g items 1-18,
A. Clinic, visit, and patient	dentification	l		<b>10.</b> Do any of your first degree relative (parent, brother, sister, child) have	
1. Clinic ID:				disease other than emphysema or a	
<b>2.</b> Patient ID:				Yes	( 1
2 Detient and 1				specify	
3. Patient name code:				No	( ;
4. Visit date (date this form	is initiated):			Don't know	( ;
		·		C. Respiratory symptoms	
day	mon	year		11. Ask the patient how much sputum	
5. Visit ID code:	_ <u>S_</u>			(phlegm) he/she usually brings up day; is the amount clinically signif	
<b>6.</b> Form & revision:	h	_b	3	( <sup>Y</sup>	
B. Family history					
7. Do any of your first degr	ee relatives			D. Weight loss in past 3 months	
(parent, brother, sister, c emphysema:				12. What is your usual weight:	lbs
Yes		(	1)		01 10
No		(	2)	13. 10% of usual weight (divide item 1	2 by 10):
Don't know		(			
8. Do any of your first deg	ee relatives				lbs
(parent, brother, sister, c congenital emphysema ( antitrypsin deficiency):	hild) have			14. How much weight have you lost in past 3 months (enter 000 if none lo	
Yes		(	1)		lbs
No		(	2)	15. Has the patient lost more than 10%	of
Don't know		(	3)	his/her usual weight in the past 3 r (ie, is the value for item 14 greater	nonths
9. Do any of your first degr (parent, brother, sister, c asthma:				the value for item 13):	Yes ( <sup>No</sup>
Yes		(	1)		<u>19.</u>
No		Ì	2)	16 Was the mainty law - 1 1	
Don't know		Ì	3)	16. Was the weight loss planned:	$\binom{\text{No}}{1}$ (No

- 17. What is the explanation for the weight loss:
- **18.** Should the patient be excluded based on the weight loss:



## E. Alcohol use

**19.** How frequently do you drink alcohol:

Daily or almost every day	(	1)
3 or 4 times per week	(	2)
Once or twice a week	(	3)
Once or twice a month	(	4)
Less than once a month	(	<sub>5</sub> )
Never	(	<sub>6</sub> )

## H. Sleep disturbances and daytime fatigue

**20.** Have you, in the past 12 months, been diagnosed by a physician as having sleep apnea:

Y	/es	N	0
(	1)	(	<sub>2</sub> )

**21.** How often are you troubled by sleepiness in the daytime or during working hours:

Never	(	1)
Less than once per week	(	2)
1-2 times per week	(	3)
3-6 times per week	(	4)
Every day	(	<sub>5</sub> )

# **22.** Do you snore loudly during sleep (that is, do those who live with you say that you snore or are noisy when you are asleep):

Yes	(	1)
No	(	2)
Not sure	(	3)

## G. Medication use

23. Are you currently prescribed oral steroids (eg, prednisone):

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

specify medication and strength

#### specify dose (amount and frequency)

(\*Note that patients are required to be in stable condition on less than 20 mg of prednisone or its equivalent (see NETT Chart 1) per day at the time of randomization.)

24. Are you currently prescribed inhaled steroids (eg, Vanceril [beclomethasone]):



specify medication and strength

specify dose (amount and frequency)

**25.** Are you currently prescribed any bronchodilator medications:



**26.** What types of bronchodilator medication are you currently prescribed *(check all that apply)* 

<ul> <li>a. Long-acting sympathomimetics (beta-agonists such as Serevent [salmeterol]):</li> </ul>	(	1)
<ul> <li>b. Short-acting sympathomimetics (beta-agonists such as Ventolin, Proventil [albuterol]):</li> </ul>	(	1)
<b>c.</b> Anticholinergics (such as Atrovent [ipratropium bromide]):	(	1)
<b>d.</b> Oral sympathomimetics (such as Brethaire [terbutaline]):	(	1)
e. Theophylline:	(	1)
f. Other (specify):	(	1)

specify

	That other types of medications are you urrently prescribed		
	Analgesics:	(	<sub>1</sub> )
b	. Antacids:	(	, 1)
C.	Antianxiety medications:	(	1)
d	. Antiarrhythmics:	(	,)
e	Antibiotics:	(	,)
f.	Anticoagulants:	(	1)
g	. Antidepressants:	(	1)
h	. Antifungals:	(	1)
i.	Antihistamines:	(	,)
j.	Antitussives:	(	,)
k	. Antihypertensives:	(	,)
1.	Aspirin:	(	1)
n	n. Decongestants:	(	1)
n	. Digitalis:	(	1)
0	Diuretics:	(	1)
р	• Expectorants:	(	_)
q	H2 blockers:	(	1)
r	Hormone replacement:	(	₁)
S	. Insulin	(	1)
t.	Mucolytics:	(	1)
u	Nasal steroids:	(	1)
v	• Nitroglycerine:	(	₁)
W	v. Non steroidal anti-inflammatory:	(	1)
x	• Ophthalmic medications:	(	<sub>1</sub> )
У	• Oral beta blockers:	(	,)
z	. Sedatives:	(	(۱
a	a. Vitamins:	(	1)
a	<b>b.</b> Other types of medication <i>(specify)</i> :	(	1)
	specify	<i></i>	

ac. None:

( <sub>1</sub>)

## H. Oxygen use

28. Do you use oxygen at rest (not sleeping):



.....

29. Dose:

specify exact L/min dose or range used

30. Do you use oxygen on exertion:

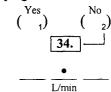
 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$ 

31. Dose:

33. Dose:

specify exact L/min dose or range used

**32.** Do you use oxygen when sleeping:



34. What type of oxygen do you use currently *(check all that apply)* 

a. 1	None:	(	,)
		36. —	Ĺ
b. (	Compressed gas (tanks):	(	1)
<b>c.</b> I	Liquid:	(	1)
<b>d.</b> (	Concentrator:	(	1)
e. (	Other (specify):	(	1)

specify

**35.** What type of delivery device do you use currently *(check all that apply)* 

<b>a.</b> Nasal cannula:	(	1)
<b>b.</b> Oxymizer:	(	1)
c. Pendant:	(	1)
d. Transtracheal:	(	1)
e. Pulse/demand delivery device:	(	1)
f. Other (specify):	(	1)

I. Health care in the past 3 months

have you stayed overnight in a

care facility (enter 00 if none):

or urgent care visits):

you in your residence:

## 43. In the past 3 months, did you have any visits or contacts with health care 36. How many nights in the past 3 months have you stayed overnight in a hospital or other acute care facility (enter 00 if none): # nights If yes, please describe: 37. How many nights in the past 3 months rehabilitation hospital, nursing home, or other nonacute care facility (enter 00 if none): # nights 38. How many times in the past 3 months Yes have you been seen at an emergency room (department), triage area, or urgent # times 39. How many times in the past 3 months have you visited a physician, physician's assistant, or nurse in their office or have J. Administrative information you visited an outpatient clinic for any reason (exclude hospital stays, visits to subacute 46. Clinic Coordinator PIN: care facilities, and emergency room, triage area, 47. Clinic Coordinator signature: # times 40. How many times in the past 3 months has a health care professional (provider) (eg, 48. Date form reviewed: home health agency nurse, physical therapist, occupational therapist) visited day mon

# times

41. How many times in the past 3 months has a health care service worker (eg, aide, attendant) come to your home for health reasons:

# times

42. How many times in the past 3 months, has a health equipment technician come to your home to adjust, service, or care for some item of health care equipment used by you:

# times

workers other than those just mentioned:

Patient ID:



44. In the past 3 months, has your illness required any family members or friends to restrict their work or social activities:

No \_\_)

45. About how many hours in the past week have family members or friends spent in helping with your care (enter 000 if none):

# hours

year

HF - Form HF Heart Function Summary (rev 4)

Date	file	created:	13	May	2006
Observations:			2788		
Varia	ables:	:			46

Variable	Variable Label	Trino	Variable	Format
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 converted to No. of days from RZ	Num	8	
hf407	7 Resting EKG obtained	Char	1	
hf408	#8 cnvrtd to #days from RZ/scr strt	Num	8	
hf409	9 EKG findings	Char	1	
hf410	10 Echocardiogram obtained	Char	1	
hf411	#11 cnvrtd to #days from RZ/scr strt	Num	8	
hf412	12 Mean RA pressure/tricuspid peak syst	Char	1	
hf413	13 Rt heart cath should be done?	Char	1	
hf414	14 Estimated mean RA pressure	Char	1	
hf415	15 Estimated tricuspid systolic peak ve	Char	2	
hf416	16 Calculated peak systolic PPA	Char	2	
hf417	17 S1 assessment?	Char	1	
hf418	18 Peak systolic PPA >=45 mmHg	Char	1	
hf419	19 Can LVEF be estimated?	Char	1	
hf420	20 Estimated LVEF	Char	1	
hf421	21 Dobutamine-radionuclide scan done	Char	1	
hf422	#22 cnvrtd to #days from RZ/scr strt	Num	8	
hf423	23 Indication of coronary disease?	Char	1	
hf424	24 Right heart catheterization done	Char	1	
hf425	#25 cnvrtd to #days from RZ/scr strt	Num	8	
hf427	27 Measured peak systolic PA<45 mmHg	Char	1	
hf428	28 Measured mean PA pressure<35 mmHg	Char	1	
hf429	29 Patient ineligible - catherization r	Char	1	
hf430	30 Evaluation by cardiologist done	Char	1	
hf431	#31 cnvrtd to #days from RZ/scr strt	Num	8	
hf433	33 Cardiologist's findings	Char	1	
hf426a	26a Measured RA mean pressure (mmHg)	Char	2	
hf426b	26b Measured systolic RV pressure (mmHg)	Char	2	
hf426bs	26b Sign - measured systolic RV pressure	Char	1 2	
hf426c hf426d	26c Measured diastolic RV pressure (mmHg	Char Char	2	
hf426a	26d Measured systolic PA pressure (mmHg) 26e Measured diastolic PA pressure (mmHg	Char	2	
hf426f	26f Measured mean PA pressure (mmHg)	Char	2	
hf426q	26g Measured PA occlusion pressure (mmHg	Char	3	
hf426h	26h Measured cardiac output (1/min)	Char	3	
hf426i	26i Calculated PVR (dynes/sec/cm -5)	Char	3	
hf432a	32a ECG abnormality	Char	1	
hf432b	32b Lft ventricular ejection fraction <4	Char	1	
hf432c	32c Dobutamine-radionuclide scan finding	Char	1	
hf432d	32d S3 gallop on physical exam	Char	1	
hf432e	32e >5 premature ventricular beats noted	Char	1	
hf432f	32f Unstable angina	Char	1	
hf432q	32g Other reason for evaluation	Char	1	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

106

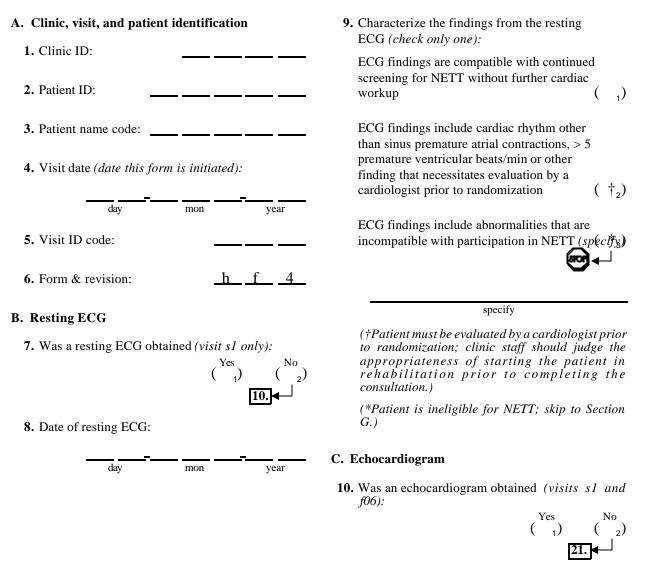
**Purpose** Record results of resting ECG, echocardiogram, cardiac scan, right heart catheterization (not the substudy), and evaluation by cardiologist.

When: Visits s1 and f06 (echocardiogram).

Administered by: Study Physician and Clinic Coordinator.

#### Respondent: None.

**Instructions**: Mark any relevant reports with the patient's ID number and name code and staple the reports to this form. If a STOP condition is checked and this is the s1 or rz assessment, the patient is ineligible. Complete Section G but do not key this form. Complete one Form HF prior to starting Core Rehabilitation; use visit ID code s1. If right heart catheterization and/or evaluation by a cardiologist are/is done post rehabilitation, update the visit s1 HF form prior to randomization to record the results of those evaluations.



**11.** Date of echocardiogram:



**12.** Could both RA pressure and tricuspid peak systolic velocity be estimated from the echocardiogram:

$$( \begin{array}{c} Yes \\ 1 \end{array} ) \qquad ( \begin{array}{c} No \\ 2 \end{array} )$$

2)

**13.** When RA pressure and/or tricuspid peak systolic velocity cannot be estimated from the echocardiogram at visit s1, the study physician may judge whether to do right heart catheterization to rule out pulmonary hypertension: Does the study physician judge that right heart catheterization should be done to rule out pulmonary hypertension:

 $(\overset{\text{Yes}}{\ast}) \qquad (\overset{\text{No}}{\dagger}_2)$  **19.** 

(\*If this is visit s1, patient must have right heart catheterization done before randomization; clinic staff should judge the appropriateness of starting the patient in rehabilitation prior to completing the right heart catheterization.)

 $(\dagger Right heart catheterization is not required to be done.)$ 

14. Estimated mean RA pressure (check only one)

5 mmHg:	(	1)
10 mmHg:	(	<sub>2</sub> )
15 mmHg:	(	<sub>3</sub> )

- **15.** Estimated tricuspid peak systolic velocity:
- **16.** Calculated peak systolic PPA  $(item \ 14 + 4* (item \ 15)^2):$
- **17.** Is this the s1 assessment:



mmHg

m/sec

**18.** Is calculated peak systolic P<sub>PA</sub> (*item 16*) 45 mmHg or greater:

 $\begin{pmatrix} \text{Yes} \\ (*_1) \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$ 

(\*The patient must have right heart catheterization before randomization to rule out pulmonary hypertension.) **19.** Can left ventricular ejection fraction (LVEF) be estimated from the echocardiogram:



(\*If this is visit s1, patient must be evaluated by a cardiologist prior to randomization.)

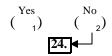
**20.** Estimated left ventricular ejection fraction (LVEF)

≥45%:	()
< 45%:	$(*_{2})$

(\*If this is visit s1, patient must be evaluated by a cardiologist prior to randomization; clinic staff should judge the appropriateness of starting the patient in rehabilitation prior to completing the cardiologist evaluation.)

#### D. Dobutamine-radionuclide scan findings

**21.** Was a dobutamine-radionuclide scan done (*visit s1 only*):



22. Date of dobutamine-radionuclide scan:

**23.** Do the dobutamine-radionuclide scan findings indicate coronary artery disease or ventricular dysfunction:

 $\begin{pmatrix} \text{Yes} \\ * \\ 1 \end{pmatrix}$   $\begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$ 

(\*Patient must be evaluated by a cardiologist prior to randomization; clinic staff should judge the appropriateness of starting the patient in rehabilitation prior to completing the consultation.)

#### E. Right heart catheterization

**24.** Was right heart catheterization done (*visit s1*):

**25.** Date of right heart catheterization:



**26.** Right heart catheterization findings (end expiration)

a. Measured RA mean pressure:

**b.** Measured systolic RV pressure (*circle* + *or* -):

+ - \_\_\_\_\_\_mmHg
c. Measured diastolic RV pressure: \_\_\_\_\_\_\_mmHg
d. Measured pack systelia RA

- **d.** Measured peak systolic PA pressure:
- e. Measured diastolic PA pressure:
- f. Measured mean PA pressure:
- **g.** Measured PA occlusion (wedge) pressure:

mmHg

mmHg

mmHg

mmHg

mmHg

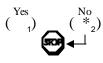
h. Measured cardiac output:

L/min

i. Calculated PVR:

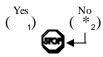
dynes/sec/cm<sup>-5</sup>

27. Is measured peak systolic PA pressure (*item 26d*) < 45 mmHg (< 50 mmHg in Denver):



(\*The patient is ineligible for NETT; skip to section G.)

**28.** Is measured mean PA pressure (*item 26f*) < 35 mmHg (< 38 in Denver):



(\*The patient is ineligible for NETT; skip to section G.)

Patient ID:

**29.** Do any right heart catheterization findings render the patient ineligible for NETT:

Yes (*specify*):

 $\begin{pmatrix} 2 \end{pmatrix}$ 

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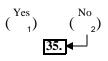
specify reason for ineligibility

(\*The patient is ineligible for NETT; skip to Section G.)

#### F. Cardiologist evaluation

No

**30.** Was the patient evaluated by a cardiologist (*visit s1*):



**31.** Date of cardiologist's evaluation:



**32.** Reasons for cardiologist evaluation (*check all that apply*)

FF-57		
<b>a.</b> ECG abnormality:	(	1)
<b>b.</b> Left ventricular ejection fraction <45% or unable to evaluate LVEF:	(	1)
<b>c.</b> Dobutamine-radionuclide scan findings:	(	1)
<b>d.</b> S <sub>3</sub> gallop on physical exam:	(	1)
<b>e</b> > 5 premature ventricular beats/min:	(	1)
<b>f.</b> Unstable angina:	(	1)
<b>g.</b> Other ( <i>specify</i> ):	(	1)

specify

**33.** Cardiologist's findings:

Cleared for surgery with respect to cardiac		
condition	(	1)
Ineligible for surgery (specify reason):	(	*_)
and the second	-	

specify

(\*The patient is ineligible for NETT.)

**34.** Name of cardiologist (*please print*):

G. Administrative information	
<b>35.</b> Study Physician PIN:	
<b>36.</b> Study Physician signature:	
<b>37.</b> Clinic Coordinator PIN:	
<b>38.</b> Clinic Coordinator signature:	
<b>39.</b> Date form reviewed:	
day mon	year

HI - Form HI Interim History (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			5186
Varia	ables:	:			75

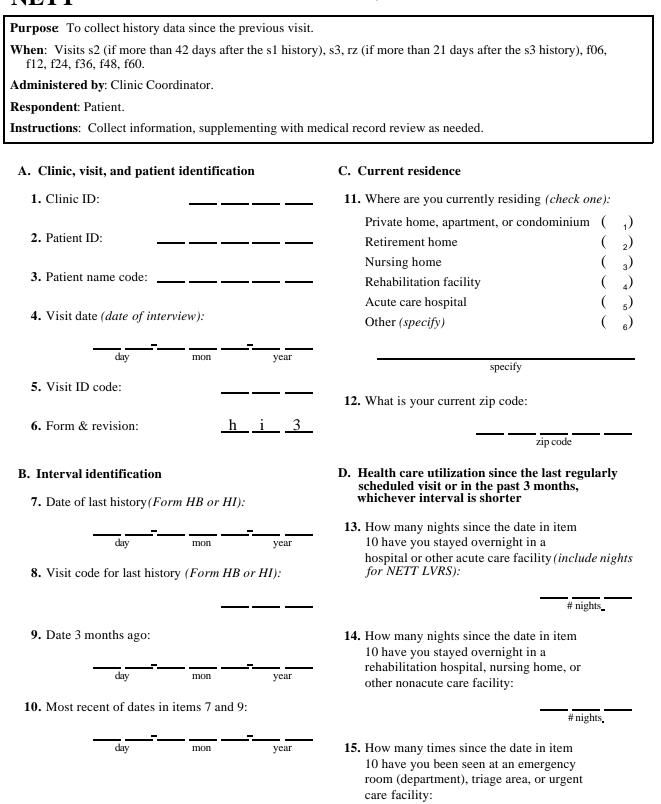
Variable			Variable	
Name	Variable Label	Туре	Length	Format
			2	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days from RZ/scr strt	Num	8	
hi307	#7 cnvrtd to \$#days from RZ/scr strt	Char	7	
hi308	8 Visit code of last history form	Char	3	
hi309	#9 cnvrtd to #days from RZ/scr strt	Char	7	
hi310	#10 cnvrtd to #days from RZ/scr strt	Char	7	
hi311	11 Current residence	Char	1	
hi313	13 No. of nights in hospital	Char	3	
hi314	14 No. of nights in non-acute facility 15 No. of visits to ER	Char	3	
hi315		Char Char	3 3	
hi316	1 1	Char	3	
hi317 hi318	7 1	Char	3	
hi319	4	Char	3	
hi320	19 No. of home visits by equipment tec 20 Visits by other health care workers	Char	1	
hi321	21 Family activities restricted	Char	1	
hi322	22 Hours family spent caring for patie	Char	3	
hi324	24 Smoked since item 10 date	Char	1	
hi325	25 Patient using any nicotine products	Char	1	
hi326	26 Health problems since last visit	Char	1	
hi327	27 Currently taking oral steroids	Char	1	
hi328	28 Currently taking inhaled steroids	Char	1	
hi329	29 Currently using bronchodilators	Char	1	
hi332	32 Use oxygen at rest (not sleeping)	Char	1	
hi334	34 Use oxygen on exertion	Char	1	
hi336	36 Use oxygen when sleeping	Char	1	
hi337	37 Dose 02 used when sleeping	Char	2	
hi330a	30a Long-acting sympathomimetics	Char	1	
hi330b	30b Short-acting sympathomimetics	Char	1	
hi330c	30c Anticholinergics	Char	1	
hi330d	30d Oral sympathomimetics	Char	1	
hi330e	30e Theophylline	Char	1	
hi330f	30f Other bronchodilator	Char	1	
hi331a	31a Analgesics	Char	1	
hi331aa	31aa Vitamins	Char	1	
hi331ab	31ab Other type of medication	Char	1	
hi331ac	31ac None	Char	1	
hi331b	31b Antacids	Char	1	
hi331c	31c Antianxiety medications	Char	1	
hi331d	31d Antiarrhythmics	Char	1	
hi331e	31e Antibiotics	Char	1	
hi331f	31f Anticoagulants	Char	1	
hi331g	31g Antidepressants	Char	1	
hi331h	31h Antifungals	Char	1	
hi331i	31i Antihistamines	Char	1	
hi331j	31j Antitussives	Char	1	
hi331k	31k Antihypertensives	Char	1	
hi3311	311 Aspirin	Char	1	
hi331m	31m Decongestants	Char	1	
hi331n	31n Digitalis	Char	1	
hi3310	310 Diuretics	Char	1	
hi331p	31p Expectorants	Char	1	
hi331q hi331r	31q H2 blockers	Char	1 1	
hi331r hi331s	31r Hormone replacement 31s Insulin	Char Char	1	
hi331t	31t Mucolytics	Char	1	
hi331u	31u Nasal steroids	Char	1	
hi331v	31v Nitroglycerine	Char	1	
111001 V	51	Unur	±	

HI - Form HI Interim History (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			5186
Varia	ables:	:			75

Variable Name	Variable Label	Туре	Variable Length	Format
hi331w	31w Non steroidal anti-inflammatory	Char	1	
hi331x hi331y	31x Ophthalmic medications 31v Oral beta blockers	Char Char	1	
hi331z	2	Char	1	
hi338a	38a None	Char	1	
hi338b	38b Compressed gas (tanks)	Char	1	
hi338c	38c Liquid	Char	1	
hi338d	38d Concentrator	Char	1	
hi338e	38e Other	Char	1	
hi339a	39a Nasal cannula	Char	1	
hi339b	39b Oxymizer	Char	1	
hi339c	39c Pendant	Char	1	
hi339d	39d Transtracheal	Char	1	
hi339e	39e Pulse/demand delivery device	Char	1	
hi339f	39f Other type of delivery device	Char	1	
newnett	New NETT patient ID no.	Char	5	
visit	<pre>s1,s2,s3,rz,n,fxx where xx=mos from RZ</pre>	Char	3	

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# times

- **16.** How many times since the date in item 10 have you visited a physician, physician's assistant, or nurse in their office or have you visited an outpatient clinic for any reason (exclude hospital stays, visits to nonacute care facilities, and emergency room, triage area, or urgent care visits; exclude NETT screening, followup, and rehab visits; by followup visits we mean the regularly scheduled NETT in person followup visits, eg, f06, f12, f24, etc):
- #times\_ **17.** How many times since the date in item 10 has a health care professional (provider) (eg, home health agency nurse, physical therapist, occupational therapist) visited you in your residence:

#times

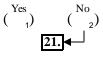
18. How many times since the date in item 10 has a health care service worker (eg, aide, attendant) come to your residence for health reasons:

#times\_

**19.** How many times since the date in item 10 has a health equipment technician come to your residence to adjust, service, or care for some item of health equipment used by you:

# times

20. Since the date in item 10, have you had any visits with health care workers other than those just mentioned (exclude NETT screening, followup, and rehab visits; by followup visits we mean the regularly scheduled NETT in person followup visits, eg, f06, f12, f24, etc):



If yes, describe:

21. Since the date in item 10, has your illness required any family members or friends to restrict their work or social activities (include efforts to help you participate in NETT):

have family members or friends spent in helping with your care (include efforts to help you participate in NETT):

22. About how many hours in the past week

**23.** What pulmonary rehabilitation activities have you completed since the date in item 10 (at s3, summarize as "Core and Cont rehab"):

Patient ID:

specify

specify

specify

#### E. Interim history

24. Have you smoked any tobacco products since the date in item 10:

(<sup>Yes</sup> (<sup>\*</sup>₁)

(\*If visit is prior to randomization, patient is ineligible.)

**25.** Is the patient using nicotine products:

( <sup>No</sup><sub>2</sub>)  $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$ 

# hours

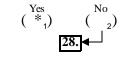
26. Have you had any serious health problem since your last visit:

 $\binom{\text{Yes}}{1}$ 

If yes, specify:

specify

27. Are you currently prescribed oral steroids (eg, prednisone):



specify medication

specify dose (amount and frequency)

(\*If this is s2, s3, or rz, the patient must be stable on 20 mg or less prednisone or its equivalent (see NETT Chart 1) per day at the time of randomization; otherwise the patient is ineligible for NETT. Clinic staff need to judge whether the patient should continue with screening.)

**28.** Are you currently prescribed inhaled steroids (eg, Vanceril [beclomethasone]):



specify medication

specify dose (amount and frequency)

**29.** Are you currently prescribed any bronchodilator medications:

$$\begin{array}{c} \text{Yes} & \text{No} \\ 1 & \begin{pmatrix} & 2 \end{pmatrix} \\ \hline 31. \checkmark \end{array}$$

(

**30.** What types of bronchodilator medication are you currently prescribed (*check all that apply*)

a. Long-acting sympathomimetics (beta-agonists such as Serevent [salmeterol]):	(	1)
<b>b.</b> Short-acting sympathomimetics (beta-agonists such as Ventolin, Proventil [albuterol]):	(	1)
<b>c.</b> Anticholinergics (such as Atrovent [ipratropium bromide]):	(	1)
<b>d.</b> Oral sympathomimetics (such as Brethaire [terbutaline]):	(	1)
e. Theophylline:	(	1)
<b>f.</b> Other ( <i>specify</i> ):	(	1)

- Patient ID: **31.** What other types of medications are you currently prescribed **a.** Analgesics: 1) **b.** Antacids: <sub>1</sub>) c. Antianxiety medications: 1) **d.** Antiarrhythmics: ( \_) e. Antibiotics: 1) 1) **f.** Anticoagulants: **g.** Antidepressants: ( ₁) **h.** Antifungals: ( 1) i. Antihistamines: 1) j. Antitussives: ( \_) **k.** Antihypertensives: 1) (
  - **l.** Aspirin: <sub>1</sub>) m. Decongestants: ( 1) **n.** Digitalis: 1) ( **o.** Diuretics: <sub>1</sub>) **p.** Expectorants: ( \_) q. H<sub>2</sub> blockers: ( 1) r. Hormone replacement: 1) s. Insulin ( 1) t. Mucolytics: ( 1) **u.** Nasal steroids: \_) v. Nitroglycerine: \_) w. Non steroidal anti-inflammatory: 1) x. Ophthalmic medications: 1) y. Oral beta blockers: ( \_) **z.** Sedatives: 1) aa. Vitamins: <sub>1</sub>) **ab.** Other types of medication (*specify*): ( 1)

specify

ac. None:

( <sub>1</sub>)

specify

#### F. Oxygen use

**32.** Do you use oxygen at rest (not sleeping):

$$\begin{array}{c} \text{No} \\ 1 \end{array} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix} \\ \hline 34. \checkmark \end{array}$$

۲ (

33. Dose:

specify exact L/min or range used

**34.** Do you use oxygen on exertion:

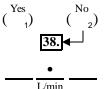


35. Dose:

37. Dose:

specify exact L/min dose or range used

**36.** Do you use oxygen when sleeping:



<sub>1</sub>)

,)

Interim History

**38.** What type of oxygen do you use currently (*check all that apply*)

a. None: ( b. Compressed gas (tanks): ( c. Liquid: (

**d.** Concentrator: ( \_\_\_\_\_)

**e.** Other (*specify*):

specify

39. What type of delivery device do you use currently (check all that apply)
a. Nasal cannula:

(1)
b. Oxymizer:
(1)
c. Pendant:
d. Transtracheal:
(1)
e. Pulse/demand delivery device:
(1)
f. Other (specify):
(1)

specify

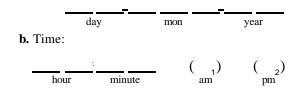
### G. Next followup visit

**40.** Was the next followup visit scheduled (answer No if this is the s3/rz visit):

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$ 

**41.** Date and time of next followup visit:

a. Date:



#### H. Administrative information

- 42. Clinic Coordinator PIN:
- **43.** Clinic Coordinator signature:

44. Date form reviewed:



IACPARAM	- Selected IAC parameters			
Date file c Observation Variables:	2			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
da950	Alpha diff at -950,(RU+LU)-(RL+LL)	Num	8	
du1950	Upper-lower diff in % emph at -950	Num	8	
dul960	Upper-lower diff in % emph at -960	Num	8	
ida950	Binary -950alpha dif,1=up lob pred,0=oth	Num	8	
idul950	BinU-Ldiff,%emph,-950,1=uplob pred,0=oth	Num	8	
idul960	BinU-Ldiff,%emph,-960,1=uplob pred,0=oth	Num	8	
newnett	New NETT patient ID no.	Char	5	
rul950	Upper/lower ratio of % emph at -950	Num	8	
rul960	Upper/lower ratio of % emph at -960	Num	8	
visit	Visit code: s1, f06, or f36	Char	3	
wa950	Alpha at -950 for whole lung	Num	8	
wcpe950	% emphysema in core at -950	Num	8	
wcpe960	% emphysema in core at -960	Num	8	
wpe950	% emphysema in whole lung at -950	Num	8	
wpe960	% emphysema in whole lung at -960	Num	8	
wppe950	% emphysema in peel at -950	Num	8	
wppe960	% emphysema in peel at -960	Num	8	
wrcp950	Core/peel ratio of % emph at -950	Num	8	
wrcp960	Core/peel ratio of % emph at -960	Num	8	

INELIG -Reasons for ineligibility Date file created: 13 May 2006 Observations: 2557 Variables: 31 Variable Variable Name Variable Label Туре Length Format PFT and/or CT scan inel1 Num 8 inel2 Smoking 8 Num inel3 Bronchietasis Num 8 inel4 Pleural/interstitial disease 8 Num 8 inel5 Pulmonary nodule Num inel6 MI or CHF Num 8 Other cardiac inel7 Num 8 Hypertension 8 inel8 Num inel9 Cardiac dysrhthmia Num 8 inel10 Previous thoracotomy 8 Num inel11 Laser or LVRS Num 8 inel12 Syncope Num 8 inel13 6 min walk or exercise 8 Num inel14 Hx/physical exam Num 8 inel15 Blood/urine 8 Num inel16 BMI Num 8 inel17 Weight loss Num 8 8 inel18 Sputum Num inel19 Prednisone Num 8 inel20 Other disease Num 8 inel21 Physician/surgeon judgement 8 Num inel22 Current illness Num 8 inel23 Giant bulla Num 8 inel24 Refused procedure/rz Num 8 inel25 Unable to complete PFTs Num 8 8 inel26 Needed >6 liter O2 Num inel27 Insurance issues Num 8 inel28 Deceased Num 8 inel29 Time window issues 8 Num inel30 Participating in other study 8 Num 5 newnett New NETT patient ID no. Char

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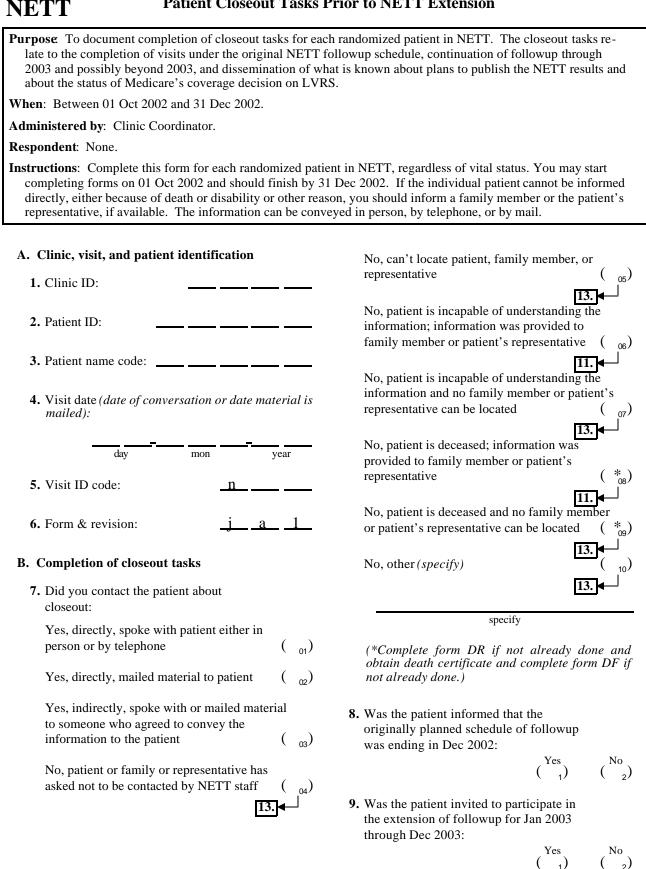
JA - Form JA Patient Closeout Tasks Prior to NETT Extension (rev 1)

Date	file	created:	13	May	2006
Obser	rvatio	ons:			1208
Varia	ables:	:			10

Variable Name	Variable Label	Туре	Variable Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
ja107	7 Contact patient about closeout	Char	2	
ja108	8 Informed about end of original follo	Char	1	
ja109	9 Invited to followup extension	Char	1	
ja110	10 Informed about possible contact	Char	1	
ja111	11 Informed about how to hear NETT resu	Char	1	
ja112	12 Informed about how to hear MEDICARE	Char	1	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

National Emphysema Treatment Trial

### Patient Closeout Tasks Prior to NETT Extension



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**10.** Was the patient informed that NETT might contact him/her about continuing followup beyond 2003:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

**11.** Was the patient (or family or representative) informed how they would hear about NETT results:

**12.** Was patient (or family or representative) informed how they would hear about the Medicare coverage decision:

\_

#### C. Administrative information

**13.** Clinic Coordinator PIN:

**14.** Clinic Coordinator signature:

**15.** Date form reviewed:

LCORE IAC left lung core file -Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format ae50 No. of voxels above -50 HU in a region Num 8 ae100 No. of voxels above -100 HU in a region Num 8 ae150 No. of voxels above -150 HU in a region Num 8 ae200 No. of voxels above -200 HU in a region 8 Num ae250 No. of voxels above -250 HU in a region Num 8 aint Ankle intercept Num 8 airv Volume of region that is air (ml) Num 8 ankl Ankle Num 8 aslp Ankle slope Num 8 No. of voxels below -600 HU in a region be600 Nıım 8 No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region be620 Num 8 be640 Num 8 No. of voxels below -660 HU in a region be660 Num 8 be810 No. of voxels below -810 HU in a region Num 8 No. of voxels below -830 HU in a region be830 Num 8 be850 No. of voxels below -850 HU in a region Num 8 be870 No. of voxels below -870 HU in a region Num 8 No. of voxels below -890 HU in a region be890 Num 8 No. of voxels below -900 HU in a region be900 Num 8 No. of voxels below -910 HU in a region be910 Num 8 be920 No. of voxels below -920 HU in a region Num 8 No. of voxels below -930 HU in a region be930 Num 8 No. of voxels below -940 HU in a region be940 Num 8 No. of voxels below -950 HU in a region be950 Num 8 be960 No. of voxels below -960 HU in a region Num 8 ccutoff See IAC Scan Analysis variables listing Num 8 cvm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 cvsd See IAC Scan Analysis variables listing CVXM Num 8 See IAC Scan Analysis variables listing cvxsd Num 8 See IAC Scan Analysis variables listing Num 8 CVVM cvysd See IAC Scan Analysis variables listing Nıım 8 cvzm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing cvzsd Num 8 entityve Histogram pgm version number Char 18 fwhm See IAC Scan Analysis variables listing Nıım 8 histolef Num 8 hlcreate Num 8 hlcreate cnvrtd to #days frm RZ/scr strt hu10 HU value below which 10% of voxels fall Num 8 HU value below which 15% of voxels fall hu15 Nıım 8 hu20 HU value below which 20% of voxels fall Num 8 intercep Value used to convert voxels into HU Num 8 8 Knee intercept Num kint knee See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing kslp Num 8 kurt Kurtosis Nıım 8 lae50 No. of voxels above -50 HU in a region Nıım 8 lae100 No. of voxels above -100 HU in a region Num 8 lae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region No. of voxels above -250 HU in a region lae200 8 Num lae250 Num 8 laint Ankle intercept Num 8 lairv Volume of region that is air (ml) Num 8 8 lankl Ankle Num laslp Ankle slope Num 8 1be600 No. of voxels below -600 HU in a region Num 8 No. of voxels below -620 HU in a region 1be620 8 Num lbe640 No. of voxels below -640 HU in a region Num 8

10010	ind lefe lang core file			
Date file d	created: 13 May 2006			
Observation				
Variables:	207			
Maniah la				
Variable Name	Variable Label	Trino o	Variable	Format
Name	Vallable Label	Туре	Length	Format
lbe660	No. of voxels below -660 HU in a region	Num	8	
lbe810	No. of voxels below -810 HU in a region	Num	8	
lbe830	No. of voxels below -830 HU in a region	Num	8	
lbe850	No. of voxels below -850 HU in a region	Num	8	
lbe870	No. of voxels below -870 HU in a region	Num	8	
lbe890	No. of voxels below -890 HU in a region	Num	8	
lbe900	No. of voxels below -900 HU in a region	Num	8	
lbe910	No. of voxels below -910 HU in a region	Num	8	
lbe920	No. of voxels below -920 HU in a region	Num	8	
lbe930 lbe940	No. of voxels below -930 HU in a region No. of voxels below -940 HU in a region	Num Num	8 8	
lbe950	No. of voxels below -950 HU in a region	Num	8	
1be960	No. of voxels below -960 HU in a region	Num	8	
lcvm	See IAC Scan Analysis variables listing	Num	8	
lcvsd	See IAC Scan Analysis variables listing	Num	8	
lcvxm	See IAC Scan Analysis variables listing	Num	8	
lcvxsd	See IAC Scan Analysis variables listing	Num	8	
lcvym	See IAC Scan Analysis variables listing	Num	8	
lcvysd	See IAC Scan Analysis variables listing	Num	8	
lcvzm	See IAC Scan Analysis variables listing	Num	8	
lcvzsd	See IAC Scan Analysis variables listing	Num	8	
lfwhm	See IAC Scan Analysis variables listing	Num	8	
lhu10 lhu15	HU value below which 10% of voxels fall HU value below which 15% of voxels fall	Num	8 8	
lhu20	HU value below which 20% of voxels fall	Num Num	8	
lkint	Knee intercept	Num	8	
lknee	See IAC Scan Analysis variables listing	Num	8	
lkslp	See IAC Scan Analysis variables listing	Num	8	
lkurt	Kurtosis	Num	8	
lmean	Mean	Num	8	
lmed	Median	Num	8	
lsd	Standard deviation	Num	8	
lskew	Skewness	Num	8	
ltisv ltotv	Region vol that is tissue & blood(ml) Total volume of region (cubic ml)	Num Num	8 8	
ltotvx	Total number of voxels in a region	Num	8	
lvar	Variance	Num	8	
mae50	No. of voxels above -50 HU in a region	Num	8	
mae100	No. of voxels above -100 HU in a region	Num	8	
mae150	No. of voxels above -150 HU in a region	Num	8	
mae200	No. of voxels above -200 HU in a region	Num	8	
mae250	No. of voxels above -250 HU in a region	Num	8	
maint	Ankle intercept	Num	8	
mairv	Volume of region that is air (ml)	Num	8	
mankl	Ankle Ankle slope	Num	8	
maslp mbe600	No. of voxels below -600 HU in a region	Num Num	8 8	
mbe620	No. of voxels below -620 HU in a region	Num	8	
mbe640	No. of voxels below -640 HU in a region	Num	8	
mbe660	No. of voxels below -660 HU in a region	Num	8	
mbe810	No. of voxels below -810 HU in a region	Num	8	
mbe830	No. of voxels below -830 HU in a region	Num	8	
mbe850	No. of voxels below -850 HU in a region	Num	8	
mbe870	No. of voxels below -870 HU in a region	Num	8	
mbe890	No. of voxels below -890 HU in a region	Num	8	
mbe900	No. of voxels below -900 HU in a region	Num	8	
mbe910 mbe920	No. of voxels below -910 HU in a region No. of voxels below -920 HU in a region	Num Num	8 8	
11100020	NO. OF VOXETS DETOW -320 NO IN a region	IN UIII	0	

LCORE - IAC left lung core file

LCORE -	IAC left lung core file			
Date file c Observation Variables:				
Variable Name	Variable Label	Туре	Variable Length	Format
mbe930	No. of voxels below -930 HU in a region	Num	8	
mbe940	No. of voxels below -940 HU in a region	Num	8	
mbe950 mbe960	No. of voxels below -950 HU in a region No. of voxels below -960 HU in a region	Num	8 8	
mcvm	See IAC Scan Analysis variables listing	Num Num	° 8	
mcvsd	See IAC Scan Analysis variables listing	Num	8	
mcvxm	See IAC Scan Analysis variables listing	Num	8	
mcvxsd	See IAC Scan Analysis variables listing	Num	8	
mcvym	See IAC Scan Analysis variables listing	Num	8	
mcvysd	See IAC Scan Analysis variables listing	Num	8	
mcvzm	See IAC Scan Analysis variables listing	Num	8	
mcvzsd mean	See IAC Scan Analysis variables listing Mean	Num Num	8 8	
med	Median	Num	8	
mfwhm	See IAC Scan Analysis variables listing	Num	8	
mhu10	HU value below which 10% of voxels fall	Num	8	
mhu15	HU value below which 15% of voxels fall	Num	8	
mhu20	HU value below which 20% of voxels fall	Num	8	
mkint	Knee intercept	Num	8	
mknee	See IAC Scan Analysis variables listing	Num	8 8	
mkslp mkurt	See IAC Scan Analysis variables listing Kurtosis	Num Num	° 8	
mmean	Mean	Num	8	
mmed	Median	Num	8	
msd	Standard deviation	Num	8	
mskew	Skewness	Num	8	
mtisv	Region vol that is tissue & blood(ml)	Num	8	
mtotv	Total volume of region (cubic ml)	Num	8	
mtotvx mvar	Total number of voxels in a region Variance	Num Num	8 8	
newnett	New NETT patient ID no.	Char	5	
passver	non herr pactone is not	Char	13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
slicethi	Slice thickness	Char	14	
tisv totv	Region vol that is tissue & blood(ml) Total volume of region (cubic ml)	Num Num	8 8	
totvx	Total number of voxels in a region	Num	8	
uae50	No. of voxels above -50 HU in a region	Num	8	
uae100	No. of voxels above -100 HU in a region	Num	8	
uae150	No. of voxels above -150 HU in a region	Num	8	
uae200	No. of voxels above -200 HU in a region	Num	8	
uae250 uaint	No. of voxels above -250 HU in a region Ankle intercept	Num Num	8 8	
uairv	Volume of region that is air (ml)	Num	8	
uankl	Ankle	Num	8	
uaslp	Ankle slope	Num	8	
ube600	No. of voxels below -600 HU in a region	Num	8	
ube620	No. of voxels below -620 HU in a region	Num	8	
ube640	No. of voxels below -640 HU in a region	Num	8	
ube660 ube810	No. of voxels below -660 HU in a region No. of voxels below -810 HU in a region	Num Num	8 8	
ube810 ube830	No. of voxels below -830 HU in a region	Num	° 8	
ube850	No. of voxels below -850 HU in a region	Num	8	
ube870	No. of voxels below -870 HU in a region	Num	8	
ube890	No. of voxels below -890 HU in a region	Num	8	
ube900	No. of voxels below -900 HU in a region	Num	8	

LCORE	- IAC left lung core file			
Date file Observat Variables				
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ube910	No. of voxels below -910 HU in a region	Num	8	
ube920	No. of voxels below -920 HU in a region	Num	8	
ube930	No. of voxels below -930 HU in a region	Num	8	
ube940	No. of voxels below -940 HU in a region	Num	8	
ube950	No. of voxels below -950 HU in a region	Num	8	
ube960	No. of voxels below -960 HU in a region	Num	8	
ucvm	See IAC Scan Analysis variables listing	Num	8	
ucvsd	See IAC Scan Analysis variables listing	Num	8	
ucvxm	See IAC Scan Analysis variables listing	Num	8	
ucvxsd	See IAC Scan Analysis variables listing	Num	8	
ucvym	See IAC Scan Analysis variables listing	Num	8	
ucvysd	See IAC Scan Analysis variables listing	Num	8	
ucvzm	See IAC Scan Analysis variables listing	Num	8	
ucvzsd	See IAC Scan Analysis variables listing	Num	8	
ufwhm	See IAC Scan Analysis variables listing	Num	8	
uhu10	HU value below which 10% of voxels fall	Num	8	
uhu15	HU value below which 15% of voxels fall	Num	8	
uhu20	HU value below which 20% of voxels fall	Num	8	
ukint	Knee intercept	Num	8	
uknee	See IAC Scan Analysis variables listing	Num	8	
ukslp	See IAC Scan Analysis variables listing	Num	8	
ukurt	Kurtosis	Num	8	
umean	Mean	Num	8	
umed	Median	Num	8	
usd	Standard deviation	Num	8	
uskew	Skewness	Num	8	
utisv	Region vol that is tissue & blood(ml)	Num	8	
utotv	Total volume of region (cubic ml)	Num	8	
utotvx	Total number of voxels in a region	Num	8	
uvar	Variance	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

LHOLE -	IAC left lung holes file			
Date file cr Observations Variables:				
Variable Name	Variable Label	Туре	Variable Length	Format
Name alpha_1 alpha_2 alpha_3 alpha_4 alpha_5 alpha_6 cl_1 cl_2 cl_3 cl_4 cl_5 cl_6 cutoff_1 cutoff_2 cutoff_3 cutoff_4 cutoff_5 cutoff_6 entityve hwcreate intercep lalpha_1 lalpha_2 lalpha_3 lalpha_4 lalpha_5 lalpha_6 lc1_1 lc1_2 lc1_3 lc1_4 cutoff_5 cutoff_6 entityve hwcreate intercep lalpha_3 lalpha_4 lalpha_5 lalpha_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lc1_1 lc1_5 lc1_6 lc1_1 lc1_2 lc1_3 lc1_4 lc1_5 lc1_6 lcutoff1 lcutoff2 lcutoff3 lcutoff4 lcutoff5 lcuto	At -950, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list Y intercept at -950 Y intercept at -970 Y intercept at -970 Y intercept at -870 Y intercept at -870 At -950, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -950, see IAC Scan Analysis vbl list At -950, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list At -950, see IAC Scan Analysis vbl list At -950, see IAC Scan Analysis vbl list At -950, see IAC Scan Analysis vbl list	Num Num Num Num Num Num Num Num Num Num	Length  8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	Format
malpha_5 malpha_6 mc1_1 mc1_2 mc1_3 mc1_4	At -890, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list Y intercept at -950 Y intercept at -930 Y intercept at -910 Y intercept at -890	Num Num Num Num Num Num	8 8 8 8 8 8 8 8	
<pre>mc1_6 mcutoff1 mcutoff2 mcutoff3 mcutoff4 mcutoff5</pre>	Y intercept at -870 Y intercept at -850 At -950, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list At -890, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list	Num Num Num Num Num Num Num	8 8 8 8 8 8 8 8 8	

LHOLE IAC left lung holes file -

ucutoff3

ucutoff4

ucutoff5

ucutoff\_

Voxel size

visit

vxsize

	-	
Date file Observatio Variables:	created: 13 May 2006 ns: 2236 82	
Variable Name	Variable Label	Туре
newnett passver scandate slicethi	New NETT patient ID no. scandate cnvrtd to #days frm RZ/scr strt Slice thickness	Char Char Num Char
ualpha_1	At -950, see IAC Scan Analysis vbl list	Num
ualpha_2	At -930, see IAC Scan Analysis vbl list	Num
ualpha_3	At -910, see IAC Scan Analysis vbl list	Num
ualpha_4	At -890, see IAC Scan Analysis vbl list	Num
ualpha_5	At -870, see IAC Scan Analysis vbl list	Num
ualpha_6	At -850, see IAC Scan Analysis vbl list	Num
uc1_1	Y intercept at -950	Num
uc1_2	Y intercept at -930	Num
uc1_3	Y intercept at -910	Num
uc1_4	Y intercept at -890	Num
uc1_5	Y intercept at -870	Num
uc1_6	Y intercept at -850	Num
ucutoff1	At -950, see IAC Scan Analysis vbl list	Num
ucutoff2	At -930, see IAC Scan Analysis vbl list	Num

At -910, see IAC Scan Analysis vbl list

At -890, see IAC Scan Analysis vbl list

At -870, see IAC Scan Analysis vbl list At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ

Variable

Length

5

8

8

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8

8 8

8

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8

8

8

8 3

8

Num

Num

Num

Num

Char

Num

13

14

Format

LPEEL IAC left lung peel file -Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format ae50 No. of voxels above -50 HU in a region Num 8 ae100 No. of voxels above -100 HU in a region Num 8 ae150 No. of voxels above -150 HU in a region Num 8 ae200 No. of voxels above -200 HU in a region 8 Num ae250 No. of voxels above -250 HU in a region Num 8 aint Ankle intercept Num 8 airv Volume of region that is air (ml) Num 8 ankl Ankle Num 8 aslp Ankle slope Num 8 No. of voxels below -600 HU in a region be600 Nıım 8 No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region be620 Num 8 be640 Num 8 No. of voxels below -660 HU in a region be660 Num 8 be810 No. of voxels below -810 HU in a region Num 8 No. of voxels below -830 HU in a region be830 Num 8 be850 No. of voxels below -850 HU in a region Num 8 be870 No. of voxels below -870 HU in a region Num 8 No. of voxels below -890 HU in a region be890 Num 8 No. of voxels below -900 HU in a region be900 Num 8 No. of voxels below -910 HU in a region be910 Num 8 be920 No. of voxels below -920 HU in a region Num 8 No. of voxels below -930 HU in a region be930 Num 8 No. of voxels below -940 HU in a region be940 Num 8 No. of voxels below -950 HU in a region be950 Num 8 be960 No. of voxels below -960 HU in a region Num 8 ccutoff See IAC Scan Analysis variables listing Num 8 cvm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 cvsd See IAC Scan Analysis variables listing CVXM Num 8 See IAC Scan Analysis variables listing cvxsd Num 8 See IAC Scan Analysis variables listing Num 8 CVVM cvysd See IAC Scan Analysis variables listing Nıım 8 cvzm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing cvzsd Num 8 entityve Histogram pgm version number Char 18 fwhm See IAC Scan Analysis variables listing Nıım 8 histolef Num 8 hlcreate cnvrtd to #days frm RZ/scr strt hlcreate Num 8 hu10 HU value below which 10% of voxels fall Num 8 HU value below which 15% of voxels fall hu15 Nıım 8 hu20 HU value below which 20% of voxels fall Num 8 intercep Value used to convert voxels into HU Num 8 8 Knee intercept Num kint knee See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing kslp Num 8 kurt Kurtosis Nıım 8 lae50 No. of voxels above -50 HU in a region Nıım 8 lae100 No. of voxels above -100 HU in a region Num 8 lae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region No. of voxels above -250 HU in a region lae200 8 Num lae250 Num 8 laint Ankle intercept Num 8 lairv Volume of region that is air (ml) Num 8 8 lankl Ankle Num Ankle slope laslp Num 8 1be600 No. of voxels below -600 HU in a region Num 8 No. of voxels below -620 HU in a region 1be620 8 Num lbe640 No. of voxels below -640 HU in a region Num 8

LPEEL -	IAC left lung peel file			
Date file o Observatior Variables:	1			
Variable Name	Variable Label	Туре	Variable Length	Format
lbe660	No. of voxels below -660 HU in a region	Num	8	
lbe810	No. of voxels below -810 HU in a region	Num	8	
lbe830	No. of voxels below -830 HU in a region	Num	8	
lbe850 lbe870	No. of voxels below -850 HU in a region No. of voxels below -870 HU in a region	Num Num	8 8	
1be890	No. of voxels below -890 HU in a region	Num	8	
lbe900	No. of voxels below -900 HU in a region	Num	8	
lbe910	No. of voxels below -910 HU in a region	Num	8	
lbe920	No. of voxels below -920 HU in a region	Num	8	
lbe930	No. of voxels below -930 HU in a region	Num	8	
lbe940	No. of voxels below -940 HU in a region No. of voxels below -950 HU in a region	Num	8	
lbe950 lbe960	No. of voxels below -950 HU in a region	Num Num	8 8	
lcvm	See IAC Scan Analysis variables listing	Num	8	
lcvsd	See IAC Scan Analysis variables listing	Num	8	
lcvxm	See IAC Scan Analysis variables listing	Num	8	
lcvxsd	See IAC Scan Analysis variables listing	Num	8	
lcvym	See IAC Scan Analysis variables listing	Num	8	
lcvysd	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num	8	
lcvzm lcvzsd	See IAC Scan Analysis variables listing	Num Num	8 8	
lfwhm	See IAC Scan Analysis variables listing	Num	8	
lhu10	HU value below which 10% of voxels fall	Num	8	
lhu15	HU value below which 15% of voxels fall	Num	8	
lhu20	HU value below which 20% of voxels fall	Num	8	
lkint	Knee intercept	Num	8	
lknee	See IAC Scan Analysis variables listing	Num Num	8	
lkslp lkurt	See IAC Scan Analysis variables listing Kurtosis	Num	8 8	
lmean	Mean	Num	8	
lmed	Median	Num	8	
lsd	Standard deviation	Num	8	
lskew	Skewness	Num	8	
ltisv	Region vol that is tissue & blood(ml)	Num	8	
ltotv ltotvx	Total volume of region (cubic ml)	Num Num	8 8	
lvar	Total number of voxels in a region Variance	Num	8	
mae50	No. of voxels above -50 HU in a region	Num	8	
mae100	No. of voxels above -100 HU in a region	Num	8	
mae150	No. of voxels above -150 HU in a region	Num	8	
mae200	No. of voxels above -200 HU in a region	Num	8	
mae250	No. of voxels above -250 HU in a region	Num	8 8	
maint mairv	Ankle intercept Volume of region that is air (ml)	Num Num	8	
mankl	Ankle	Num	8	
maslp	Ankle slope	Num	8	
mbe600	No. of voxels below -600 HU in a region	Num	8	
mbe620	No. of voxels below -620 HU in a region	Num	8	
mbe640	No. of voxels below -640 HU in a region No. of voxels below -660 HU in a region	Num	8	
mbe660 mbe810	No. of voxels below -810 HU in a region	Num Num	8 8	
mbe830	No. of voxels below -830 HU in a region	Num	8	
mbe850	No. of voxels below -850 HU in a region	Num	8	
mbe870	No. of voxels below -870 HU in a region	Num	8	
mbe890	No. of voxels below -890 HU in a region	Num	8	
mbe900	No. of voxels below -900 HU in a region	Num	8	
mbe910 mbe920	No. of voxels below -910 HU in a region No. of voxels below -920 HU in a region	Num Num	8 8	
11106320	NO. OF VOXETS DETOW -920 HU IN a region	NUIII	ŏ	

LPEEL -	IAC left lung peel file			
Date file o Observatior Variables:				
Variable Name	Variable Label	Туре	Variable Length	Format
mbe930	No. of voxels below -930 HU in a region	Num	8	
mbe940	No. of voxels below -940 HU in a region	Num	8	
mbe950 mbe960	No. of voxels below -950 HU in a region	Num	8	
mcvm	No. of voxels below -960 HU in a region See IAC Scan Analysis variables listing	Num Num	8 8	
mcvsd	See IAC Scan Analysis variables listing	Num	8	
mcvxm	See IAC Scan Analysis variables listing	Num	8	
mcvxsd	See IAC Scan Analysis variables listing	Num	8	
mcvym	See IAC Scan Analysis variables listing	Num	8	
mcvysd	See IAC Scan Analysis variables listing	Num	8	
mcvzm	See IAC Scan Analysis variables listing	Num	8	
mcvzsd mean	See IAC Scan Analysis variables listing Mean	Num Num	8 8	
med	Median	Num	8	
mfwhm	See IAC Scan Analysis variables listing	Num	8	
mhu10	HU value below which 10% of voxels fall	Num	8	
mhu15	HU value below which 15% of voxels fall	Num	8	
mhu20	HU value below which 20% of voxels fall	Num	8	
mkint	Knee intercept	Num	8	
mknee	See IAC Scan Analysis variables listing	Num	8 8	
mkslp mkurt	See IAC Scan Analysis variables listing Kurtosis	Num Num	8	
mmean	Mean	Num	8	
mmed	Median	Num	8	
msd	Standard deviation	Num	8	
mskew	Skewness	Num	8	
mtisv	Region vol that is tissue & blood(ml)	Num	8	
mtotv	Total volume of region (cubic ml)	Num	8	
mtotvx mvar	Total number of voxels in a region Variance	Num Num	8 8	
newnett	New NETT patient ID no.	Char	5	
passver	non herr pactone is not	Char	13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
slicethi	Slice thickness	Char	14	
tisv totv	Region vol that is tissue & blood(ml) Total volume of region (cubic ml)	Num Num	8 8	
totvx	Total number of voxels in a region	Num	8	
uae50	No. of voxels above -50 HU in a region	Num	8	
uae100	No. of voxels above -100 HU in a region	Num	8	
uae150	No. of voxels above -150 HU in a region	Num	8	
uae200	No. of voxels above -200 HU in a region	Num	8	
uae250 uaint	No. of voxels above -250 HU in a region Ankle intercept	Num Num	8 8	
uairv	Volume of region that is air (ml)	Num	8	
uankl	Ankle	Num	8	
uaslp	Ankle slope	Num	8	
ube600	No. of voxels below -600 HU in a region	Num	8	
ube620	No. of voxels below -620 HU in a region	Num	8	
ube640	No. of voxels below -640 HU in a region	Num	8	
ube660 ube810	No. of voxels below -660 HU in a region No. of voxels below -810 HU in a region	Num	8 8	
ube810 ube830	No. of voxels below -810 HU in a region	Num Num	8	
ube850	No. of voxels below -850 HU in a region	Num	8	
ube870	No. of voxels below -870 HU in a region	Num	8	
ube890	No. of voxels below -890 HU in a region	Num	8	
ube900	No. of voxels below -900 HU in a region	Num	8	

LPEEL -	IAC left lung peel file			
Date file c Observation Variables:				
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ube910	No. of voxels below -910 HU in a region	Num	8	
ube920	No. of voxels below -920 HU in a region	Num	8	
ube930	No. of voxels below -930 HU in a region	Num	8	
ube940	No. of voxels below -940 HU in a region	Num	8	
ube950	No. of voxels below -950 HU in a region	Num	8	
ube960	No. of voxels below -960 HU in a region	Num	8	
ucvm	See IAC Scan Analysis variables listing	Num	8	
ucvsd	See IAC Scan Analysis variables listing	Num	8	
ucvxm	See IAC Scan Analysis variables listing	Num	8	
ucvxsd	See IAC Scan Analysis variables listing	Num	8	
ucvym	See IAC Scan Analysis variables listing	Num	8	
ucvysd	See IAC Scan Analysis variables listing	Num	8	
ucvzm	See IAC Scan Analysis variables listing	Num	8	
ucvzsd	See IAC Scan Analysis variables listing	Num	8	
ufwhm	See IAC Scan Analysis variables listing	Num	8	
uhu10	HU value below which 10% of voxels fall	Num	8	
uhu15	HU value below which 15% of voxels fall	Num	8	
uhu20	HU value below which 20% of voxels fall	Num	8	
ukint	Knee intercept	Num	8	
uknee	See IAC Scan Analysis variables listing	Num	8	
ukslp	See IAC Scan Analysis variables listing	Num	8	
ukurt	Kurtosis	Num	8	
umean	Mean	Num	8	
umed	Median	Num	8	
usd	Standard deviation	Num	8	
uskew	Skewness	Num	8	
utisv	Region vol that is tissue & blood(ml)	Num	8	
utotv	Total volume of region (cubic ml)	Num	8	
utotvx	Total number of voxels in a region	Num	8	
uvar	Variance	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

LVER2 IAC left lung ver2 file \_ Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format ae50 No. of voxels above -50 HU in a region Num 8 ae100 No. of voxels above -100 HU in a region Num 8 ae150 No. of voxels above -150 HU in a region Num 8 ae200 No. of voxels above -200 HU in a region 8 Num ae250 No. of voxels above -250 HU in a region Num 8 aint Ankle intercept Num 8 airv Volume of region that is air (ml) Num 8 ankl Ankle Num 8 aslp Ankle slope Num 8 No. of voxels below -600 HU in a region be600 Nıım 8 No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region be620 Num 8 be640 Num 8 No. of voxels below -660 HU in a region be660 Num 8 be810 No. of voxels below -810 HU in a region Num 8 No. of voxels below -830 HU in a region be830 Num 8 be850 No. of voxels below -850 HU in a region Num 8 be870 No. of voxels below -870 HU in a region Num 8 No. of voxels below -890 HU in a region be890 Num 8 No. of voxels below -900 HU in a region be900 Num 8 No. of voxels below -910 HU in a region be910 Num 8 be920 No. of voxels below -920 HU in a region Num 8 No. of voxels below -930 HU in a region be930 Num 8 No. of voxels below -940 HU in a region be940 Num 8 No. of voxels below -950 HU in a region Num be950 8 be960 No. of voxels below -960 HU in a region Num 8 ccutoff See IAC Scan Analysis variables listing Num 8 cvm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 cvsd See IAC Scan Analysis variables listing CVXM Num 8 See IAC Scan Analysis variables listing cvxsd Num 8 See IAC Scan Analysis variables listing Num 8 CVVM cvysd See IAC Scan Analysis variables listing Nıım 8 cvzm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing cvzsd Num 8 entityve Histogram pgm version number Char 18 fwhm See IAC Scan Analysis variables listing Nıım 8 histolef Num 8 hlcreate Num 8 hlcreate cnvrtd to #days frm RZ/scr strt hu10 HU value below which 10% of voxels fall Num 8 hu15 HU value below which 15% of voxels fall Nıım 8 hu20 HU value below which 20% of voxels fall Num 8 intercep Value used to convert voxels into HU Num 8 8 Knee intercept Num kint knee See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing kslp Num 8 kurt Kurtosis Nıım 8 lae50 No. of voxels above -50 HU in a region Nıım 8 lae100 No. of voxels above -100 HU in a region Num 8 lae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region No. of voxels above -250 HU in a region lae200 8 Num lae250 Num 8 laint Ankle intercept Num 8 lairv Volume of region that is air (ml) Num 8 8 lankl Ankle Num laslp Ankle slope Num 8 1be600 No. of voxels below -600 HU in a region Num 8 No. of voxels below -620 HU in a region 1be620 8 Num lbe640 No. of voxels below -640 HU in a region Num 8

LVER2 - IAC left lung ver2 file

Date	file	created:	13	May	2006
Observations:					2236
Variables:					207

Variable Name	Variable Label	Туре	Variable Length	Format
lbe660	No. of voxels below -660 HU in a region	Num	8	
lbe810	No. of voxels below -810 HU in a region	Num	8	
1be830	No. of voxels below -830 HU in a region	Num	8	
1be850	No. of voxels below -850 HU in a region	Num	8	
1be870	No. of voxels below -870 HU in a region	Num	8	
lbe890	No. of voxels below -890 HU in a region	Num	8	
lbe900	No. of voxels below -900 HU in a region	Num	8	
lbe910	No. of voxels below -910 HU in a region	Num	8	
lbe920	No. of voxels below -920 HU in a region	Num	8	
lbe930	No. of voxels below -930 HU in a region	Num	8	
lbe940	No. of voxels below -940 HU in a region	Num	8	
lbe950	No. of voxels below -950 HU in a region	Num	8	
lbe960	No. of voxels below -960 HU in a region	Num	8	
lcvm	See IAC Scan Analysis variables listing	Num	8	
lcvsd	See IAC Scan Analysis variables listing	Num	8	
lcvxm	See IAC Scan Analysis variables listing	Num	8	
lcvxsd	See IAC Scan Analysis variables listing	Num	8	
lcvym	See IAC Scan Analysis variables listing	Num	8	
lcvysd lcvzm	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num Num	8 8	
lcvzsd	See IAC Scan Analysis variables listing	Num	8	
lfwhm	See IAC Scan Analysis variables listing	Num	8	
lhu10	HU value below which 10% of voxels fall	Num	8	
lhu15	HU value below which 15% of voxels fall	Num	8	
lhu20	HU value below which 20% of voxels fall	Num	8	
lkint	Knee intercept	Num	8	
lknee	See IAC Scan Analysis variables listing	Num	8	
lkslp	See IAC Scan Analysis variables listing	Num	8	
lkurt	Kurtosis	Num	8	
lmean	Mean	Num	8	
lmed	Median	Num	8	
lsd	Standard deviation	Num	8	
lskew	Skewness	Num	8	
ltisv	Region vol that is tissue & blood(ml)	Num	8	
ltotv	Total volume of region (cubic ml)	Num	8	
ltotvx	Total number of voxels in a region	Num	8	
lvar mae50	Variance No. of voxels above -50 HU in a region	Num Num	8 8	
mae100	No. of voxels above -100 HU in a region	Num	8	
mae150	No. of voxels above -150 HU in a region	Num	8	
mae200	No. of voxels above -200 HU in a region	Num	8	
mae250	No. of voxels above -250 HU in a region	Num	8	
maint	Ankle intercept	Num	8	
mairv	Volume of region that is air (ml)	Num	8	
mankl	Ankle	Num	8	
maslp	Ankle slope	Num	8	
mbe600	No. of voxels below -600 HU in a region	Num	8	
mbe620	No. of voxels below -620 HU in a region	Num	8	
mbe640	No. of voxels below -640 HU in a region	Num	8	
mbe660	No. of voxels below -660 HU in a region	Num	8	
mbe810	No. of voxels below -810 HU in a region	Num	8	
mbe830	No. of voxels below -830 HU in a region	Num	8	
mbe850	No. of voxels below -850 HU in a region	Num	8	
mbe870 mbe890	No. of voxels below -870 HU in a region No. of voxels below -890 HU in a region	Num	8 8	
mbe900	No. of voxels below -890 HU in a region	Num Num	8	
mbe910	No. of voxels below -910 HU in a region	Num	8	
mbe920	No. of voxels below -920 HU in a region	Num	8	
			ũ	

LVER2 IAC left lung ver2 file \_ Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Length Format Type mbe930 No. of voxels below -930 HU in a region Num 8 mbe940 No. of voxels below -940 HU in a region Num 8 mbe950 No. of voxels below -950 HU in a region 8 Num mbe960 No. of voxels below -960 HU in a region 8 Num mcvm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing mcvsd Num 8 See IAC Scan Analysis variables listing Num 8 mcvxm See IAC Scan Analysis variables listing Num 8 mcvxsd mcvvm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Nıım mcvysd 8 See IAC Scan Analysis variables listing mcvzm Num 8 See IAC Scan Analysis variables listing mcvzsd Num 8 mean Mean Num 8 med Median Num 8 mfwhm See IAC Scan Analysis variables listing Num 8 mhu10 HU value below which 10% of voxels fall Num 8 mhu15 HU value below which 15% of voxels fall Num 8 HU value below which 20% of voxels fall mhu20 Num 8 mkint Knee intercept Num 8 mknee See IAC Scan Analysis variables listing Num 8 mkslp See IAC Scan Analysis variables listing Nıım 8 Kurtosis mkurt Num 8 mmean Mean Num 8 mmed Median Num 8 Standard deviation msd Num 8 Skewness 8 mskew Num mtisv Region vol that is tissue & blood(ml) 8 Nıım Total volume of region (cubic ml) Num 8 mt.ot.v Total number of voxels in a region mtotvx Num 8 mvar Variance Num 8 newnett New NETT patient ID no. Char 5 passver Char 13 scandate cnvrtd to #days frm RZ/scr strt scandate Num 8 Standard deviation sd Num 8 Skewness skew Nıım 8 slicethi Slice thickness Char 14 tisv Region vol that is tissue & blood(ml) Num 8 totv Total volume of region (cubic ml) Num 8 totvx Total number of voxels in a region Num 8 No. of voxels above -50 HU in a region 11ae50 Nıım 8 No. of voxels above -100 HU in a region uae100 Num 8 uae150 No. of voxels above -150 HU in a region Num 8 uae200 No. of voxels above -200 HU in a region 8 Num uae250 No. of voxels above -250 HU in a region Num 8 Ankle intercept uaint Num 8 Volume of region that is air (ml) uairv Nıım 8 Ankle uankl Nıım 8 uaslp Ankle slope Num 8 ube600 No. of voxels below -600 HU in a region 8 Num No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region ube620 8 Num 11be640 Num 8 No. of voxels below -660 HU in a region ube660 Num 8 ube810 No. of voxels below -810 HU in a region Num 8 ube830 No. of voxels below -830 HU in a region Num 8 No. of voxels below -850 HU in a region No. of voxels below -870 HU in a region ube850 Num 8 ube870 Num 8 No. of voxels below -890 HU in a region ube890 8 Num No. of voxels below -900 HU in a region ube900 Num 8

LVER2 -	IAC left lung ver2 file			
Date file o Observation Variables:	1			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ube910	No. of voxels below -910 HU in a region	Num	8	
ube920	No. of voxels below -920 HU in a region	Num	8	
ube930	No. of voxels below -930 HU in a region	Num	8	
ube940	No. of voxels below -940 HU in a region	Num	8	
ube950	No. of voxels below -950 HU in a region	Num	8	
ube960	No. of voxels below -960 HU in a region	Num	8	
ucvm	See IAC Scan Analysis variables listing	Num	8	
ucvsd	See IAC Scan Analysis variables listing	Num	8	
ucvxm	See IAC Scan Analysis variables listing	Num	8	
ucvxsd	See IAC Scan Analysis variables listing	Num	8	
ucvym	See IAC Scan Analysis variables listing	Num	8	
ucvysd	See IAC Scan Analysis variables listing	Num	8	
ucvzm	See IAC Scan Analysis variables listing	Num	8	
ucvzsd	See IAC Scan Analysis variables listing	Num	8	
ufwhm	See IAC Scan Analysis variables listing	Num	8	
uhu10	HU value below which 10% of voxels fall	Num	8	
uhu15	HU value below which 15% of voxels fall	Num	8	
uhu20	HU value below which 20% of voxels fall	Num	8	
ukint	Knee intercept	Num	8	
uknee	See IAC Scan Analysis variables listing	Num	8	
ukslp	See IAC Scan Analysis variables listing	Num	8	
ukurt	Kurtosis	Num	8	
umean	Mean	Num	8	
umed	Median	Num	8	
usd	Standard deviation	Num	8	
uskew	Skewness	Num	8	
utisv	Region vol that is tissue & blood(ml)	Num	8	
utotv	Total volume of region (cubic ml)	Num	8	
utotvx	Total number of voxels in a region	Num	8	
uvar	Variance	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

MM - Form MM 6 Minute Walk Test (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			7031
Varia	ables:	:			27

Variable			Variable	
Name	Variable Label	Туре	Length	Format
dist ft	6MW distance (feet)	Num	8	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr strt	Num	8	
mm207	Day 1 or Day 2, unused after 21May99	Char	1	
mm307	7 Resting & walking O2 titration done	Char	1	
mm308	8 Two hours or more since last meal	Char	1	
mm309	9 Bronchodilator taken in past 4 hours	Char	1	
mm310	10 Patient rested for 10 minutes	Char	1	
mm311	11 O2 used during 6 minute walk test	Char	1	
mm312	12 Walking oxygen requirement	Char	2	
mm315	15 Total duration of test (min)	Char	2	
mm316	16 Item 15 equal to 6.0	Char	1	
mm317	17 Borg scale-perceived breathlessness	Char	3 3	
mm318	18 Borg scale-perceived leg muscle fati	Char	3	
mm320	20 S1, S2, S3 or RZ assessment	Char	1	
mm321	21 Other reason for ineligibility?	Char	1	
mm319a	19a Test lasted 6 minutes	Char	1	
mm319b	19b Chest pain	Char	1	
mm319c	19c Near syncope	Char	1	
mm319d	19d Ataxic gait	Char	1	
mm319e	19e Lower extremity claudication	Char	1	
mm319f	19f Mental confusion	Char	1	
mm319g	19g Patient refused to continue	Char	1	
mm319h	19h Staff request	Char	1	
mm319i	19i Other	Char	1	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

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**Purpose** Guide tester in performing 6 minute walk testing and record data as obtained.

When: Visits s1, s2 (if the s1 6 minute walk test was done more than 42 days prior to the start of Core Rehabilitation), s3, rz (if more than 21 days after the s3 6 minute walk), f06, f12, and f24.

Administered by: O<sub>2</sub> Titration/6 Minute Walk Tester.

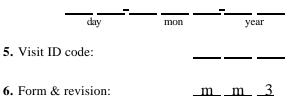
**Instructions**: You should have the patient's oxygen titration results (Form MO), a stop watch, portable oxygen delivery system (nasal cannula), meter stick or tape measure, and NETT Flash Cards #8 and 9 available. If the walk is done in a corridor, you need to assure that traffic in the corridor will not interfere with the test. Resting and walking oxygen titration assessments should have been completed prior to 6 minute walk testing. The patient should rest for 10 minutes prior to starting the 6 minute walk. During the 6 minute walk the patient will use the oxygen prescription resulting from the NETT oxygen titration assessment. The patient should have taken a shortacting bronchodilator within 4 hours of testing and at least 2 hours should have elapsed since the patient last ate a meal. The patient should wear loose fitting clothes and comfortable shoes. If the patient does not complete the walk satisfactorily, the patient may try again, but only one Form MM can be keyed for each visit.



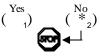
- 1. Clinic ID:
- 2. Patient ID:

3. Patient name code: \_\_\_\_\_

**4.** Visit date (*date of walk*):



- **B.** Checks on patient condition
  - **7.** Did the resting and walking oxygen titration assessments have normal terminations:



(\*These assessments must have normal terminations for patient to proceed with the 6 minute walk test.)

**8.** Has it been at least 2 hours since the patient ate a meal:



(\*Wait until it has been at least 2 hours since the patient last ate a meal; then check Yes and proceed with testing.)

**9.** Has the patient taken a short-acting bronchodilator within 4 hours:



(\*Administer short-acting bronchodilator; and then check Yes and proceed with testing after 15 minutes.)

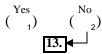
**10.** Has the patient rested for 10 minutes:



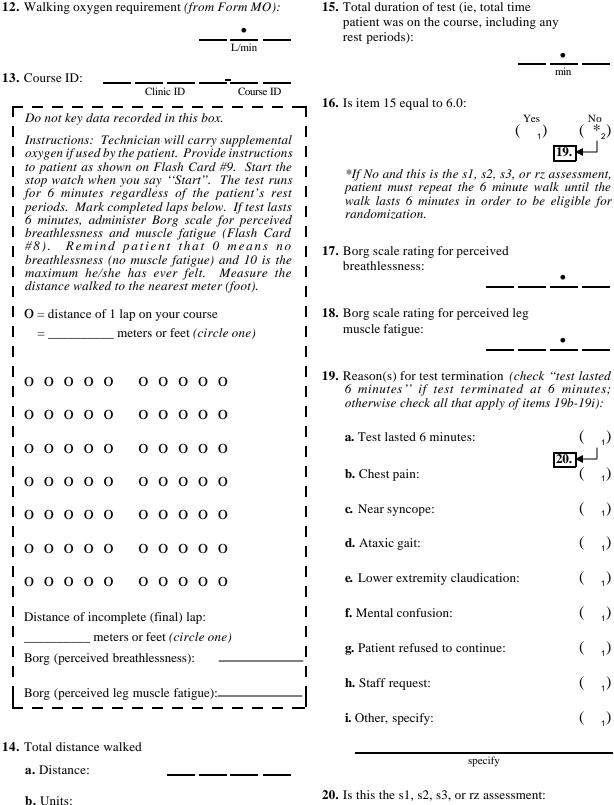
(\*After patient has rested for 10 minutes, check Yes and proceed with testing.)

#### C. 6 minute walk test

**11.** Will the patient use oxygen during the 6 minute walk test:



**12.** Walking oxygen requirement (*from Form MO*):



min

Patient ID:

Meters

Feet

1)

,)

1)

<sub>1</sub>)

₁)

<sub>1</sub>)

₁)

<sub>1</sub>)

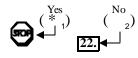
<sub>1</sub>)

(1)

22.

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**21.** Is there any reason to declare the patient ineligible for NETT based on this assessment:



specify reason for ineligibility

(\*Complete section D, Administrative information. The patient is ineligible for NETT.)

#### **D.** Administrative information

**22.** O<sub>2</sub> Titration/6 Minute Walk Tester PIN:

**23.** O<sub>2</sub> Titration/6 Minute Walk Tester signature:

**24.** Clinic Coordinator PIN:

**25.** Clinic Coordinator signature:

**26.** Date form reviewed:

day mon year

MO - Form MO Oxygen Titration (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			5873
Varia	ables:	:			31

Variable			Variable	
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr strt	Num	8	
mo308	8 At least 2 hours since last meal	Char	1	
mo309	9 Short-acting bronchodilator in past	Char	1	
mo310	10 Pulse oximeter model	Char	1	
mo311	11 Pulse oximeter ECG-gated	Char	1	
mo312	12 Pulse oximeter probe site	Char	1	
mo313	13 SpO2 at end of resting titration (%)	Char	3	
mo314	14 Heart rate at end of resting titrati	Char	3	
mo315	15 Oxygen required at end of titration	Char	1	
mo316	16 Resting oxygen requirement	Char	2	
mo317	17 Reason for ending resting titration	Char	1	
mo318	18 O2 titration being done on same day	Char	1	
mo319	19 Treadmill speed for Part 1	Char	1	
mo320	20 Duration of Part 1 (<= 1 mph walk)	Char	2	
mo321	21 Lowest SpO2 in last minute	Char	3	
mo322	22 Heart rate linked to SpO2	Char	3	
mo323	23 O2 flow rate linked to SpO2	Char	2	
mo324	24 Reason for terminating Part 1	Char	1	
mo325	25 Part 1: Borg-perceived breathlessnes	Char	3	
mo326	26 Part 1: Borg-perceived leg muscle fa	Char	3	
mo327	27 Part 2 attempted	Char	1	
mo328	28 Treadmill speed for Part 2	Char	1	
mo329	29 Duration of Part 2	Char	1	
mo330	30 SpO2 at end of Part 2	Char	3	
mo331	31 O2 flow rate at end of Part 2	Char	2	
mo332	32 Reason for terminating Part 2	Char	1	
mo333	33 Patient can do 6min walk on 6L/min O	Char	1	
mo334	34 O2 prescription for 6 minute walk	Char	2	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## NETT

### **Oxygen Titration**

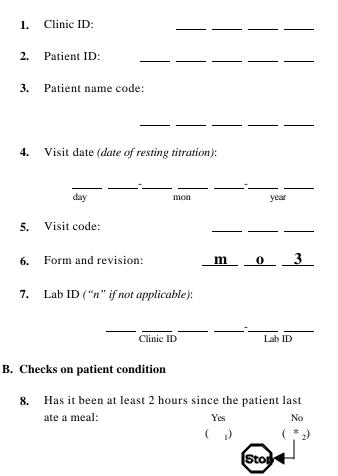
Purpose: Guide tester in performing resting and walking oxygen titration assessments and record data as obtained.When: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to start of Core Rehabilitation), s3, rz (if more than 21 days since post rehabilitation assessment), f06, f12, and f24.

Administered by: O<sub>2</sub> Titration/6 Minute Walk Tester.

**Instructions:** Resting and walking oxygen titration assessments are done prior to the six minute walk. The patient should have taken a short-acting bronchodilator within 4 hours of testing, should not have eaten a meal within 2 hours of testing, and should be wearing loose fitting clothes and comfortable shoes. Fill in your alphabetic clinic ID code in the first part of item 7. If the titration is done in your pulmonary function lab, write in the lab's ID code in the second part of item 7. If the assessment is done elsewhere, enter "n" in the second part of item 7. If your pulse oximeter prints a report, mark the report with the patient's ID number and name code and attach the report to this form. The Part 2 walking titration is optional. If the patient does not do the Part 2 walk, the patient will use the oxygen flow in use at the end of Part 1 walk for the 6 minute walk.

#### A. Clinic, visit, and patient identification

#### C. Resting oxygen titration



(\*Wait until it has been at least 2 hours since the patient last ate a meal; then check Yes and proceed with testing.) **9.** Has the patient taken a short-acting bronchodilator within 4 hours:



) keved

(\*Administer short-acting bronchodilator; and then check "Yes" and proceed with testing after 15 minutes.)

**10.** Pulse oximeter manufacturer/model:

Criticare 504 USP	(	<sub>1</sub> )
Nellcor N200	(	2)
Ohmeda Biox 3740	(	3)
Sensormedic 767501-102	(	<sub>4</sub> )
Other (specify):	(	<sub>5</sub> )

manufacturer/model

11.	Is pulse oximeter ECG-gated:	Yes	No
		( <sub>1</sub> )	( <sub>2</sub> )

**12.** Pulse oximeter probe site:

Finger Ear	(	1)
Forehead	(	2) 3)
Other (specify):	(	4)

probe site

# NETT

**Instructions:** The patient should be seated and instructed not to talk. Oxygen should be stopped. Start oxygen (nasal cannula only) if (a) SpO<sub>2</sub> is 85% or less at any time or (b) SpO<sub>2</sub> < 90% after 5 minutes on room air. If oxygen is started, increase oxygen in 1 L/min increments until SpO<sub>2</sub> just exceeds 90%; terminate the resting titration once SpO<sub>2</sub> exceeds 90% and is stable for 1 minute. If oxygen is not started and SpO<sub>2</sub> is 90% or more after 5 minutes on room air, the resting titration is over. At end of titration, record SpO<sub>2</sub>, heart rate, and oxygen requirement. Terminate the titration if oxygen flow requirement ever exceeds 6 L/min.

#### Resting oxygen titration data:

- **13.** SpO<sub>2</sub> at end of resting titration:
- **14.** Heart rate at end of resting titration:

beats/min

%

**15.** Was the patient on oxygen at the end of titration: Yes No



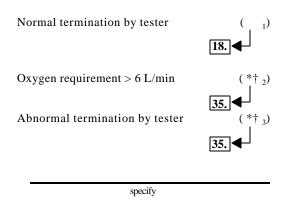
**16.** Resting oxygen requirement at end of resting titration:

L/min

Reasons for terminating resting titration:

17.

Patient ID:



Terminated by patient

specify reason

(\*If this assessment is for s1, s2, s3, or rz, the patient is ineligible for the NETT. Complete Section F.)

(†If this is a followup assessment, the patient may not do the walking titration or the 6 minute walk test. Complete Section F.)

#### D. Walking oxygen titration

18. Is the walking oxygen titration being done on the same day as the resting oxygen titration:
 Yes
 No

Yes No (\_\_1) (\*\_2)

\*If No, explain why not and specify date of walking oxygen titration:

explain

specify date

# NETT

**Instructions:** All patients complete Part 1 of this assessment, treadmill walk at 1 mph or less. Patients who can walk at 1 mph with less than 6 L/min oxygen should attempt to do Part 2 of this assessment, treadmill walk at 2 mph or 3 mph. Part 2 is to be done immediately after Part 1 and should last no longer than 4 additional minutes. Record the lowest SpO<sub>2</sub> observed in each minute and the heart rate and oxygen delivery rate linked with the lowest SpO<sub>2</sub>. Borg scores are recorded only for Part 1 and only if Part 1 terminates normally.

Part 1: Treadmill speed, 1st NETT titration: Begin walk on treadmill at 1 mph. Patients unable to maintain a pace of 1 mph may be titrated downward in the first minute of exertion to a tolerable pace. Treadmill speed, all subsequent NETT titrations: Use treadmill speed used in 1<sup>st</sup> NETT titration. If patient cannot sustain the speed used in the 1<sup>st</sup> NETT titration, a lower speed may be used. All titrations: Initial oxygen flow rate will be that at end of resting titration. Stand patient on the treadmill. If SpO<sub>2</sub> drops below 90%, titrate oxygen to a saturation between 90% and 94% and record saturation in time 0. Patient may keep his/her fingers on the rails to maintain balance but should not grip the rails. Have patient begin walking. If SpO<sub>2</sub> drops below 90%, increase oxygen flow by 1 L/min while patient continues walking. If SpO<sub>2</sub> does not increase to at least 90% within 1 minute, increase oxygen flow by an additional 1 L/min. Adjust oxygen flow by 1 L/min increments to maintain SpO<sub>2</sub> between 90% and 94%. If oxygen flow is incremented to keep  $SpO_2 \ge 90\%$  and that increment results in  $SpO_2 > 94\%$ , you do not need to decrease oxygen flow. Do not adjust oxygen flow with fractional increments. Oxygen flow can be adjusted every minute, or more or less frequently at technician's discretion. Patient may rest at technician's discretion and then continue at the speed and oxygen flow in use when exercise halted. Criteria for termination: Maintenance of SpO<sub>2</sub> at least 90% and no greater than 94% for 3 minutes after last adjustment of oxygen flow (maintenance of  $SpO_2 \ge 90\%$  for at least 3 minutes if oxygen is never started). If titration is terminated normally, administer Borg scale (Flash Card #8) for perceived breathlessness and leg muscle fatigue. Remind patient that 0 means no breathlessness (muscle fatigue) and 10 is the maximum he/she has ever felt. Abnormal termination: Terminate the titration if oxygen requirement exceeds 6 L/min.

**Part 2:** This part is optional. If done, do it immediately after Part 1 (ie, no interruption, patient continues to walk on treadmill). It should last no longer than 4 additional minutes. Within the first minute, increase treadmill speed to 2.0 or 3.0 mph (highest speed tolerated comfortably) while patient remains on the treadmill. If the patient is unable to walk comfortably at 2.0 mph, record the ending  $SpO_2$  and oxygen flow rate and terminate the assessment. If the patient is able to continue with the Part 2 walk, the initial oxygen flow rate will be that at end of Part 1. If

Patient ID:

 $SpO_2$  drops below 90%, increase oxygen flow by 1 L/min while patient continues walking. Continue to adjust oxygen flow in 1 L/min increments as needed to keep  $SpO_2$ at or above 90%. Assessment ends when  $SpO_2$  has been stable at or above 90% for 3 consecutive minutes or the 4 minute maximum is reached. Record  $SpO_2$  and oxygen flow when the titration terminates.

Part 1: Treadmill speed (after adjustment in 1 <sup>st</sup> minute if necessary):			
	Lowest SpO <sub>2</sub> (%)	Heart rate (beats/min) linked to lowest SpO <sub>2</sub>	O <sub>2</sub> flow rate (L/min) linked to lowest SpO <sub>2</sub>
Time	in min	value	value
0			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
Borg (perceived breathlessness):			
Borg (perceived leg muscle fatigue):			

Part 2: Treadmill speed 2 mph or 3 mph			r 3 mph
	Lowest SpO <sub>2</sub> (%)	Heart rate (beats/min) linked to	O <sub>2</sub> flow rate (L/min) linked to
Time	in min	SpO <sub>2</sub> value	SpO <sub>2</sub> value
1			
2			
3			
4			
SpO <sub>2</sub> at end (%):			
O <sub>2</sub> flow rate at end (L/min):			

**19.** Treadmill speed for Part 1 ( $\leq$  1 mph walk):

1.0 mph	(	<sub>1</sub> )
Other (specify)	(	<sub>2</sub> )

specify in mph

- **20.** Duration of Part 1 ( $\leq$  1 mph walk):
- **21.** Lowest SpO<sub>2</sub> in last minute (last SpO<sub>2</sub> value recorded in table for Part 1):
- **22.** Heart rate linked to  $\text{SpO}_2$  in item 21 (last heart rate value recorded in table for Part 1):

beats/min

%

min

**23.** Oxygen flow rate linked to SpO<sub>2</sub> in item 21 (last oxygen flow rate value recorded in table for Part 1) (*enter 0.0 if patient was not on oxygen*):

**24.** Reason for terminating Part 1 ( $\leq$  1 mph walk):

Normal termination by tester  $\begin{pmatrix} & & \\ & & \end{pmatrix}$ Oxygen requirement > 6 L/min Abnormal termination by tester  $\begin{pmatrix} & & \\ & & \\ & & & & \\ & & & \\ & & & \\ & &$ 

specify reason

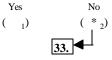
Terminated by patient

specify reason

(\*If this assessment is for s1, s2, s3, or rz, the patient is ineligible for NETT; if this is a followup assessment, the patient may not do the 6 minute walk test; complete Section F.) **25.** Borg scale rating for perceived breathlessness (Part 1):

\_ \_\_\_ •\_\_ \_\_\_

- **26.** Borg scale rating for perceived leg muscle fatigue (Part 1):
- 27. Was Part 2 (2.0/3.0 mph walk) attempted:



(\*Oxygen prescription for 6 minute walk is flow recorded in item 23.)

**28.** Treadmill speed for Part 2 (2.0/3.0 mph walk):

2.0 mph	(	1)
3.0 mph	(	<sub>2</sub> )

**29.** Duration of Part 2 (2.0/3.0 mph walk) (*enter* "0" *if patient walked less than 30 seconds*):

min

- **30.** SpO<sub>2</sub> when Part 2 (2.0/3.0 mph walk) terminated:
- **31.** Oxygen flow rate in use when Part 2 (2.0/3.0 mph walk) terminated (*enter 0.0 if oxygen was not in use at end of Part 2*):

L/min

%

# NETT 32. Reason for terminating Part 2 (2.0/3.0 mph walk): SpO<sub>2</sub> stable at or above 90% for 3 consecutive minutes 4 minutes of walking without stabilization and oxygen requirement at end of Part $2 \le 5$ L/min

4 minutes of walking without stabilization and oxygen requirement at end of Part 2 is 6 L/min	(‡3)
Patient could not walk at 2 mph comfortably	(**_4)

Abnormal termination by tester †† \_)

specify reason

#### (\*\* 6) Terminated by patient

specify reason

(\*Oxygen prescription for 6 minute walk is flow in use at end of Part 2.)

(†Oxygen prescription for 6 minute walk is 1 L/min more than flow in use at end of Part 2.)

(*‡Clinic staff should judge appropriateness of proceeding* with the 6 minute walk with patient using 6 L/min oxygen.)

(\*\*Oxygen prescription for 6 minute walk is 1 L/min more than flow in use when the Part 2 walk terminated. If this addition of 1 L/min raises the oxygen flow to > 6 L/min, clinic staff should judge appropriateness of proceeding with the 6 minute walk with the patient using 6 L/min of oxygen.)

(*††If this assessment is for s1, s2, s3, or rz, the patient is* ineligible for NETT; complete Section F. If this assessment is a followup assessment, the patient may not do the 6 minute walk test; complete Section F.)

#### E. Oxygen prescription for 6 minute walk

\* 1)

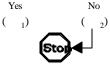
† <sub>2</sub>)

34.

34.

35.

Do clinic staff judge that patient can do the 6 33. minute walk safely on 6 L/min oxygen or less:



L/min

Oxygen prescription for 6 minute walk (enter 0.0 if 34. oxygen not required):

### F. Administrative information

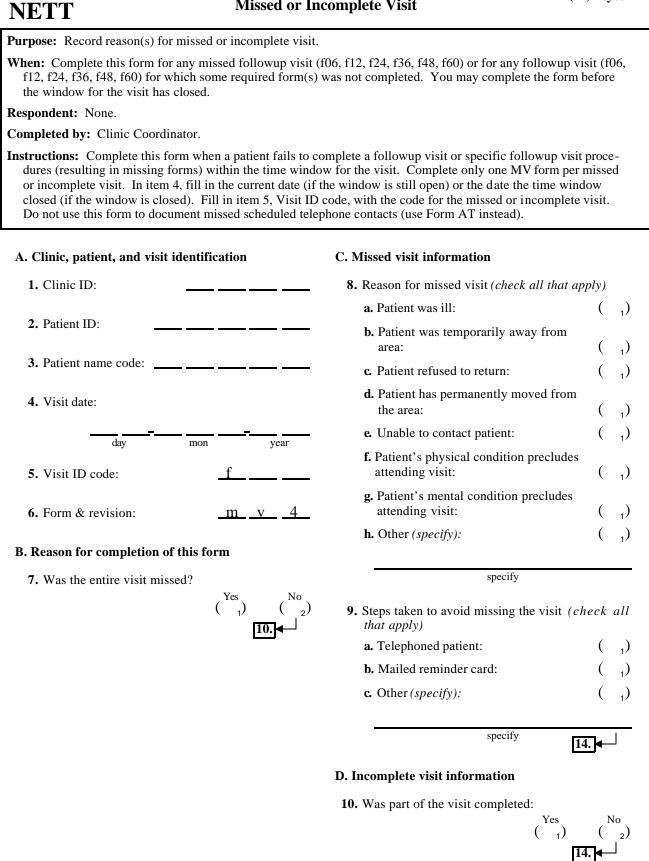
- **35.** O<sub>2</sub> Titration/6 Minute Walk Tester PIN:
- O<sub>2</sub> Titration/6 Minute Walk Tester signature: 36.
- Clinic Coordinator PIN: 37.
- Clinic Coordinator signature: 38.
- 39. Date form reviewed:

day mon year MV - Form MV Missed or Incomplete Visit (rev 4)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			1331
Varia	ables:	:			45

Variable	Variable Label	<b>T</b>	Variable	
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr strt	Num	8	
mv407	7 Was the entire visit missed?	Char	1	
mv410	10 Visit partially completed	Char	1	
mv408a	8a Ill	Char	1	
mv408b	8b Temporarily out of area	Char	1	
mv408c	8c Refused to return	Char	1	
mv408d	8d Permanently moved from area	Char	1	
mv408e	8e Unable to contact patient	Char	1	
mv408f	8f Physical condition precludes visit	Char	1	
mv408g	8g Mental condition precludes visit	Char	1	
mv408h	8h Other reason for missed visit	Char	1	
mv409a	9a Telephoned patient	Char	1	
mv409b	9b Mailed reminder card	Char	1	
mv409c	9c Other steps taken	Char	1	
mv411a	11a Blood and urine analyses (BU)	Char	1	
mv411b	11b Exercise testing (EW)	Char	1	
mv411c	11c Heart function (HF)	Char	1	
mv411d	11d Interim history (HI)	Char	1	
mv411e	11e O2 titration (MO)	Char	1	
mv411f	11f Six minute walk test (MM)	Char	1	
mv411g	11g Physical exam (PE)	Char	1	
mv411h	11h Pulmonary function (PF)	Char	1	
mv411i	11i Pulmonary mechanics (PM)	Char	1	
mv411j	11j MOS SF 36 (QF)	Char	1	
mv411k	11k St Georges respiratory quest (QG)	Char	1	
mv4111	111 Shortness of breath quest (QS)	Char	1	
mv411m	11m Quality of well-being scale (QW)	Char	1	
mv411n	11n CT scan (RC)	Char	1	
mv4110	110 Chest radiograph (RR)	Char	1	
mv411p	11p Trail making test (TM)	Char	1	
mv411q	11q Alternalte Trail making (TO)	Char	1	
mv411r	11r Cardiovascular Substudy (VC)	Char	1	
mv411s	11s ABG Exercise Substudy (ES)	Char	1	
mv411t	11t Other	Char	1	
mv412a	12a Patient was ill	Char	1	
mv412b	12b Patient refused procedure	Char	1	
mv412c	12c Procedure forgotten	Char	1	
mv412d	12d Other reason form not done	Char	1	
mv413a	13a Tried to reschedule procedure	Char	1	
mv413b	13b Tried to interview by phone	Char	1	
mv413c	13c Tried to gain cooperation	Char	1	
mv413d	13d Other attempt made	Char	1	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

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NETT Form MV Revision 4 (05 Dec 00)

<b>11.</b> Check form(s) not completed ( <i>check all th apply</i> )	ıat	
a. Blood and urine analyses (Form BU):	(	1)
<b>b.</b> Exercise testing (Form EW):	(	1)
c. Heart function (Form HF):	(	1)
d. Interim history (Form HI):	(	1)
e. O <sub>2</sub> titration (Form MO):	(	1)
<b>f.</b> Six minute walk test (Form MM):	(	1)
g. Physical examination (Form PE):	(	1)
h. Pulmonary function (Form PF):	(	1)
i. Pulmonary mechanics (Form PM):	(	*1)
<b>j.</b> MOS SF 36 (Form QF):	(	1)
<b>k.</b> St. George's respiratory questionnaire (Form QG):	(	1)
<b>l.</b> UCSD shortness of breath questionnaire (Form QS):	(	1)
<b>m.</b> Quality of well-being scale (Form QW):	(	1)
<b>n.</b> CT scan (Form RC):	(	1)
o. Chest radiograph (Form RR):	(	1)
p. Trail Making Test (Form TM; f24, f48):	(	1)
<b>q.</b> Alternate Trail Making Test (Form TO; f12, f36, f60):	(	1)
r. Cardiovascular Substudy (Form VC):	(	*_)
s. ABG Exercise Substudy (Form ES):	(	*_)
t. Other (specify):	(	1)

#### specify

\*Check only if patient is enrolled in the substudy and missed the procedure.

12.	Reason form(s) not completed (check apply)	all	that
	<b>a.</b> Patient was ill:	(	1)
	<b>b.</b> Patient refused procedure:	(	1)
	c. Procedure forgotten:	(	1)
	<b>d.</b> Other ( <i>specify</i> ):	(	1)

specify

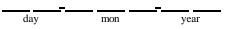
13. Attempts made to complete form(s) (check all that apply) **a.** Attempted to reschedule procedure: ( \_\_\_) **b.** Attempted to collect interview data by phone from patient: 1) ( **c.** Attempted to gain patient cooperation: <sub>1</sub>) ( **d.** Other (*specify*): ( 1)

Patient ID:

specify

### E. Administrative information

**14.** Date form reviewed:



- **15.** Clinic Coordinator PIN:
- **16.** Clinic Coordinator signature:

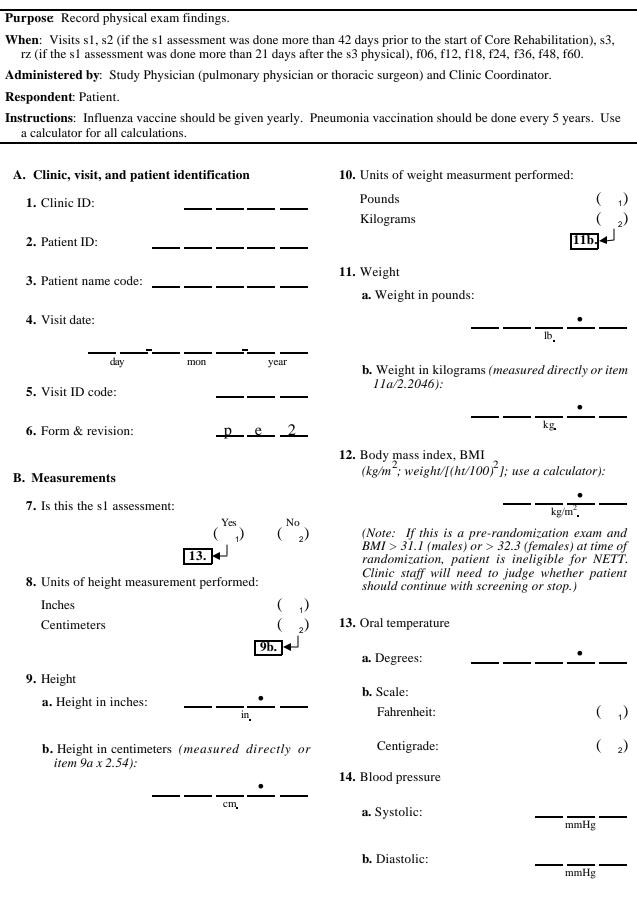
PE - Form PE Physical Examination (rev 2)

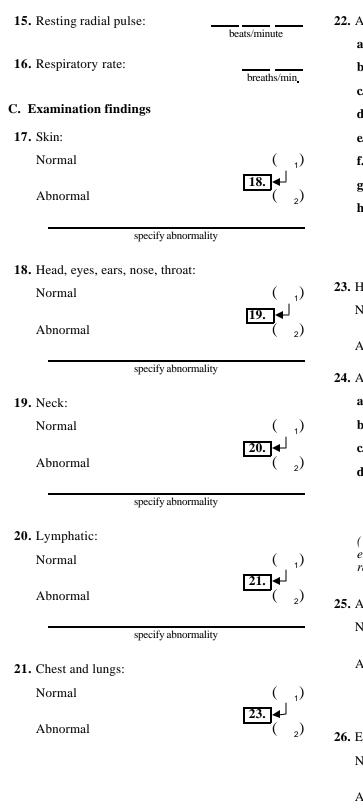
Date file created: 13 May 2006 Observations: 6627 Variables: 39

Variable Name	Variable Label	Туре	Variable Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
pe207	7 S1 assessment?	Char	1	
pe212	12 BMI (kg/m**2)	Char	3	
pe215	15 Resting radial pulse (beats/min)	Char	3	
pe216	16 Respiratory rate (breaths/min)	Char	2	
pe217	17 Skin	Char	1	
pe218	18 Head, eyes, ENT	Char	1	
pe219	19 Neck	Char	1	
pe220	20 Lymphatic	Char	1	
pe221	21 Chest and lungs	Char	1	
pe223	23 Heart	Char	1	
pe225	25 Abdomen	Char	1	
pe226	26 Extremities	Char	1	
pe228	28 Nervous system	Char	1	
pe229	29 Influenza vaccine up-to-date	Char	1	
pe230	30 Pneumonia vaccine up-to-date	Char	1	
pe213a	13a Temperature (degrees)	Char	4	
pe213b	13b Fahrenheit/Centigrade	Char	1	
 pe214a	14a Systolic blood pressure (mm/Hg)	Char	3	
pe214b	14b Diastolic blood pressure (mm/Hg)	Char	3	
- pe222a	22a Dullness to percussion	Char	1	
pe222b	22b Rales or crackles	Char	1	
pe222c	22c Ronchi	Char	1	
pe222d	22d Wheezes	Char	1	
pe222e	22e Hyperresonance	Char	1	
pe222f	22f Hyperinflation	Char	1	
pe222g	22g Acute respiratory distress	Char	1	
pe222h	22h Other chest/lung abnormality	Char	1	
pe224a	24a Neck vein distension	Char	1	
pe224b	24b S3 gallop	Char	1	
pe224c	24c premature beats	Char	1	
pe224d	24d Other heart abnormality	Char	1	
pe227a	27a Edema	Char	1	
pe227b	27b Cyanosis	Char	1	
pe227c	27c Clubbing	Char	1	
pe227d	27d Other extremity abnormality	Char	1	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## NETT

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Patient ID:

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Abnormality (check all that apply)		
<b>a.</b> Dullness to percussion:	(	1)
<b>b.</b> Rales or crackles:	(	1)
c. Ronchi:	(	1)
<b>d.</b> Wheezes:	(	1)
e. Hyperresonance:	(	1)
<b>f.</b> Hyperinflation:	(	1)
g. Acute respiratory distress:	(	1)
<b>h.</b> Other ( <i>specify</i> ):	(	1)

specify abnormality

. Heart:	
Normal	( <sub>1</sub> )
Abnormal	<b>25.</b> ↓ ( 2)
. Abnormality (check all that apply)	
a. Neck vein distension:	( <sub>1</sub> )
<b>b.</b> S <sub>3</sub> gallop:	(*_1)
<b>c.</b> Premature beats:	( <sub>1</sub> )
<b>d.</b> Other ( <i>specify</i> ):	()

specify abnormality

(\*If this is a pre-randomization examination, evaluation by a cardiologist is required prior to randomization.)

25. Abdomen: Normal



specify abnormality

**26.** Extremities: Normal

Abnormal

Abnormal

#### 1) **a.** Edema: ( **31.** Study Physician PIN: 1) **b.** Cyanosis: **32.** Study Physician signature: c. Clubbing: ( 1) **d.** Other (specify): ( 1) specify abnormality 33. Clinic Coordinator PIN: 28. Nervous system: 34. Clinic Coordinator signature: Normal 1) Abnormal 35. Date form reviewed: specify abnormality day mon **D.** Vaccinations **29.** Is the patient up-to-date with respect to influenza vaccination: ( 1) Yes

2) (

3)

( ₄)

**27.** Abnormality (*check all that apply*)

Patient ID: E. Administrative information



specify

No, but not appropriate to vaccinate the patient

at this time (tell patient when he/she should be vaccinated or revaccinated)

Other (specify)

No, patient will be vaccinated at this visit

**30.** Is the patient up-to-date with respect to pneumonia vaccination (eg, pneumovax):

Yes (	1)
No, but not appropriate to vaccinate the patient at this time ( <i>tell patient when he/she s h o u l a</i>	
vaccinated or revaccinated) (	<sub>2</sub> )
No, patient will be vaccinated at this visit (	3)
Other (specify) (	<sub>4</sub> )

specify

PM - Form PM Lung Mechanics (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			404
Varia	ables:	:			104

Variable			Variable	
Variable Name	Variable Label	Type	Variable Length	Format
Manie	Variable laber	турс	Deligen	rormae
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr	Num	8	
newnett	New NETT patient ID no.	Char	5	
pm307	7 lst: Effort recorded	Char	1	
pm308	8 1st: Maximum volume (liters)	Char	4	
pm309	9 1st: Static recoil pressure (cmH2O)	Char	3	
pm310	10 1st: Pair of data points	Char	2	
pm312	12 2nd: Effort recorded	Char	1	
pm313	13 2nd: Maximum volume (liters)	Char	4	
pm314	14 2nd: Static recoil pressure (cmH2O)	Char	3	
pm315	15 2nd: Pair of data points	Char	2	
pm317	17 3rd: Effort recorded	Char	1	
pm318	18 3rd: Maximum volume (liters)	Char	4	
pm319	19 3rd: Static recoil pressure (cmH2O)	Char	3	
pm320	20 3rd: Pair of data points	Char	2	
pm322	22 Resistance measurements recorded	Char	1	
pm323	23 Inspiratory resistance (cm/L/sec)	Char	3	
pm324	24 Expiratory resistance (cm/L/sec) 25 Flow-volume curve recorded	Char	3	
pm325		Char	1	
pm326	26 FEV1 (liters)	Char	3	
pm327	27 FVC (liters) 28 Max peak flow rate (l/sec)	Char	3	
pm328		Char Char	4	
pm311a1 pm311a2	11a Pressure (cmH2O)	Char Char	3	
pm311b1	11a Absolute volume (liters) 11b Pressure (cmH2O)	Char	4 3	
pm311b2	11b Absolute volume (liters)	Char	4	
pm311c1	11c Pressure (cmH2O)	Char	4	
pm311c2	11c Absolute volume (liters)	Char	4	
pm311d1	11d Pressure (cmH2O)	Char	3	
pm311d2	11d Absolute volume (liters)	Char	4	
pm311e1	11e Pressure (cmH2O)	Char	3	
pm311e2	11e Absolute volume (liters)	Char	4	
pm311f1	11f Pressure (cmH2O)	Char	3	
pm311f2	11f Absolute volume (liters)	Char	4	
pm311g1	11g Pressure (cmH2O)	Char	3	
pm311g2	11g Absolute volume (liters)	Char	4	
pm311h1	11h Pressure (cmH2O)	Char	3	
pm311h2	11h Absolute volume (liters)	Char	4	
pm311i1	11i Pressure (cmH2O)	Char	3	
pm311i2	11i Absolute volume (liters)	Char	4	
pm311j1	11j Pressure (cmH2O)	Char	3	
pm311j2	11j Absolute volume (liters)	Char	4	
pm311k1	11k Pressure (cmH2O)	Char	3	
pm311k2	11k Absolute volume (liters)	Char	4	
pm31111	111 Pressure (cmH2O)	Char	3	
pm31112	111 Absolute volume (liters)	Char	4	
pm316a1	16a Pressure (cmH2O)	Char	3	
pm316a2	16a Absolute volume (liters)	Char	4	
pm316b1	16b Pressure (cmH2O)	Char	3	
pm316b2	16b Absolute volume (liters)	Char	4	
pm316c1	16c Pressure (cmH2O)	Char	3	
pm316c2	16c Absolute volume (liters)	Char	4	
pm316d1	16d Pressure (cmH2O)	Char	3	
pm316d2	16d Absolute volume (liters)	Char	4	
pm316e1	16e Pressure (cmH2O)	Char	3	
pm316e2	16e Absolute volume (liters)	Char	4	
pm316f1	16f Pressure (cmH2O)	Char	3	
pm316f2	16f Absolute volume (liters)	Char	4	

Date file created:13 May 2006 Observations:404 404 Variables:104Variables:104TypeLengthFormatpm316g116g Pressure (cmH20)Char3pm316g116g Pressure (cmH20)Char4pm316h116h Pressure (cmH20)Char4pm316116h Pressure (cmH20)Char3pm316116h Pressure (cmH20)Char3pm316116h Pressure (cmH20)Char3pm316116h Pressure (cmH20)Char3pm316112h Pressure (cmH20)Char3 <td< th=""><th>PM -</th><th>Form PM Lung Mechanics (rev 3)</th><th></th><th></th><th></th></td<>	PM -	Form PM Lung Mechanics (rev 3)			
NameVariable LabelTypeLengthFormatpm316g116g Pressure (cmH20)Char3pm316h116h Pressure (cmH20)Char3pm316h116h Pressure (cmH20)Char3pm316i116i Pressure (cmH20)Char3pm316i116i Pressure (cmH20)Char3pm316i216i Absolute volume (liters)Char4pm316i216i Absolute volume (liters)Char4pm312112i Pressure (cmH20)Char4pm321a121a Absolute volume (liters)Char4pm321a221b Absolute volume (liters)Char4pm321c121c Pressure (cmH20)Char3pm321c221c Absolute volume (liters)Char3pm321c221d Absolute volume (liters)	Observation	s: 404			
pm316h2         lef         Absolute volume (liters)         Char         4           pm316h1         16h         Pressure (cmH2O)         Char         3           pm316h2         16h         Absolute volume (liters)         Char         3           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         4           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         4           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         3           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         4           pm321a2         21a         Absolute volume (liters)         Char         3           pm321a2         21b         Absolute volume (liters)         Char         4           pm321c1         21c         Pressure (cmH2O)         Char         4 <td< td=""><td></td><td>Variable Label</td><td>Туре</td><td></td><td>Format</td></td<>		Variable Label	Туре		Format
pm316h2         lef         Absolute volume (liters)         Char         4           pm316h1         16h         Pressure (cmH2O)         Char         3           pm316h2         16h         Absolute volume (liters)         Char         3           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         4           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         4           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         3           pm316i1         16i         Pressure (cmH2O)         Char         3           pm316i2         16i         Absolute volume (liters)         Char         4           pm321a2         21a         Absolute volume (liters)         Char         3           pm321a2         21b         Absolute volume (liters)         Char         4           pm321c1         21c         Pressure (cmH2O)         Char         4 <td< td=""><td>pm316a1</td><td>16g Pressure (cmH20)</td><td>Char</td><td>З</td><td></td></td<>	pm316a1	16g Pressure (cmH20)	Char	З	
pm316h1       16h Pressure (cmH20)       Char       3         pm316h1       16h Absolute volume (liters)       Char       4         pm31611       16i Pressure (cmH20)       Char       3         pm31611       16i Pressure (cmH20)       Char       3         pm31611       16j Pressure (cmH20)       Char       3         pm31621       16j Absolute volume (liters)       Char       3         pm31611       16i Pressure (cmH20)       Char       3         pm31621       16k Absolute volume (liters)       Char       4         pm31612       16k Absolute volume (liters)       Char       4         pm31612       16k Absolute volume (liters)       Char       4         pm31612       16k Absolute volume (liters)       Char       4         pm32121       12h Pressure (cmH20)       Char       3         pm32122       21b Absolute volume (liters)       Char       4         pm32121       21c Pressure (cmH20)       Char       3         pm32122       21c Absolute volume (liters)       Char       4         pm32122       21c Absolute volume (liters)       Char       3         pm32122       12h Absolute volume (liters)       Char       3					
pm316h2         16h Absolute volume (liters)         Char         4           pm316i1         16i Pressure (cmH2O)         Char         3           pm316i2         16i Absolute volume (liters)         Char         3           pm316j1         16j Pressure (cmH2O)         Char         3           pm316j2         16j Absolute volume (liters)         Char         3           pm316k1         16k Pressure (cmH2O)         Char         3           pm316k2         16k Absolute volume (liters)         Char         4           pm316k1         16k Pressure (cmH2O)         Char         3           pm316k2         16k Absolute volume (liters)         Char         4           pm312k1         21a Pressure (cmH2O)         Char         4           pm321k2         21b Absolute volume (liters)         Char         4           pm321c1         21c Pressure (cmH2O)         Char         3           pm321c2         21c Absolute volume (liters)         Char         4           pm321c1         21c Pressure (cmH2O)         Char         4           pm321c1         21e Pressure (cmH2O)         Char         4           pm321c2         21e Absolute volume (liters)         Char         4	1 5				
pm3161116iPressure (cmH2O)Char3pm3161216iAbsolute volume (liters)Char4pm3161116jPressure (cmH2O)Char3pm3161116kPressure (cmH2O)Char3pm3161216kAbsolute volume (liters)Char4pm3161116lPressure (cmH2O)Char3pm3161216kAbsolute volume (liters)Char4pm321a111aPressure (cmH2O)Char3pm321a221aAbsolute volume (liters)Char4pm321a121bPressure (cmH2O)Char3pm321b221bAbsolute volume (liters)Char4pm321c221cAbsolute volume (liters)Char4pm321c221cAbsolute volume (liters)Char4pm321c221cAbsolute volume (liters)Char4pm321c121fPressure (cmH2O)Char3pm321c221cAbsolute volume (liters)Char4pm321c121fPressure (cmH2O)Char3pm321c221cAbsolute volume (liters)Char4pm321c121fPressure (cmH2O)Char3pm321c221cAbsolute volume (liters)Char4pm321c221fAbsolute volume (liters)Char4pm321c221fAbsolute volume (liters)Char4pm321c221fAbsolute volume (liters) <td>-</td> <td></td> <td></td> <td></td> <td></td>	-				
pm316i216i Absolute volume (liters)Char4pm316j116j Pressure (cmH2O)Char3pm316i216j Absolute volume (liters)Char3pm316k116k Pressure (cmH2O)Char3pm316k116i Pressure (cmH2O)Char3pm316k116i Pressure (cmH2O)Char3pm316k116i Pressure (cmH2O)Char3pm316k116i Pressure (cmH2O)Char3pm321b221a Absolute volume (liters)Char4pm321b121b Pressure (cmH2O)Char3pm321b221b Absolute volume (liters)Char4pm321c121c Pressure (cmH2O)Char3pm321c221c Absolute volume (liters)Char4pm321c121d Pressure (cmH2O)Char3pm321c221c Absolute volume (liters)Char4pm321c121f Pressure (cmH2O)Char3pm321c221c Absolute volume (liters)Char4pm321c121f Pressure (cmH2O)Char3pm321c221c Absolute volume (liters)Char4pm321c221f Absolute volume (liters)Char4<	-				
pm316j1       16j Pressure (cmH2O)       Char       3         pm316k1       16k Pressure (cmH2O)       Char       4         pm31612       16l Absolute volume (liters)       Char       4         pm321a1       21a Absolute volume (liters)       Char       4         pm321a2       21a Absolute volume (liters)       Char       3         pm321b1       21b Pressure (cmH2O)       Char       3         pm321c2       21c Absolute volume (liters)       Char       3         pm321c1       21c Pressure (cmH2O)       Char       3         pm321c2       21c Absolute volume (liters)       Char       4         pm321c1       21e Pressure (cmH2O)       Char       3         pm321c2       21d Absolute volume (liters)       Char       4         pm321c1       21f Pressure (cmH2O)       Char       4         pm321c1       21f Pressure (cmH2O)       Char       3         pm321c1       21f Pressure (cmH2O)       Char       3         pm321g1	1				
pm31612       16j Absolute volume (liters)       Char       4         pm316k1       16k Absolute volume (liters)       Char       3         pm316k1       16l Absolute volume (liters)       Char       3         pm316k1       16l Absolute volume (liters)       Char       3         pm316k1       16l Absolute volume (liters)       Char       3         pm31k12       21a Pressure (cmH2O)       Char       3         pm321b2       21b Absolute volume (liters)       Char       4         pm321c1       21c Pressure (cmH2O)       Char       3         pm321c2       21c Absolute volume (liters)       Char       4         pm321c1       21d Pressure (cmH2O)       Char       3         pm321c2       21d Absolute volume (liters)       Char       4         pm321c1       21d Pressure (cmH2O)       Char       3         pm321c2       21d Absolute volume (liters)       Char       4         pm321c2       21e Absolute volume (liters)       Char       4         pm321c2       21e Absolute volume (liters)       Char       3         pm321c2       21e Absolute volume (liters)       Char       4         pm321c1       21f Pressure (cmH2O)       Char					
pm316k1       16k       Pressure (cmH2O)       Char       3         pm31611       16k       Pressure (cmH2O)       Char       4         pm31611       16k       Pressure (cmH2O)       Char       4         pm31612       16k       Absolute volume (liters)       Char       4         pm321a1       21a       Pressure (cmH2O)       Char       3         pm321b1       21b       Pressure (cmH2O)       Char       4         pm321b2       21b       Absolute volume (liters)       Char       4         pm321c1       21c       Pressure (cmH2O)       Char       3         pm31d11       21c       Pressure (cmH2O)       Char       3         pm321d2       21c       Absolute volume (liters)       Char       4         pm321d2       21c       Absolute volume (liters)       Char       4         pm321f1       21f       Pressure (cmH2O)       Char       3         pm321f2       21f       Absolute volume (liters)       Char       4         pm321g1       21f       Pressure (cmH2O)       Char       3         pm321g2       21g       Absolute volume (liters)       Char       4         pm321g1					
m316k2         16k Absolute volume (liters)         Char         4           pm31611         161 Pressure (cmH2O)         Char         3           pm31612         161 Absolute volume (liters)         Char         3           pm321a1         21a Pressure (cmH2O)         Char         3           pm321b1         21b Pressure (cmH2O)         Char         3           pm321b2         21b Absolute volume (liters)         Char         3           pm321c2         21c Absolute volume (liters)         Char         4           pm321c1         21e Pressure (cmH2O)         Char         3           pm321c2         21e Absolute volume (liters)         Char         4           pm321c1         21f Pressure (cmH2O)         Char         3           pm321c2         21f Absolute volume (liters)         Char         4           pm321g1         21g Pressure (cmH2O)         Char         3           pm321g2         21g Absolute volume (liters)         Char         4 <td></td> <td>5</td> <td></td> <td></td> <td></td>		5			
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pm32112211 Absolute volume (liters)Char4pm329a29a Flow at 90% FVCChar4pm329b29b Flow at 80% FVCChar4pm329c29c Flow at 70% FVCChar4pm329d29d Flow at 60% FVCChar4pm329e29e Flow at 50% FVCChar4pm329f29f Flow at 40% FVCChar4pm329g29g Flow at 30% FVCChar4pm329h29h Flow at 20% FVCChar4pm329i29i Flow at 10% FVCChar4	pm32111	211 Pressure (cmH2O)	Char	3	
pm329b       29b       Flow at 80%       FVC       Char       4         pm329c       29c       Flow at 70%       FVC       Char       4         pm329d       29d       Flow at 60%       FVC       Char       4         pm329d       29d       Flow at 60%       FVC       Char       4         pm329d       29d       Flow at 50%       FVC       Char       4         pm329e       29e       Flow at 40%       FVC       Char       4         pm329f       29f       Flow at 30%       FVC       Char       4         pm329g       29g       Flow at 20%       FVC       Char       4         pm329i       29i       Flow at 10%       FVC       Char       4	pm32112	211 Absolute volume (liters)	Char		
pm329c29c Flow at 70% FVCChar4pm329d29d Flow at 60% FVCChar4pm329e29e Flow at 50% FVCChar4pm329f29f Flow at 40% FVCChar4pm329g29g Flow at 30% FVCChar4pm329h29h Flow at 20% FVCChar4pm329i29i Flow at 10% FVCChar4	pm329a	29a Flow at 90% FVC	Char	4	
pm329d29d Flow at 60% FVCChar4pm329e29e Flow at 50% FVCChar4pm329f29f Flow at 40% FVCChar4pm329g29g Flow at 30% FVCChar4pm329h29h Flow at 20% FVCChar4pm329i29i Flow at 10% FVCChar4	pm329b	29b Flow at 80% FVC	Char	4	
pm329e       29e Flow at 50% FVC       Char       4         pm329f       29f Flow at 40% FVC       Char       4         pm329g       29g Flow at 30% FVC       Char       4         pm329g       29g Flow at 20% FVC       Char       4         pm329h       29h Flow at 20% FVC       Char       4         pm329i       29i Flow at 10% FVC       Char       4	pm329c	29c Flow at 70% FVC	Char	4	
pm329f       29f Flow at 40% FVC       Char       4         pm329g       29g Flow at 30% FVC       Char       4         pm329h       29h Flow at 20% FVC       Char       4         pm329i       29i Flow at 10% FVC       Char       4	pm329d	29d Flow at 60% FVC	Char	4	
pm329g         29g Flow at 30% FVC         Char         4           pm329h         29h Flow at 20% FVC         Char         4           pm329i         29i Flow at 10% FVC         Char         4	pm329e	29e Flow at 50% FVC	Char	4	
pm329h         29h         Flow at 20%         FVC         Char         4           pm329i         29i         Flow at 10%         FVC         Char         4	pm329f	29f Flow at 40% FVC	Char	4	
pm329i 29i Flow at 10% FVC Char 4	pm329g	29g Flow at 30% FVC	Char	4	
	pm329h		Char	4	
visit s1,s2,s3,rz,n,fxx where xx=mos from RZ Char 3	pm329i		Char	4	
	visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## Lung Mechanics

Purpose: Record lung mechanics data
When: Visits rz, f06, f48.
Administered by: Pulmonary Function Coordinator and Clinic Coordinator.
Respondent: None.
Instructions: Record as much information as is available. Code missing items as "m."

### A. Clinic, visit, and patient identification

Clinic ID: 1. 2. Patient ID: 3. Patient name code: 4. Visit date: day mon year 5. Visit ID code: <u>pm3</u> 6. Form & revision:

### **B. Pressure-volume curve** (record up to 3 efforts)

7. Is there a first effort to record:

$$\begin{array}{c} \text{Yes} & \text{No} \\ 1 & (2) \\ \hline 22. \end{array}$$

**8.** Maximum volume for 1st effort:

(

9. Static recoil pressure at maximum volume for 1st effort:

cmH<sub>2</sub>O

**10.** How many pairs of data points will you record for the 1st effort (*up to 12 pairs of data points may be recorded*):

**11.** Data points for 1st effort (*record pressure and absolute volume values in the specified formats*)

	Pressure (cmH <sub>2</sub> O) (xx.x)	Absolute volume (L) (xx.xx)
a.		
b.		
c.		
d.		
e.		
f.		
g.		
h.		
i.		
j.		
k.		
1.		

**12.** Is there a second effort to record:



13. Maximum volume for 2nd effort:

14. Static recoil pressure at maximum volume for 2nd effort:

cmH<sub>2</sub>O

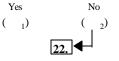
**15.** How many pairs of data points will you record for the 2nd effort (*up to 12 pairs of data points may be recorded*):

## NETT

**16.** Data points for 2nd effort (*record pressure and absolute volume values in the specified formats*):

	Pressure (cmH <sub>2</sub> O) (xx.x)	Absolute volume (L) (xx.xx)
a.		
b.		
с.		
d.		
e.		
f.		
g.		
h.		
i.		
j.		
k.		
1.		

**17.** Is there a third effort to record:



**18.** Maximum volume for 3rd effort:

liters-BTPS

**19.** Static recoil pressure at maximum volume for 3rd effort:

cmH<sub>2</sub>O

**20.** How many pairs of data points will you record for the 3rd effort (*up to 12 pairs of data points may be recorded*):

Patient ID:

**21.** Data points for 3rd effort (*record pressure and absolute volume values in the specified formats*):

	Pressure (cmH <sub>2</sub> O) (xx.x)	Absolute volume (L) (xx.xx)
a.		
b.		
c.		
d.		
e.		
f.		
g.		
h.		
i.		
j.		
k.		
1.		

- C. Resistance during tidal breathing (esophageal balloon method, post bronchodilator; NOT from plethysmographic panting method)
  - 22. Will resistance measurements measured with esophageal balloon technique be recorded:



23. Inspiratory resistance:

cmH<sub>2</sub>O/L/sec

24. Expiratory resistance:

cmH<sub>2</sub>O/L/sec

# NETT

- **D.** Maximal flow-volume curve (record the curve with the greatest sum of FEV<sub>1</sub> plus FVC, post bronchodilator; record flow at deciles of FVC)
  - **25.** Will the maximal flow-volume curve be recorded:
    - Yes No (1) (2) **30.**

**26.** FEV<sub>1</sub>:

27.

FVC:

• liters-BTPS

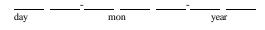
liters/sec

liters-BTPS

- 28. Maximum peak expiratory flow rate:
- Flow at deciles of FVC: 29. Flow (liters/sec) Decile of FVC (xx.xx) 90% FVC a. 80% FVC b. 70% FVC c. 60% FVC d. 50% FVC e. f. 40% FVC 30% FVC g. 20% FVC h. 10% FVC i.

### E. Administrative information

- **30.** Pulmonary Function Coordinator PIN:
- 31. Pulmonary Function Coordinator signature:
- **32.** Clinic Coordinator PIN:
- **33.** Clinic Coordinator signature:
- 34. Date form reviewed:



PULMFUNC - Lung function values based on PF form (rev 4)

Date file created: 13 May 2006 Observations: 6727 Variables: 40

Variable Name	Variable Label	Туре	Variable Length	Format
abgdate	abg date cnvrtd to #days frm RZ/scr strt	Num	8	
artcohb	Room air resting arterial CoHb (%)	Num	8	
artph	Room air resting arterial pH	Num	8	
dlco	DLCO, ml,min, mmHg STPD	Num	8	
dlcodate	DLCOdate cnvrtd to #days frm RZ/scr strt	Num	8	
dlcopp	DLCO % predicted	Num	8	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
frc	Post BD mean FRC (plethys, liters-BTPS)	Num	8	
lvdate	LungVolDt cnvrtd to #days frmRZ/scr strt	Num	8	
mep	PEmax (MEP, cmH2O)	Num	8	
mip	PImax (MIP, cmH2O)	Num	8	
mipmepdt	MIPMEPDt cnvrtdto #days frm RZ/scr strt	Num	8	
mvv	Post BD MVV (L/min BTPS)	Num	8	
mvvdate	MVV date cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
paco2	Room air resting PaCO2 (mmHg)	Num	8	
pac2 pac2	Room air resting PaO2 (mmHg)	Num	8	
postfev1	Post BD FEV1 (liters-BTPS)	Num	8	
postfvc	Post BD FVC (liters-BTPS)	Num	8	
preddlco	Predicted DLCO (ml/min/mmHg STPD)	Num	8	
predfev1	Predicted FEV1 (liters-BTPS)	Num	8	
predfvc	Predicted FVC (liters-BTPS)	Num	8	
predrv	Predicted RV (liters-BTPS)	Num	8	
predtlc	Predicted TLC (liters-BTPS)	Num	8	
prefev1	Pre BD FEV1 (liters-BTPS)	Num	8	
prefevpp	Pre BD FEV1 % predicted	Num	8	
prefvc	Pre BD FVC (liters-BTPS)	Num	8	
prefvcpp	Pre BD FVC % predicted	Num	8	
pstfevpp	Post BD FEV1 % predicted	Num	8	
pstfvcpp	Post BD FVC % predicted	Num	8	
rv	Post BD RV (TLC-SVC, liters-BTPS)	Num	8	
rvpp	Post BD RV % predicted	Num	8	
spirodt	Spirodatecnvrtd to #days frmRZ/scr strt	Num	8	
svc	Post BD maximum SVC (liters-BTPS)	Num	8	
tlc	Post BD mean TLC (liters-BTPS)	Num	8	
tlcpp	Post BD mean TLC % predicted	Num	8	
valv	VALV (liters-BTPS)	Num	8	
vi	VI (liters-BTPS)	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
VIUIC	51,52,55,12,11,1AA WHELE AA 105 11011 12	CITAL	5	

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**Purpose** To summarize the pulmonary function results. When: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to start of Core Rehabilitation), s3, rz (if more than 21 days since post rehabilitation assessment), f06, f12, f24, f36, f48, f60 (at all visits) Administered by: Pulmonary Function Coordinator and Clinic Coordinator. Respondent: None. Instructions: Spirometry should be performed with the patient in a sitting position. Transcribe the measured values from the pulmonary function laboratory and ABG reports and/or Pulmonary Function Worksheet (Form PW) to this form; reports should be marked with the patient's ID number and name code and stapled to this form. Use NETT predicted values where predicted values are requested; obtain the appropriate value from the patient's chart of predicted values. Spirometry should be done pre and post bronchodilator (BD); MVV, body plethysmography, DLCO, and respiratory pressures should be performed post BD. Use a calculator for all calculations. A. Clinic, visit, and patient identification 10. Post BD values 1. Clinic ID: a. FVC: liters-BTPS 2. Patient ID: **b.** FEV1: liters-BTPS **3.** Patient name code: **c.** Is this an s1, s2, s3, or rz assessment: 4. Visit date (date pulmonary function testing \_) *initiated*): day mon year d. Predicted FEV1 (obtain from NETT chart for patient): 5. Visit ID code: liters-BTPS **6.** Form & revision: e. Maximum of pre and post BD FEV1 7. Lab ID: (maximum of items 9b and 10b): Clinic ID Lab ID liters-BTPS **B.** Spirometry 8. Was spirometry performed: **f.** FEV<sub>1</sub> % predicted [(*item 10e/item 10d*) \* 100]: Yes No % 11. Date spirometry performed: 9. Pre BD values year dav mon a. FVC: liters-BTPS **b.** FEV 1: liters-BTPS

## C. Post BD MVV

12. Was post BD MVV performed:

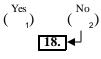
 $( \begin{array}{c} Yes & ( \begin{array}{c} No \\ 1 \end{pmatrix} & ( \begin{array}{c} 2 \end{pmatrix} \\ \hline 15. \checkmark \end{bmatrix}$ 13. MVV:  $- \begin{array}{c} \bullet \\ \hline L/min BTPS \end{array}$ 

**14.** Date MVV performed:

day mon year

### D. Lung volumes (body plethysmography)

**15.** Were post BD lung volumes performed:



### 16. Post BD values

a. Mean TLC:

**b.** Maximum SVC:

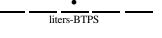
**c.** RV (*item 16a - item 16b*):

liters-BTPS

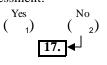
•

liters-BTPS

d. Mean FRC (plethys):



**e.** Is this an s1, s2, s3, or rz assessment:



**f.** Predicted TLC (*obtain from NETT chart for patient*):

Patient ID:



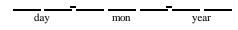
**g.** Post BD TLC % predicted [(item 16a/item 16f) \* 100]:

**h.** Predicted RV (*obtain from NETT chart for patient*):

**i.** Post BD RV % predicted [(*item 16c/item 16h*) \* 100]:

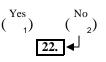


**17.** Date lung volumes performed:

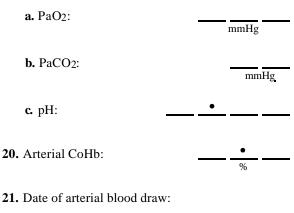


### E. Resting room air arterial blood gas analysis

18. Was arterial blood drawn:



19. Room air resting ABG values



day mon year

### F. Diffusing capacity (D<sub>L</sub>CO)

22. Was DLCO performed (*s1/s2 and f12*):

(<sup>Yes</sup>) (<sup>No</sup><sub>2</sub>) **25.**↓

- **23.** DLCO values
  - **a.** DLCO (uncorrected for hemoglobin, uncorrected for altitude):

ml/min/mmHg STPD

liters-BTPS

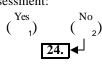
•

**b.** V<sub>I</sub>:

c. VALV:

liters-BTPS

d. Is this an s1, s2, s3, or rz assessment:



e. Was the test performed in Denver:

(Yes (No) (Yes) (Yes)

**f.** Alveolar PO<sub>2</sub> (*calculate as* [(619 - 47) \* 0.21 - (*item 19b/*0.8)]):

mmHg

**g.** Altitude corrected DLCO (*calculate as item 23a* \* [1.0 + 0.0035 (*item 23f* - 120)]):

ml/min/mmHg STPD

**h.** Predicted DLCO (*obtain from NETT chart for patient*):

ml/min/mmHg STPD

i. DLCO % predicted [(item 23a or item 23g/item 23h) \* 100]:

%

**24.** Date D<sub>L</sub>CO performed:

day mon year

### G. Respiratory mouth pressures

**25.** Were respiratory mouth pressures measured:

Y	es		N	ο
(	1)		(	2)
	Г	30.	<b>I</b> ▲	

**26.** What units are the pressures measured in:

cm H <sub>2</sub> O	(	1)
mm Hg	(	2)

Patient ID:

- **27.** PI<sub>max</sub> (MIP):
- **28.** PE<sub>max</sub> (MEP):
- **29.** Date respiratory mouth pressures measured:

day mon year

### H. Administrative information

- **30.** Pulmonary Function Coordinator PIN:
- **31.** Pulmonary Function Coordinator signature:
- **32.** Clinic Coordinator PIN:
- **33.** Clinic Coordinator signature:
- **34.** Date form reviewed:

day mon year

QB - Form QB Beck Depression Inventory (rev 2)

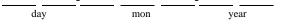
Date	file	created:	13	May	2006
Obser	vatio	ons:			2000
Varia	bles:	:			6

Variable Name	Variable Label	Tvpe	Variable Length	Format
Ivanic	Variable haber	TYPC	Lengen	rormae
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
qb207	7 Beck inventory: score of 1st 13 items	Char	2	
qb208	8 Beck Inventory: score of last 8 items	Char	2	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## NETT

Purpose: To assist the psychosocial clinician in assessing depression. When: At visit s1 as part of the Rehabilitation Evaluation (assessment must be completed before Core Rehabilitation begins). Administered by: Rehabilitation staff and Clinic Coordinator. Respondent: Patient. **Instructions**: A label with the patient's ID, name code, and appropriate visit code (s1) should be affixed in the upper right corner of pages 2-7. The patient should complete pages 2-7 (items A-U). Staple page 1 to the completed questionnaire. The sum of the first 13 items (A-M) should be recorded, as well as the sum of the last 8 items (N-U). Note that item S (19) is scored as 0 if the respondent has been trying to lose weight. Only items on page 1 are keyed to the NETT database. A. Clinic, visit, and patient identification **B.** Administrative information (To be completed by clinic staff) Clinic ID: 1. 7. Score of first 13 items (A-M): 2. Patient ID: (0-39) 8. Score of last 8 items (N-U): 3. Patient name code: (0-24)9. Examiner name (please print): 4. Visit date: 10. Examiner signature: day year mon 1 \_ \_\_\_\_ Visit code: 5. Clinic Coordinator PIN: 11. <u>q b</u> 2 Form & revision: 6. 12. Clinic Coordinator signature:

**13.** Date form reviewed:



# **163** *Affix label here*Pt ID: \_\_\_\_\_\_\_ Namecode: \_\_\_\_\_\_

## **Beck Depression Inventory**

Date:		
<b>A</b> . (1)	Circle I do not feel sad	
	I feel sad	1
	I am sad all the time and I can't snap out of it	2
	I am so sad or unhappy that I can't stand it	3
<b>B</b> . (2)	I am not particularly discouraged about the future	0
	I feel discouraged about the future	1
	I feel I have nothing to look forward to	2
	I feel that the future is hopeless and that things cannot improve	3
<b>C</b> . (3)	I do not feel like a failure	0
	I feel I have failed more than the average person	1
	As I look back on my life, all I can see is a lot of failures	2
	I feel I am a complete failure as a person	3

# National Emphysema Treatment Trial

## 

		Circl	e One
<b>D</b> . (4)	I get as much satisfaction out of things as I used to	••••	0
	I don't enjoy things the way I used to		1
	I don't get real satisfaction out of anything anymore		2
	I am dissatisfied or bored with everything	••••	3
E. (5)	I don't feel I am particularly guilty		0
	I feel guilty a good part of the time		1
	I feel quite guilty most of the time	••••	2
	I feel guilty all of the time		3
<b>F</b> . (6)	I don't feel I am being punished		0
	I feel I may be punished		1
	I expect to be punished		2
	I feel I am being punished	••••	3
<b>G</b> . (7)	I don't feel disappointed in myself		0
	I am disappointed in myself		1
	I am disgusted with myself		2
	I hate myself		3

	~ _
<b>7 C</b> Affix label here	55
Pt ID:	
Namecode:	
L	1

	Circl	le One
H. (8)	I don't feel I am any worse than anybody else	0
	I am critical of myself for my weakness or mistakes	1
	I blame myself all the time for my faults	2
	I blame myself for everything that happens	3
I. (9)	I don't have thoughts of killing myself	0
	I have thoughts of killing myself, but I would not carry them out	1
	I would like to kill myself	2
	I would kill myself if I had the chance	3
J. (10)	I don't cry any more than usual	0
	I cry more now than I used to	1
	I cry all the time now	2
	I used to be able to cry, but now I can't even cry even though I want to	3

# 

	Circle	e One
<b>K</b> . (11)	I am no more irritated now then I ever am	0
	I get annoyed or irritated more easily than I used to	1
	I feel irritated all the time now	2
	I don't get irritated at all by the things that used to irritate me	3
L. (12)	I have not lost interest in other people	0
	I am less interested in other people than I used to be	1
	I have lost most of my interest in other people	2
	I have lost all my interests in other people	3
M. (13)	I make decisions about as well as I ever could	0
	I put off making decisions more than I used to	1
	I have greater difficulty in making decisions than before	2
	I can't make decisions at all anymore	3

 Affix label here

 Pt ID:

 Namecode:

		Circle	e One
N. (14)	I don't feel I look any worse than I used to	••••	0
	I am worried that I am looking old or unattractive	••••	1
	I feel that there are permanent changes in my appearance that make me look unattractive		2
	I believe that I look ugly	••••	3
0. (15)	I can work about as well as before	• • • •	0
	It takes an extra effort to get started at doing something		1
	I have to push myself very hard to do anything		2
	I can't do any work at all		3
<b>P</b> . (16)	I can sleep as well as usual	••••	0
	I don't sleep as well as I used to	••••	1
	I wake up 1-2 hours earlier than usual and find it hard to get back to sleep		2
	I wake up several hours earlier than I used to and cannot get back to sleep		3

# **168** *Affix label here*Pt ID: \_\_\_\_\_\_\_

	Cir	cle One
Q. (17)	I don't get more tired than usual	. 0
	I get tired more easily than I used to	. 1
	I get tired from doing almost anything	. 2
	I am too tired to do anything	. 3
<b>R</b> . (18)	My appetite is no worse than usual	. 0
	My appetite is not as good as it used to be	. 1
	My appetite is much worse now	. 2
	I have no appetite at all anymore	. 3
S. (19)	I haven't lost much weight, if any, lately	. 0
	I have lost more than 5 pounds	. 1
	I have lost more than 10 pounds	. 2
	I have lost more than 15 pounds	. 3

I am purposely trying to lose weight by eating less Yes \_\_\_\_\_ No \_\_\_\_\_

**169** *Affix label here*Pt ID: \_\_\_\_\_\_\_

	Cir	cle One
T. (20)	I am no more worried about my health than usual	. 0
	I am worried about physical problems such as aches and pains; or upset stomach; or constipation	. 1
	I am very worried about physical problems and it's hard to think of much else	. 2
	I am so worried about my physical problems, that I cannot think about anything else	
U. (21)	I have not noticed any recent change in my interest in sex	. 0
	I am less interested in sex than I used to be	. 1
	I am much less interested in sex now	. 2
	I have lost interest in sex completely	. 3

QE - Form QE Self-Evaluation Questionnaire (rev 2)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			1993
Varia	ables:	:			6

Variable			Variable	
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr	Num	8	
newnett	New NETT patient ID no.	Char	5	
qe207a	7a Scoring: form Y-1	Char	2	
qe207b	7b Scoring: form Y-2	Char	2	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

## **Self-Evaluation Questionnaire**

**Purpose**: To help staff determine initial pulmonary rehabilitation prescription with respect to psychosocial counseling.

**When**: At visit s1 as part of the Rehabilitation Evaluation (assessment must be completed before Core Rehabilitation begins).

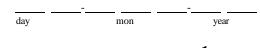
Administered by: Rehabilitation staff and Clinic Coordinator.

Respondent: Patient.

**Instructions**: A label with the patient's ID, name code, and appropriate visit code (s1) should be affixed on pages 2-4. The patient should complete pages 2-3 (items 1-40). The Y-1 and Y-2 scores should be calculated using the scoring key on page 4. Only items on page 1 are keyed to the NETT database. Staple pages 1-4 together at the close of the assessment.

A. Clinic, visit, and patient identific	ation
---	-------

- 1. Clinic ID:
- 2. Patient ID:
- 3. Patient name code:
- 4. Visit date:



5.	Visit code:	S	<u> </u>

6. Form & revision: <u>q</u> <u>e</u> <u>2</u>

### **B.** Administrative information

(To be completed by clinic staff)

7. Scoringa. Form Y-1 (sum of weights for items 1-20)

(20-80)

b. Form Y-2 (sum of weights for items 21-40)

(20-80)

- 8. Examiner
  - **a**. Name (*please print*):
  - **b**. Signature:
- 9. Clinic Coordinator
  - a. PIN:b. Signature:
- **10.** Date form reviewed:

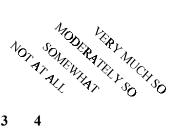
day mon year

Affix label here
Pt ID:
Namecode:
Visit ID:

## SELF-EVALUATION QUESTIONNAIRE - Form Y-1

### DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feeling best.



1. I feel calm 1 2 3 4				
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I am strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

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Affix label here
Pt ID:
Namecode:
Visit ID:

## SELF-EVALUATION QUESTIONNAIRE - Form Y-2

### DIRECTIONS:

A number of statements which people have used to describe themselves	٩.		A.		
are given below. Read each statement and then circle the appropriate	UMOR SI	Dr.	NQ.	L <sup>y</sup>	
number to the right of the statement to indicate how you generally feel.	ALMOST NEV	ONIETIN ER	ALMO OF	X4	L.
	Ţ,	ିନ୍ ଁ	«У	V V	15
21. I feel pleasant			2	3	4
22. I feel nervous and restless		1	2	3	4
23. I feel satisfied with myself		1	2	3	4
24. I wish I could be as happy as others seem to be		1	2	3	4
25. I feel like a failure		1	2	3	4
26. I feel rested		1	2	3	4
27. I am "calm, cool, and collected"		1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them		1	2	3	4
29. I worry too much over something that really doesn't matter		1	2	3	4
30. I am happy		1	2	3	4
31. I have disturbing thoughts		1	2	3	4
32. I lack self-confidence		1	2	3	4
33. I feel secure		1	2	3	4
34. I make decisions easily		1	2	3	4
35. I feel inadequate		1	2	3	4
36. I am content		1	2	3	4
37. Some unimportant thought runs through my mind and bothers me		1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind		1	2	3	4
39. I am a steady person		1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interview of the state of tension of the state of the	erests	1	2	3	4

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Affix label here
Pt ID:
Namecode:
Visit ID:

## SELF-EVALUATION QUESTIONNAIRE SCORING KEY (Form Y-1, Y-2)

### DIRECTIONS:

To use this stencil, fold this sheet in half and line up with the appropriate test page, either Form Y-1 or Form Y-2. Simply total the scoring **weights** shown on the stencil for each response category. For example, for question #1, if the respondent marked 3, then the **weight** would be 2.

NOT AT ALL NIAT SO

ALMOST SOMETIMES OFTEN ALWAYS

## Form Y-1

1.	4	3	2	1	21.	4	3	2	1
2.	4	3	2	1	22.	1	2	3	4
3.	1	2	3	4	23.	4	3	2	1
4.	1	2	3	4	24.	1	2	3	4
5.	4	3	2	1	25.	1	2	3	4
6.	1	2	3	4	26.	4	3	2	1
7.	1	2	3	4	27.	4	3	2	1
8.	4	3	2	1	28.	1	2	3	4
9.	1	2	3	4	29.	1	2	3	4
10.	4	3	2	1	30.	4	3	2	1
11.	4	3	2	1	31.	1	2	3	4
12.	1	2	3	4	32.	1	2	3	4
13.	1	2	3	4	33.	4	3	2	1
14.	1	2	3	4	34.	4	3	2	1
15.	4	3	2	1	35.	1	2	3	4
16.	4	3	2	1	36.	4	3	2	1
17.	1	2	3	4	37.	1	2	3	4
18.	1	2	3	4	38.	1	2	3	4
19.	4	3	2	1	39.	4	3	2	1
20.	4	3	2	1	40.	1	2	3	4

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QF - Form QF MOS 36-Item Short-Form Health Survey (rev 2)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			7377
Varia	ables:	:			58

Variable		_	Variable	_
Name	Variable Label	Туре	Length	Format
emotwb	SF36 Sherbourne: emotional well-being	Num	8	
enerfat	SF36 Sherbourne: energy/fatigue	Num	8	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
genhlth	SF36 Sherbourne: general health	Num	8	
limemot	SF36 Sherbourne: limits due to emotions	Num	8	
limhlth	SF36 Sherbourne: limits due to health	Num	8	
mcs	SF36 Ware: mental component scale	Num	8	
newnett	New NETT patient ID no.	Char	5	
pain	SF36 Sherbourne: pain	Num	8 8	
pcs	SF36 Ware: physical component scale	Num	° 8	
physfunc qf210	SF36 Sherbourne: physical functioning 10 Health, in general	Num Char	° 1	
qf210 qf211	10 Health, in general 11 Health now compared to 1 yr ago	Char	1	
qf215	15 Physical health interfered w/activit	Char	1	
qf216	16 Bodily pain in past 4 weeks	Char	1	
qf210 qf217	17 Pain interfered with normal work	Char	1	
qf219	19 Health interfered with social activi	Char	1	
qf212a	12a Vigorous activities	Char	1	
qf212b	12b Moderate activities	Char	1	
qf212c	12c Lifting/carrying groceries	Char	1	
qf212d	12d Climbing several flights of stairs	Char	1	
qf212e	12e Climbing one flight of stairs	Char	1	
qf212f	12f Bending, kneeling, stooping	Char	1	
qf212q	12g Walking more than a mile	Char	1	
qf212h	12h Walking several blocks	Char	1	
qf212i	12i Walking one block	Char	1	
qf212j	12j Bathing/dressing self	Char	1	
qf213a	13a Cut down time working	Char	1	
qf213b	13b Accomplished less than liked	Char	1	
qf213c	13c Limited activities	Char	1	
qf213d	13d Difficulty performing activities	Char	1	
qf214a	14a Cut down time working	Char	1	
qf214b	14b Accomplished less than liked	Char	1	
qf214c	14c Was less careful	Char	1	
qf218a	18a Feel full of pep	Char	1	
qf218b	18b Been nervous	Char	1	
qf218c	18c Felt down in the dumps	Char	1	
qf218d	18d Felt calm and peaceful	Char	1	
qf218e	18e Have lots of energy	Char	1	
qf218f	18f Felt downhearted and blue	Char	1	
qf218g	18g Felt worn out	Char	1	
qf218h qf218i	18h Been happy 18i Felt tired	Char Char	1	
qf220a	20a Get sick easier than other people	Char	1	
qf220a qf220b	20b Healthy as anybody	Char	1	
qf2200	20c Expect health to get worse	Char	1	
qf2200	20d Health is excellent	Char	1	
socfunc	SF36 Sherbourne: social functioning	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
wgenhlth	SF36 Ware: general health	Num	8	
wmenhlth	SF36 Ware: mental health	Num	8	
wpain	SF36 Ware: pain	Num	8	
wphyfunc	SF36 Ware: physical functioning	Num	8	
wrolemot	SF36 Ware: role emotions	Num	8	
wrolephy	SF36 Ware: role physical	Num	8	
wsocfunc	SF36 Ware: social functioning	Num	8	
wvital	SF36 Ware: vitality	Num	8	

**MOS 36-Item Short-Form Health Survey** 

**Purpose**: To obtain the patient's views of his/her health. When: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to the start of Core Rehabilitation), s3, rz (if more than 21 days since post rehabilitation assessment), f06, f12, f18, f24, f36, f48, f60. Administered by: Self-administered, but Quality of Life Assessor must be available at visits to answer questions and review completed forms. **Respondent**: Patient without help from spouse or family. Instructions: Clinic staff complete page 1 of this form; the patient completes pages 2-8. A QOL label (with patient ID, name code, and appropriate visit code) should be affixed to the upper right corner of pages 2-8. Pre randomization: The patient should meet with the Quality of Life Assessor, be trained in completion of the form, and then should complete the form. The Quality of Life Assessor should review the completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by clinic staff and re-attached to pages 2-8. Post randomization: Pages 2-8 should be mailed to the patient 2 weeks prior to the scheduled NETT clinic visit with instructions to complete the form at home and to bring the completed form to the next NETT clinic visit. When the patient returns for the visit, the Quality of Life Assessor should review the form for completeness and obtain responses for missing items during the clinic visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be completed by clinic staff and re-attached to pages 2-8. Use the date the form was completed for the visit date. If the patient did not write in a date, use the date of the clinic visit for the visit date. A. Clinic, visit, and patient identification **B.** Administrative information (To be completed by clinic staff after survey is 1. Clinic ID: *completed.*) 7. Quality of Life Assessor 2. Patient ID: a. PIN: 3. Patient name code: **b**. Signature:

**4.** Visit date (*date patient completed the form*):

day mon year

- 5. Visit code:
- 6. Form & revision: <u>**q**</u> <u>**f**</u>

2

- 8. Clinic Coordinator
  - a. PIN:
  - **b**. Signature:
- **9.** Date form reviewed:



<b>177</b> Affix label here	7
Pt ID:	
Namecode:	
í L	l

## **MOS 36-Item Short-Form Health Survey**

**Instructions:** This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

(Items 1-9 are reserved for clinic use.)

10. In general, would you say your health is:

Excellent	Circle	e <b>One</b> 1
Very good		2
Good		3
Fair		4
Poor		5

11. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

<b>17</b> Affix label here	'8
Pt ID:	
Namecode:	
ı L	

**12.** The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

			Circle one	<b>)</b>
Activities		Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, s heavy objects, partici sports:	uch as running, lifting pating in strenuous	1	2	3
b. Moderate activities, s pushing a vacuum cle playing golf:	0	1	2	3
c. Lifting or carrying gr	oceries:	1	2	3
d. Climbing several flig	hts of stairs:	1	2	3
e. Climbing one flight o	of stairs:	1	2	3
f. Bending, kneeling, or	stooping:	1	2	3
g. Walking more than a	mile:	1	2	3
h. Walking several bloc	ks:	1	2	3
i. Walking one block:		1	2	3
j. Bathing or dressing y	ourself:	1	2	3

Affix label here	79
Pt ID:	

**13.** During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Circle one		
	Yes	No	
a. Cut down on the amount of time you spent on work or other activities:	1	2	
b. Accomplished less than you would like:	1	2	
c. Were limited in the kind of work or other activities:	1	2	
d. Had difficulty performing the work or activities (for example, it took extra effort):	1	2	

**14.** During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Circle one		
	Yes	No	
a. Cut down on the amount of time you spent on work or other activities:	1	2	
b. Accomplished less than you would like:	1	2	
c. Didn't do work or other activities as carefully as usual:	1	2	

<b>18</b> Affix label here	80
Pt ID:	
Namecode:	

**15.** During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Circle	• <b>One</b> 1
Slightly		2
Moderately		3
Quite a bit		4
Extremely		5

16. How much bodily pain have you had during the past 4 weeks?

None	. 1
Very mild	. 2
Mild	. 3
Moderate	. 4
Severe	. 5
Very severe	. 6

<b>18</b> Affix label here	1
Pt ID:	
Namecode:	
L	

**17.** During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	<b>Circle One</b> 1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

**18.** These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

		Circle one						
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time		
a. Did you feel full of pep?	1	2	3	4	5	6		
b. Have you been a very nervous person?	1	2	3	4	5	6		
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6		
d. Have you felt calm and peaceful?	1	2	3	4	5	6		

	Circle one							
	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time		
e. Did you have a lot of energy?	1	2	3	4	5	6		
f. Have you felt downhearted and blue?	1	2	3	4	5	6		
g. Did you feel worn out?	1	2	3	4	5	6		
h. Have you been a happy person?	1	2	3	4	5	6		
i. Did you feel tired?	1	2	3	4	5	6		

**19.** During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Circle	e <b>One</b> 1
Most of the time		2
Some of the time		3
A little of the time		4
None of the time		5

	Circle one						
	Definitely true	Mostly true	Don't know	Mostly false	Definitely false		
a. I seem to get sick a little easier than other people	1	2	3	4	5		
b. I am as healthy as anybody I know	1	2	3	4	5		
c. I expect my health to get worse	1	2	3	4	5		
d. My health is excellent	1	2	3	4	5		

#### **20.** How TRUE or FALSE is *each* of the following statements for you.

**21.** Date completed:

Please bring this completed survey with you to your scheduled NETT clinic visit.

QG - Form QG The St Georges Respiratory Questionnaire (rev 2)

Date	file	created:	13	May	2006
Observations:					7383
Varia	ables:	:			59

Variable Name	Variable Label	Туре	Variable Length	Format
act	SGRQ activity score	Num	8	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
imp	SGRQ impact score	Num	8	
newnett	New NETT patient ID no.	Char	5	
qg210	10 Coughed over last year	Char	1	
qg211	11 Brought up phlegm over last year	Char	1	
qg212	12 Had shortness of breath over last ye	Char	1	
qq213	13 Had wheezing attacks over last year	Char	1	
qg214	14 Had chest trouble over last year	Char	1	
qg215	15 Length of attack of chest trouble	Char	1	
qg216	16 Number of good days/week	Char	1	
qg217	17 Wheeze worse in the morning	Char	1	
qg218	18 Describe chest condition	Char	1	
qq219	19 Chest trouble affects work	Char	1	
qq220	20 Breathless when sitting/lying still	Char	1	
qg220 qg221	21 Breathless when washing/dressing	Char	1	
qq222	22 Breathless when washing around house	Char	1	
qg222 qg223	23 Breathless when walking on level	Char	1	
qg223 qg224	24 Breathless when walking up stairs	Char	1	
qg224 qg225	25 Breathless when walking hills	Char	1	
qg225 qg226	5	Char	1	
qg220 qg227	26 Breathless when playing sports 27 Cough hurts	Char	1	
qg227 qg228	27 Cough makes me tired	Char	1	
	29 Breathless when I talk	Char	1	
qg229		Char	1	
qg230			1	
qg231	31 Cough disturbs sleep	Char		
qg232	32 Get exhausted easily	Char	1	
qg233	33 Cough is embarrassing	Char	1	
qg234	34 Chest trouble is nuisance to family/	Char	1	
qg235	35 Panic when cannot get breath	Char	1	
qg236	36 Feel not in control of chest problem	Char	1	
qg237	37 Do not expect chest to get better	Char	1	
qg238	38 Frail because of chest	Char	1	
qg239	39 Exercise is not safe	Char	1	
qg240	40 Everything seems too much of an effo	Char	1	
qg241	41 Medication does not help very much	Char	1	
qg242	42 Embarrassed to use medication in pub	Char	1	
qg243	43 Unpleasant side effects from medicin	Char	1	
qg244	44 Medication interferes with life a lo	Char	1	
qg245	45 Takes a long time to wash/dress	Char	1	
qg246	46 Takes a long time to take bath/showe	Char	1	
qg247	47 Walk slower than other people	Char	1	
qg248	48 Housework takes a long time	Char	1	
qg249	49 Walk slowly up stairs or stop	Char	1	
qg250	50 Must slow down/stop if walk fast	Char	1	
qg251	51 Difficult to do easy things	Char	1	
qg252	52 Difficult to do moderate things	Char	1	
qg253	53 Difficult to do strenous things	Char	1	
qg254	54 Cannot play sports or games	Char	1	
qg255	55 Cannot go out for entertainment	Char	1	
qg256	56 Cannot go out shopping	Char	1	
qg257	57 Cannot do housework	Char	1	
qg258	58 Cannot go far from bed or chair	Char	1	
qg259	59 How chest affects patient	Char	1	
qg241a	41a Take any medications	Char	1	
sgrqtot	SGRQ overall score	Num	8	
symp	SGRQ symptoms score	Num	8	

QG -	Form QG	The St	Georges	Respiratory	Questionn	naire	(rev 2)	
Date file c Observation Variables:		13 May	2006 7383 59					
Variable Name	Variable	e Label				Туре	Variable Length	Format
visit	s1,s2,s	3,rz,n,i	fxx where	e xx=mos from	n RZ	Char	3	

#### The St. George's Respiratory Questionnaire

Purpose: To learn more about how the patient's breathing troubles him/her and affects his/her life.
When: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to the start of Core Rehabilitation), s3, rz (if more than 21 days since post rehabilitation assessment), f06, f12, f18, f24, f36, f48, f60.
Administered by: Self-administered, but Quality of Life Assessor must be available at visits to answer questions and review completed questionnaires.
Respondent: Patient without help from spouse or family.
Instructions: Clinic staff complete page 1 of this form; the patient completes pages 2-13. A QOL label (with patient ID, name code, and appropriate visit code) should be affixed to the upper right corner of pages 2-13. Pre randomization: The patient should meet with the Quality of Life Assessor, be trained in completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by clinic staff and re-attached to pages 2-13. Post randomization: Pages 2-13 should be mailed to the patient 2 weeks prior to the scheduled NETT clinic visit. When the patient returns for the visit, the Quality of Life Assessor should review the completed by clinic staff and re-attached near the should near the patient returns for the visit, the Quality of Life Assessor should be mailed to the patient 2 weeks prior to the next NETT clinic visit. When the patient returns for the visit, the Quality of Life Assessor should review the form at home and to bring the completed form for completeness and obtain responses for missing items during the clinic visit. If the

patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be completed by clinic staff and re-attached to pages 2-13. Use the date the form was completed for the visit date. If the patient did not write in a date, use the date of the clinic visit for the visit date.

#### A. Clinic, visit, and patient identification

- 1. Clinic ID: \_\_\_\_\_
- 2. Patient ID:\_\_\_\_\_
- 3. Patient name code:
- **4.** Visit date (*date patient completed the form*):

day mon year

5. Visit code:

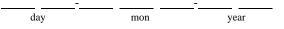
6. Form & revision: <u>q g 2</u>

#### **B.** Administrative information

(*To be completed by clinic staff after questionnaire is completed*)

- 7. Quality of Life Assessor
  - a. PIN:b. Signature:
- 8. Clinic Coordinator
  - a. PIN:
  - **b**. Signature:

9. Date form reviewed:



	187
Affix label here Pt ID:	·

#### The St. George's Respiratory Questionnaire

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

(Items 1-9 are reserved for clinic use.)

#### Part 1

Questions about how much chest trouble you have had over the last year. Please circle one answer for each question.

**10.** Over the last year, I have coughed:

# Circle One Most days a week 1 Several days a week 2 A few days a month 3 Only with chest infections 4 Not at all 5

### National Emphysema Treatment Trial

**188** *Affix label here*Pt ID: \_\_\_\_\_\_\_

#### **11.** Over the last year, I have brought up phlegm (sputum):

Most days a week	Circle	e <b>One</b> 1
Several days a week		2
A few days a month		3
Only with chest infections		4
Not at all	••••	5

**12.** Over the last year, I have had shortness of breath:

Most days a week	1
Several days a week	2
A few days a month	3
Only with chest infections	4
Not at all	5

#### **13.** Over the last year, I have had attacks of wheezing:

Most days a week	<b>Circle One</b> 1
Several days a week	2
A few days a month	3
Only with chest infections	4
Not at all	5

**14.** During the last year, how many severe or very unpleasant attacks of chest trouble have you had:

Go to 16.◀	
No attacks Go to 16.	5
1 attack	4
2 attacks	3
3 attacks	2
More than 3 attacks	1

Affix label here	0
Pt ID:	
Namecode:	
ı L	

**15.** How long did the worst attack of chest trouble last:

A week or more	Circle	e One
A week or more	• • • • •	1
3 or more days		2
1 or 2 days		3
Less than a day	••••	4

**16.** Over the last year, in an average week, how many good days (with little chest trouble) have you had:

No good days 1	ĺ
1 or 2 good days	2
3 or 4 good days 3	3
Nearly every day is good	1
Every day is good	5

**17.** If you have a wheeze, is it worse in the morning:

No	1
Yes	2
Don't have a wheeze	3

<b>19</b> Affix label here	)1
Pt ID:	
Namecode:	
i L	

#### Part 2

#### Section 1

19.

**18.** How would you describe your chest condition:

	<b>Circle One</b>
The most important problem I have	1
Causes me quite a lot of problems	2
Causes me a few problems	3
Causes no problem	4
If you have ever had paid employment:	
My chest trouble made me stop work	1
My chest trouble interferes/interfered with my work or made me change my work	2
My chest trouble does not/did not affect my work	3
Never had paid employment	4

Affix label here	2
Pt ID:	
Namecode:	
l	

#### Section 2

Questions about what activities usually make you feel breathless <u>these days</u>. For each item, please circle either 1 for True or 2 for False as it applies to you.

	Circl TRUE	e One FALSE
<b>20.</b> Sitting or lying still:	1	2
<b>21.</b> Getting washed or dressed:	1	2
<b>22.</b> Walking around the home:	1	2
<b>23.</b> Walking outside on the level:	1	2
<b>24.</b> Walking up a flight of stairs:	1	2
<b>25.</b> Walking hills:	1	2
<b>26.</b> Playing sports or games:	1	2

#### Section 3

Some more questions about your cough and breathlessness <u>these days</u>. For each item, please circle either 1 for True or 2 for False as it applies to you.

	Circl	<b>Circle One</b>	
	TRUE	FALSE	
<b>27.</b> My cough hurts:	1	2	
<b>28.</b> My cough makes me tired:	1	2	

Affix label here	3
Pt ID:	

	Circl TRUE	e One FALSE
<b>29.</b> I am breathless when I talk:	1	2
<b>30.</b> I am breathless when I bend over:	1	2
<b>31.</b> My cough or breathing disturbs my sleep:	1	2
<b>32.</b> I get exhausted easily:	1	2

#### Section 4

Questions about other effects that your chest trouble may have on you <u>these days</u>. For each item, please circle 1 for True or 2 for False as it applies to you.

		Circl TRUE	e One FALSE
33.	My cough or breathing is embarrassing in public:	1	2
34.	My chest trouble is a nuisance to my family, friends, or neighbors:	1	2
35.	I get afraid or panic when I cannot get my breath:	1	2
36.	I feel that I am not in control of my chest problem:	1	2
37.	I do not expect my chest to get any better:	1	2
38.	I have become frail or an invalid because of my chest:	1	2

<b>1</b> Affix label here	94
Pt ID:	ļ
Namecode:	
l L	

		Circl TRUE	e One FALSE
39.	Exercise is not safe for me:	1	2
40.	Everything seems too much of an effort:	1	2
<u>Sectior</u> 41a.	<u>15</u> Do you take any medications:	YES 1 Go te	NO 2 0 45.∢_

Questions about your medication. To complete this section, please circle either 1 for True or 2 for False as it applies to you.

	<b>Circle One</b>	
	TRUE	FALSE
<b>41.</b> My medication does not help me very much:	1	2
<b>42.</b> I get embarrassed using my medication in public:	1	2
<b>43.</b> I have unpleasant side effects from my medication:	1	2
<b>44.</b> My medication interferes with my life a lot:	1	2

<b>19</b> Affix label here	5
Pt ID:	
Namecode:	
LJ	

#### Section 6

These are questions about how your activities might be affected by your breathing. For each question, please circle 1 for True if one or more parts applies to you because of your breathing. Otherwise, circle 2 for False.

		Circ. TRUE	le One FALSE
45.	I take a long time to get washed or dressed:	1	2
46.	I cannot take a bath or shower, or I take a long time:	1	2
47.	I walk slower than other people, or I stop for rests:	1	2
48.	Jobs such as housework take a long time, or I have to stop for rests:	1	2
49.	If I walk up one flight of stairs, I have to go slowly or stop:	1	2
50.	If I hurry or walk fast, I have to stop or slow down:	1	2
51.	My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls, or play golf:	g 1	2
52.	My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim:	1	2
53.	My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports:	1	2

#### 

#### Section 7

We would like to know how your chest trouble <u>usually</u> affects your daily life. Please circle either 1 for True or 2 for False as it applies to you <u>because of your chest</u> <u>trouble</u>. (Remember that True only applies to you if you can not do something because of your breathing.)

	Circl TRUE	e One FALSE
<b>54.</b> I cannot play sports or games:	1	2
<b>55.</b> I cannot go out for entertainment or recreation:	1	2
<b>56.</b> I cannot go out of the house to do the shopping:	1	2
<b>57.</b> I cannot do housework:	1	2
<b>58.</b> I cannot move far from my bed or chair:	1	2

## **197** *Affix label here*Pt ID: \_\_\_\_\_\_

Here is a list of other activities that your chest trouble may prevent you doing. (You do not have to circle these, they are just to remind you of ways in which your breathlessness may affect you):

Going for walks or walking the dog

Doing things at home or in the garden

Sexual intercourse

Going out to church, or place of entertainment

Going out in bad weather or into smoky rooms

Visiting family or friends or playing with children

Please write in any other important activities that your chest trouble may stop you doing:

	<b>19</b> Affix label here	8
	Pt ID:	
Ì	Namecode:	
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**59.** Now, would you circle (one only) which you think best describes how your chest affects you:

	Circle	e One
It does not stop me doing anything I would like to do	• • • •	1
It stops me doing one or two things I would like to do	••••	2
It stops me doing most of the things I would like to do	••••	3
It stops me doing everything I would like to do	••••	4

**60.** Date completed:

Please bring this completed questionnaire with your to your scheduled NETT clinic visit.

QS - Form QS UCSD Med Center Pulmonary Rehab Shortness-of-Breath Questionnaire (rev 2)

Variable

Date	file	created	:	13	May	2006
Obser	vatio	ons:				7385
Varia	bles:	:				29

Variable

Variabic			Variabic	
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
qs210	10 Breathlessness, at rest	Char	1	
qs211	11 Walking on a level at own pace	Char	1	
qs212	12 Walking on a level w/others same age	Char	1	
qs213	13 Walking up a hill	Char	1	
qs214	14 Walking up stairs	Char	1	
qs215	15 Breathlessness, while eating	Char	1	
qs216	16 Breathlessness, standing up from chai	Char	1	
qs217	17 Breathlessness, brushing teeth	Char	1	
qs218	18 Breathlessness, shaving/brushing hair	Char	1	
qs219	19 Breathlessness, showering/bathing	Char	1	
qs220	20 Breathlessness, dressing	Char	1	
qs221	21 Breathlessness, picking up	Char	1	
qs222	22 Breathlessness, doing dishes	Char	1	
qs223	23 Breathlessness, sweeping/vacuuming	Char	1	
qs224	24 Breathlessness, making bed	Char	1	
qs225	25 Breathlessness, shopping	Char	1	
qs226	26 Breathlessness, doing laundry	Char	1	
qs227	27 Breathlessness, washing car	Char	1	
qs228	28 Breathlessness, mowing lawn	Char	1	
qs229	29 Breathlessness, watering lawn	Char	1	
qs230	30 Breathlessness, sexual activities	Char	1	
qs231	31 Shortness of breath	Char	1	
qs232	32 Fear of hurting self by overexertion	Char	1	
qs233	33 Fear of shortness of breath	Char	1	
sobqtot	UCSD SOBQ total score	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

National Emphysema Treatment Trial

#### UCSD Medical Center Pulmonary Rehabilitation Program Shortness-of-Breath Questionnaire

Purpose: To obtain the patient's views of his/her shortness of breath.

**When**: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to the start of Core Rehabilitation), s3, rz (if more than 21 days since post rehabilitation assessment), f06, f12, f18, f24, f36, f48, f60.

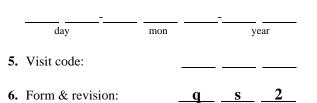
Administered by: Self-administered, but Quality of Life Assessor must be available at visits to answer questions and review completed forms.

Respondent: Patient without help from spouse or family.

**Instructions**: Clinic staff complete page 1 of this form; the patient completes pages 2-5. A QOL label (with patient ID, name code, and appropriate visit code) should be affixed to the upper right corner of pages 2-5. **Pre randomization**: The patient should meet with the Quality of Life Assessor, be trained in completion of the form, and then should complete the form. The Quality of Life Assessor should review the completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by clinic staff and re-attached to pages 2-5. **Post randomization**: Pages 2-5 should be mailed to the patient 2 weeks prior to the scheduled NETT clinic visit with instructions to complete the form at home and to bring the completed form to the next NETT clinic visit. When the patient returns for the visit, the Quality of Life Assessor should review the form at home and to bring the completed form to the next NETT clinic visit, the patient should complete the form at the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be completed by clinic staff and re-attached to pages 2-5. Use the date the form was completed for the visit date. If the patient did not write in a date, use the date of the clinic visit for the visit date.

#### A. Clinic, visit, and patient identification

- 1. Clinic ID: \_\_\_\_\_ \_\_\_\_
- 2. Patient ID: \_\_\_\_\_ \_\_\_\_ \_\_\_\_
- **3.** Patient name code:
- **4.** Visit date (*date patient completed the form*):



#### **B.** Administrative information (*To be completed by clinic st*

(To be completed by clinic staff after questionnaire is completed.)

- 7. Quality of Life Assessor
  - **a**. PIN:
    - b. Signature:
- 8. Clinic Coordinator
  - a. PIN:
  - **b**. Signature:
- 9. Date form reviewed:

day mon year

1.



#### UCSD Medical Center Pulmonary Rehabilitation Program Shortness-of-Breath Questionnaire

Please rate the breathlessness you experience when you do, or if you were to do, each of the following tasks. **Do not skip any items**. If you've never performed a task or no longer perform it, give your best estimate of the breathlessness you would experience while doing that activity. Please review the two sample questions below before turning the page to begin the questionnaire.

#### When I do, or if I were to do, the following tasks, I would rate my breathlessness as:

Brushing	teeth: $0 1 2 3 4 5$
5	5 Maximal or unable to do because of breathlessness
4	4 Severe
3	3
2	2
1	
0	) None at all

Harry has felt moderately short of breath during the past week while brushing his teeth and so circles a three for this activity.

2.	Mowing the lawn:	0	1	2	3	4	5
----	------------------	---	---	---	---	---	---

Anne has never mowed the lawn before but estimates that she would have been too breathless to do this activity during the past week. She circles a five for this activity.

**202** *Affix label here*Pt ID: \_\_\_\_\_\_\_

(Items 1-9 are reserved for clinic use.)

#### When I do, or if I were to do, the following tasks, I would rate my breathlessness as:

	0	None at all						
	1							
	2							
	3							
	4	Severe						
	5	Maximal or una	able to do	because c	of breathle	ssness		
					Circl	e one		
10.	At rest:		0	1	2	3	4	5
11.	Walking							
	at your ov	wn pace:	0	1	2	3	4	5
12	Wallzing	on a level with						
14.	others yo		0	1	2	3	4	5
	others yo	ui age.	U	1	4	5	-	J
13.	Walking	up a hill:	0	1	2	3	4	5
	-	-						
14.	Walking	up stairs:	0	1	2	3	4	5
15	While out	tina	0	1	2	3	4	5
15.	While eat	ung.	U	1	2	3	4	5
16.	Standing	up from a						
	chair:		0	1	2	3	4	5
17.	Brushing	teeth:	0	1	2	3	4	5
10	<b>C1</b>	1/						
18.	Shaving a		Δ	1	2	7	Λ	E
	brushing	nair:	0	1	2	3	4	5
19	Showerin	ng/bathing:	0	1	2	3	4	5
<b>1</b> /•		5, Juning.	v	•	-	·	•	J

**203** *Affix label here*Pt ID: \_\_\_\_\_\_\_

0 None at all						
1						
2 3						
4 Severe						
5 Maximal or una	able to do	because o	f breathle	ssness		
20 Duraciana	0	1		e one	4	_
<b>20.</b> Dressing:	0	1	2	3	4	5
<b>21.</b> Picking up and						
straightening:	0	1	2	3	4	5
<b>22.</b> Doing dishes:	0	1	2	3	4	5
23. Sweeping / vacuuming:	0	1	2	3	4	5
-	-				-	
24. Making bed:	0	1	2	3	4	5
<b>25.</b> Shopping:	0	1	2	3	4	5
<b>26.</b> Doing laundry:	0	1	2	3	4	5
<b>20.</b> Donig launary.	U	Ĩ	4	0	-	J
<b>27.</b> Washing car:	0	1	2	3	4	5
<b>28.</b> Mowing lawn:	0	1	2	3	4	5
<b>29.</b> Watering lawn:	0	1	2	3	4	5
<b>30.</b> Sexual activities:	0	1	2	3	4	5

#### When I do, or if I were to do, the following tasks, I would rate my breathlessness as:

<b>20</b> Affix label here	4
Pt ID:	
Namecode:	
i L	

	<ul> <li>0 None at all</li> <li>1</li> <li>2</li> <li>3</li> <li>4 Severe</li> <li>5 Maximal or u</li> </ul>	nable to do	because o	f breathle	ssness		
31.	Shortness of breath:	0	1	Circl 2	e one 3	4	5
32.	Fear of "hurting myself" by overexerting:	0	1	2	3	4	5
33.	Fear of shortness of breath:	0	1	2	3	4	5
34.	Date completed:						

#### How much do these limit you in your daily life?

Please bring this completed questionnaire with your to your scheduled NETT clinic visit.

Date	file	created:	13	May	2006
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Varia	ables:	:			261

Variable			Variable	
Name	Variable Label	Туре	Length	Format
Traine		1100	Longen	10111100
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
qw252	52 Any other symptoms	Char	1	
qw271	71 Health rating (0-100)	Char	3	
qw211a	11a Blind/severely impaired vision-both	Char	1	
qw211b	11b Blind/severely impaired vision-one e	Char	1	
qw211c	11c Speech problems	Char	1	
qw211d	11d Missing/paralyzed hands, feet, arms,	Char	1 1	
qw211e qw211f	11e Missing/paralyzed fingers/toes	Char Char	1	
qw2111 qw211g	11f Any deformity 11g General fatigue/weakness	Char	1	
qw2119 qw211h	11h Unwanted weight gain or loss	Char	1	
qw2111i	111 Under or over weight	Char	1	
qw2111 qw211j	11j Problem chewing food adequately	Char	1	
qw211k	11k Hearing loss of deafness	Char	1	
qw2111	111 Noticeable skin problems	Char	1	
qw211m	11m Eczema or burning/itching rash	Char	1	
qw212a	12a Dentures	Char	1	
qw212b	12b Oxygen tank	Char	1	
qw212c	12c Prosthesis	Char	1	
qw212d	12d Eye glasses or contact lenses	Char	1	
qw212e	12e Hearing aide	Char	1	
qw212f	12f Magnifying glass	Char	1	
qw212g	12g Neck, back or leg brace	Char	1	
qw213a	13a Vision problems - no days	Char	1	
qw213b	13b Vision problems - yesterday	Char	1	
qw213c	13c Vision problems - 2 days ago	Char	1	
qw213d	13d Vision problems - 3 days ago	Char	1	
qw214a	14a Eye pain - no days	Char	1	
qw214b	14b Eye pain - yesterday	Char	1	
qw214c	14c Eye pain – 2 days ago	Char	1	
qw214d	14d Eye pain - 3 days ago	Char	1	
qw215a	15a Headache - no days	Char	1	
qw215b	15b Headache – yesterday	Char	1	
qw215c	15c Headache – 2 days ago	Char	1	
qw215d	15d Headache – 3 days ago	Char	1	
qw216a	16a Dizziness, earache - no days	Char	1	
qw216b	16b Dizziness, earache - yesterday	Char	1	
qw216c	16c Dizziness, earache - 2 days ago	Char	1	
qw216d	16d Dizziness, earache - 3 days ago	Char	1	
qw217a	17a Difficulty hearing - no days	Char	1	
qw217b	17b Difficulty hearing - yesterday	Char	1	
qw217c	17c Difficulty hearing - 2 days ago	Char	1 1	
qw217d	17d Difficulty hearing - 3 days ago	Char	1	
qw218a qw218b	18a Stuffy/bloody nose - no days 18b Stuffy/bloody nose - yesterday	Char Char	1	
qw2180 qw218c	18c Stuffy/bloody nose - 2 days ago	Char	1	
qw2100 qw218d	18d Stuffy/bloody nose - 3 days ago	Char	1	
qw210a qw219a	19a Sore throat/hoarseness - no days	Char	1	
qw219d qw219b	19b Sore throat/hoarseness - yesterday	Char	1	
qw2190 qw219c	19c Sore throat/hoarseness - 2 days ago	Char	1	
qw2190 qw219d	19d Sore throat/hoarseness - 3 days ago	Char	1	
qw220a	20a Tooth ache/jaw pain - no days	Char	1	
qw220b	20b Tooth ache/jaw pain - yesterday	Char	1	
qw220c	20c Tooth ache/jaw pain - 2 days ago	Char	1	
qw220d	20d Tooth ache/jaw pain - 3 days ago	Char	1	
qw221a	21a Bleeding lips/tongue - no days	Char	1	
-				

Date	file	created	:	13	May	2006
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Varia	:				261	

vallables.	201			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
riamo		1100	20119011	20211020
qw221b	21b Bleeding lips/tongue – yesterday	Char	1	
qw221c	21c Bleeding lips/tongue - 2 days ago	Char	1	
qw221d	21d Bleeding lips/tongue - 3 days ago	Char	1	
qw222a	22a Coughing/wheezing - no days	Char	1	
qw222b	22b Coughing/wheezing – yesterday	Char	1	
qw222c	22c Coughing/wheezing - 2 days ago	Char	1	
qw222d	22d Coughing/wheezing – 3 days ago	Char	1	
qw223a	23a Shortness of breath - no days	Char	1	
qw223b	23b Shortness of breath - yesterday	Char	1	
qw223c	23c Shortness of breath - 2 days ago	Char	1	
qw223d	23d Shortness of breath - 3 days ago	Char	1	
qw224a	24a Chest pain/pressure - no days	Char	1	
qw224b	24b Chest pain/pressure - yesterday	Char	1	
qw224c	24c Chest pain/pressure - 2 days ago	Char	1	
qw224d	24d Chest pain/pressure - 3 days ago	Char	1	
qw225a	25a Upset stomach/nausea - no days	Char	1	
qw225b	25b Upset stomach/nausea - yesterday	Char	1	
qw225c	25c Upset stomach/nausea - 2 days ago	Char	1	
qw225d	25d Upset stomach/nausea - 3 days ago	Char	1	
qw226a	26a Diarrhea, constipation - no days	Char	1	
qw226b	26b Diarrhea, constipation - yesterday	Char	1	
qw226c	26c Diarrhea, constipation - 2 days ago	Char	1	
qw226d qw227a	26d Diarrhea, constipation - 3 days ago 27a Pain/blood in urine - no days	Char Char	1 1	
qw227a qw227b	27b Pain/blood in urine - yesterday	Char	1	
qw2276 qw227c	27c Pain/blood in urine - 2 days ago	Char	1	
qw227d	27d Pain/blood in urine - 3 days ago	Char	1	
qw228a	28a Loss of bladder control - no days	Char	1	
qw228b	28b Loss of bladder control - yesterday	Char	1	
qw228c	28c Loss of bladder control - 2 days ago	Char	1	
qw228d	28d Loss of bladder control - 3 days ago	Char	1	
qw229a	29a Genital pain - no days	Char	1	
qw229b	29b Genital pain - yesterday	Char	1	
qw229c	29c Genital pain - 2 days ago	Char	1	
qw229d	29d Genital pain - 3 days ago	Char	1	
qw230a	30a Broken bone - no days	Char	1	
qw230b	30b Broken bone - yesterday	Char	1	
qw230c	30c Broken bone - 2 days ago	Char	1	
qw230d	30d Broken bone - 3 days ago	Char	1	
qw231a	31a Pain in neck/back - no days	Char	1	
qw231b	31b Pain in neck/back – yesterday	Char	1	
qw231c	31c Pain in neck/back – 2 days ago	Char	1	
qw231d	31d Pain in neck/back – 3 days ago	Char	1	
qw232a	32a Pain in hips/sides – no days	Char	1	
qw232b	32b Pain in hips/sides – yesterday	Char	1	
qw232c	32c Pain in hips/sides – 2 days ago	Char	1	
qw232d	32d Pain in hips/sides - 3 days ago	Char	1	
qw233a	33a Pain in any joints - no days	Char	1	
qw233b	33b Pain in any joints - yesterday	Char	1	
qw233c	33c Pain in any joints - 2 days ago	Char	1	
qw233d	33d Pain in any joints - 3 days ago	Char	1	
qw234a	34a Swelling - no days	Char	1	
qw234b	34b Swelling - yesterday	Char	1	
qw234c	34c Swelling - 2 days ago	Char	1	
qw234d	34d Swelling - 3 days ago	Char	1 1	
qw235a qw235b	35a Fever, chills or sweats - no days	Char Char	1	
qw2350 qw235c	35b Fever, chills or sweats - yesterday 35c Fever, chills or sweats - 2 days ago	Char Char	1	
4w2000	JUC LEVEL, CHILLS OF SWEALS - 2 days ago	CHAL	T	

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Varia	bles:	:			261

Variable			Variable	
Variable Name	Variable Label	Туре	Variable Length	Format
Name	Variable laber	TAbe	Deligen	rormae
qw235d	35d Fever, chills or sweats - 3 days ago	Char	1	
qw236a	36a Loss of consciousness - no days	Char	1	
qw236b	36b Loss of consciousness - yesterday	Char	1	
qw236c	36c Loss of consciousness - 2 days ago	Char	1	
qw236d	36d Loss of consciousness - 3 days ago	Char	1	
qw237a	37a Difficulty w/balance - no days	Char	1	
qw237b	37b Difficulty w/balance - yesterday	Char	1	
qw237c	37c Difficulty w/balance - 2 days ago	Char	1	
qw237d	37d Difficulty w/balance - 3 days ago	Char	1	
qw238a	38a Sleep problems - no days	Char	1	
qw238b	38b Sleep problems - yesterday	Char	1	
qw238c	38c Sleep problems – 2 days ago	Char	1	
qw238d	38d Sleep problems – 3 days ago	Char	1	
qw239a	39a Nervous, shaky - no days	Char	1	
qw239b	39b Nervous, shaky - yesterday	Char	1	
qw239c	39c Nervous, shaky – 2 days ago	Char	1	
qw239d	39d Nervous, shaky - 3 days ago	Char	1	
qw240a	40a Downhearted, blue - no days	Char	1	
qw240b	40b Downhearted, blue – yesterday	Char	1	
qw240c	40c Downhearted, blue – 2 days ago	Char	1	
qw240d	40d Downhearted, blue – 3 days ago	Char	1	
qw241a	41a Excessive worry, anxiety - no days	Char	1	
qw241b	41b Excessive worry, anxiety - yesterday	Char	1	
qw241c	41c Excessive worry, anxiety - 2 days ag	Char	1	
qw241d	41d Excessive worry, anxiety - 3 days ag	Char	1	
qw242a	42a Feeling out of control - no days	Char	1	
qw242b	42b Feeling out of control - yesterday	Char	1	
qw242c	42c Feeling out of control - 2 days ago	Char	1	
qw242d	42d Feeling out of control - 3 days ago	Char	1	
qw243a	43a Feeling lonely - no days	Char	1	
qw243b	43b Feeling lonely - yesterday	Char	1	
qw243c	43c Feeling lonely - 2 days ago	Char	1	
qw243d	43d Feeling lonely - 3 days ago	Char	1	
qw244a	44a Frustrated, irritated - no days	Char	1	
qw244b	44b Frustrated, irritated - yesterday	Char	1	
qw244c	44c Frustrated, irritated - 2 days ago	Char	1	
qw244d	44d Frustrated, irritated - 3 days ago	Char	1 1	
qw245a	45a Hangover - no days	Char Char	1	
qw245b	45b Hangover - yesterday	Char	1	
qw245c qw245d	45c Hangover - 2 days ago 45d Hangover - 3 days ago	Char	1	
qw2450 qw246a	46a Decreased sexual interest - no days	Char	1	
qw246b	46b Decreased sexual interest - yesterda	Char	1	
qw246c	46c Decreased sexual interest - 2 days a	Char	1	
qw246d	46d Decreased sexual interest - 3 days a	Char	1	
qw247a	47a Confusion, memory loss - no days	Char	1	
qw247b	47b Confusion, memory loss - yesterday	Char	1	
qw247c	47c Confusion, memory loss - 2 days ago	Char	1	
qw247d	47d Confusion, memory loss - 3 days ago	Char	1	
qw248a	48a Obsessive thoughts - no days	Char	1	
qw248b	48b Obsessive thoughts - yesterday	Char	1	
qw248c	48c Obsessive thoughts - 2 days ago	Char	1	
qw248d	48d Obsessive thoughts - 3 days ago	Char	1	
qw249a	49a Take any medications - no days	Char	1	
qw249b	49b Take any medications - yesterday	Char	1	
qw249c	49c Take any medications - 2 days ago	Char	1	
qw249d	49d Take any medications - 3 days ago	Char	1	
qw250a	50a Medically prescribed diet - no days	Char	1	
-	4			

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			7370
Varia	ables	:			261

Variables:	261			
Variable		_	Variable	
Name	Variable Label	Туре	Length	Format
qw250b	50b Medically prescribed diet – yesterda	Char	1	
qw250c	50c Medically prescribed diet - 2 days a	Char	1	
qw2500 qw250d	50d Medically prescribed diet - 3 days a	Char	1	
qw251a	51a Appetite loss/overeating - no days	Char	1	
qw251b	51b Appetite loss/overeating - yesterday	Char	1	
qw251c	51c Appetite loss/overeating - 2 days ag	Char	1	
aw251d	51d Appetite loss/overeating - 3 days ag	Char	1	
qw252ab	52a Other symptom - yesterday	Char	1	
qw252ac	52a Other symptom - 2 days ago	Char	1	
qw252ad	52a Other symptom - 3 days ago	Char	1	
qw252bb	52b Other symptom - yesterday	Char	1	
qw252bc	52b Other symptom – 2 days ago	Char	1	
qw252bd	52b Other symptom – 3 days ago	Char	1	
qw253a	53a Been in hospital – no days	Char	1	
qw253b	53b Been in hospital - yesterday	Char	1	
qw253c	53c Been in hospital - 2 days ago	Char	1	
qw253d	53d Been in hospital - 3 days ago	Char	1	
qw254a	54a Need help w/personal care - no days	Char	1	
qw254b	54b Need help w/personal care - yesterda	Char	1 1	
qw254c qw254d	54c Need help w/personal care - 2 days a 54d Need help w/personal care - 3 days a	Char	1	
qw255a	55a Drive a vehicle - no days	Char Char	1	
qw255b	55a Drive a vehicle - yesterday	Char	1	
qw255c	55c Drive a vehicle - 2 days ago	Char	1	
qw255d	55d Drive a vehicle - 3 days ago	Char	1	
qw256a	56a Use public transportation - no days	Char	1	
qw256b	56b Use public transportation - yesterda	Char	1	
qw256c	56c Use public transportation - 2 days a	Char	1	
qw256d	56d Use public transportation - 3 days a	Char	1	
qw257a	57a Not drive - no days	Char	1	
qw257b	57b Not drive – yesterday	Char	1	
qw257c	57c Not drive – 2 days ago	Char	1	
qw257d	57d Not drive - 3 days ago	Char	1	
qw258a	58a Trouble climbing stairs – no days	Char	1	
qw258b	58b Trouble climbing stairs - yesterday	Char	1	
qw258c	58c Trouble climbing stairs - 2 days ago	Char	1	
qw258d	58d Trouble climbing stairs - 3 days ago	Char	1	
qw259a	59a Avoid walking - no days	Char	1 1	
qw259b qw259c	59b Avoid walking - yesterday	Char Char	1	
qw2590 qw259d	59c Avoid walking - 2 days ago 59d Avoid walking - 3 days ago	Char	1	
qw260a	60a Limp/use cane - no days	Char	1	
qw260b	60b Limp/use cane - yesterday	Char	1	
qw260c	60c Limp/use cane - 2 days ago	Char	1	
qw260d	60d Limp/use cane - 3 days ago	Char	1	
qw261a	61a Avoid bending - no days	Char	1	
qw261b	61b Avoid bending - yesterday	Char	1	
qw261c	61c Avoid bending - 2 days ago	Char	1	
qw261d	61d Avoid bending - 3 days ago	Char	1	
qw262a	62a Trouble lifting - no days	Char	1	
qw262b	62b Trouble lifting - yesterday	Char	1	
qw262c	62c Trouble lifting - 2 days ago	Char	1	
qw262d	62d Trouble lifting - 3 days ago	Char	1	
qw263a	63a Other physical limitations - no days	Char	1	
qw263b	63b Other physical limitations - yesterd	Char	1	
qw263c	63c Other physical limitations - 2 days	Char	1 1	
qw263d qw264a	63d Other physical limitations - 3 days 64a Spend day in bed - no days	Char Char	1	
Yw207a	ora opena day in bea no days	Char	Ŧ	

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			7370
Varia	ables:	:			261

Variable Name	Variable Label	Туре	Variable Length	Format
qw264b	64b Spend day in bed - yesterday	Char	1	
qw264c	64c Spend day in bed - 2 days ago	Char	1	
qw264d	64d Spend day in bed - 3 days ago	Char	1	
qw265a	65a Spend day in wheelchair - no days	Char	1	
qw265b	65b Spend day in wheelchair - yesterday	Char	1	
qw265c	65c Spend day in wheelchair - 2 days ago	Char	1	
qw265d	65d Spend day in wheelchair - 3 days ago	Char	1	
qw266a	66a Wheelchair in other's control-no da	Char	1	
qw266b	66b Wheelchair in other's control-veste	Char	1	
qw266c	66c Wheelchair in other's control-2 day	Char	1	
qw266d	66d Wheelchair in other's control-3 day	Char	1	
qw267a	67a Need help w/activities - no days	Char	1	
gw267b	67b Need help w/activities - yesterday	Char	1	
gw267c	67c Need help w/activities - 2 days ago	Char	1	
qw267d	67d Need help w/activities - 3 days ago	Char	1	
qw268a	68a Avoid activities - no days	Char	1	
qw268b	68b Avoid activities - yesterday	Char	1	
qw268c	68c Avoid activities – 2 days ago	Char	1	
qw268d	68d Avoid activities - 3 days ago	Char	1	
qw269a	69a Change plans - no days	Char	1	
qw269b	69b Change plans - yesterday	Char	1	
qw269c	69c Change plans - 2 days ago	Char	1	
qw269d	69d Change plans - 3 days ago	Char	1	
qwb 1	QWB score 1 day ago	Num	8	
qwb <sup>2</sup>	QWB score 2 days ago	Num	8	
qwb_3	QWB score 3 days ago	Num	8	
qwb_ave	QWB over all 3 days (average)	Num	8	
qwb_tot	QWB over all 3 days (sum)	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

**Purpose**: To assess the patient's health problems in the last 3 days.

**When**: Visits s1, s2 (if the s1 assessment was done more than 42 days prior to the start of Core Rehabilitation), s3, rz (if more than 21 days since post rehabilitation assessment), f06, f12, f18, f24, f36, f48, f60.

Administered by: Self-administered, but Quality of Life Assessor must be available at visits to answer questions and review completed forms.

Respondent: Patient without help from spouse or family.

**Instructions**: Clinic staff complete page 1 of this form; the patient completes pages 2-12. A QOL label (with patient ID, name code, and appropriate visit code) should be affixed to the upper right corner of pages 2-12. **Pre randomization**: The patient should meet with the Quality of Life Assessor, be trained in completion of the form, and then should complete the form. The Quality of Life Assessor should review the completed form for missing responses and resolve any problems before the patient leaves the clinic. Page 1 should then be completed by clinic staff and re-attached to pages 2-12. **Post randomization**: Pages 2-12 should be mailed to the patient 2 weeks prior to the scheduled NETT clinic visit with instructions to complete the form at home and to bring the completed form to the next NETT clinic visit. When the patient returns for the visit, the Quality of Life Assessor should review the form at the visit. If the patient did not bring a completed form to the visit, the patient should complete the form at the visit. Page 1 should be completed by clinic staff and re-attached to pages 2-12. Use the date the form at the visit. Page 1 should be completed by clinic staff and re-attached to pages 2-12. Use the date the form was completed for the visit date. If the patient did not write in a date, use the date of the clinic visit for the visit date. For items 13-69, checked responses should be keyed as "1", otherwise they should be left blank.

#### A. Clinic, visit, and patient identification

- 1. Clinic ID: \_\_\_\_\_
- 2. Patient ID: \_\_\_\_\_ \_\_\_\_
- **3.** Patient name code:
- **4.** Visit date (*date patient completed the form*):

day mon year

- 5. Visit code:
- 6. Form & revision: <u>q</u> <u>w</u> <u>2</u>

#### **B.** Administrative information

(*To be completed by clinic staff after questionnaire is completed.*)

- 7. Quality of Life Assessor
  - **a**. PIN: \_\_\_\_\_ \_\_\_\_

mon

- **b**. Signature:
- 8. Clinic Coordinator
  - a. PIN:
  - **b**. Signature:
- 9. Date form reviewed:

day

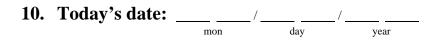
year

<b>21</b> Affix label here	1
Pt ID:	
Namecode:	
i L	

#### **QWB - Quality of Well-Being Scale V1.04**

This survey asks about health problems that you have experienced in the last three days, not including today. Please make sure to answer all questions. Thank you for your patience and time in carefully completing this survey.

(Items 1-9 are reserved for clinic use.)



#### Part I - Acute and Chronic Symptoms

**11.** Please indicate whether you currently experience each of the following health symptoms or problems.

Do you have:

-		Circle One	
		YES	NO
<b>a</b> . Blindness or sev	verely impaired vision in both eyes	1	2
<b>b</b> . Blindness or sev one eye	verely impaired vision in only	1	2
c. Speech problem to speak clear	s such as stuttering, or being unable ly	1	2
<b>d</b> . Missing or paral	lyzed hands, feet, arms, or legs	1	2
e. Missing or paral	lyzed fingers or toes	1	2
• •	of the face, fingers, hand or arm, back (e.g. severe scoliosis)	1	2
<b>g</b> . General fatigue,	tiredness, or weakness	1	2

Affix label here	12
Pt ID:	
Namecode:	

Do you have:

_		Circle YES	One NO
h.	A problem with unwanted weight gain or weight loss	1	2
i.	A problem with being under or over weight	1	2
j.	Problems chewing your food adequately	1	2
k.	Any hearing loss or deafness	1	2
l.	Any noticeable skin problems, such as bad acne or large burns or scars on face, body, arms,		
	or legs	1	2
m.	Eczema or burning/itching rash	1	2

**12.** Which of the following health aides do you use/have?

	Circle YES	One NO
a. Dentures	1	2
<b>b</b> . Oxygen tank	1	2
c. Prosthesis	1	2
<b>d</b> . Eye glasses or contact lenses	1	2
e. Hearing aide	1	2
<b>f</b> . Magnifying glass	1	2
<b>g</b> . Neck, back, or leg brace	1	2

**213** *Affix label here*Pt ID:
Namecode:

For the following list of problems indicate which days (if any) over the past 3 days, not including today, you had the problem. If you have not had the symptom in the past 3 days, <u>do not leave the question blank</u>, please check "no days". If you have experienced the symptom in the past 3 days, please check which of the days you had it; if you experienced it on more than one of the days, check all days that apply.

For example, if you had a headache yesterday and the day before that:

Did you have:	No days	Yesterday	2 days ago	3 days ago
A headache?		1	<b>\</b>	

	r the past 3 days, did you have: ase check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
13.	Any problems with your vision not corrected with glasses or contact lenses (such as double vision, distorted vision, flashes, or floaters)?				
14.	Any eye pain, irritation, discharge, or excessive sensitivity to light?				
15.	A headache?				
16.	Dizziness, earache, or ringing in your ears?				
17.	Difficulty hearing, or discharge, or bleeding from an ear?				
18.	Stuffy or runny nose, or bleeding from the nose?				
19.	A sore throat, difficulty swallowing, or hoarse voice?				

	r the past 3 days, did you have: ase check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
20.	A tooth ache or jaw pain?				
21.	Sore or bleeding lips, tongue, or gums?				
22.	Coughing or wheezing?				
23.	Shortness of breath or difficulty breathing?				
24.	Chest pain, pressure, palpitations, fast or skipped heart beat, or other discomfort in the chest?				
25.	An upset stomach, abdominal pain, nausea, heartburn, or vomiting?				
26.	Difficulty with bowel movements, diarrhea, constipation, black tar-like stools, or any pain or discomfort in the rectal area?				
27.	Pain, burning, or blood in urine?				
28.	Loss of bladder control, frequent night-time urination, or difficulty with urination?				
29.	Genital pain, itching, burning, or abnormal discharge, or pelvic cramping or abnormal bleeding? (Does not include normal menstruation)				

<b>21</b> Affix label here	5
Pt ID:	
Namecode:	

	r the past 3 days, did you have: ase check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
30.	A broken arm, wrist, foot, leg, or any other broken bone (other than in the back)?				
31.	Pain, stiffness, cramps, weakness, or numbness in the neck or back?				
32.	Pain, stiffness, cramps, weakness, or numbness in the hips or sides?				
33.	Pain, stiffness, cramps, weakness, or numbness in any of the joints or muscles of the hand, feet, arms, or legs?				
34.	Swelling of ankles, hands, feet or abdomen?				
35.	Fever, chills, or sweats?				
36.	Loss of consciousness, fainting, or seizures?				
37.	Difficulty with your balance, standing, or walking?				

<b>2</b> Affix label here	16
Pt ID:	
Namecode:	ļ
l L	3

The following symptoms are about your feelings, thoughts, and behaviors.

the p	se check which days (if any) over bast 3, not including today, you had:	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
38.	Trouble falling asleep or staying asleep?				
39.	Spells of feeling nervous or shaky?				
40.	Spells of feeling upset, downhearted, or blue?				
41.	Excessive worry or anxiety?				
42.	Feelings that you had little or no control over events in your life?				
43.	Feelings of being lonely or isolated?				
44.	Feelings of frustration, irritation, or close to losing your temper?				
45.	A hangover?				
46.	Any decrease of sexual interest or performance?				
47.	Confusion, difficulty understanding the written or spoken word, or significant memory loss?				
48.	Thoughts or images you could not get out of your mind?				

# **217** *Affix label here*Pt ID: \_\_\_\_\_\_\_

the p	se check which days (if any) over bast 3, not including today, you had:	a. No days	No Yesterday 2 days		d. 3 days ago
49.	To take any medication including over-the-counter remedies (aspirin/Tylenol, allergy medications, insulin, hormones, estrogen, thyroid, prednisone)?				
50.	To stay on a medically prescribed diet for health reasons?				
51.	A loss of appetite or over- eating?				

52. In the last 3 days did you have any symptoms, health complaints, or pains that have not been mentioned? (circle one)
 YES NO
 1
 2

2 **53.**◀

If yes, what were the symptoms and on which days did you have them?

	b. Yesterday	c. 2 days ago	d. 3 days ago
a.			
b.			

**218** *Affix label here*Pt ID: \_\_\_\_\_\_
Namecode: \_\_\_\_\_\_

## Part II - Self Care

	r the last 3 days: ase check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
53.	Did you spend any part of the day or night as a patient in a hospital, nursing home, or rehabilitation center?				
54.	Because of any impairment or health problem, did you need help with your personal care needs, such as eating, dressing, bathing, or getting around your home?				

## **Part III - Mobility**

Over the last 3 days: (please check all days that apply)		a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
55.	Which days did you drive a motor vehicle?				
56.	Which days did you use public transportation such as a bus, subway, Medi-van, train, or airplane?				

**219** *Affix label here*Pt ID: \_\_\_\_\_\_
Namecode: \_\_\_\_\_\_

Over the last 3 days: (please check all days that apply)		a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
57.	Which days did you either not drive a motor vehicle or not use public transportation because of your health, or need help from another person to use?				

## **Part IV - Physical Activity**

	r the last 3 days did you: ase check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
58.	Have trouble climbing stairs or inclines or walking off the curb?				
59.	Avoid walking, have trouble walking, or walk more slowly than other people your age?				
60.	Limp or use a cane, crutches, or walker?				
61.	Avoid or have trouble bending over, stooping, or kneeling?				
62.	Have any trouble lifting or carrying everyday objects such as books, a briefcase, or groceries?				
63.	Have any other limitations in physical movements?				

NETT

	r the last 3 days did you: ase check all days that apply)	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
64.	Spend all or most of the day in a bed, chair, or couch because of health reasons?				
65.	Spend all or most of the day in a wheelchair?	Go to 67			
66.	If in a wheelchair, on which days did someone else control its movement?				

## Part V - Usual Activity

Over the last 3 days: (please check all days that apply):	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
<b>67.</b> Because of any physical or emotional health reasons, on which days did you avoid, need help with, or were limited in doing some of your usual activities, such as <b>work, school</b> <b>or housekeeping</b> ?				

 221

 Affix label here

 Pt ID:

 Namecode:

	r the last 3 days: ase check all days that apply):	a. No days	b. Yesterday	c. 2 days ago	d. 3 days ago
68.	Because of any physical or emotional health reasons, on which days did you avoid or feel limited in doing some of your usual activities, such as visiting family or friends, hobbies, shopping, recreational, or religious activities?				
69.	On which days did you have to change any of your plans or activities because of your health? (Consider only activities that you did not report in the last 2 questions.)	Go to 71			

70. If activities are limited, please describe:

**71.** Think about a scale of 0 to 100, with zero being the least desirable state of health that you could imagine and 100 being perfect health. What number, from 0 to 100 would you give to the state of your health, on average, over the last 3 days? (Please circle one)

0 10 20 30 40 50 60 70 80 90 100

# Please bring this completed questionnaire with your to your scheduled NETT clinic visit.

Date file Observatio Variables:				
Variable Name	Variable Label	Turno	Variable Length	Format
Name	Vallable Label	Туре	Lengen	FOIMAL
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
heterobl	1=heterog, 0=other, at BL	Num	8	
newnett	New NETT patient ID no.	Char	5	
rc209	9 Description of axial distribution of	Char	1	
rc210	10 Description craniocaudal distributio	Char	1	
rc207a	7a Volumetric helical/spiral	Char	1	
rc207b	7b HRCT-suspended end expiration (FRC)	Char	1	
rc207c	7c HRCT-suspended full inspiration (TLC	Char	1	
rc208al	8a HRCT severity: upper left zone	Char	1	
rc208ar	8a HRCT severity: upper right zone	Char	1	
rc208bl	8b HRCT severity: middle left zone	Char	1	
rc208br	8b HRCT severity: middle right zone	Char	1	
rc208cl	8c HRCT severity: lower left zone	Char	1	
rc208cr	8c HRCT severity: lower right zone	Char	1	
rc211a	11a Evidence of prior thoracic surgery	Char	1	
rc211b	11b Pulmonary nodules or masses	Char	1	
rc211c	11c Interstitial lung disease	Char	1	
rc211d	11d Bronchiectasis	Char	1	
rc211e	11e Active infection	Char	1	
rc211f	11f Giant bulla	Char	1	
rc211g	11g Lobar or segmental collapse	Char	1	
rc211h	11h Mediastinal/hilar mass, enlarged lym	Char	1	
rc211i	11i Enlarged pulmonary arteries	Char	1	
rc211j	11j Pleural thickening or effusion	Char	1	
rc211k	11k Skeletal deformity	Char	1	
rc2111	111 Other ancillary observation	Char	1	
rc211m	11m None	Char	1	
upplobbl	1=upper lobe predominant, 0=other, at BL	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

RC - Form RC CT Scan Report (rev 2)

223

NEII	
Purpose To record evaluations of CT scans.	
When: Visits s1, f06, and f36.	
Respondent: Radiologist and Clinic Coordinator.	
Instructions: This form should be completed by the Radio	plogist and reviewed by the Clinic Coordinator.
A. Clinic, visit, and patient identification	C. Evaluation
1. Clinic ID:	<b>8.</b> Severity of HRCT
2. Patient ID:	Instructions: Score emphysema severity from the <b>Inspiratory HRCT</b> ; score each zone of each lung; only integer scores are allowed (0,1,2,3,4).
<b>3.</b> Patient name code:	<b>Upper zone</b> = lung apex to the top of the aortic arch
4. Visit date (date of CT scan):	<b>Mid zone</b> = aortic arch to the right inferior pulmonary vein
day mon year	Lower zone = right inferior pulmonary vein to the most caudal extent of the lungs
5. Visit ID code:	
<b>6.</b> Form & revision: <u>r c 2</u>	0 = Normal (none) 1 = Mild (1-25%)
B. Computed tomography	2 = Moderate (26-50%)
	3 = Marked (51-75%)
7. CT scans obtained:	<b>4</b> = Severe (> 75%)
<b>a.</b> Volumetric helical/spiral:	Right Left
$\begin{pmatrix} Yes \\ 1 \end{pmatrix}$ $\begin{pmatrix} No \\ 2 \end{pmatrix}$ <b>b.</b> HRCT-suspended end expiration	<b>a.</b> Upper zone: (0-4) (0-4)
(FRC): $\begin{pmatrix} Yes \\ 1 \end{pmatrix} \begin{pmatrix} No \\ 2 \end{pmatrix}$	<b>b.</b> Middle zone: $(0-4)$ $(0-4)$
<b>c.</b> HRCT-suspended full inspiration (TLC):	<b>c.</b> Lower zone: $(0-4)$ $(0-4)$
	<b>9.</b> Best description of the axial distribution of emphysema ( <i>check one only</i> ):
	Peripheral/subpleural predominantly across individual CT images ( 1) Central/axial predominantly across individual CT images ( 2) Evenly distributed (central and peripheral)

Evenly distributed (central and peripheral) across individual CT images ( 3) 10. Best description of the craniocaudal

distribution of emphysema(check only on	e):	
Upper lobe predominant	(	1)
Lower lobe predominant	(	2)
Diffuse	(	3)
Superior segments of lower lobes predominantly involved	(	<sub>4</sub> )
<b>11. Ancillary observations</b> (from HRCT and 5-8 mm helical CT) ( <i>check all that ap</i>	ply)	
<b>a.</b> Evidence of prior thoracic surgery:	(	1)
<b>b.</b> Pulmonary nodules or masses:	(	1)
<b>c.</b> Interstitial lung disease (such as pulmonary fibrosis):	(	1)
d. Bronchiectasis:	(	1)
e. Active infection:	(	1)
<b>f.</b> Giant bulla (at least 1/3 of the volume of the lung in which the bulla is located):	(	*1)
g. Lobar or segmental collapse:	(	1)
<b>h.</b> Mediastinal/Hilar mass(es) or enlarged lymph nodes:	(	1)
i. Enlarged pulmonary arteries:	(	1)
<b>j.</b> Pleural thickening or effusion:	(	1)
<b>k.</b> Skeletal deformity (scoliosis, kyphosis, or compression fractures):	(	1)
<b>l.</b> Other ( <i>specify</i> ):	(	1)

specify

**m.** None ((*\*Presence of a giant bulla is exclusionary.*)

#### D. Administrative information

**12.** Location of stored CT scans:

specify location

Patient ID:

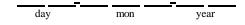
**13.** Radiologist PIN:

14. Radiologist signature:

**15.** Clinic Coordinator PIN:

**16.** Clinic Coordinator signature:

**17.** Date form reviewed:



(\_\_\_\_)

RCORE IAC right lung core file -Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format ae50 No. of voxels above -50 HU in a region Num 8 ae100 No. of voxels above -100 HU in a region Num 8 ae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region ae200 8 Num ae250 No. of voxels above -250 HU in a region Num 8 aint Ankle intercept Num 8 airv Volume of region that is air (ml) Num 8 ankl Ankle Num 8 aslp Ankle slope Num 8 No. of voxels below -600 HU in a region be600 Num 8 No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region be620 Num 8 be640 Num 8 No. of voxels below -660 HU in a region be660 Num 8 be810 No. of voxels below -810 HU in a region Num 8 be830 No. of voxels below -830 HU in a region Num 8 be850 No. of voxels below -850 HU in a region Num 8 be870 No. of voxels below -870 HU in a region Num 8 No. of voxels below -890 HU in a region be890 Num 8 No. of voxels below -900 HU in a region be900 Num 8 be910 No. of voxels below -910 HU in a region Num 8 be920 No. of voxels below -920 HU in a region Num 8 No. of voxels below -930 HU in a region be930 Num 8 No. of voxels below -940 HU in a region be940 Num 8 No. of voxels below -950 HU in a region be950 Num 8 be960 No. of voxels below -960 HU in a region Num 8 ccutoff See IAC Scan Analysis variables listing 8 Num See IAC Scan Analysis variables listing Num 8 cvm See IAC Scan Analysis variables listing Num 8 cvsd See IAC Scan Analysis variables listing CVXM Num 8 cvxsd See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 CVVM cvysd See IAC Scan Analysis variables listing Nıım 8 cvzm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing cvzsd Num 8 Histogram pgm version number Char entityve 18 fwhm See IAC Scan Analysis variables listing Nıım 8 historig Num 8 hrcreate Num 8 hrcreate cnvrtd to #days frm RZ/scr strt hu10 HU value below which 10% of voxels fall Num 8 hu15 HU value below which 15% of voxels fall Num 8 hu20 HU value below which 20% of voxels fall Num 8 intercep Value used to convert voxels into HU Num 8 8 Knee intercept Num kint knee See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing kslp Num 8 kurt Kurtosis Nıım 8 lae50 No. of voxels above -50 HU in a region Nıım 8 lae100 No. of voxels above -100 HU in a region Num 8 lae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region No. of voxels above -250 HU in a region lae200 8 Num lae250 Num 8 laint Ankle intercept Num 8 lairv Volume of region that is air (ml) Num 8 Num 8 lankl Ankle laslp Ankle slope Num 8 1be600 No. of voxels below -600 HU in a region Num 8 No. of voxels below -620 HU in a region 1be620 8 Num lbe640 No. of voxels below -640 HU in a region Num 8

ROOTE	ind right rang core rife			
Date file d	created: 13 May 2006			
Observatior				
Variables:	207			
Variable			Variable	
Name	Variable Label	Type	Length	Format
Ivanic	variable laber	Type	Deligen	rormae
lbe660	No. of voxels below -660 HU in a region	Num	8	
lbe810	No. of voxels below -810 HU in a region	Num	8	
lbe830	No. of voxels below -830 HU in a region	Num	8	
lbe850	No. of voxels below -850 HU in a region	Num	8	
lbe870 lbe890	No. of voxels below -870 HU in a region No. of voxels below -890 HU in a region	Num Num	8 8	
lbe900	No. of voxels below -900 HU in a region	Num	8	
lbe910	No. of voxels below -910 HU in a region	Num	8	
lbe920	No. of voxels below -920 HU in a region	Num	8	
lbe930	No. of voxels below -930 HU in a region	Num	8	
lbe940	No. of voxels below -940 HU in a region	Num	8	
lbe950	No. of voxels below -950 HU in a region	Num	8	
lbe960 lcvm	No. of voxels below -960 HU in a region See IAC Scan Analysis variables listing	Num Num	8 8	
lcvsd	See IAC Scan Analysis variables listing	Num	8	
lcvxm	See IAC Scan Analysis variables listing	Num	8	
lcvxsd	See IAC Scan Analysis variables listing	Num	8	
lcvym	See IAC Scan Analysis variables listing	Num	8	
lcvysd	See IAC Scan Analysis variables listing	Num	8	
lcvzm	See IAC Scan Analysis variables listing	Num	8	
lcvzsd lfwhm	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num	8	
lhu10	HU value below which 10% of voxels fall	Num Num	8 8	
lhu15	HU value below which 15% of voxels fall	Num	8	
lhu20	HU value below which 20% of voxels fall	Num	8	
lkint	Knee intercept	Num	8	
lknee	See IAC Scan Analysis variables listing	Num	8	
lkslp	See IAC Scan Analysis variables listing	Num	8	
lkurt	Kurtosis Mean	Num	8	
lmean lmed	Median	Num Num	8 8	
lsd	Standard deviation	Num	8	
lskew	Skewness	Num	8	
ltisv	Region vol that is tissue & blood(ml)	Num	8	
ltotv	Total volume of region (cubic ml)	Num	8	
ltotvx	Total number of voxels in a region	Num	8	
lvar mae50	Variance No. of voxels above -50 HU in a region	Num Num	8 8	
mae100	No. of voxels above -100 HU in a region	Num	8	
mae150	No. of voxels above -150 HU in a region	Num	8	
mae200	No. of voxels above -200 HU in a region	Num	8	
mae250	No. of voxels above -250 HU in a region	Num	8	
maint	Ankle intercept	Num	8	
mairv	Volume of region that is air (ml)	Num	8	
mankl maslp	Ankle Ankle slope	Num Num	8 8	
mbe600	No. of voxels below -600 HU in a region	Num	8	
mbe620	No. of voxels below -620 HU in a region	Num	8	
mbe640	No. of voxels below -640 HU in a region	Num	8	
mbe660	No. of voxels below -660 HU in a region	Num	8	
mbe810	No. of voxels below -810 HU in a region	Num	8	
mbe830	No. of voxels below -830 HU in a region	Num	8	
mbe850 mbe870	No. of voxels below -850 HU in a region No. of voxels below -870 HU in a region	Num Num	8 8	
mbe890	No. of voxels below -870 HU in a region	Num	8	
mbe900	No. of voxels below -900 HU in a region	Num	8	
mbe910	No. of voxels below -910 HU in a region	Num	8	
mbe920	No. of voxels below -920 HU in a region	Num	8	

RCORE - IAC right lung core file

RCORE -	IAC right lung core file			
Date file c Observation Variables:				
Variable Name	Variable Label	Туре	Variable Length	Format
mbe930	No. of voxels below -930 HU in a region	Num	8	
mbe940	No. of voxels below -940 HU in a region	Num	8	
mbe950 mbe960	No. of voxels below -950 HU in a region	Num	8	
mcvm	No. of voxels below -960 HU in a region See IAC Scan Analysis variables listing	Num Num	8 8	
mcvsd	See IAC Scan Analysis variables listing	Num	8	
mcvxm	See IAC Scan Analysis variables listing	Num	8	
mcvxsd	See IAC Scan Analysis variables listing	Num	8	
mcvym	See IAC Scan Analysis variables listing	Num	8	
mcvysd	See IAC Scan Analysis variables listing	Num	8	
mcvzm	See IAC Scan Analysis variables listing	Num Num	8 8	
mcvzsd mean	See IAC Scan Analysis variables listing Mean	Num	8	
med	Median	Num	8	
mfwhm	See IAC Scan Analysis variables listing	Num	8	
mhu10	HU value below which 10% of voxels fall	Num	8	
mhu15	HU value below which 15% of voxels fall	Num	8	
mhu20	HU value below which 20% of voxels fall	Num	8	
mkint	Knee intercept	Num	8	
mknee mkslp	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num Num	8 8	
mkurt	Kurtosis	Num	8	
mmean	Mean	Num	8	
mmed	Median	Num	8	
msd	Standard deviation	Num	8	
mskew	Skewness	Num	8	
mtisv	Region vol that is tissue & blood(ml)	Num	8	
mtotv	Total volume of region (cubic ml)	Num	8	
mtotvx mvar	Total number of voxels in a region Variance	Num Num	8 8	
newnett	New NETT patient ID no.	Char	5	
passver	New MEIT pactone ID Not	Char	13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
slicethi	Slice thickness	Char	14	
tisv totv	Region vol that is tissue & blood(ml) Total volume of region (cubic ml)	Num Num	8 8	
totvx	Total number of voxels in a region	Num	8	
uae50	No. of voxels above -50 HU in a region	Num	8	
uae100	No. of voxels above -100 HU in a region	Num	8	
uae150	No. of voxels above -150 HU in a region	Num	8	
uae200	No. of voxels above -200 HU in a region	Num	8	
uae250	No. of voxels above -250 HU in a region	Num	8 8	
uaint uairv	Ankle intercept Volume of region that is air (ml)	Num Num	8	
uankl	Ankle	Num	8	
uaslp	Ankle slope	Num	8	
ube600	No. of voxels below -600 HU in a region	Num	8	
ube620	No. of voxels below -620 HU in a region	Num	8	
ube640	No. of voxels below -640 HU in a region	Num	8	
ube660	No. of voxels below -660 HU in a region	Num	8	
ube810 ube830	No. of voxels below -810 HU in a region No. of voxels below -830 HU in a region	Num Num	8 8	
ube850	No. of voxels below -850 HU in a region	Num	° 8	
ube870	No. of voxels below -870 HU in a region	Num	8	
ube890	No. of voxels below -890 HU in a region	Num	8	
ube900	No. of voxels below -900 HU in a region	Num	8	

RCORE -	IAC right lung core file			
Date file Observatio Variables:	created: 13 May 2006 ns: 2236 207			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ube910	No. of voxels below -910 HU in a region	Num	8	
ube920	No. of voxels below -920 HU in a region	Num	8	
ube930	No. of voxels below -930 HU in a region	Num	8	
ube940	No. of voxels below -940 HU in a region	Num	8	
ube950	No. of voxels below -950 HU in a region	Num	8	
ube960	No. of voxels below -960 HU in a region	Num	8	
ucvm	See IAC Scan Analysis variables listing	Num	8	
ucvsd	See IAC Scan Analysis variables listing	Num	8	
ucvxm	See IAC Scan Analysis variables listing	Num	8	
ucvxsd	See IAC Scan Analysis variables listing	Num	8	
ucvym	See IAC Scan Analysis variables listing	Num	8	
ucvysd	See IAC Scan Analysis variables listing	Num	8	
ucvzm	See IAC Scan Analysis variables listing	Num	8	
ucvzsd	See IAC Scan Analysis variables listing	Num	8	
ufwhm	See IAC Scan Analysis variables listing	Num	8	
uhu10	HU value below which 10% of voxels fall	Num	8	
uhu15	HU value below which 15% of voxels fall	Num	8	
uhu20	HU value below which 20% of voxels fall	Num	8	
ukint	Knee intercept	Num	8	
uknee	See IAC Scan Analysis variables listing	Num	8	
ukslp	See IAC Scan Analysis variables listing	Num	8	
ukurt	Kurtosis	Num	8	
umean	Mean	Num	8	
umed	Median	Num	8	
usd	Standard deviation	Num	8	
uskew	Skewness	Num	8	
utisv	Region vol that is tissue & blood(ml)	Num	8	
utotv	Total volume of region (cubic ml)	Num	8	
utotvx	Total number of voxels in a region	Num	8	
uvar	Variance	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

RESID - Residence over time

Date file created: 07 May 2006 Observations: 19778 Variables: 3

Variable Name	Variable Label	Туре	Variable Length	Format
newnett	New NETT patient ID no.	Char	5	
resid	1=home,2=nursng/rehab,3=acute care	Num	8	
visit	Visit code fxx where xx=mos since RZ	Char	3	

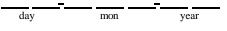
IAC right lung holes file RHOLE -Date file created: 13 May 2006 Observations: 2236 Variables: 82 Variable Variable Name Variable Label Type Length Format At -950, see IAC Scan Analysis vbl list alpha 1 Num 8 At -930, see IAC Scan Analysis vbl list alpha 2 8 Num alpha<sup>3</sup> At -910, see IAC Scan Analysis vbl list Num 8 At -890, see IAC Scan Analysis vbl list alpha\_4 Num 8 alpha\_5 At -870, see IAC Scan Analysis vbl list Num 8 At -850, see IAC Scan Analysis vbl list Num 8 alpha 6 c1 1 Y intercept at -950 8 Num c1\_2 Y intercept at -930 Num 8 c1 3 Y intercept at -910 Num 8 c1\_4 Y intercept at -890 Num 8 c1\_5 Y intercept at -870 Num 8 Y intercept at -850 c1 6 Num 8 cutoff 1 At -950, see IAC Scan Analysis vbl list Num 8 cutoff<sup>2</sup> At -930, see IAC Scan Analysis vbl list Num 8 cutoff\_3 At -910, see IAC Scan Analysis vbl list Num 8 cutoff\_4 cutoff\_5 cutoff\_6 At -890, see IAC Scan Analysis vbl list Num 8 At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list Num 8 Num 8 entityve Hole pgm version number Char 18 hwcreate cnvrtd to #days frm RZ/scr strt Num 8 hwcreate Value used to convert voxels into HU intercep Num 8 lalpha 1 At -950, see IAC Scan Analysis vbl list Num 8 At -930, see IAC Scan Analysis vbl list lalpha 2 Num 8 lalpha 3 At -910, see IAC Scan Analysis vbl list 8 Num lalpha 4 At -890, see IAC Scan Analysis vbl list Num 8 lalpha 5 At -870, see IAC Scan Analysis vbl list Num 8 At -850, see IAC Scan Analysis vbl list Num 8 lalpha 6 lc1\_1 lc1\_2 Y intercept at -950 Num 8 Y intercept at -930 Num 8 lc1<sup>3</sup> Y intercept at -910 Num 8 lc1 4 Y intercept at -890 Num 8 lc1\_5 Y intercept at -870 8 Num lc1 6 Y intercept at -850 Num 8 At -950, see IAC Scan Analysis vbl list lcutoff1 Num 8 At -930, see IAC Scan Analysis vbl list lcutoff2 Num 8 lcutoff3 At -910, see IAC Scan Analysis vbl list Num 8 lcutoff4 At -890, see IAC Scan Analysis vbl list Num 8 lcutoff5 At -870, see IAC Scan Analysis vbl list 8 Num At -850, see IAC Scan Analysis vbl list At -950, see IAC Scan Analysis vbl list lcutoff Num 8 malpha 1 Num 8 At -930, see IAC Scan Analysis vbl list malpha 2 Num 8 malpha 3 At -910, see IAC Scan Analysis vbl list Num 8 At -890, see IAC Scan Analysis vbl list Num 8 malpha\_4 malpha \_\_\_\_\_ 5 At -870, see IAC Scan Analysis vbl list Num 8 At -850, see IAC Scan Analysis vbl list malpha 6 Num 8 mc1 1 Y intercept at -950 Num 8 mc1\_2 Y intercept at -930 Num 8 mc1\_3 Y intercept at -910 Num 8 mc1\_4 Y intercept at -890 8 Num mc1\_5 mc1\_6 Y intercept at -870 8 Num Y intercept at -850 Num 8 At -950, see IAC Scan Analysis vbl list mcutoff1 Nıım 8 mcutoff2 At -930, see IAC Scan Analysis vbl list Num 8 At -910, see IAC Scan Analysis vbl list 8 mcutoff3 Num mcutoff4 At -890, see IAC Scan Analysis vbl list Num 8 At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list mcutoff5 Num 8 mcutoff Num 8 New NETT patient ID no. newnett Char 5

RHOLE -IAC right lung holes file Date file created: 13 May 2006 Observations: 2236 82 Variables: Variable Variable Variable Label Name Туре Length Format passver Char 13 rigthwho 8 Num scandate scandate cnvrtd to #days frm RZ/scr strt 8 Num slicethi Slice thickness Char 14 At -950, see IAC Scan Analysis vbl list At -930, see IAC Scan Analysis vbl list At -910, see IAC Scan Analysis vbl list ualpha 1 Num 8 ualpha\_2 ualpha\_3 Num 8 Num 8 ualpha\_4 At -890, see IAC Scan Analysis vbl list Num 8 ualpha\_5 At -870, see IAC Scan Analysis vbl list Num 8 At -850, see IAC Scan Analysis vbl list 8 ualpha 6 Num ucl\_1 ucl\_2 Y intercept at -950 Num 8 Y intercept at -930 8 Num uc1\_3 Y intercept at -910 8 Num ucl<sup>4</sup> Y intercept at -890 Num 8 uc1\_5 8 Y intercept at -870 Num uc1\_6 Y intercept at -850 Num 8 ucutoff1 At -950, see IAC Scan Analysis vbl list Num 8 At -930, see IAC Scan Analysis vbl list 8 ucutoff2 Num ucutoff3 At -910, see IAC Scan Analysis vbl list Num 8 At -890, see IAC Scan Analysis vbl list ucutoff4 Num 8 ucutoff5 At -870, see IAC Scan Analysis vbl list 8 Num ucutoff\_ At -850, see IAC Scan Analysis vbl list Num 8 visit Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ Char 3 vxsize Voxel size Num 8

RP -	Form RP Perfusion Scan (rev 2)			
Date file o Observation Variables:	created: 13 May 2006 ns: 1614 17			
Variable	Venichle Tehel	<b>—</b>	Variable	Downot
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
prat	perfusion ratio: (Ur+Ul) / (Mr+Ml+Lr+Ll)	Num	8	
rp207al	7a % perfusion: upper Lt	Char	3	
rp207ar	7a % perfusion: upper Rt	Char	3	
rp207bl	7b % perfusion: middle Lt	Char	3	
rp207br	7b % perfusion: middle Rt	Char	3	
rp207cl	7c % perfusion: lower Lt	Char	3	
rp207cr	7c % perfusion: lower Rt	Char	3	
rp208al	8a Perfusion homogenity score: upper Lt	Char	1	
rp208ar	8a Perfusion homogenity score: upper Rt	Char	1	
rp208bl	8b Perfusion homogenity score: middle Lt	Char	1	
rp208br	8b Perfusion homogenity score: middle Rt	Char	1	
rp208cl	8c Perfusion homogenity score: lower Lt	Char	1	
rp208cr	8c Perfusion homogenity score: lower Rt	Char	1	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

When: Visit rz.				
Respondent: Nuclear medie	cine physician and Clinic Co	ordinator.		
nator. Transcribe values		lear medicine physician and review the perfusion scan report. Mark th ack of this form.		
A. Clinic, visit, and patie	ent identification	8. Qualitative analysis of p homogeneity in each zor		
1. Clinic ID:		nomogenentj m even zor		
		A = homogenous perfusi	on	
2. Patient ID:		B = mildly heterogenous	perfusion	
3. Patient name code:		C = moderate to severe h of perfusion	eterogeneity	
4. Visit date (date of pe	rfusion scan):		Right	Lef
day	mon year	a. Upper zone:	(A-C)	(A-0
5. Visit ID code:	<u>r z</u>	<b>b.</b> Middle zone:	(A-C)	(A-0
<b>6.</b> Form & revision:	<u>r p 2</u>	<b>c.</b> Lower zone:	(A-C)	(A-0
B. Perfusion scan evalua	ntion			(
7. Percent of perfusion i	in each lung zone:	G. Administrative information	tion	
Right	Left	9. Location of perfusion sca	an:	
<b>a.</b> Upper:		specif	fy location	
<b>b.</b> Middle:	%	<b>10.</b> Name of nuclear medicity (please print):	ne physician	
D. WILLUIC.				
%	%			
<b>c.</b> Lower:		<b>11.</b> Clinic Coordinator PIN:		
%	%	12. Clinic Coordinator signa	ature:	

**13.** Date of review:



IAC right lung peel file RPEEL -Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format ae50 No. of voxels above -50 HU in a region Num 8 ae100 No. of voxels above -100 HU in a region Num 8 ae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region ae200 8 Num ae250 No. of voxels above -250 HU in a region Num 8 aint Ankle intercept Num 8 airv Volume of region that is air (ml) Num 8 ankl Ankle Num 8 aslp Ankle slope Num 8 No. of voxels below -600 HU in a region be600 Nıım 8 No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region be620 Num 8 be640 Num 8 No. of voxels below -660 HU in a region be660 Num 8 be810 No. of voxels below -810 HU in a region Num 8 No. of voxels below -830 HU in a region be830 Num 8 be850 No. of voxels below -850 HU in a region Num 8 be870 No. of voxels below -870 HU in a region Num 8 No. of voxels below -890 HU in a region be890 Num 8 No. of voxels below -900 HU in a region be900 Num 8 be910 No. of voxels below -910 HU in a region Num 8 be920 No. of voxels below -920 HU in a region Num 8 No. of voxels below -930 HU in a region be930 Num 8 No. of voxels below -940 HU in a region be940 Num 8 No. of voxels below -950 HU in a region be950 Num 8 be960 No. of voxels below -960 HU in a region Num 8 ccutoff See IAC Scan Analysis variables listing 8 Num See IAC Scan Analysis variables listing Num 8 cvm See IAC Scan Analysis variables listing Num 8 cvsd See IAC Scan Analysis variables listing CVXM Num 8 cvxsd See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 CVVM cvysd See IAC Scan Analysis variables listing Nıım 8 cvzm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing cvzsd Num 8 Histogram pgm version number Char entityve 18 fwhm See IAC Scan Analysis variables listing Nıım 8 historig Num 8 hrcreate Num 8 hrcreate cnvrtd to #days frm RZ/scr strt hu10 HU value below which 10% of voxels fall Num 8 hu15 HU value below which 15% of voxels fall Num 8 hu20 HU value below which 20% of voxels fall Num 8 intercep Value used to convert voxels into HU Num 8 8 Knee intercept Num kint knee See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing kslp Num 8 kurt Kurtosis Nıım 8 lae50 No. of voxels above -50 HU in a region Nıım 8 lae100 No. of voxels above -100 HU in a region Num 8 lae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region No. of voxels above -250 HU in a region lae200 8 Num lae250 Num 8 laint Ankle intercept Num 8 lairv Volume of region that is air (ml) Num 8 8 lankl Ankle Num laslp Ankle slope Num 8 1be600 No. of voxels below -600 HU in a region Num 8 No. of voxels below -620 HU in a region 1be620 8 Num lbe640 No. of voxels below -640 HU in a region Num 8

	The fight fung peer fife			
Date file d	created: 13 May 2006			
Observation				
Variables:	207			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
		21 -	- 0 -	
lbe660	No. of voxels below -660 HU in a region	Num	8	
lbe810	No. of voxels below -810 HU in a region	Num	8	
lbe830 lbe850	No. of voxels below -830 HU in a region No. of voxels below -850 HU in a region	Num	8 8	
lbe870	No. of voxels below -870 HU in a region	Num Num	8	
1be890	No. of voxels below -890 HU in a region	Num	8	
lbe900	No. of voxels below -900 HU in a region	Num	8	
lbe910	No. of voxels below -910 HU in a region	Num	8	
lbe920	No. of voxels below -920 HU in a region	Num	8	
1be930	No. of voxels below -930 HU in a region	Num	8	
lbe940 lbe950	No. of voxels below -940 HU in a region No. of voxels below -950 HU in a region	Num Num	8 8	
lbe960	No. of voxels below -960 HU in a region	Num	8	
lcvm	See IAC Scan Analysis variables listing	Num	8	
lcvsd	See IAC Scan Analysis variables listing	Num	8	
lcvxm	See IAC Scan Analysis variables listing	Num	8	
lcvxsd	See IAC Scan Analysis variables listing	Num	8	
lcvym	See IAC Scan Analysis variables listing	Num	8	
lcvysd lcvzm	See IAC Scan Analysis variables listing	Num	8	
lcvzsd	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num Num	8 8	
lfwhm	See IAC Scan Analysis variables listing	Num	8	
lhu10	HU value below which 10% of voxels fall	Num	8	
lhu15	HU value below which 15% of voxels fall	Num	8	
lhu20	HU value below which 20% of voxels fall	Num	8	
lkint	Knee intercept	Num	8	
lknee lkslp	See IAC Scan Analysis variables listing	Num Num	8 8	
lkurt	See IAC Scan Analysis variables listing Kurtosis	Num	8	
lmean	Mean	Num	8	
lmed	Median	Num	8	
lsd	Standard deviation	Num	8	
lskew	Skewness	Num	8	
ltisv	Region vol that is tissue & blood(ml)	Num	8	
ltotv ltotvx	Total volume of region (cubic ml) Total number of voxels in a region	Num Num	8 8	
lvar	Variance	Num	8	
mae50	No. of voxels above -50 HU in a region	Num	8	
mae100	No. of voxels above -100 HU in a region	Num	8	
mae150	No. of voxels above -150 HU in a region	Num	8	
mae200	No. of voxels above -200 HU in a region	Num	8	
mae250 maint	No. of voxels above -250 HU in a region Ankle intercept	Num Num	8 8	
mairv	Volume of region that is air (ml)	Num	8	
mankl	Ankle	Num	8	
maslp	Ankle slope	Num	8	
mbe600	No. of voxels below -600 HU in a region	Num	8	
mbe620	No. of voxels below -620 HU in a region	Num	8	
mbe640	No. of voxels below -640 HU in a region	Num	8	
mbe660 mbe810	No. of voxels below -660 HU in a region No. of voxels below -810 HU in a region	Num Num	8 8	
mbe830	No. of voxels below -810 HU in a region	Num	8	
mbe850	No. of voxels below -850 HU in a region	Num	8	
mbe870	No. of voxels below -870 HU in a region	Num	8	
mbe890	No. of voxels below -890 HU in a region	Num	8	
mbe900	No. of voxels below -900 HU in a region	Num	8	
mbe910 mbe920	No. of voxels below -910 HU in a region	Num	8	
11100920	No. of voxels below -920 HU in a region	Num	8	

RPEEL - IAC right lung peel file

RPEEL -	IAC right lung peel file			
Date file c Observation Variables:	-			
Variable Name	Variable Label	Туре	Variable Length	Format
mbe930	No. of voxels below -930 HU in a region	Num	8	
mbe940	No. of voxels below -940 HU in a region	Num	8	
mbe950 mbe960	No. of voxels below -950 HU in a region No. of voxels below -960 HU in a region	Num	8 8	
mcvm	See IAC Scan Analysis variables listing	Num Num	8	
mcvsd	See IAC Scan Analysis variables listing	Num	8	
mcvxm	See IAC Scan Analysis variables listing	Num	8	
mcvxsd	See IAC Scan Analysis variables listing	Num	8	
mcvym	See IAC Scan Analysis variables listing	Num	8	
mcvysd mcvzm	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num Num	8 8	
mcvzsd	See IAC Scan Analysis variables listing	Num	8	
mean	Mean	Num	8	
med	Median	Num	8	
mfwhm	See IAC Scan Analysis variables listing	Num	8	
mhu10 mhu15	HU value below which 10% of voxels fall HU value below which 15% of voxels fall	Num Num	8 8	
mhu20	HU value below which 20% of voxels fall	Num	8	
mkint	Knee intercept	Num	8	
mknee	See IAC Scan Analysis variables listing	Num	8	
mkslp	See IAC Scan Analysis variables listing	Num	8	
mkurt mmean	Kurtosis Mean	Num Num	8 8	
mmed	Median	Num	o 8	
msd	Standard deviation	Num	8	
mskew	Skewness	Num	8	
mtisv	Region vol that is tissue & blood(ml)	Num	8	
mtotv mtotvx	Total volume of region (cubic ml) Total number of voxels in a region	Num Num	8 8	
mvar	Variance	Num	8	
newnett	New NETT patient ID no.	Char	5	
passver	-	Char	13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd skew	Standard deviation Skewness	Num Num	8 8	
slicethi	Slice thickness	Char	14	
tisv	Region vol that is tissue & blood(ml)	Num	8	
totv	Total volume of region (cubic ml)	Num	8	
totvx	Total number of voxels in a region	Num	8	
uae50 uae100	No. of voxels above -50 HU in a region No. of voxels above -100 HU in a region	Num Num	8 8	
uae150	No. of voxels above -150 HU in a region	Num	8	
uae200	No. of voxels above -200 HU in a region	Num	8	
uae250	No. of voxels above $-250$ HU in a region	Num	8	
uaint	Ankle intercept	Num	8	
uairv uankl	Volume of region that is air (ml) Ankle	Num Num	8 8	
uaslp	Ankle slope	Num	8	
ube600	No. of voxels below -600 HU in a region	Num	8	
ube620	No. of voxels below -620 HU in a region	Num	8	
ube640	No. of voxels below -640 HU in a region	Num	8	
ube660 ube810	No. of voxels below -660 HU in a region No. of voxels below -810 HU in a region	Num Num	8 8	
ube810 ube830	No. of voxels below -830 HU in a region	Num	o 8	
ube850	No. of voxels below -850 HU in a region	Num	8	
ube870	No. of voxels below -870 HU in a region	Num	8	
ube890	No. of voxels below -890 HU in a region	Num	8	
ube900	No. of voxels below -900 HU in a region	Num	8	

RPEEL -	IAC right lung peel file			
Date file Observatio Variables:				
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ube910	No. of voxels below -910 HU in a region	Num	8	
ube920	No. of voxels below -920 HU in a region	Num	8	
ube930	No. of voxels below -930 HU in a region	Num	8	
ube940	No. of voxels below -940 HU in a region	Num	8	
ube950	No. of voxels below -950 HU in a region	Num	8	
ube960	No. of voxels below -960 HU in a region	Num	8	
ucvm	See IAC Scan Analysis variables listing	Num	8	
ucvsd	See IAC Scan Analysis variables listing	Num	8	
ucvxm	See IAC Scan Analysis variables listing	Num	8	
ucvxsd	See IAC Scan Analysis variables listing	Num	8	
ucvym	See IAC Scan Analysis variables listing	Num	8	
ucvysd	See IAC Scan Analysis variables listing	Num	8	
ucvzm	See IAC Scan Analysis variables listing	Num	8	
ucvzsd	See IAC Scan Analysis variables listing	Num	8	
ufwhm	See IAC Scan Analysis variables listing	Num	8	
uhu10	HU value below which 10% of voxels fall	Num	8	
uhu15	HU value below which 15% of voxels fall	Num	8	
uhu20	HU value below which 20% of voxels fall	Num	8	
ukint	Knee intercept	Num	8	
uknee	See IAC Scan Analysis variables listing	Num	8	
ukslp	See IAC Scan Analysis variables listing	Num	8	
ukurt	Kurtosis	Num	8	
umean	Mean	Num	8	
umed	Median	Num	8	
usd	Standard deviation	Num	8	
uskew	Skewness	Num	8	
utisv	Region vol that is tissue & blood(ml)	Num	8	
utotv	Total volume of region (cubic ml)	Num	8	
utotvx	Total number of voxels in a region	Num	8	
uvar	Variance	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

RR - Form RR Chest Radiograph Summary (rev 2)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			3401
Varia	ables:	:			17

Variable Name	Variable Label	Туре	Variable Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
rr207	7 Hyperinflation score	Char	1	
rr208a	8a Evidence of prior thoracic surgery	Char	1	
rr208b rr208c rr208d rr208e rr208f rr208g rr208h rr208h	<pre>8b Pumonary nodules or masses 8c Pumonary fibrosis 8d Bronchiectasis 8e Active infection 8f Unsuspected malignancy 8g Mediastinal masses or other abnormal 8h Enlarged pulmonary arteries 8i Pleural thickening or effusion</pre>	Char Char Char Char Char Char Char Char	1 1 1 1 1 1 1	
rr208j	8j Skeletal deformity	Char	1	
rr208k	8k Other observation	Char	1	
rr208l	8l None	Char	1	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

Purpose To record evaluations of chest radiog	graphs.				
When: Visits s1, f06, and f36.					
Respondent: Radiologist and Clinic Coordina	tor.				
<b>Instructions</b> : This form should be completed by	by the i	radiol	ogist and reviewed by the Clinic Coordinate	or.	
A. Clinic, visit, and patient identification			j. Skeletal deformity	(	1)
<b>1.</b> Clinic ID:			<b>k.</b> Other ( <i>specify</i> ):	(	1)
2. Patient ID:			specify		
<b>3.</b> Patient name code:			l. None	(	1)
			G. Administrative information		
<b>4.</b> Visit date ( <i>date of chest radiographs</i> ):			9. Radiologist PIN:		
day mon	year		<b>10.</b> Radiologist signature:		
5. Visit ID code:					
6. Form & revision: <u>r</u>	<u>r</u>	2	<b>11.</b> Clinic Coordinator PIN:		
<b>B.</b> Chest radiograph evaluation			<b>12.</b> Clinic Coordinator signature:		
7. Hyperinflation score (from latera radiograph; check only one):	lch	est			
Normal	(	<sub>0</sub> )			
Minimal curve	(	1)	<b>13.</b> Date of review:		
Flat	(	2)	<u>_</u>		
Inverted	(	3)	day mon	year	
8. Ancillary observations (check all that a	apply).	:			
a. Evidence of prior thoracic surgery	(	1)			
<b>b.</b> Pulmonary nodules or masses	(	1)			
c. Pulmonary fibrosis	(	1)			
d. Bronchiectasis	(	1)			
e. Active infection	(	1)			
f. Unsuspected malignancy	(	1)			
<b>g.</b> Mediastinal masses or other abnormalities	(	1)			
h. Enlarged pulmonary arteries	) (	1) 1)			
i. Pleural thickening or effusion	Ì	1) 1)			

RVER2 IAC right lung ver2 file -Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format ae50 No. of voxels above -50 HU in a region Num 8 ae100 No. of voxels above -100 HU in a region Num 8 ae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region ae200 8 Num ae250 No. of voxels above -250 HU in a region Num 8 aint Ankle intercept Num 8 airv Volume of region that is air (ml) Num 8 ankl Ankle Num 8 aslp Ankle slope Num 8 No. of voxels below -600 HU in a region be600 Num 8 No. of voxels below -620 HU in a region No. of voxels below -640 HU in a region be620 Num 8 be640 Num 8 No. of voxels below -660 HU in a region be660 Num 8 be810 No. of voxels below -810 HU in a region Num 8 be830 No. of voxels below -830 HU in a region Num 8 be850 No. of voxels below -850 HU in a region Num 8 be870 No. of voxels below -870 HU in a region Num 8 No. of voxels below -890 HU in a region be890 Num 8 No. of voxels below -900 HU in a region be900 Num 8 be910 No. of voxels below -910 HU in a region Num 8 be920 No. of voxels below -920 HU in a region Num 8 No. of voxels below -930 HU in a region be930 Num 8 No. of voxels below -940 HU in a region be940 Num 8 No. of voxels below -950 HU in a region be950 Num 8 be960 No. of voxels below -960 HU in a region Num 8 ccutoff See IAC Scan Analysis variables listing 8 Num See IAC Scan Analysis variables listing Num 8 cvm See IAC Scan Analysis variables listing Num 8 cvsd See IAC Scan Analysis variables listing CVXM Num 8 cvxsd See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 CVVM cvysd See IAC Scan Analysis variables listing Nıım 8 cvzm See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing cvzsd Num 8 Histogram pgm version number Char entityve 18 fwhm See IAC Scan Analysis variables listing Nıım 8 historig Num 8 hrcreate Num 8 hrcreate cnvrtd to #days frm RZ/scr strt hu10 HU value below which 10% of voxels fall Num 8 hu15 HU value below which 15% of voxels fall Num 8 hu20 HU value below which 20% of voxels fall Num 8 intercep Value used to convert voxels into HU Num 8 8 Knee intercept Num kint knee See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing kslp Num 8 kurt Kurtosis Nıım 8 lae50 No. of voxels above -50 HU in a region Nıım 8 lae100 No. of voxels above -100 HU in a region Num 8 lae150 No. of voxels above -150 HU in a region Num 8 No. of voxels above -200 HU in a region No. of voxels above -250 HU in a region lae200 8 Num lae250 Num 8 laint Ankle intercept Num 8 lairv Volume of region that is air (ml) Num 8 8 lankl Ankle Num laslp Ankle slope Num 8 1be600 No. of voxels below -600 HU in a region Num 8 No. of voxels below -620 HU in a region 1be620 Num 8 lbe640 No. of voxels below -640 HU in a region Num 8

Date file created: 13 May 2006 Observations: 2236 207 Variables: Variable Variable Variable Label Name Туре Length Format lbe660 No. of voxels below -660 HU in a region Num 8 lbe810 No. of voxels below -810 HU in a region Num 8 lbe830 No. of voxels below -830 HU in a region 8 Num lbe850 No. of voxels below -850 HU in a region 8 Num No. of voxels below -870 HU in a region No. of voxels below -890 HU in a region lbe870 Num 8 lbe890 Num 8 No. of voxels below -900 HU in a region lbe900 Num 8 No. of voxels below -910 HU in a region lbe910 Num 8 No. of voxels below -920 HU in a region 1be920 Num 8 No. of voxels below -930 HU in a region 1be930 Nıım 8 lbe940 No. of voxels below -940 HU in a region Num 8 No. of voxels below -950 HU in a region lbe950 Num 8 No. of voxels below -960 HU in a region 1be960 Num 8 lcvm See IAC Scan Analysis variables listing Num 8 lcvsd See IAC Scan Analysis variables listing Num 8 lcvxm See IAC Scan Analysis variables listing Num 8 lcvxsd See IAC Scan Analysis variables listing Num 8 See IAC Scan Analysis variables listing Num 8 lcvvm lcvysd See IAC Scan Analysis variables listing Num 8 lcvzm See IAC Scan Analysis variables listing Num 8 lcvzsd See IAC Scan Analysis variables listing Num 8 lfwhm See IAC Scan Analysis variables listing Num 8 HU value below which 10% of voxels fall 1hu10 Num 8 lhu15 HU value below which 15% of voxels fall Num 8 lhu20 HU value below which 20% of voxels fall Num 8 lkint Knee intercept Num 8 lknee See IAC Scan Analysis variables listing Num 8 lkslp See IAC Scan Analysis variables listing Num 8 Kurtosis lkurt Num 8 lmean Mean Num 8 lmed Median Num 8 lsd Standard deviation Nıım 8 lskew Skewness Num 8 ltisv Region vol that is tissue & blood(ml) Num 8 ltotv Total volume of region (cubic ml) Num 8 ltotvx Total number of voxels in a region Nıım 8 lvar Variance Num 8 No. of voxels above -50 HU in a region No. of voxels above -100 HU in a region No. of voxels above -150 HU in a region mae50 Num 8 mae100 Num 8 mae150 Nıım 8 mae200 No. of voxels above -200 HU in a region Num 8 mae250 No. of voxels above -250 HU in a region Num 8 8 maint Ankle intercept Num mairv Volume of region that is air (ml) Num 8 mankl Ankle Num 8 Ankle slope maslp Nıım 8 mbe600 No. of voxels below -600 HU in a region Nıım 8 mbe620 No. of voxels below -620 HU in a region Num 8 mbe640 No. of voxels below -640 HU in a region Num 8 No. of voxels below -660 HU in a region No. of voxels below -810 HU in a region mbe660 8 Num mbe810 Num 8 No. of voxels below -830 HU in a region mbe830 Num 8 mbe850 No. of voxels below -850 HU in a region Num 8 Num mbe870 No. of voxels below -870 HU in a region 8 No. of voxels below -890 HU in a region No. of voxels below -900 HU in a region mbe890 Num 8 mbe900 Num 8 No. of voxels below -910 HU in a region mbe910 Nıım 8 mbe920 No. of voxels below -920 HU in a region Num 8

RVER2

-

IAC right lung ver2 file

RVER2 -	IAC right lung ver2 file			
Date file c Observation Variables:	created: 13 May 2006 ls: 2236 207			
Variable Name	Variable Label	Туре	Variable Length	Format
mbe930	No. of voxels below -930 HU in a region	Num	8	
mbe940	No. of voxels below -940 HU in a region	Num	8	
mbe950	No. of voxels below -950 HU in a region	Num	8	
mbe960	No. of voxels below -960 HU in a region	Num	8	
mcvm mcvsd	See IAC Scan Analysis variables listing See IAC Scan Analysis variables listing	Num Num	8 8	
mcvsu	See IAC Scan Analysis variables listing	Num	8	
mcvxsd	See IAC Scan Analysis variables listing	Num	8	
mcvym	See IAC Scan Analysis variables listing	Num	8	
mcvysd	See IAC Scan Analysis variables listing	Num	8	
mcvzm	See IAC Scan Analysis variables listing	Num	8	
mcvzsd	See IAC Scan Analysis variables listing	Num	8	
mean	Mean	Num	8	
med	Median	Num	8	
mfwhm	See IAC Scan Analysis variables listing	Num	8	
mhu10	HU value below which 10% of voxels fall	Num	8	
mhu15	HU value below which 15% of voxels fall	Num	8	
mhu20 mkint	HU value below which 20% of voxels fall	Num	8 8	
mknee	Knee intercept See IAC Scan Analysis variables listing	Num Num	о 8	
mkslp	See IAC Scan Analysis variables listing	Num	8	
mkurt	Kurtosis	Num	8	
mmean	Mean	Num	8	
mmed	Median	Num	8	
msd	Standard deviation	Num	8	
mskew	Skewness	Num	8	
mtisv	Region vol that is tissue & blood(ml)	Num	8	
mtotv	Total volume of region (cubic ml)	Num	8	
mtotvx	Total number of voxels in a region	Num	8	
mvar	Variance	Num	8	
newnett	New NETT patient ID no.	Char	5 13	
passver scandate	scandate cnvrtd to #days frm RZ/scr strt	Char Num	13	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
slicethi	Slice thickness	Char	14	
tisv	Region vol that is tissue & blood(ml)	Num	8	
totv	Total volume of region (cubic ml)	Num	8	
totvx	Total number of voxels in a region	Num	8	
uae50	No. of voxels above -50 HU in a region	Num	8	
uae100	No. of voxels above -100 HU in a region	Num	8	
uae150	No. of voxels above -150 HU in a region	Num	8	
uae200 uae250	No. of voxels above $-200$ HU in a region No. of voxels above $-250$ HU in a region	Num Num	8 8	
uaez50 uaint	Ankle intercept	Num	8	
uairv	Volume of region that is air (ml)	Num	8	
uankl	Ankle	Num	8	
uaslp	Ankle slope	Num	8	
ube600	No. of voxels below -600 HU in a region	Num	8	
ube620	No. of voxels below -620 HU in a region	Num	8	
ube640	No. of voxels below -640 HU in a region	Num	8	
ube660	No. of voxels below -660 HU in a region	Num	8	
ube810	No. of voxels below -810 HU in a region	Num	8	
ube830	No. of voxels below -830 HU in a region	Num	8	
ube850 ube870	No. of voxels below -850 HU in a region No. of voxels below -870 HU in a region	Num Num	8 8	
ube870 ube890	No. of voxels below -870 HU in a region	Num	8	
ube890 ube900	No. of voxels below -900 HU in a region	Num	0 8	
		21 0411	0	

RVER2 -	IAC right lung ver2 file			
Date file Observatio Variables:	created: 13 May 2006 ns: 2236 207			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
ube910	No. of voxels below -910 HU in a region	Num	8	
ube920	No. of voxels below -920 HU in a region	Num	8	
ube930	No. of voxels below -930 HU in a region	Num	8	
ube940	No. of voxels below -940 HU in a region	Num	8	
ube950	No. of voxels below -950 HU in a region	Num	8	
ube960	No. of voxels below -960 HU in a region	Num	8	
ucvm	See IAC Scan Analysis variables listing	Num	8	
ucvsd	See IAC Scan Analysis variables listing	Num	8	
ucvxm	See IAC Scan Analysis variables listing	Num	8	
ucvxsd	See IAC Scan Analysis variables listing	Num	8	
ucvym	See IAC Scan Analysis variables listing	Num	8	
ucvysd	See IAC Scan Analysis variables listing	Num	8	
ucvzm	See IAC Scan Analysis variables listing	Num	8	
ucvzsd	See IAC Scan Analysis variables listing	Num	8	
ufwhm	See IAC Scan Analysis variables listing	Num	8	
uhu10	HU value below which 10% of voxels fall	Num	8	
uhu15	HU value below which 15% of voxels fall	Num	8	
uhu20	HU value below which 20% of voxels fall	Num	8	
ukint	Knee intercept	Num	8	
uknee	See IAC Scan Analysis variables listing	Num	8	
ukslp	See IAC Scan Analysis variables listing	Num	8	
ukurt	Kurtosis	Num	8	
umean	Mean	Num	8	
umed	Median	Num	8	
usd	Standard deviation	Num	8	
uskew	Skewness	Num	8	
utisv	Region vol that is tissue & blood(ml)	Num	8	
utotv	Total volume of region (cubic ml)	Num	8	
utotvx	Total number of voxels in a region	Num	8	
uvar	Variance	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	
			Ŭ,	

SUBNEJM - Subgroup status as defined in primary outcome paper

Date	file	created:	07	May	2006
Obser	rvatio	ons:			1218
Varia	ables:	:			5

Variable Name	Variable Label	Туре	Variable Length	Format
ifdl ifrc maxcat newnett ul	<pre>1=FEV&lt;=20%,dlco&lt;=20%,0=oth,blnk=nonhirsk 1=FEV&lt;=20%,nonhetero,0=oth,blnk=nonhirsk 1=F&lt;=25W or M&lt;=40W, 0=other, blnk=hi rsk New NETT patient ID no. 1=uppr lobe, 0=other, blank=high risk</pre>	Num Num Num Char Num	8 8 5 8	

Date	file	created:	07	May	2006
Obsei	rvatio	ons:			494
Varia	ables:	:			4

Variable			Variable	
Name	Variable Label	Type	Length	Format
,			0	
abg	1=in ABG substudy, 0 otherwise	Num	8	
cardio	1=in CV substudy, 0 otherwise	Num	8	
lmech	1=in Lung Mech substudy, 0 otherwise	Num	8	
newnett	New NETT patient ID no.	Char	5	

TMTO - Form TM/TO Trail Making Test

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			3894
Varia	ables:	:			10

Variable			Variable	
Name	Variable Label	Туре	Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to #days frm RZ/scr strt	Num	8	
newnett	New NETT patient ID no.	Char	5	
tm209	9 Is this the Rehab assessment	Char	1	
tm210	10 Patient ineligible	Char	1	
tm207m	7 Trail A: time (min)	Char	2	
tm207s	7 Trail A: time (sec)	Char	2	
tm208m	8 Trail B: time (min)	Char	2	
tm208s	8 Trail B: time (sec)	Char	2	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

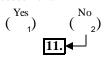
Purpose: Record results of Trail Making Test.	
When: Visit s1 as part of the Rehabilitation Evaluation (ass begins), f24, f48. Use Alternate Trail Making Test (Form	
Administered by: Rehabilitation staff, Clinic Coordinator,	or other staff trained in its administration.
Respondent: Patient.	
<b>Instructions:</b> A stopwatch and NETT Flash Card #10 should directed below. When testing is completed, attach a labele code to each of pages 2-5. Staple page 1 to pages 2-5. O	l with the patient ID, name code, and appropriate visit
A. Clinic, patient and visit identification	<b>10.</b> Based on this assessment is there any reason to declare the patient ineligible for
1. Clinic ID:	NETT:
<b>2.</b> Patient ID:	$\begin{pmatrix} Yes \\ 1 \end{pmatrix} \begin{pmatrix} No \\ 2 \end{pmatrix}$
3. Patient name code:	specify reason for ineligibility
4. Visit date (date of assessment):	
	D. Administrative information
day mon year	
5. Visit code:	<b>11.</b> Examiner name ( <i>please print</i> ):
6. Form & revision: <u>t m 2</u>	<b>12.</b> Examiner signature:
B. Test	
<b>Instructions</b> : Administer Sample A as instructed on NETT Flash Card #10. After the patient com-	13. Clinic Coordinator PIN:
pletes Sample A, administer Trail A as instructed on NETT Flash Card #10.	<b>14.</b> Clinic Coordinator signature:
7. Trail A time:	<b>15.</b> Date form reviewed:
<b>Instructions</b> : After the patient completes Trail A, administer Sample B as instructed on NETT Flash Card #10. After the patient completes Sample B, administer Trail B as instructed on NETT Flash Card #10.	day mon year

8. Trail B time:

#### minutes seconds

#### C. Screen

**9.** Is this the Rehab Eval (s1/s2) assessment:

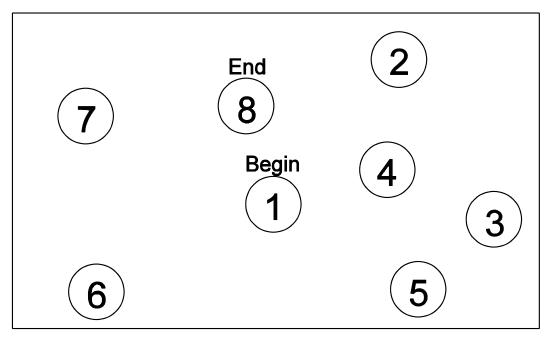


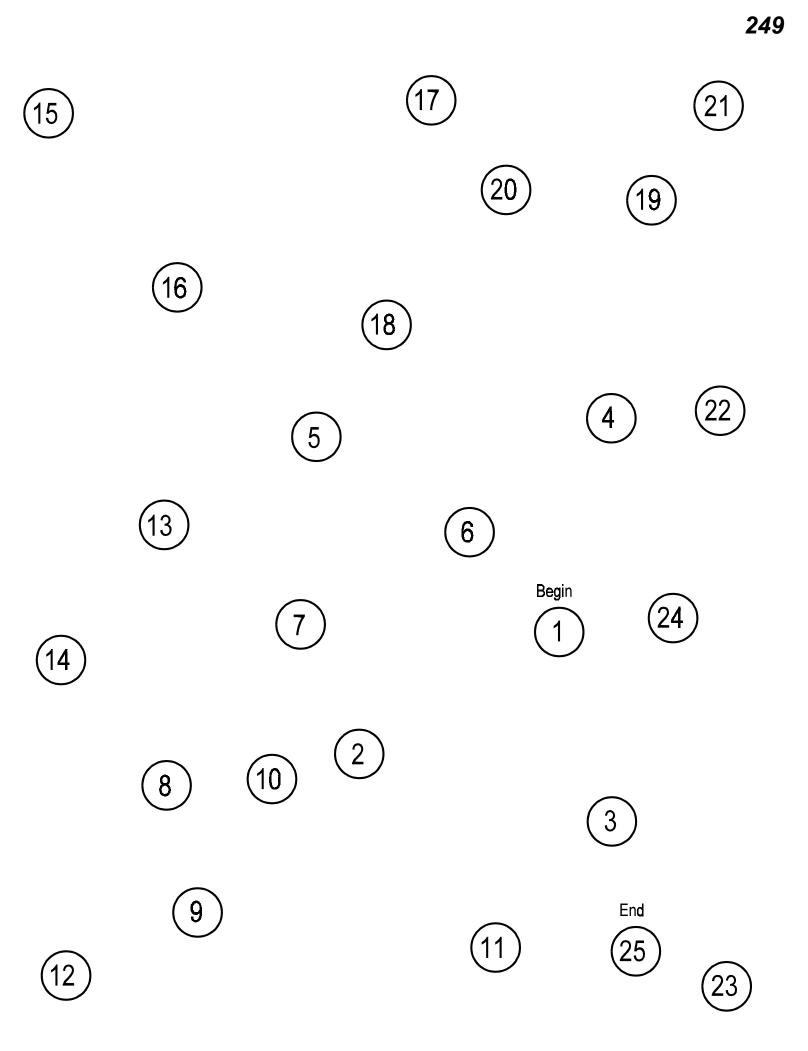
	<b>248</b>
	Affix label here
Pt ID:	
Nameco	le:
	ا لــــــــــــــــــــــــــــــــــــ

# TRAIL MAKING

# Part A

### SAMPLE



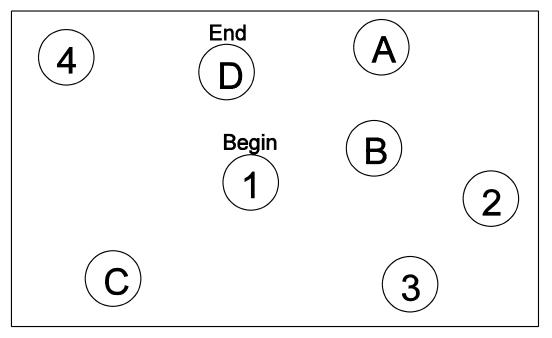


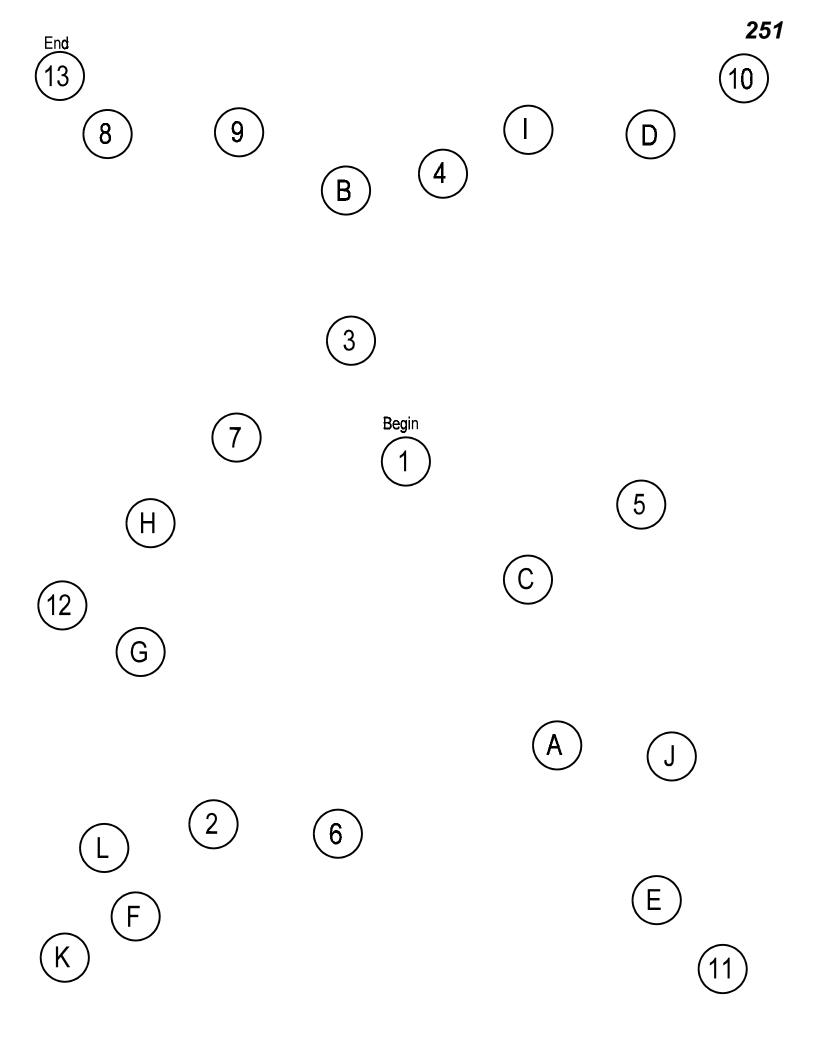
	<b>250</b>
	Affix label here
Pt ID:	
Nameco	de:

# TRAIL MAKING









UE\_ADMIT - Admissions to non-acute care facilities based on UE form

Date file c Observation Variables:	ereated: 13 May 2006 s: 69 6			
Variable Name	Variable Label	Туре	Variable Length	Format
newnett ue237 ue238 ue239 ue207a ue207b	New NETT patient ID no. #37 cnvrtd to # of days frm RZ/scr 38 Patient discharged #39 cnvrtd to # of days frm RZ/scr #7a cnvrtd to # of days frm RZ/scr 7b Visit code	Char Num Char Num Num Char	5 8 1 8 8 3	

Date file created: 13 May 2006 Observations: 324 Variables: 9

Variable Name	Variable Label	Туре	Variable Length	Format
newnett	New NETT patient ID no.	Char	5	
ue220	20 Extra education sessions	Char	1	
ue222	22 No of extra education sessions	Char	3	
ue225	25 Extra exercise sessions prescribed	Char	1	
ue227	27 No of extra exercise sessions	Char	3	
ue230	30 Extra psychosocial sessions prescrib	Char	1	
ue232	32 No of extra sessions	Char	3	
ue207a	#7a cnvrtd to # of days frm RZ/scr	Num	8	
ue207b	7b Visit code	Char	3	

UE_LVR14	- Identifies LVRS patients with 3	LVRS more	than 14 day	vs after RZ
Date file	created: 13 May 2006			
Observatio				
Variables:	31			
Variable			Variable	
Name	Variable Label	Туре	Length	Format
newnett	New NETT patient ID no.	Char	5	
ue214	#14 cnvrtd to # of days frm RZ/scr	Num	8	
ue215a	15a COPD exacerbation	Char	1	
ue215b	15b Pneumonia	Char	1	
ue215c	15c Other illness	Char	1	
ue215d	15d Other issue related to patient	Char	1	
ue215e	15e Surgeon not available	Char	1	
ue215f	15f Other scheduling problem	Char	1	
ue215q	15g Other reason	Char	1	
ue216a	16a Spirometry	Char	1	
ue216b	16b MVV	Char	1	
ue216c	16c Lung volumes	Char	1	
ue216d	16d DLCO	Char	1	
ue216e	16e ABGs	Char	1	
ue216f	16f Respiratory mouth pressures	Char	1	
ue216q	16g Oxygen titration	Char	1	
ue216h	16h 6 minute walk(s)	Char	1	
ue216i	16i Exercise test	Char	1	
ue216j	16j Chest x-ray	Char	1	
ue216k	16k CT scan	Char	1	
ue2161	161 Perfusion scan	Char	1	
ue216m	16m Blood analyses	Char	1	
ue216n	16n Urine analysis	Char	1	
ue2160	160 Physical exam	Char	1	
ue216p	16p Interim history	Char	1	
ue216q	16g SF-36	Char	1	
ue216r	16r SGRQ	Char	1	
ue216s	16s UCSD SOBQ	Char	1	
ue216t	16t OWB	Char	1	
ue216u	16u Other repeated tests	Char	1	
ue216v	16v No repeated tests	Char	1	

UE\_NNETT - Identifies participants with LVRS outside NETT

Date file created: 13 May 2006 Observations: 44 Variables: 6

Variable			Variable	
Name	Variable Label	Туре	Length	Format
newnett	New NETT patient ID no.	Char	5	
ue241	41 Type of LVRS	Char	1	
ue242	42 Operated on right lung	Char	1	
ue243	#43 cnvrtd to # of days frm RZ/scr	Num	8	
ue244	44 Operated on left lung	Char	1	
ue245	#45 cnvrtd to # of days frm RZ/scr	Num	8	

UE\_NOREH - Identifies participants with no complete rehab sessions after RZ
Date file created: 13 May 2006
Observations: 108
Variables: 1
Variables: 1
Variable Label Type Length Format

newnett New NETT patient ID no. Char 5

UE\_REF - Identifies participants randomized to LVRS but who refused LVRS

Date file created: 13 May 2006 Observations: 28 Variables: 7

Variable			Variable	
Name	Variable Label	Туре	Length	Format
newnett	New NETT patient ID no.	Char	5	
ue209	9 Patient refused NETT LVRS	Char	1	
ue210a	10a Rehab provided enough benefit	Char	1	
ue210b	10b LVRS too risky	Char	1	
ue210c	10c Other reason for LVRS refusal	Char	1	
ue211a	11a LVRS performed as assigned	Char	1	
ue211b	11b LVRS not done for other reason	Char	1	

UE_TRNS	- Identifies participants receivin	g lung	transplant du	iring followup
Date file c Observation Variables:				
Variable Name	Variable Label	Туре	Variable Length	Format
newnett ue248 ue249	New NETT patient ID no. 48 Bilateral transplant done #49 cnvrtd to # of days frm RZ/scr	Char Char Num	5 1 8	

National Emphysema Treatment Trial NETT

Revision 2 (10 Sep 99)

#### **Unusual Event**

() keyed

Purpose: To record unusual events, adverse events reportable to NETT, or other events that impact on NETT treatment or participation.

When: As needed for randomized or non-randomized NETT patients.

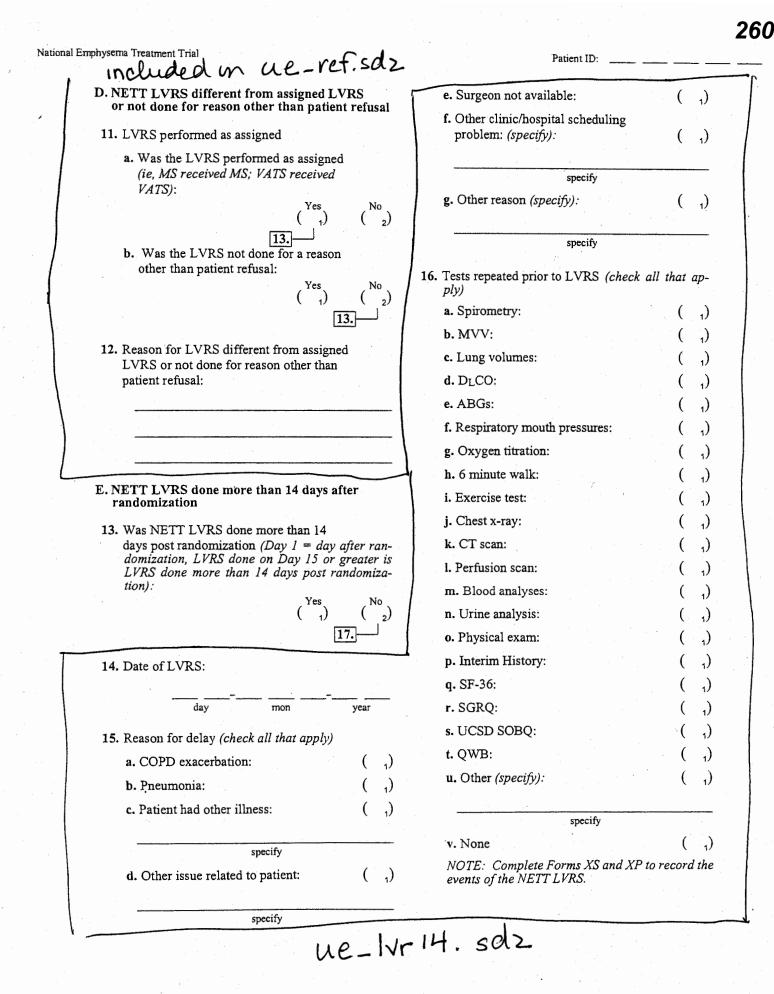
Administered by: Clinic Coordinator and Study Physician.

Respondent: None.

Instructions: Use this form as needed to record incidence of unusual events and adverse events reportable to NETT (see PPM 36). Events to be reported on this form include refusal of NETT LVRS; NETT LVRS different from assigned or LVRS not done for reason other than patient refusal; NETT LVRS done more than 14 days after randomization; failure to complete any post randomization NETT rehabilitation; prescription of additional NETT rehabilitation sessions post randomization (prescription of additional sessions prior to randomization should be documented on Form AA); non NETT LVRS for a NETT patient; lung transplant; unusual or adverse event that occurs during a NETT procedure, rehabilitation session, or examination; other unusual or adverse event that occurs during screening or followup that you consider reportable to NETT, associated with the patient's participation in NETT, or that impacts on the patient's treatment for emphysema or participation in NETT.

This form is constructed to cover each of the listed events in a section. You do not have to repeat information recorded on a previously completed UE form.

A. Clinic, visit, and patient identification 8. Treatment assignment: Medical treatment 1. Clinic ID: Median sternotomy 2. Patient ID: VATS Not randomized 3. Patient name code: 40. 4. Visit date (date this form is initiated): C. Refusal of NETT LVRS 9. Did the patient refuse to schedule NETT mon уеаг dav LVRS: 5. Visit ID code: u\_\_e\_\_2\_ 6. Form & revision: 10. Reason for refusal (check all that apply) B. Visit interval and treatment assignment a. Feels that rehab provided enough identification 1) benefit: 1) b. Feels LVRS is too risky: 7. Most recent scheduled screening or followup visit (telephone or clinic) c. Other (specify): a. Date: day mon vear specify **b.** Visit code: specify included in all us files except us\_ref.sdz included in ue\_ref, sdz ue\_ Writ.sdz ue\_nnett.sdz ue-trns.sdz NETT Form UE 1 of 6 ue-noreh.sdz Unusual Event



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Patient ID: F. Failure to complete any post randomization 24. Topics covered: rehabilitation 17. Did the patient complete at least one post randomization rehabilitation program session or evaluation: No Yes 2) 25. Were extra exercise sessions prescribed: ue\_noreh.sdz  $\left(\begin{array}{c} 1\\ 1\end{array}\right)$ 18. Reason for not completing any post 30 randomization rehabilitation program sessions or evaluations: 26. Reason for prescribing extra exercise sessions: G. Prescription of extra rehabilitation sessions post randomization 27. Number of extra exercise sessions prescribed: 19. Were extra rehabilitation sessions prescribed for the patient post randomization: Yes No 28. Time frame for completion of extra ົ,) ( 2) exercise sessions: 35. 20. Were extra education sessions prescribed: Yes No 2) 1) 25. 29. Type of exercise sessions prescribed: 21. Reason for prescribing extra education sessions: 30. Were extra psychosocial sessions prescribed: 22. Number of extra education sessions prescribed: 31. Reason for prescribing extra 23. Time frame for completion of the extra psychosocial sessions: education sessions: 32. Number of extra psychosocial sessions prescribed: ue\_exreh.sdz NETT Form UE 3 of 6 Unusual Event Revision 2 (10 Sep 99)

262 ue\_nnett.sdz National Emphysema Treatment Trial ue-exrep.sdz 33. Time frame for completion of extra 41. Type of LVRS (check only one): psychosocial sessions: MS 1) VATS 2) 3) Other (specify) specify 34. Nature of extra psychosocial sessions (specify general content): 42. Was the right lung operated on: Yes 44. 43. Date of right lung LVRS: H. Admission to medical institution other than acute care hospital dav mon vear (Eg, extended care facility, skilled nursing facility, rehabilitation hospital) 44. Was the left lung operated on: Yes 35. Was the patient admitted to a medical institution other than an acute care hospital: No 45. Date of left lung LVRS: ue-admit.sdz 40. day mon year 36. Reason for admission: 46. Who did the surgery a. Name of surgeon: b. Name of hospital/institution: 37. Date admitted: c. Location of hospital/institution: day mon уеаг 38. Has the patient been discharged: J. Lung transplant Yes No (Specify as much information as known; enter d if ,) you don't have the information requested) 40. 47. Did the patient receive a lung transplant: 39. Date discharged: No ( 2) 51. day mon year 48. Was the transplant bilateral (check only one): I. Non NETT LVRS (Specify as much information as known; enter d if ,) Yes you don't have the information requested) 2) No, right side only 40. Did the patient receive LVRS outside of No, left side only NETT: Yes ( ue\_trns.sdz NETT Form UE Revision 2 (10 Sep 99)

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ue\_trns.sdz National Emphysema Treatment Trial Patient ID: 49. Date of transplant: 55. P d day mon year 50. Who did the surgery a. Name of surgeon: b. Name of hospital/institution: c. Location of hospital/institution: K. Unusual event during a NETT procedure, rehabilitation session, or examination 51. Did the patient experience an unusual event during a NETT procedure, rehabilitation session, or examination: Yes ( No 58. 52. Nature of event:

53. Date event started: day imon year 54. Date event resolved (enter n if event is not yet resolved):

day mon year

Procedure, session, or examination during which event occurred (check	all that apply)
a. Spirometry:	
b. MVV:	( <sub>1</sub> )
c. Lung volumes:	( <sub>1</sub> )
d. D <sub>L</sub> CO:	( 1)
e. Respiratory mouth pressures:	( <sub>1</sub> )
f. Pulmonary mechanics:	( 1)
g. Oxygen titration:	
h. 6 minute walk:	( <sub>1</sub> )
i. Max exercise test:	( <sub>1</sub> )
j. Chest x-ray:	( 1)
k. CT scan:	( <sub>1</sub> )
1. Perfusion scan:	( <sub>1</sub> )
m. ECG:	( <sub>1</sub> )
n. Echocardiogram:	( 1)
o. Dobutamine radionuclide scan:	( <sub>1</sub> )
p. Right heart catheterization:	( <sub>1</sub> )
q. Blood draw:	( <sub>1</sub> )
r. Physical exam:	( <sub>1</sub> )
s. Rehab exercise session:	( <sub>1</sub> )
t. During LVRS:	( <sub>1</sub> )
u. While hospitalized post LVRS:	( <sub>1</sub> )
v. Other (specify):	( <sub>1</sub> )

specify

56. What action was taken:

# ue-ueae.sdz

----

# ue-ueae.sdz

Yes

Patient ID:

- 57. IRB/adverse event reporting
  - a. Will this event be reported to the clinic's IRB:

b. Does this clinic consider this event an adverse event reportable to NETT (per PPM 36):

\*If Yes, key this form, send the CC a copy of this UE form, a narrative of the event, and a copy of correspondence with your IRB; by checking Yes, you have stated that this event is considered an adverse event reportable to NETT per PPM 36.

- L. Other event judged reportable to NETT or that impacts on the patient's treatment for emphysema or participation in NETT
- 58. Did the clinic, patient or family experience some other event that (1) the clinic judges is an adverse event reportable to NETT or (2) impacts on the patient's treatment for emphysema or participation in NETT:

Yes No 64.

year

59. Nature of event:

60. Date event started:

day

61. Date event resolved (enter n if event is not yet resolved):

mon

day mon vear 62. What action was taken:

- 63. IRB/adverse event reporting
  - a. Will this event be reported to the clinic's IRB:

Yes 1) (<sup>No</sup> 2)

b. Does this clinic consider this event an adverse event reportable to NETT (as defined in PPM 36):

\*If Yes, key this form, send the CC a copy of this UE form, a narrative of the event, and a copy of the correspondence with your IRB; by checking Yes, you have stated that this event is considered an adverse event reportable to NETT per PPM 36.

M. Administrative information

- 64. Study Physician PIN:
- 65. Study Physician signature:

66. Clinic Coordinator PIN:

- 67. Clinic Coordinator signature:
- 68. Date form reviewed:

day	mon	ye	ar

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VALIDS - demographic data treatment assignment and vital status

Date	file	created:	13	8 May	2006
Obsei	rvatio	ons:			3775
Varia	ables:	:			8

Variable Name	Variable Label	Туре	Variable Length	Format
deathdt eligdt enrolldt ethnic gender medid newnett vitstat	Death date cnvrtd to #days frm RZ/scr Date finl scr cycl strtd,#days frmRZ/scr RZ date as #days frm RZ/scr (ie, 0) w=white, o=other m=male, f=female blnk=nonRZ, 1=medical, 2=MS, 3=VATS New NETT patient ID no. 1=dead, blank=alive	Num Num Char Char Num Char Char	8 8 1 1 8 5 1	

VC - Form VC Cardiovascular Substudy (rev 1)

Date	file	created:	07	May	2006
Observations:					218
Varia	ables:	:			28

Variable			Variable	
Name	Variable Label	Туре	Length	Format
artsat	Arterial sat (oximetry, VC#26)	Num	8	
со	Cardiac output (L/min, VC#23)	Num	8	
form	Data source (Scharf file or VC form)	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr	Num	8	
hemogc	Hemoglobin at cath $(q/dL, VC#29)$	Num	8	
hr	Heart rate (beats/min, VC#24)	Num	8	
lvef	MUGA L ventric ejection fraction (VC#30)	Num	8	
map	Mean arterial pressure (mmHg, VC#8)	Num	8	
mnpaexp	Mean pulm art end exp (mmHg, VC#19)	Num	8	
mnpainsp	Mean pulm art end insp (mmHg, VC#20)	Num	8	
mvo2	Mixed venous O2 sat fraction (VC#25)	Num	8	
newnett	New NETT patient ID no.	Char	5	
padexp	Pulm art end diast exp (mmHg, VC#17)	Num	8	
padinsp	Pulm art end diast insp (mmHg, VC#18)	Num	8	
pasexp	Pulm art end syst exp (mmHg, VC#15)	Num	8	
pasinsp	Pulm art end syst insp (mmHg, VC#16)	Num	8	
pcwexp	Pulm cap wedge end exp (mmHg, VC#21)	Num	8	
pcwinsp	Pulm cap wedge end insp (mmHg, VC#22)	Num	8	
pesexp	End exp esophageal (mmHg, VC#32)	Num	8	
pesinsp	End insp esophageal (mmHg, VC#33)	Num	8	
raexp	R atrial end exp (mmHg, VC#9)	Num	8	
rainsp	R atrial end insp (mmHg, VC#10)	Num	8	
rvdexp	R ventric end diast exp (mmHg, VC#13)	Num	8	
rvdinsp	R ventric end diast insp (mmHg, VC#14)	Num	8	
rvef	R ventric ejection fraction (VC#27)	Num	8	
rvsexp	R ventric end syst exp (mmHg, VC#11)	Num	8	
rvsinsp	R ventric end syst insp (mmHg, VC#12)	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	

267 National Emphysema Treatment Trial () keyed Cardiovascular Substudy NETT Purpose: Record data for Cardiovascular Substudy. When: s1 and f06. Instructions: Use Form VC only for patients participating in the Cardiovascular Substudy. Right heart catheterization data collected for patients who require the procedure for NETT screening because of echocardiogram findings or other reason are recorded on Form HF, Heart Function Summary. If a Cardiovascular Substudy patient requires right heart catheterization for screening, the right heart catheterization data will be recorded on both this form and Form HF. If a Cardiovascular Substudy patient does not require right heart catheterization for screening, the right heart catheterization data need be recorded only on Form VC. At visit f06, only Cardiovascular Substudy patients will have right heart catheterization, and the right heart catheterization data obtained at f06 should be completed only on Form VC (not on Form HF). If you key this form for the s1 visit and the patient is randomized, then you must also account for the Cardiovascular Substudy followup visit at 6 months (f06), either by completing Form VC for f06 (if the patient completes any of the substudy procedures) or by completing Form MV (if the patient misses all of the substudy procedure). A. All clinic, visit, and patient identification 10. Right atrial end inspiratory pressure (circle + or -): RAINSO 1. Clinic ID: 2. Patient ID: 11. Right ventricular end systolic expiratory RVSexp pressure: 3. Patient name code: mmHg 4. Visit date (date of catheterization): 12. Right ventricular end systolic inspiratory day mon vear pressure: 5. Visit ID code: mmHg 13. Right ventricular end diastolic expiratory RVDEXP 6. Form & revision: <u>v c 1</u> pressure (circle + or -): **B.** Eligibility for substudy \_\_\_\_\_\_mmHg 7. Is the patient in sinus rhythm: 14. Right ventricular end diastolic inspiratory RND insp pressure (circle + or -): mmHg The patient is ineligible for the substudy, but may be eligible for the main trial. 15. Pulmonary arterial end systolic PASexp expiratory pressure: C. Substudy data 8. Mean arterial pressure: mmHg mmHg 9. Right atrial end expiratory pressure (circle + or -): 16. Pulmonary arterial end systolic PASinsp + - RAetp \_\_\_\_\_ inspiratory pressure: mmHg

Patient ID:

17. Pulmonary arterial end diastolic 29. Hemoglobin measured at catheterization: expiratory pressure: HEMOGC. PADCKP mmHg 30. Left ventricular ejection fraction (from MUGA): 18. Pulmonary arterial end diastolic INEF inspiratory pressure: PADinsp 31. Were esophageal pressures measured: mmHg (Yes 19. Mean pulmonary arterial end expiratory 34 pressure: 32. End expiratory esophageal pressure ManpAuto mmHø (circle + or -): PESexp 20. Mean pulmonary arterial end inspiratory mmHg pressure: Man PAinsp 33. End inspiratory esophageal pressure (circle + or -): mmHg 21. Pulmonary capillary wedge end PESINSP mmHg expiratory pressure: **D.** Administrative information RWEXD mmHg 34. Study physician PIN 22. Pulmonary capillary wedge end inspiratory pressure (circle + or -): 35. Study physician signature: PCWINSP mmHg 23. Cardiac output: 36. Clinic Coordinator PIN: L/min **C.O** 37. Clinic Coordinator signature: 24. Heart rate: bpm HR 25. MVO<sub>2</sub> (mixed venous oxygen saturation fraction): 38. Date form reviewed: MV07\_ day mon year 26. Arterial saturation (oximetry) fraction: • ARTSAT 27. Right ventricular ejection fraction: RV9.F 28. Was hemoglobin measured at catheterization:  $\binom{\text{Yes}}{1}$ 30.

Cardiovascular Substudy

WCORE - IAC whole lung core file

Date	file	created:	13	May	2006
Observations:					2236
Varia	ables:	:			64

Variable Name	Variable Label	Туре	Variable Length	Format
actair	Actual air value in the CT scan	Num	8	
actbt	Actual blood tissue value in the CT scan	Num	8	
ae50	No. of voxels above -50 HU in a region	Num	8	
ae100	No. of voxels above -100 HU in a region	Num	8	
ae150	No. of voxels above -150 HU in a region	Num	8	
ae200	No. of voxels above -200 HU in a region	Num	8	
ae250	No. of voxels above -250 HU in a region	Num	8	
aint	Ankle intercept	Num	8	
airv	Volume of region that is air (ml)	Num	8	
ankl	Ankle	Num	8	
aslp	Ankle slope	Num	8	
be600	No. of voxels below -600 HU in a region	Num	8	
be620	No. of voxels below -620 HU in a region	Num	8	
be640	No. of voxels below -640 HU in a region	Num	8	
be660	No. of voxels below -660 HU in a region	Num	8	
be810	No. of voxels below $-810$ HU in a region	Num	8	
be830 be850	No. of voxels below -830 HU in a region No. of voxels below -850 HU in a region	Num Num	8 8	
be870	No. of voxels below -830 HU in a region	Num	8	
be890	No. of voxels below -890 HU in a region	Num	8	
be900	No. of voxels below -900 HU in a region	Num	8	
be910	No. of voxels below -910 HU in a region	Num	8	
be920	No. of voxels below -920 HU in a region	Num	8	
be930	No. of voxels below -930 HU in a region	Num	8	
be940	No. of voxels below -940 HU in a region	Num	8	
be950	No. of voxels below -950 HU in a region	Num	8	
be960	No. of voxels below -960 HU in a region	Num	8	
ccutoff	See IAC Scan Analysis variables listing	Num	8	
CVM	See IAC Scan Analysis variables listing	Num	8	
cvsd	See IAC Scan Analysis variables listing	Num	8	
CVXM	See IAC Scan Analysis variables listing	Num	8	
cvxsd	See IAC Scan Analysis variables listing	Num	8	
cvym	See IAC Scan Analysis variables listing	Num	8	
cvysd	See IAC Scan Analysis variables listing	Num	8	
cvzm cvzsd	See IAC Scan Analysis variables listing	Num Num	8 8	
entityve	See IAC Scan Analysis variables listing Histogram pgm version number	Char	18	
fwhm	See IAC Scan Analysis variables listing	Num	8	
histowho	bee ino bean marybib variableb riberny	Num	8	
hu10	HU value below which 10% of voxels fall	Num	8	
hu15	HU value below which 15% of voxels fall	Num	8	
hu20	HU value below which 20% of voxels fall	Num	8	
hwcreate	hwcreate cnvrtd to #days frm RZ/scr strt	Num	8	
intercep	Value used to convert voxels into HU	Num	8	
kint	Knee intercept	Num	8	
knee	See IAC Scan Analysis variables listing	Num	8	
kslp	See IAC Scan Analysis variables listing	Num	8	
kurt	Kurtosis	Num	8	
mean	Mean	Num	8	
med	Median	Num	8	
newnett	New NETT patient ID no.	Char	5	
nomair nombt	Nominal air value in a CT scan Nominal blood tissue value in a CT scan	Num Num	8 8	
passver	NOMITHAL DIOOU LISSUE VALUE IN A CI SCAN	Char	8 13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
slicethi	Slice thickness	Char	14	

WCORE - IAC whole lung core file

Date file created: 13 May 2006 Observations: 2236 Variables: 64

Variable			Variable	
Name	Variable Label	Туре	Length	Format
tisv	Region vol that is tissue & blood(ml)	Num	8	
totv	Total volume of region (cubic ml)	Num	8	
totvx	Total number of voxels in a region	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

WHOLE -IAC whole lung holes file Date file created: 13 May 2006 Observations: 2236 Variables: 28 Variable Variable Variable Label Name Туре Length Format alpha 1 At -950, see IAC Scan Analysis vbl list Num 8 At -930, see IAC Scan Analysis vbl list alpha<sup>2</sup> 8 Num alpha 3 At -910, see IAC Scan Analysis vbl list 8 Num alpha\_4 At -890, see IAC Scan Analysis vbl list 8 Num At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list 8 alpha\_5 Num alpha 6 Num 8 Y intercept at -950 c1 1 Num 8 Y intercept at -930 c1\_2 Num 8 c1\_3 Y intercept at -910 Num 8 c1\_4 Y intercept at -890 8 Num c1\_5 c1\_6 Y intercept at -870 8 Num Y intercept at -850 Num 8 cutoff 1 At -950, see IAC Scan Analysis vbl list 8 Num cutoff<sup>2</sup> At -930, see IAC Scan Analysis vbl list Num 8 cutoff\_3 8 At -910, see IAC Scan Analysis vbl list Num cutoff\_4 cutoff\_5 cutoff\_6 At -890, see IAC Scan Analysis vbl list Num 8 At -870, see IAC Scan Analysis vbl list At -850, see IAC Scan Analysis vbl list Num 8 8 Num 18 entityve Hole pgm version number Char hwcreate hwcreate cnvrtd to #days frm RZ/scr strt Num 8 8 intercep Value used to convert voxels into HU Num New NETT patient ID no. 5 newnett Char passver Char 13 scandate cnvrtd to #days frm RZ/scr strt Num 8 scandate Slice thickness Char 14 slicethi Visit s1, f06-6mosaftrRZ, f36-36mos aftrRZ Char 3 visit vxsize Voxel size Num 8 wholehol Num 8

WPEEL - IAC whole lung peel file

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			2236
Varia	ables:	:			65

Variable Name	Variable Label	Туре	Variable Length	Format
aatair	Actual air value in the CT scan		0	
actair		Num	8	
actbt	Actual blood tissue value in the CT scan	Num	8	
ae50	No. of voxels above -50 HU in a region	Num	8	
ae100	No. of voxels above -100 HU in a region	Num	8	
ae150	No. of voxels above -150 HU in a region	Num	8	
ae200	No. of voxels above -200 HU in a region	Num	8	
ae250	No. of voxels above -250 HU in a region	Num	8	
aint	Ankle intercept	Num	8	
airv	Volume of region that is air (ml)	Num	8	
ankl	Ankle	Num	8 8	
aslp ba(00	Ankle slope	Num		
be600	No. of voxels below -600 HU in a region	Num	8	
be620	No. of voxels below -620 HU in a region	Num	8	
be640	No. of voxels below -640 HU in a region	Num	8	
be660	No. of voxels below -660 HU in a region	Num	8	
be810	No. of voxels below -810 HU in a region	Num	8	
be830	No. of voxels below -830 HU in a region	Num	8	
be850	No. of voxels below -850 HU in a region	Num	8	
be870	No. of voxels below -870 HU in a region	Num	8	
be890	No. of voxels below -890 HU in a region	Num	8	
be900	No. of voxels below -900 HU in a region	Num	8	
be910	No. of voxels below -910 HU in a region	Num	8	
be920	No. of voxels below -920 HU in a region	Num	8	
be930	No. of voxels below $-930$ HU in a region	Num	8	
be940	No. of voxels below -940 HU in a region	Num	8	
be950	No. of voxels below -950 HU in a region	Num	8	
be960	No. of voxels below -960 HU in a region	Num	8	
ccutoff	See IAC Scan Analysis variables listing	Num	8	
CVM	See IAC Scan Analysis variables listing	Num	8	
cvsd	See IAC Scan Analysis variables listing	Num	8	
CVXM	See IAC Scan Analysis variables listing	Num	8	
cvxsd	See IAC Scan Analysis variables listing	Num	8	
cvym	See IAC Scan Analysis variables listing	Num	8	
cvysd	See IAC Scan Analysis variables listing	Num	8	
CVZM	See IAC Scan Analysis variables listing	Num	8	
cvzsd	See IAC Scan Analysis variables listing	Num	8	
entityve	Histogram pgm version number	Char	18	
fwhm	See IAC Scan Analysis variables listing	Num	8	
histowho	III welve below which 100 of would fell	Num	8	
hul0	HU value below which 10% of voxels fall	Num	8	
hu15	HU value below which 15% of voxels fall HU value below which 20% of voxels fall	Num	8	
hu20		Num	8	
hwcreate	hwcreate cnvrtd to #days frm RZ/scr strt	Num	8	
intercep	Value used to convert voxels into HU	Num	8	
kint knee	Knee intercept See IAC Scan Analysis variables listing	Num Num	8 8	
kslp	See IAC Scan Analysis variables listing	Num	о 8	
kurt	Kurtosis	Num	о 8	
mean	Mean	Num	8	
med	Median	Num	о 8	
newnett	New NETT patient ID no.	Char	o 5	
nomair	Nominal air value in a CT scan	Num	5 8	
nombt	Nominal all value in a CI scan Nominal blood tissue value in a CT scan	Num	о 8	
passver	Nominal Diood Cissue Value III a Ci Scall	Char	° 13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
0170 M	ORCHITCOD	muill	0	

WPEEL - IAC whole lung peel file

Date file created: 13 May 2006 Observations: 2236 Variables: 65

Variable Name	Variable Label	Туре	Variable Length	Format
slicethi	Slice thickness	Char	14	
tisv	Region vol that is tissue & blood(ml)	Num	8	
totv	Total volume of region (cubic ml)	Num	8	
totvx	Total number of voxels in a region	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

WVER2 - IAC whole lung ver2 file

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			2236
Varia	ables:	:			64

Variable Name	Variable Label	Туре	Variable Length	Format
actair	Actual air value in the CT scan	Maria	0	
actbt	Actual blood tissue value in the CT scan	Num Num	8 8	
ae50	No. of voxels above -50 HU in a region			
ae100		Num	8 8	
ae150	No. of voxels above -100 HU in a region	Num		
ae200	No. of voxels above -150 HU in a region No. of voxels above -200 HU in a region	Num	8 8	
ae250		Num		
	No. of voxels above -250 HU in a region	Num	8 8	
aint airv	Ankle intercept	Num	° 8	
ankl	Volume of region that is air (ml) Ankle	Num Num	° 8	
aslp	Ankle slope	Num	8	
be600	No. of voxels below -600 HU in a region	Num	8	
be620	No. of voxels below -620 HU in a region	Num	8	
be640	No. of voxels below -640 HU in a region	Num	8	
be660	No. of voxels below -660 HU in a region	Num	8	
be810	No. of voxels below -810 HU in a region	Num	8	
be830	No. of voxels below -830 HU in a region	Num	8	
be850	No. of voxels below -850 HU in a region	Num	8	
be870	No. of voxels below -830 HU in a region	Num	8	
be890	No. of voxels below -890 HU in a region	Num	8	
be900	No. of voxels below -900 HU in a region	Num	8	
be910	No. of voxels below -910 HU in a region	Num	8	
be920	No. of voxels below -920 HU in a region	Num	8	
be930	No. of voxels below -930 HU in a region	Num	8	
be940	No. of voxels below -940 HU in a region	Num	8	
be950	No. of voxels below -950 HU in a region	Num	8	
be960	No. of voxels below -960 HU in a region	Num	8	
ccutoff	See IAC Scan Analysis variables listing	Num	8	
CVM	See IAC Scan Analysis variables listing	Num	8	
cvsd	See IAC Scan Analysis variables listing	Num	8	
cvxm	See IAC Scan Analysis variables listing	Num	8	
cvxsd	See IAC Scan Analysis variables listing	Num	8	
cvym	See IAC Scan Analysis variables listing	Num	8	
cvysd	See IAC Scan Analysis variables listing	Num	8	
cvzm	See IAC Scan Analysis variables listing	Num	8	
cvzsd	See IAC Scan Analysis variables listing	Num	8	
entityve	Histogram pgm version number	Char	18	
fwhm	See IAC Scan Analysis variables listing	Num	8	
histowho		Num	8	
hu10	HU value below which 10% of voxels fall	Num	8	
hu15	HU value below which 15% of voxels fall	Num	8	
hu20	HU value below which 20% of voxels fall	Num	8	
hwcreate	hwcreate cnvrtd to #days frm RZ/scr strt	Num	8	
intercep	Value used to convert voxels into HU	Num	8	
kint	Knee intercept	Num	8	
knee	See IAC Scan Analysis variables listing	Num	8	
kslp	See IAC Scan Analysis variables listing	Num	8	
kurt	Kurtosis	Num	8	
mean	Mean	Num	8	
med	Median	Num	8	
newnett	New NETT patient ID no.	Char	5	
nomair	Nominal air value in a CT scan	Num	8	
nombt	Nominal blood tissue value in a CT scan	Num	8	
passver		Char	13	
scandate	scandate cnvrtd to #days frm RZ/scr strt	Num	8	
sd	Standard deviation	Num	8	
skew	Skewness	Num	8	
slicethi	Slice thickness	Char	14	

WVER2 - IAC whole lung ver2 file

Date file created: 13 May 2006 Observations: 2236 Variables: 64

Variable			Variable	
Name	Variable Label	Туре	Length	Format
tisv	Region vol that is tissue & blood(ml)	Num	8	
totv	Total volume of region (cubic ml)	Num	8	
totvx	Total number of voxels in a region	Num	8	
var	Variance	Num	8	
visit	Visit s1,f06-6mosaftrRZ,f36-36mos aftrRZ	Char	3	
vxsize	Voxel size	Num	8	

XP - Form XP Post-operative Summary Report (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			580
Varia	ables:	:			84

Variables:	84			
Variable		-	Variable	
Name	Variable Label	Туре	Length	Format
adumil	1-Advantia ilova in 20 dava nost on	Num	8	
adynil aldure	1=Adynamic ileus in 30 days post op Max days w/airleak on R or L aftr closr	Num	8	
aldyne	Y/N airleak either side ever in 30 days	Num	8	
bleed	1=Bleedng,CT>750ml/24hr in30dayspostop	Num	8	
bltrnsf	1=Bleeding req transfus in30dayspostop	Num	8	
cecvol	1=Cecal volvulus in 30 days post op	Num	8	
cholecys	1=Cholecystitis in 30 days post op	Num	8	
ctinf	1=CT site infection in 30 days post op	Num	8	
cva	1=Cerebrovascular event in 30days postop	Num	8	
delir	1=Delirium in 30 days post op	Num	8	
divert	1=Diverticulitis in 30 days post op	Num	8	
dvt	1=DVT in 30 days post op	Num	8	
empyema	1=Empyema in 30 days post op	Num	8	
epicth	1=Epidural cath complic in 30days postop	Num	8	
exacbron	1=Exacerb of bronchitis in 30days postop	Num	8	
fextub	1=Fail early extubat in30days postop	Num	8	
form	Form abreviation and revision number	Char	4	
formdate fwean	#4 cnvrtd to # of days frm RZ/scr	Num Num	8 8	
qibld	1=Failure to wean in 30 days post op 1=GI bleed in 30 days post op	Num	8	
mediast	1=Mediastinitis in 30 days post op	Num	8	
mi	1=Myocardial infarction in 30days postop	Num	8	
newnett	New NETT patient ID no.	Char	5	
nopost	1=No complications in 30 days post op	Num	8	
othr	1=Other complic in 30 days post op	Num	8	
perfvis	1=Perforated viscus in 30 days post op	Num	8	
phleb	1=Phlebitis in 30 days post op	Num	8	
pneumon	1=Pneumonia in 30 days post op	Num	8	
pneuthor	1=Pneumothorax in 30 days post op	Num	8	
pulmembo	1=Pulmonary embolus in 30 days post op	Num	8	
read72	1=Readmit tohosp in72hrs in30dayspostop	Num	8 8	
readicu reopal	1=Readmit to ICU in 30days postop 1=Reoperatn for airleak in30dayspostop	Num Num	о 8	
reopbld	1=Reoperath for bleeding in30days postop	Num	8	
reopdehi	1=Sternal dehisc req reop in30dayspostop	Num	8	
sepsis	1=Sepsis in 30 days post op	Num	8	
sterdebr	1=Sternal debridement in 30 days post op	Num	8	
swi	1=Suprficial wound inf in30dayspostop	Num	8	
tia	1=TIA in 30 days post op	Num	8	
trach	1=Tracheostomy in 30 days post op	Num	8	
urinet	1=Urinary retention in 30 days post op	Num	8	
uti	1=Urinary tract infection in30dayspostop	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
xp307 xp308	#7 cnvrtd to # of days frm RZ/scr	Num	8 8	
xp309	#8 cnvrtd to # of days frm RZ/scr 9 Air leak RT side	Num Char	1	
xp310	10 Duration of air leak (days) - RT	Char	2	
xp312	12 Air leak LFT side	Char	1	
xp313	13 Duration of air leak (days) - LFT	Char	2	
xp315	15 Tubes placed to suction - RT side	Char	1	
xp316	16 Tubes removed - RT side	Char	1	
xp317	<pre>#17 cnvrtd to # of days frm RZ/scr</pre>	Num	8	
xp318	18 Tubes placed to suction - LFT side	Char	1	
xp319	19 Tubes removed - LFT side	Char	1	
xp320	#20 cnvrtd to # of days frm RZ/scr	Num	8	
xp322 xp323	22 Number of days on ventilator 23 Number of days intubated	Char Char	2 2	
xp324	24 Number of post-op intubations	Char	2	
11P 2 1	- namber of post of incubations	Unut	2	

XP - Form XP Post-operative Summary Report (rev 3)

Date	file	created:	13	May	2006
Obsei	rvatio	ons:			580
Varia	ables:	:			84

Variable Name	Variable Label	Туре	Variable Length	Forma
xp325	25 Number of days with epidural analges	Char	2	
xp326	26 Number of days with PCA	Char	2	
xp327	27 Arrhythmia in 30 day post-op period	Char	1	
xp330	30 Discharged in 30day post-op period	Char	1	
xp331	#31 cnvrtd to # of days frm RZ/scr	Num	8	
xp332	32 Discharged to	Char	1	
xp333	33 Discharged with test tube	Char	1	
xp334	34 Re-hospitalized w/in 30 days of LVRS	Char	1	
xp335	#35 cnvrtd to # of days frm RZ/scr	Num	8	
xp338	38 Patient dischared after readmission	Char	1	
xp339	#39 cnvrtd to # of days frm RZ/scr	Num	8	
xp311a	11a Talc treatment – RT side	Char	1	
xp311b	11b Blood patch - RT side	Char	1	
xp311c	11c Pleurodesis - RT side	Char	1	
xp311d	11d Other treatment - RT side	Char	1	
xp311e	11e No treatment – RT side	Char	1	
xp314a	14a Talc treatment – LFT side	Char	1	
xp314b	14b Blood patch - LFT side	Char	1	
xp314c	14c Pleurodesis – LFT side	Char	1	
xp314d	14d Other treatment - LFT side	Char	1	
xp314e	14e No treatment – LFT side	Char	1	
xp321a	21a Number of days in surgical ICU	Char	2	
xp321b	21b Number of days in medical ICU	Char	2	
xp328a	28a Pharmacologic tx for arrhythmia	Char	1	
xp328b	28b Cardioversion tx for arrhythmia	Char	1	
xp328c	28c No treatment for arrhythmia	Char	1	

NETT

<sub>1</sub>)

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1)

3)

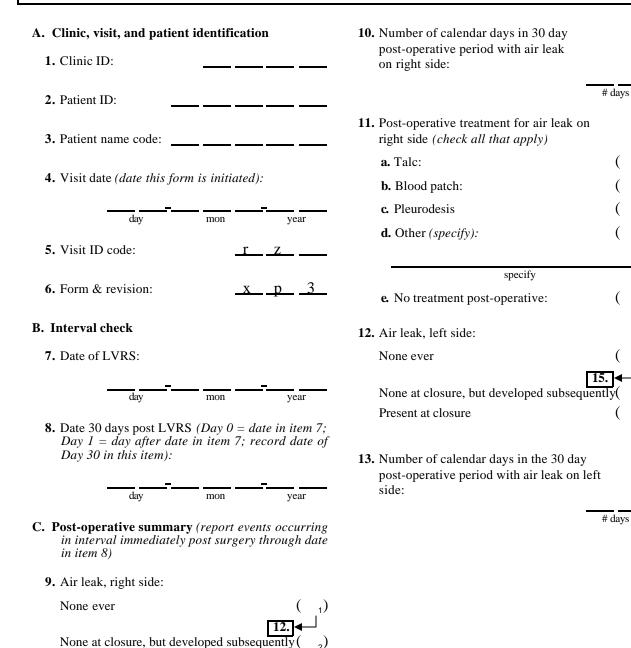
**Purpose** To summarize the 30 day post-operative period.

When: 30 days after surgery (if patient died on or before Day 30 post surgery, complete as soon as information is available).

Administered by: Clinic Coordinator and thoracic surgeon.

#### Respondent: None.

**Instructions**: This form summarizes the health events occurring in the 30 day period after surgery. The 30 day period is defined as: day of surgery=Day 0; day after surgery=Day 1; count forward till you reach Day 30. Report events that occur from the close of the intra-operative period on Day 0 through Day 30 on this form. Do not report events that happened on Day 31 or later on this form. Do not report intra-operative events on this form. If the patient died **during the surgery**, do not complete this form



Present at closure

3)

<sub>1</sub>)

21

21

year

# days

# days

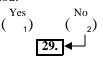
# days

# days

# days

# days

Patient ID: 14. Post-operative treatment for air leak on 19. Have all chest tubes been removed from left side (check all that apply) the left side: 1) a. Talc: Yes No, at least 1 chest tube remains 30 days 1) **b.** Blood patch: post-op c. Pleurodesis <sub>1</sub>) ₁) **d.** Other (specify): No, patient died with at least 1 chest tube still in place specify  $\begin{pmatrix} 1 \end{pmatrix}$ e. No treatment post-operative: **20.** Date last left side chest tube was removed: 15. Were any of the right side chest tubes ever placed to suction during the 30 day day mon post-operative period: Yes 1) 21. Number of calendar days in ICU in 30 day post-op period (total days, if more than one No 2) ICU stay) No right side chest tube(s) 3) a. Surgical ICU: 18. 16. Have all chest tubes been removed from **b.** Medical ICU: the right side: Yes ( 1) 22. Number of calendar days on No, at least 1 chest tube remains 30 days ventilator in 30 day post-op period: post-op ,) 18. No, patient died with at least 1 chest 23. Number of calendar days intubated in 30 day post-op period: tube still in place: 24. Number of post-op intubations in 17. Date last right side chest tube was 30 day post-op period (ie, subsequent removed: to intra-operative intubation): day mon year 25. Number of calendar days with epidural analgesia in 30 day 18. Were any of the left side chest tubes ever post-op period: placed to suction during the 30 day post-operative period: 26. Number of calendar days with patient Yes 1) controlled analgesia (PCA) in 30 day No ,) post-op period: No left side chest tube(s) 3) 21. **27.** Did the patient experience an arrhythmia in the 30 day post-operative period:



28.	Treatment for arrhythmia (check all that a	oply	)
	<b>a.</b> Pharmacologic:	(	1)
	<b>b.</b> Cardioversion:	(	, 1)
	<b>c.</b> No treatment required:	(	1)
29.	Other post-operative complications (check apply)	all t	that
	<b>a.</b> Failure of early extubation (> 4 hours from end of operation):	(	1)
	<b>b.</b> Tracheostomy:	(	1)
	<b>c.</b> Failure to wean:	(	1)
	<b>d.</b> Reoperation for air leak:	(	1)
	e. Myocardial infarction:	(	1)
	f. Bleeding: chest tube output > 750 ml in 24 hours:	(	1)
	g. Reoperation for bleeding:	(	1)
	<b>h.</b> Post-operative bleeding requiring transfusion:	(	1)
	i. Superficial wound infection (not extending below fascial layer):	(	1)
	j. Mediastinitis:	(	1)
	k. Empyema:	(	1)
	<b>I.</b> Sternal dehiscence requiring reoperation:	(	1)
	<b>m.</b> Pneumonia (infiltrate with fever, elevated WBC, positive sputum - need 2 of 3):	(	.)
	<b>n.</b> Urinary tract infection:	(	1)
	<b>o.</b> Urinary retention:	(	1)
	<b>p.</b> Exacerbation of bronchitis:	(	1)
	q. Phlebitis:	(	1)
	<b>r.</b> Epidural catheter complications:	(	1)
	s. Sepsis:	(	1)
	<b>t.</b> Chest tube site infection:	(	1)
	<b>u.</b> Sternal debridement:	(	1)
	v. Gastrointestinal bleed:	(	1)
	<b>w.</b> Adynamic ileus (NG tube or NPO for > 48 hours):	(	1)
	<b>x.</b> Cecal volvulus:	(	1)
	y. Perforated viscus:	(	1)
	z. Cholecystitis:	(	1)

			)
	aa. Diverticulitis:	(	1)
	ab. Cerebrovascular accident:	(	1)
	<b>ac.</b> Transient ischemic attack/RIND (symptoms last < 24 hours):	(	1/
	ad. Delirium:	(	1/
	<b>ae.</b> DVT documented by non-invasive vascular studies:	) (	1/
	<b>af.</b> Pulmonary embolus (high probability V/Q scan):	(	1/
	<b>ag.</b> Readmission to hospital within 72 hours of initial discharge from hospital:	(	1)
	<b>ah.</b> Readmission to MICU or SICU (after transfer to other unit or home; ie, any readmission to the MICU or SICU):	(	1/
	<b>ai.</b> Other ( <i>specify</i> ):	(	1/
	a. Onto (specijy).	(	1,
	specify		
	specify	(	,
•	aj. None of the above	(	1)
30.		(	1.
30.	<ul><li>aj. None of the above</li><li>Was the patient ever discharged from the hospital during the 30 day post-operative</li></ul>	(	
30.	<ul><li>aj. None of the above</li><li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li><li>Yes</li><li>No, patient was never discharged and survito at least the day after the date in item 8</li></ul>	( ved	1.
30.	<ul><li>aj. None of the above</li><li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li><li>Yes</li><li>No, patient was never discharged and survi</li></ul>	( ved (	1, 1, 2,
30.	<ul> <li>aj. None of the above</li> <li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li> <li>Yes</li> <li>No, patient was never discharged and survito at least the day after the date in item 8</li> <li>No, patient died on or before the date in item</li> </ul>	( ved ( ] ■ 8	1, 1, 2,
	<ul> <li>aj. None of the above</li> <li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li> <li>Yes</li> <li>No, patient was never discharged and survito at least the day after the date in item 8</li> <li>No, patient died on or before the date in item</li> </ul>	( ved ( ] <b>-</b> ₩ 8 ( ]	1/ 2/ 
	<ul> <li>aj. None of the above</li> <li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li> <li>Yes</li> <li>No, patient was never discharged and survito at least the day after the date in item 8</li> <li>No, patient died on or before the date in item 4</li> <li>Mo, patient died on or before the date in item 4</li> <li>Date of hospital discharge (<i>initial discharmore than one</i>):</li> </ul>	( ved ( ] <b>-</b> ₩ 8 ( ]	1/ 2/ 
31.	<ul> <li>aj. None of the above</li> <li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li> <li>Yes</li> <li>No, patient was never discharged and survito at least the day after the date in item 8</li> <li>No, patient died on or before the date in item 4</li> <li>Mo, patient died on or before the date in item 4</li> <li>Date of hospital discharge (<i>initial discharmore than one</i>):</li> </ul>	( ( ] ◀ - ( ] ◀ - arge	1/ 2/ 
51.	aj. None of the above         Was the patient ever discharged from the hospital during the 30 day post-operative period:         Yes         No, patient was never discharged and survito at least the day after the date in item 8         No, patient died on or before the date in item without ever having been discharged         40.         Date of hospital discharge (initial discharger than one):         day	( ( ] ◀ - ( ] ◀ - arge	
31.	aj. None of the above         Was the patient ever discharged from the hospital during the 30 day post-operative period:         Yes         No, patient was never discharged and survito at least the day after the date in item 8         Mo, patient died on or before the date in item without ever having been discharged         Image: Additional discharge (initial discharge day mon)         Image: Additional day day day discharge day mon         More was patient discharged to:	( ( ] ◀ - ( ] ◀ - arge	
31.	aj. None of the above         Was the patient ever discharged from the hospital during the 30 day post-operative period:         Yes         No, patient was never discharged and survito at least the day after the date in item 8         Mo, patient died on or before the date in ite without ever having been discharged         Image: Additional discharge (initial discharge day mon)         Image: Additional discharge day mon)         Where was patient discharged to:         Patient's home	( ( ] ◀ - ( ] ◀ - arge	
31.	<ul> <li>aj. None of the above</li> <li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li> <li>Yes</li> <li>No, patient was never discharged and survito at least the day after the date in item 8</li> <li>Mo, patient died on or before the date in iter without ever having been discharged</li> <li>Date of hospital discharge (<i>initial discharge than one</i>):</li> <li>day mon</li> <li>Where was patient discharged to:</li> <li>Patient's home</li> <li>Relative or friend's home</li> </ul>	( ( ] ◀ - ( ] ◀ - arge	1/ 2/ 3/ 2/ 1/ 2/ 3/
31.	<ul> <li>aj. None of the above</li> <li>Was the patient ever discharged from the hospital during the 30 day post-operative period:</li> <li>Yes</li> <li>No, patient was never discharged and survito at least the day after the date in item 8</li> <li>No, patient died on or before the date in iter without ever having been discharged</li> <li>40.</li> <li>Date of hospital discharge (<i>initial discharger than one</i>):</li> <li>day mon</li> <li>Where was patient discharged to:</li> <li>Patient's home</li> <li>Relative or friend's home</li> <li>Nursing home</li> </ul>	( ved ( ] ◀ - m 8 ( ] ◀ - arge ( ( ( (	1/ 2/ 3/ 2/ 1/ 2/ 3/

\_ \_

**33.** Was the patient discharged with a chest tube in place attached to a Heimlich valve:

$$\binom{\text{Yes}}{1}$$
  $\binom{\text{No}}{2}$ 

**34.** Was the patient re-hospitalized on or before the date in item 8 at an acute care facility after discharge:

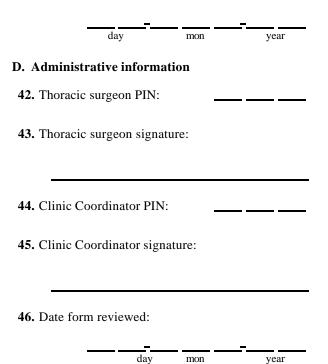
$$\begin{pmatrix} \text{Yes} & \text{No} \\ 1 & \begin{pmatrix} 2 \\ 2 \end{pmatrix}$$

**35.** Date of readmission (*earliest date if multiple readmissions*):



**36.** Reason for readmission:

**41.** Date of death:



37. Events/treatment (describe):

**38.** Was the patient discharged after readmission (*discharge on or before the date in item* 8):

Yes  $( \ _{1} )$ No, still in hospital after readmission  $( \ _{2} )$ No, died in hospital after readmission  $( \ _{3} )$ **40.** 

**39.** Date of discharge (*latest date if multiple discharges during the 30 day post-op period*):

day mon year

40. 30 day vital status:

Survived to at least the day after the date in item 8 (

Dead on or before the date in item 8

1)

42.

XS - Form XS Surgery (Intra-operative) Summary Report (rev 3)

Date	file	created:	13	May	2006
Obser	rvatio	ons:			580
Varia	ables	:			101

Variable			Variable	
Name	Variable Label	Type	Length	Format
		71 -	- 0 -	
airlkcle	Air leak at end of closure, R or L	Num	8	
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr	Num	8	
maxincl	Length (cm) of longest incision, R or L	Num	8	
newnett	New NETT patient ID no.	Char	5	
totninc	Total no. of VATS incisions, R+L	Num	8	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
xs307	#7 cnvrtd to # of days frm RZ/scr	Num	8	
xs308	8 Bilateral LVRS	Char	1	
xs309	9 Side receiving LVRS	Char	1	
xs310	10 Median sternotomy performed	Char	1	
xs311	11 Orientation of incision	Char	1	
xs312	12 VATS performed	Char	1	
xs315	15 Other procedure done	Char	1	
xs329	29 Chest tubes on right side	Char	1	
xs330	30 Number of chest tubes: right side	Char	2	
xs332	32 Chest tubes on left side	Char	1	
xs333	33 Number of chest tubes: left side	Char	2	
xs335	35 Estimated blood loss (ml)	Char	4	
xs339	39 Arrhythmia during LVRS	Char	1	
xs343	43 Anesthesia time (min)	Char	3	
xs344	44 Time from incision to closure (min)	Char	3	
xs346	46 Tissue specimens saved	Char	1	
xs313a	13a Number of incisions (RT)	Char	2	
xs313b	13b Number of incisions (LFT)	Char	2	
xs314a	14a Length of incisions (RT)	Char	3	
xs314b	14b Length of incisions (LFT)	Char	3	
xs316a	16a Adhesions: right side	Char	1	
xs316b	16b Adhesions: left side	Char	1	
xs317a	17a Location of disease: right side	Char	1	
xs317b	17b Location of disease: left side	Char	1	
xs318a	18a Amount of lung removed: right side	Char	1	
xs318b	18b Amount of lung removed: left side	Char	1	
xs319a	19a Ethicon stapler: right side	Char	1	
xs319b	19b US Surgical stapler: right side	Char	1	
xs319c	19c 3M stapler: right side	Char	1 1	
xs319d	19d Endo GIA 30 stapler: right side	Char		
xs319e	19e Endo TA 30 stapler: right side	Char Char	1	
xs319f	19f Other type stapler: right side		1 1	
xs320a	20a Ethicon stapler: left side	Char		
xs320b xs320c	20b US Surgical stapler: left side	Char Char	1 1	
	20c 3M stapler: left side	Char	1	
xs320d xs320e	20d Endo GIA 30 stapler: left side 20e Endo TA 30 stapler: left side	Char	1	
xs320f	20f Other type stapler: left side	Char	1	
xs321a	21a 3.5 staple length: right side	Char	1	
xs321b	21b 3.8 staple length: right side	Char	1	
xs321c	21c 4.8 staple length: right side	Char	1	
xs321d	21d Other staple length: right side	Char	1	
xs322a	22a 3.5 staple length: left side	Char	1	
xs322b	22b 3.8 staple length: left side	Char	1	
xs322c	22c 4.8 staple length: left side	Char	1	
xs322d	22d Other staple length: left side	Char	1	
xs323a	23a Number of cartridges used: right sid	Char	2	
xs323b	23b Number of cartridges used: left side	Char	2	
xs324a	24a Peristrips: right side	Char	1	
xs324b	24b Seamguard: right side	Char	1	
xs3240	24c PTFE: right side	Char	1	
100210	Lie lith. Light blue	Unur	±	

XS - Form XS Surgery (Intra-operative) Summary Report (rev 3)

Date	file	created:	13	May	2006
Obser	rvatio	ons:			580
Varia	ables	:			101

Variable			Variable	
Name	Variable Label	Туре	Length	Format
xs324d	24d Other buttressing material: right si	Char	1	
xs324e	24e No buttressing material: right side	Char	1	
xs325a	25a Peristrips: left side	Char	1	
xs325b	25b Seamguard: left side	Char	1	
xs325c	25c PTFE: left side	Char	1	
xs325d	25d Other buttressing material: left sid	Char	1	
xs325e	25e No buttressing material: left side	Char	1	
xs326a	26a Pleural tent done: right side	Char	1	
xs326b	26b Pleural tent done: left side	Char	1	
xs326c	26c Pleural tent not done	Char	1	
xs327a	27a Pleurodesis done: right side	Char	1	
xs327b	27b Pleurodesis done: left side	Char	1	
xs327c	27c Pleurodesis not done	Char	1	
xs328a	28a Air leak at end of closure - RT	Char	1	
xs328b	28b Air leak at end of closure - LFT	Char	1	
xs331a	31a Chest tubes to water seal - RT	Char	1	
xs331b	31b Chest tubes to suction - RT	Char	1	
xs331c	31c Other chest tubes - RT	Char	1	
xs334a	34a Chest tubes to water seal - LFT	Char	1	
xs334b	34b Chest tubes to suction - LFT		1	
xs3340 xs334c	34b chest tubes to succion - LFT 34c Other chest tubes - LFT	Char	1	
		Char		
xs336a	36a Transfusion - whole blood/packed red	Char	1	
xs336b	36b Number of units transfused	Char	2	
xs337a	37a Patient received fresh frozen plasma	Char	1	
xs337b	37b Number of units of frozen plasma	Char	2	
xs338a	38a Patient received platelets	Char	1	
xs338b	38b Number of packs of platelets	Char	2	
xs340a	40a Pharmacologic treatment for arrhythm	Char	1	
xs340b	40b Cardioversion treatment for arrhythm	Char	1	
xs340c	40c No treatment for arrhythmia	Char	1	
xs341a	41a Hypotension	Char	1	
xs341b	41b Hypoxemia	Char	1	
xs341c	41c Hypercarbia	Char	1	
xs341d	41d Cardiac arrest	Char	1	
xs341e	41e Uncontrolled air leak	Char	1	
xs341f	41f Intra-operative death	Char	1	
xs341g	41g Other intraoperative complication	Char	1	
xs341h	41h No intraoperative complication	Char	1	
xs345a	45a Weight of removed lung: right side	Char	4	
xs345b	45b Weight of removed lung: left side	Char	4	
xs347a	47a 4-6 fragments in formation saved	Char	1	
xs347b	47b 4-6 fragments in Methacarn saved	Char	1	
xs347c	47c 4 fragments in OCT saved & snap froz	Char	1	

# Surgery (Intra-operative) Summary Report

() keyed

NETT **Purpose** To summarize the intra-operative events. When: After LVRS has been completed. Administered by: Clinic Coordinator and Thoracic Surgeon who performed the surgery. Respondent: None. Instructions: Use this form to record information related to intra-operative events. Use the Post-operative Summary Report (XP) form to report post-operative events. If surgery was not bilateral, enter "n" for questions which cannot be answered for the lung not operated on. If the patient died during surgery, complete this form, as well as the Death Report (DR) form and the Death Certificate Report (DF) form. A. Clinic, visit, and patient identification 10. Was median sternotomy performed: Yes No 1. Clinic ID: \_) <sub>2</sub>) 12. **2.** Patient ID: **11.** Orientation of incision: Vertical **3.** Patient name code: <sub>1</sub>) Transverse <sub>2</sub>) Other (specify) **4.** Visit date (*date this form is initiated*): day mon year specify 5. Visit ID code: **12.** Was VATS performed: Yes s 3 **6.** Form & revision: **B.** Surgical information 13. Number of incisions 7. Date of LVRS: a. Right side: # incisions day mon year **b.** Left side: # incisions 8. Was the LVRS bilateral: Yes No 14. Length of longest incision <sub>2</sub>) a. Right side: 10. cm specify why not **b.** Left side: cm specify why not 15. Was a procedure other than VATS or median sternotomy (or additional to describe what was done VATS or median sternotomy) performed: Yes No describe what was done 16. 9. Which side received LVRS: specify Right 1) Left 2)

16. Adhesions:	
a. Right side:	
None or minimal ( $\leq 5\%$ of pleural surface	( <sub>1</sub> )
Moderate (6-20% of pleural surface)	( <sub>2</sub> )
Marked (> 20% of pleural surface)	( <sub>3</sub> )
<b>b.</b> Left side:	
None or minimal ( $\leq 5\%$ of pleural surface	( <sub>1</sub> )
Moderate (6-20% of pleural surface)	$\begin{pmatrix} 2 \end{pmatrix}$
Marked (> 20% of pleural surface)	( 3)
<b>17.</b> Location of disease	
<b>a.</b> Right side:	
Upper lobe predominance	()
Lower lobe predominance	( <sub>2</sub> )
Diffuse	()
<b>b.</b> Left side:	
Upper lobe predominance	()
Lower lobe predominance	$\begin{pmatrix} & \\ & 2 \end{pmatrix}$
Diffuse	( <sub>3</sub> )
18. Amount of lung removed:	
a. Right lung:	
< 20%	()
20-34%	( <sub>2</sub> )
35-49%	()
50-59%	( 4)
60-80%	( <sub>5</sub> )
> 80%	( 6)
<b>b.</b> Left lung:	
< 20%	( <sub>1</sub> )
20-34%	( <sub>2</sub> )
35-49%	()
50-59%	( 4)
60-80%	( <sub>5</sub> )
> 80%	( 6)
<b>19.</b> Type(s) of stapler used on right side (chec that apply)	k all
a. Ethicon:	( <sub>1</sub> )
<b>b.</b> US Surgical/AutoSuture Company:	( <sub>1</sub> )
<b>c.</b> 3M:	( <sub>1</sub> )
<b>d.</b> Endo GIA 30:	( <sub>1</sub> )
<b>e.</b> Endo TA 30:	( <sub>1</sub> )
<b>f.</b> Other ( <i>specify</i> ):	$\begin{pmatrix} 1 \end{pmatrix}$

specify

Patient ID:

<b>20.</b> Type(s) of stapler used on left side ( <i>chec</i> apply)	k all t	hat
<b>a.</b> Ethicon:	(	1)
<b>b.</b> US Surgical/AutoSuture Company:	(	1)
<b>c.</b> 3M:	(	1)
<b>d.</b> Endo GIA 30:	(	1)
<b>e.</b> Endo TA 30:	(	1)
<b>f.</b> Other ( <i>specify</i> ):	(	1)

#### specify

21. Staple length, right side (check al.	l that apply)
<b>a.</b> 3.5:	( <sub>1</sub> )
<b>b.</b> 3.8:	( <sub>1</sub> )
<b>c.</b> 4.8:	( <sub>1</sub> )
<b>d.</b> Other ( <i>specify</i> ):	( <sub>1</sub> )

#### specify

### **22.** Staple length, left side (*check all that apply*)

<b>a.</b> 3.5:	(	1)
<b>b.</b> 3.8:	(	1)
<b>c.</b> 4.8:	(	1)
<b>d.</b> Other ( <i>specify</i> ):	(	1)

### specify

### **23.** Number of cartridges used:

# cartridges

# cartridges

( <sub>1</sub>)

# **b.** Left side:

a. Right side:

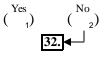
24. Type of buttressing material used on right side (check all that apply) a. Peristrips:

a. Peristrips:	(	1)
<b>b.</b> Seamguard:	(	<sub>1</sub> )
c. PTFE:	(	<sub>1</sub> )
<b>d.</b> Other ( <i>specify</i> ):	(	<sub>1</sub> )

specify

25.	Type of buttressing material used on left side (check all that apply)			<b>31.</b> Placemen <i>that appl</i>
	<b>a.</b> Peristrips:	(	1)	a. To wat
	<b>b.</b> Seamguard:	(	1)	<b>b.</b> To suc
	c. PTFE:	(	1)	c. Other (
	<b>d.</b> Other ( <i>specify</i> ):	(	1)	
	specify			<b>32.</b> Were any
	e. None:	(	1)	side:
26.	Pleural tent performed (check all that apply	v):		
	<b>a.</b> Right side	(	1)	
	<b>b.</b> Left side	(	1)	<b>22</b> Normhann
	<b>c.</b> Neither side	(	1)	<b>33.</b> Number of
27.	Pleurodesis performed (check all that apply	,	,	<b>34.</b> Placemen <i>that appl</i>
	a. Right side	(	1)	a. To wat
	<b>b.</b> Left side	(	1)	<b>b.</b> To suc
	<b>c.</b> Neither side	(	1)	<b>c.</b> Other (
28.	Air leak at end of closure (pleurovac estimation)			
	<b>a.</b> Right side:			25 Estimator
	None	(	1)	<b>35.</b> Estimated
	Minimal (occasional bubble or pinhole stream) Moderate (intermediate stream of bubble	(	<sub>2</sub> )	<b>36.</b> Whole ble transfusio
	with respiratory variation)	(	<sub>3</sub> )	<b>a.</b> Did the
	Large (large stream of nearly constant bubbles)	(	<sub>4</sub> )	whole
	<b>b.</b> Left side:			
	None	(	1)	<b>b.</b> How n
	Minimal (occasional bubble or pinhole stream)	(	<sub>2</sub> )	and/or transfu
	Moderate (intermediate stream of bubble with respiratory variation)	es (	<sub>3</sub> )	
	Large (large stream of nearly constant	Ì		<b>37.</b> Fresh froz
• •	bubbles)	(	4 <b>)</b>	<b>a.</b> Did the fresh f

29. Were any chest tubes placed on the right side:

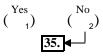


**30.** Number of chest tubes on right side:

<b>31.</b> Placement of chest tubes on right side <i>that apply</i> )	(check a	11
<b>a.</b> To water seal:	(	1)
<b>b.</b> To suction:	(	1)
<b>c.</b> Other ( <i>specify</i> ):	(	1)

specify

chest tubes placed on the left



of chest tubes on left side:

#tubes

nt of chest tubes on left side (check all ly)

<b>a.</b> To water seal:	(	1)
<b>b.</b> To suction:	(	1)
<b>c.</b> Other ( <i>specify</i> ):	(	1)

specify

d blood loss:

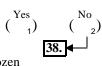
- ood or packed red cells on
  - e patient receive a transfusion of blood and/or packed red cells:



# units

ml

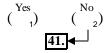
- nany units of whole blood packed red cells were used:
  - zen plasma transfusion
- e patient receive a transfusion of rozen plasma:



b. How many units of fresh frozen plasma were transfused:

# units

- 38. Platelet transfusion
  - **a.** Did the patient receive a transfusion of platelets:
  - **b.** How many packs of platelets were transfused:
- **39.** Did the patient experience an arrhythmia during the LVRS:



(Yes

- **40.** Treatment for arrhythmia (*check all that apply*)
  - a. Pharmacologic:
     ( 1)

     b. Cardioversion:
     ( 1)

     c. None:
     ( 1)
- **41.** Other intra-operative complications(*check all that apply*)

<b>a.</b> Hypotension (mean BP < 50 mmHg for more than 10 min):	(	1)
<b>b.</b> Hypoxemia (O <sub>2</sub> sat < 88% for more than 10 min):	(	1)
<b>c.</b> Hypercarbia (PCO <sub>2</sub> > 70 mmHg):	(	<sub>1</sub> )
<b>d.</b> Cardiac arrest:	(	<sub>1</sub> )
<b>e.</b> Uncontrolled air leak (as defined by surgeon):	(	1)
<b>f.</b> Intra-operative death	(	<sub>1</sub> )
<b>g.</b> Other ( <i>specify</i> ):	(	<sub>1</sub> )
specify		

- **h.** None of the above:
- **42.** Anesthesiologist PIN:
- **43.** Anesthesia time (*time from induction of anesthesia to case end*):
- **44.** Time from skin incision to closure:

minutes

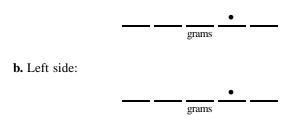
minutes

(1)

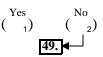
NETT Form XS Revision 3 (16 Feb 99) Patient ID:

#### **45.** Weight of lung removed:

**a.** Right side:



46. Were tissue specimens saved:



<sub>1</sub>)

1)

- 47. Specimens saved (check all that apply):
  a. 4-6 fragments in formalin
  b. 4-6 fragments in Methacarn
  - **c.** 4 fragments in OCT and snap frozen (1)
- **48.** Location of stored specimens (*specify*):

#### specify location

#### C. Administrative information

- **49.** Thoracic surgeon PIN (*surgeon who did the surgery reported on this form*):
- 50. Thoracic surgeon signature:
- 51. Clinic Coordinator PIN:
- **52.** Clinic Coordinator signature:
- **53.** Date form reviewed:



XZ - Form XZ Documentation of Randomization (rev 2)

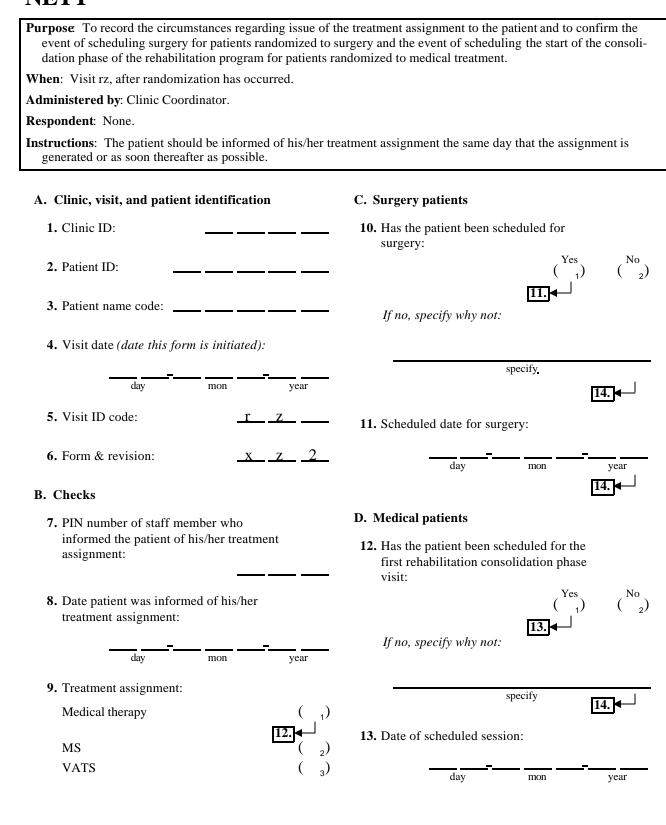
Date	file	created:	13	May	2006
Obsei	rvatio	ons:			1218
Varia	ables:	:			10

Variable Name	Variable Label	Туре	Variable Length	Format
form	Form abreviation and revision number	Char	4	
formdate	#4 cnvrtd to # of days frm RZ/scr	Num	8	
newnett	New NETT patient ID no.	Char	5	
visit	s1,s2,s3,rz,n,fxx where xx=mos from RZ	Char	3	
xz208	#8 cnvrtd to # of days frm RZ/scr	Num	8	
xz209	9 Treatment assignment	Char	1	
xz210	10 Surgery scheduled	Char	1	
xz211	#11 cnvrtd to # of days frm RZ/scr	Num	8	
xz212	12 Rehab consolidation phase scheduled	Char	1	
xz213	<pre>#13 cnvrtd to # of days frm RZ/scr</pre>	Num	8	

NETT

# **Documentation of randomization**

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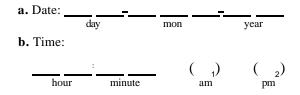


## E. Next visit

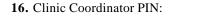
**14.** Was visit f06 scheduled:

$$\begin{pmatrix} \text{Yes} & \text{No} \\ 1 & \begin{pmatrix} 2 \\ 2 \end{pmatrix}$$

**15.** Date and time of visit f06



# F. Administrative information



- **17.** Clinic Coordinator signature:
- **18.** Date form reviewed:

