ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

ALLIANCE A221502

PULMONARY REHABILITATION BEFORE LUNG CANCER RESECTION

A Limited Access Study

ClinicalTrials.gov Identifier: TBD

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Participating Organizations
Alliance/Alliance for Clinical Trials in Oncology,
ECOG-ACRIN / ECOG-ACRIN Cancer Research Group, NRG / NRG Oncology, SWOG / SWOG
Limited to the following institutions:

Mayo Clinic Cancer Center (MN026)(Alliance, ECOG,NRG)
Mayo Clinic in Florida (FL080) (Alliance, ECOG,NRG)
Baptist Health Lexington (KY026)(SWOG, ECOG)
Baylor University Medical Center (TX012)(Alliance, SWOG)
Billings Clinic (MT002)(Alliance, ECOG, NRG)
Carle Cancer Center (IL168)(Alliance, SWOG, ECOG, NRG)
Columbus NCORP (COLUMBUS)(Alliance, SWOG,ECOG, NRG)
Franciscan St. Francis Health (IN087)(Alliance, SWOG,NRG)
Henry Ford Health Systems (MI026)(Alliance, SWOG, ECOG, NRG)
HSHS St. Vincent Hospital (WI027)(Alliance, SWOG, ECOG,NRG)
London Health Sciences Centre (11137)(Alliance, NRG, CCTG)
Mary Washington Hospital (VA056)(Alliance, ECOG, NRG)
Medical University of South Carolina (SC008)(Alliance, SWOG, ECOG, NRG)
Rush University Medical Center (IL043)(Alliance, ECOG, NRG)
Spartanburg Regional Medical Center (SC024)(Alliance, SWOG, NRG)
Stony Brook Cancer Center (NY184)(Alliance, ECOG, NRG)
University of Maryland Medical System (MD015)(Alliance, NRG)

Study Resources:

Medidata Rave® iMedidata portal
[redacted]

OPEN (Oncology Patient Enrollment Network)
[redacted]

Protocol Contacts:

Alliance Central Protocol Operations Program Office
[redacted]

Alliance Statistics and Data Center
[redacted]

A221502 Nursing Contacts
[redacted]

Protocol-related questions may be directed as follows:	
Questions	**Contact (via email)**
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair, Nursing Contact, Protocol Coordinator, and (where applicable) Data Manager
Questions related to data submission, RAVE or patient follow-up:	Data Manager
Questions regarding the protocol document and model informed consent:	Protocol Coordinator
Questions related to IRB review	Alliance Regulatory Inbox [redacted]
Questions regarding CTEP-AERS reporting:	Regulatory Affairs Manager [redacted]
Questions regarding specimens/specimen submissions:	appropriate Alliance Biorepository

Document History	Effective Date:
Activation	03/15/2017
Update 1	04/01/2017
Update 2	06/15/2017
Update 3	08/15/2017

CANCER TRIALS SUPPORT UNIT (CTSU) ADDRESS AND CONTACT INFORMATION

For regulatory requirements	**For patient enrollments:**	**For study data submission**
Regulatory documentation must be submitted to the CTSU via the Regulatory Submission Portal. Regulatory Submission Portal: (Sign in at [redacted], and select the Regulatory Submission sub-tab under the Regulatory tab.) Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately at [redacted] to receive further instruction and support. Contact the CTSU Regulatory Help Desk at [redacted] for regulatory assistance.	Please refer to the patient enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN) which can be accessed at [redacted] Contact the CTSU Help Desk with any OPEN-related questions at [redacted].	Data collection for this study will be done exclusively through Medidata Rave. Please see the data submission section of the protocol for further instructions. Do <u>not</u> submit study data or forms to CTSU Data Operations. Do <u>not</u> copy the CTSU on data submissions.
The most current version of the **study protocol and all supporting documents** must be downloaded from the protocol-specific Web page of the CTSU Member Web site located at [redacted]. Access to the CTSU members' website is managed through the Cancer Therapy and Evaluation Program - Identity and Access Management (CTEP-IAM) registration system and requires user log on with CTEP-IAM username and password. Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU RSS.		
<u>For clinical questions (i.e. patient eligibility or treatment-related)</u> see the Protocol Contacts, Page 2		
<u>For non-clinical questions (i.e. unrelated to patient eligibility, treatment, or clinical data submission)</u> contact the CTSU Help Desk by phone or e-mail: CTSU General Information Line – [redacted]. All calls and correspondence will be triaged to the appropriate CTSU representative.		
The CTSU Website is located at [redacted].		

PULMONARY REHABILITATION BEFORE LUNG CANCER RESECTION

Required Initial Laboratory Values
None

Eligibility Criteria (see Section 3.2)

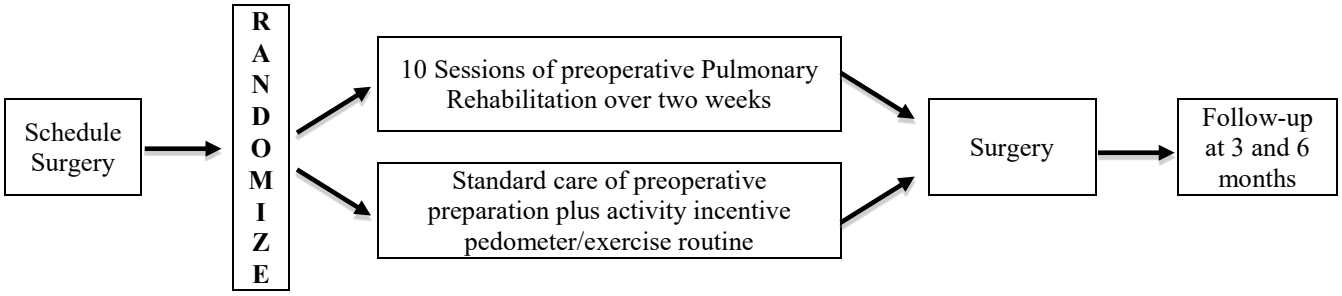
Patient is scheduled to undergo NSCLC resection: VATS or open thoracotomy for: limited resection, lobectomy, or pneumonectomy.

A doctor diagnosis of COPD.

Patient is a current or ex-smoker with a smoking history of ≥ 10 pack yrs. (see Section 3.2.3)

Age ≥ 18 years.

Schema



Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

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1.0. BACKGROUND

1.1 Study Rationale

Definitive assessment of the efficacy of preoperative Pulmonary Rehabilitation (PR) can only be addressed through a randomized, controlled clinical trial. Performing this protocol with a multicenter design ensures that the results are not unique to a narrow population or center.

We plan to obtain definitive evidence for the effectiveness of a short preoperative PR protocol on the recovery from a curative surgical resection in patients with non-small cell lung cancer (NSCLC) and Chronic Obstructive Pulmonary Disease (COPD).

1.2 Significance and Innovation of this Study

Of all cancers in men and women, lung cancer is the number one killer in the United States. With 80% of those cases comprised of NSCLC, complete surgical resection is currently the only curative treatment. However, many patients with resectable lung cancer have COPD, which increases their risk of postoperative complications and their likelihood of being considered "inoperable." It is estimated that 80% of patients with lung cancer have COPD, and about one-fourth have severe COPD[1]. While the presence of moderate or severe COPD may not absolutely contraindicate surgery, the increased morbidity and mortality associated with lung cancer treatment highlights the need for new preoperative interventions to improve clinical outcomes.

There is no intervention that can decrease the morbidity of lung cancer resection in patients emotionally frail or with poor lung function[2, 3]. Modifying the risk of postoperative pulmonary complications is not simple in patients with severe or clinically significant COPD. While comprehensive pharmacologic treatment is warranted, no evidence suggests that <u>any</u> pharmacologic intervention reduces perioperative risk. Pre-operative PR is one of the few proposed interventions in the literature that has been suggested to reduce the risk of post-operative complications**.** The role of smoking cessation as a pre-operative intervention is not clear.

Psychological distress is very prevalent in COPD and adds more risk to having a post-operative complication. Pulmonary Rehabilitation and stress reduction have been recommended in the last decade to decrease operative risk.

PR as a preoperative intervention has been repeatedly recommended in patients with poor lung function undergoing lung cancer resection,[2, 4-8] but existing protocols are not suitable for the preoperative setting and do not fit into the limited window of time available between diagnosis and surgical resection of lung cancer. Furthermore, despite recommendations, no randomized or large clinical series have been published to date, testing the effect of the current protocols of PR on post-operative outcome or recovery from surgery. The size of all reports (<25 patients) from centers that have large surgical volumes, and the lack of any randomized studies, have prompted questions regarding the feasibility of standard PR as a preoperative intervention[9,10].

Our preliminary work, based on NCI K23CA106544, developed and pilot tested a short PR that was feasible and likely very effective on postoperative outcomes and has become the foundation of this proposal. Our preliminary work also pointed out the clinical limitations of a lengthy 4-week preoperative PR (standard protocol) as patients and providers do not want to postpone the surgery. Reports over the past decade have consistently shown that quality of life is an independent predictor of overall survival for patients with lung cancer, independent of performance status and other potentially surrogate biomarkers[11-13].

In our preliminary work, we defined a feasible protocol of preoperative PR that enhanced the current methods of PR with new components that include: mindfulness during movements to promote patient's self-efficacy and emotional balance, inspiratory muscle training and slow

breathing awareness (mindfulness of the breath through pursed lips breathing). Mindfulness has well known stress reduction properties and improves quality of life. Self-efficacy or the confidence in one's ability to perform a specific behavior or task is critical to a patient's ability to manage the physical and psychological challenges of cancer treatment. In addition, inspiratory muscle training and slow breathing awareness, not routinely used in PR, have been associated with better post-operative outcomes for thoracic surgery. This innovative preoperative intervention, supported by our preliminary results, may decrease operative morbidity and improve recovery following curative lung cancer resection.

The present research team includes Dr. Sloan and colleagues who have repeatedly demonstrated over the past fifteen years a relationship particularly for patients with lung cancer between quality of life and other treatment outcomes including survival[14-16]. Furthermore, specifically among patients with advanced lung cancer, a palliative care program that included a behavioral intervention was demonstrated to improve quality of life and survival among NSCLC patients[2]. Studies showed that a consistent proportion of patients undergoing lung resection exhibit an important postoperative worsening in their QOL and physical activity[17-19] especially in the first 3 to 6 months after surgery[20] and no study to date prospectively assessed the trajectory of quality of life or physical activity after lung resection. The latter is particularly relevant in patients with COPD and resectable lung cancer that carries poorer survival and quality of life compared to non-COPD patients.

This randomized clinical trial, first of its kind, will likely reveal the benefit of behavioral interventions for patients with lung cancer and COPD facing surgical resection. This could dramatically change how behavioral interventions are used in oncology.

1.3 Study Overview

This is a study funded by the National Institute of Health. Prospectively, 194 patients will be randomized to either ten sessions of preoperative PR vs. standard care at a number of healthcare centers throughout the United States. The rationale for the need of this research is the lack of any well proven risk-reducing intervention that may decrease the morbidity of lung cancer resection in patients with COPD or that may improve their quality of life trajectory, a meaningful outcome in the overall disease progression. The proposed intervention is unique as it combines exercise and behavioral interventions that were pilot tested in a randomized single-blinded controlled design in the proposed population and proved feasible and potentially effective.

The aim is to test the effect of the proposed rehabilitation on length of stay, pulmonary complications and quality of life trajectory.

2.0 OBJECTIVES

2.1 Primary objective

2.1.1 To prospectively determine the effect of 10 sessions of customized preoperative PR on the length of hospital stay in patients that undergo a lung cancer resection and have COPD compared to a matched control group.

Hypothesis: Ten sessions of customized preoperative PR will significantly reduce the length of hospital stay.

2.2 Secondary objectives

2.2.1 To prospectively determine the effect of 10 sessions of customized preoperative PR on the number of postoperative complications in patients that undergo a lung cancer resection and have COPD compared to a matched control group.

Hypothesis: Ten sessions of customized preoperative PR will significantly reduce the number of postoperative pulmonary complications.

2.2.2 To prospectively determine the effect of a 10-session preoperative PR on the trajectory of quality of life at 3 and 6 months after the curative resection compared to a matched control group.

Hypothesis: Ten sessions of customized preoperative PR will significantly and meaningfully (more than the minimal clinically important difference) improve quality of life after surgery compared to a control group.

3.0 PATIENT SELECTION

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.1 On-Study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient. Physicians should consider the risks and benefits of any therapy, and therefore only enroll patients for whom this treatment is appropriate.

Physicians should recognize that the following may render the patient inappropriate for this protocol:

- Psychiatric illness which would prevent the patient from giving informed consent.

3.2 Eligibility Criteria

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit this page.

___ **3.2.1** Patient is scheduled to undergo NSCLC resection: video assisted thoracoscopy (VATS) or open thoracotomy for: limited resection, lobectomy, or pneumonectomy. Surgery must not be scheduled to take place < 3 weeks after registration.

___ **3.2.2** Patient has a doctor diagnosis of COPD.

___ **3.2.3** Patient is a current or ex-smoker with a smoking history of ≥ 10 pack years. (Calculated by multiplying the number of **packs** of cigarettes smoked per day by the number of years the person has smoked. For example, 1 **pack-year** is equal to smoking 20 cigarettes (1 **pack**) per day for 1 **year**, or 40 cigarettes per day for half a **year**, and so on).

___ **3.2.4** Age ≥ 18 yrs.

4.0 PATIENT REGISTRATION

4.1 CTEP Investigator Registration Procedures

Food and Drug Administration (FDA) regulations and National Cancer Institute (NCI) policy require all investigators participating in any NCI-sponsored clinical trial to register and to renew their registration annually.

Registration requires the submission of:

Human Subject Protection (HSP) training certificate

4.2 CTEP Associate Registration Procedures / CTEP-IAM Account

The Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) application is a web-based application intended for use by both Investigators (i.e., all physicians involved in the conduct of NCI-sponsored clinical trials) and Associates (i.e., all staff involved in the conduct of NCI-sponsored clinical trials).

Associates will use the CTEP-IAM application to register (both initial registration and annual re-registration) with CTEP and to obtain a user account.

Investigators will use the CTEP-IAM application to obtain a user account only. (See CTEP Investigator Registration Procedures above for information on registering with CTEP as an Investigator, which must be completed before a CTEP-IAM account can be requested.)

An active CTEP-IAM user account will be needed to access all CTEP and CTSU (Cancer Trials Support Unit) websites and applications, including the CTSU members' website.

Additional information can be found on the CTEP website at [redacted]. For questions, please contact the ***CTEP Associate Registration Help Desk*** by email at [redacted].

4.3 CTSU Site Registration Procedures

This study is supported by the NCI Cancer Trials Support Unit (CTSU).

IRB Approval:

Each investigator or group of investigators at a clinical site must obtain IRB approval for this protocol and submit IRB approval and supporting documentation to the CTSU Regulatory Office before they can be approved to enroll patients. Assignment of site registration status in the CTSU Regulatory Support System (RSS) uses extensive data to make a determination of whether a site has fulfilled all regulatory criteria including but not limited to: an active Federal Wide Assurance (FWA) number, an active roster affiliation with the Lead Network or a participating organization, a valid IRB approval, and compliance with all protocol specific requirements.

Sites participating on the NCI CIRB initiative that are approved by the CIRB for this study are not required to submit IRB approval documentation to the CTSU Regulatory Office. For sites using the CIRB, IRB approval information is received from the CIRB and applied to the RSS in an automated process. Signatory Institutions must submit a Study Specific Worksheet for Local Context (SSW) to the CIRB via IRBManager to indicate their intent to open the study locally. The CIRB's approval of the SSW is then communicated to the CTSU Regulatory Office. In order for the SSW approval to be processed, the Signatory Institution must inform the CTSU which CIRB-approved institutions aligned with the Signatory Institution are participating in the study.

4.3.1 Downloading Site Registration Documents:

Site registration forms may be downloaded from the A221502 protocol page located on the CTSU members' website. Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU RSS.

- Go to [redacted] and log in to the members' area using your CTEP-IAM username and password
- Click on the Protocols tab in the upper left of your screen

- Either enter the protocol # in the search field at the top of the protocol tree, or
- Click on the By Lead Organization folder to expand
- Click on the Alliance link to expand, then select trial protocol # A221502.
- Click on LPO Documents, select the Site Registration documents link, and download and complete the forms provided.

4.3.2 Requirements For A221502 Site Registration:

- IRB approval (For sites not participating via the NCI CIRB; local IRB documentation, an IRB-signed CTSU IRB Certification Form, Protocol of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption Form, or combination is accepted)
- Approval of Site personnel training received from Dr. Benzo's staff, as described in Section 5.2.2.

4.3.3 Submitting Regulatory Requirements

Submit required forms and documents to the CTSU Regulatory Office via the Regulatory Submission Portal, where they will be entered and tracked in the CTSU RSS.

Regulatory Submission Portal: [redacted] (members' area) → Regulatory Tab →Regulatory Submission

When applicable, original documents should be mailed to:

CTSU Regulatory Office

[redacted]

Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately at [redacted] in order to receive further instruction and support.

4.3.4 Checking Your Site's Registration Status

You can verify your site registration status on the members' section of the CTSU website.

- Go to [redacted] and log in to the members' area using your CTEP-IAM username and password
- Click on the Regulatory tab
- Click on the Site Registration tab
- Enter your 5-character CTEP Institution Code and click on Go

Note: The status given only reflects compliance with IRB documentation and institutional compliance with protocol-specific requirements outlined by the Lead Network. It does not reflect compliance with protocol requirements for individuals participating on the protocol or the enrolling investigator's status with the NCI or their affiliated networks.

4.3.5 Credentialing

This is a limited access study. Each participating site must be individually approved by the study chair or designate and be listed as a participating institution on the cover page of the protocol. All participating sites will be approved by the study chair prior to being listed on the protocol cover page. See also Section 5.0.

The confirmation of site participation eligibility by the study chair is required before any patients may be enrolled on this study.

Patients **may not** be registered to this study until at least one person from the site has been approved to perform pulmonary rehabilitation. **Training should start at least a month prior to enrollment.** It is recommended that each site have a trained backup person to cover absences.

See Section 5.0 for full instructions regarding the training requirements.

4.4 Patient Registration Requirements

Registration is to take place after surgery is scheduled.

Informed consent:

The patient must be aware of the neoplastic nature of his/her disease and willingly consent after being informed of the intervention, the experimental nature of the intervention, alternatives, potential benefits, and discomforts. Current human protection committee approval of this protocol and a consent form is required prior to patient consent and registration. Patients may be enrolled in other clinical trials while participating in this study.

Patient Completed Booklets and Other Patient Materials:

Patient questionnaire booklets to be administered at baseline are to be ordered prior to the registration of any patients. Patient completed booklets can be ordered by downloading and completing the booklet order form (located under the supplemental documents section of the A221502 web site) and faxing the form to Attn: Operational Support Clerk at [redacted]. Samples of the booklets are found in Appendices I and II, which are to be used for reference and IRB submission only. They are not to be used for patient completion.

The patient materials listed in section 5.4 must also be ordered prior to registration of any patients. Instructions for ordering these materials are provided in section 5.4.

Patient Release of Medical Records:

Medical records from admission to discharge must be submitted per Section 5.5. Patients must complete the institution's own Authorization for Release of Medical Records prior to registration.

Limited access information:

This is a limited access study. Each participating Alliance member site must be individually approved by the study chair or designate and be listed as a participating site on the cover page of the protocol. All participating sites will be approved by the study chair prior to being listed on the protocol cover page.

To become a participating site, please email [redacted] at [redacted]. Please include the names of the institution, CTEP Institution ID, Surgeon(s), PR Specialist(s) and Institutional Coordinator. See Section 5.2.

4.5 Patient Registration/Randomization Procedures.

Patient enrollment will be facilitated using the Oncology Patient Enrollment Network (OPEN). OPEN is a web-based registration system available on a 24/7 basis. To access OPEN, the site user must have an active CTEP-IAM account (check at [redacted]) and a 'Registrar' role on either the LPO or participating organization roster.

All site staff will use OPEN to enroll patients to this study. It is integrated with the CTSU Enterprise System for regulatory and roster data and, upon enrollment, initializes the patient in the Rave database. OPEN can be accessed at https://open.ctsu.org or from the OPEN tab on the CTSU members' side of the website at [redacted] A user manual is available for OPEN users on the CTSU site.

Prior to accessing OPEN, site staff should verify the following:

- All eligibility criteria have been met within the protocol stated timeframes.
- All patients have signed an appropriate consent form and HIPAA authorization form (if applicable).

Note: The OPEN system will provide the site with a printable confirmation of registration and treatment information. Please print this confirmation for your records.

Further instructional information is provided on the OPEN tab of the CTSU members' side of the CTSU website at [redacted] or at [redacted]. For any additional questions contact the CTSU Help Desk at [redacted] or [redacted].

4.6 Stratification Factors

Randomization will be stratified (equal number in both groups) by 3 variables that may bias the results if they become unbalanced after randomization:

4.6.1 Very severe lung function defined as one of the following: (FEV1 <30% predicted) or use of permanent oxygen or PCO2 >50mmgh])

Yes vs. No

NOTE: If the patient has no lung function test it will be considered NOT very severe lung function.

4.6.2 Prior Neo-adjuvant chemotherapy for this operation

Yes vs. No

4.6.3 Open thoracotomy vs. video assisted thoracoscopy (VATS).

5.0 STUDY IMPLEMENTATION

5.1 PR Clinic Requirements

It is not required that sites have a pulmonary rehabilitation program. Institutional staff will be trained to lead the rehabilitation techniques used in the study.

5.2 PR Manual and Training Requirements

5.2.1 General Requirements

- The individuals to be trained at each institution are those who have experience dealing with patients with chronic lung conditions.
- Institutions must name a physician, who could be a thoracic surgeon or thoracic pulmonologist to oversee the staff doing the intervention.
- The participating sites must have a space that is dedicated to the intervention. An appropriate space allows the patients to do the walking and movement exercises with the appointed trainer without disturbance.

5.2.2 Training of the Site Personnel for Pulmonary Rehabilitation

Patients **may not** be registered to this study until at least one person from each site has been approved to perform pulmonary rehabilitation. It is recommended that each site have a trained backup person to cover absences.

This study requires that the person who will deliver the intervention is approved by Dr. Benzo's staff. Each person who administers the intervention must be certified.

Each participating site will have one or two people who are trained to deliver the intervention (nurse, respiratory therapist or physiotherapist, or trained study coordinator).

Training should start at least a month prior to enrollment. It is anticipated that the one on one training will require four 30 minute calls with homework in between.

Dr. Benzo's staff will train the PR staff or selected interventionist for the delivery of the intervention. Training documents and videos will be sent to the participating site by Dr. Benzo's staff. Institutional staff who will be delivering the intervention will have demonstrated an understanding of the content of these materials. These interventionists will be trained in steps, which will include reviewing materials and demonstrating proficiency in leading the patient through the techniques. After the individual is comfortable with the intervention protocol s/he is to demonstrate the exercises while being recorded (cellphone, video camera). The recording can be sent to [redacted] Once the recording has been reviewed, the individual will have a one-on-one online training via Skype or FaceTime with Dr. Benzo's staff. Once it has been determined that the individual is able to deliver the intervention, Dr. Benzo's staff will email notice of this approval (in the form of a "confirmation of certification form") to the site, which will need to submit this approval to the CTSU per sections 4.3.2 and 4.3.3.

5.3 Patient Recruitment

Potential participants should not be approached for this study until it is determined that they are eligible for surgery.

Surgeons will schedule the patient's surgery in a period **not sooner than 3 weeks** from the surgical consultation to allow time for the intervention or the control-group walking practice (3 weeks is the typical wait time for most centers and does not affect the outcome of the lung cancer). The patient will be offered the study after the date is set.

5.4 Patient materials

The following materials, which will be provided to patients following registration, must be ordered from [redacted] by emailing her at: [redacted].

Intervention arm	**Control Arm**
Participant Manual	Pedometer
Patient Log	Patient Log
DVD of pulmonary rehabilitation	Exercise Pamphlet
CD/audio recording with breathing exercises	
PFlex device	

Note: In addition to the patient materials listed above, pre-stamped envelopes for submission of patient logs and booklets will be included with the packet.

5.5 Study Calendar

	Baseline	During 2 weeks of PR	After Hospital Discharge	At 3 and 6 months after surgery*
MRC Dyspnea scale	X			X
CRQ	X			X
LASA	X			X
Patient Log		X(1)		
CRA Contact			X(2)	X(4)
Hospital records			X(3)	

* A window of +/- 2 weeks before or after each time point for completion of the self-report measures will be allowed. The nurse/CRA should call the patient prior to mailing the questionnaire booklets. The call is to let the patient know that the questionnaires are on the way.

1 Patients on the intervention arm will return the completed log to local site staff at the end of the final PR visit. Patients on the control arm will be asked to mail completed patient logs to local site staff. Sites will then mail all patient logs to the address provided in Section 6.3.

2 The CRA will call the patient within 7 days from discharge to ask the 3 questions included in Appendix III.

3 Hospital records MUST include inpatient information from admissions to discharge. See Section 6.3.

4 The CRA will call the patient to let the patient know that the questionnaires are on the way.

6.0 DATA SUBMISSION

6.1 Data Collection and Submission

Data collection for this study will be done exclusively through the Medidata Rave clinical data management system. Access to the trial in Rave is granted through the iMedidata application to all persons with the appropriate roles assigned in Regulatory Support System (RSS). To access Rave via iMedidata, the site user must have an active CTEP-IAM account (check at [redacted]) and the appropriate Rave role (Rave CRA, Read-Only, Site Investigator) on either the LPO or participating organization roster at the enrolling site.

Upon initial site registration approval for the study in RSS, all persons with Rave roles assigned on the appropriate roster will be sent a study invitation e-mail from iMedidata. To accept the invitation, site users must log into the Select Login [redacted] using their CTEP-IAM user name and password, and click on the "accept" link in the upper right-corner of the iMedidata page. Please note, site users will not be able to access the study in Rave until all required Medidata and study specific trainings are completed. Trainings will be in the form of electronic learnings (eLearnings), and can be accessed by clicking on the link in the upper right pane of the iMedidata screen.

Users who have not previously activated their iMedidata/Rave account at the time of initial site registration approval for the study in RSS will also receive a separate invitation from iMedidata to activate their account. Account activation instructions are located on the CTSU website, Rave tab under the Rave resource materials (Medidata Account Activation and Study Invitation Acceptance). Additional information on iMedidata/Rave is available on the CTSU members'

website under the Rave tab at [redacted] or by contacting the CTSU Help Desk at [redacted] or by e-mail at [redacted].

A Schedule of Forms is available on the Alliance study webpage, within the Case Report Forms section.

6.2 Patient questionnaire booklets

All patient questionnaire booklets for A221502 are to be ordered prior to the registration of any patients. Baseline booklets will be administered in clinic at the time that the patient is randomized. Samples of all questionnaire/booklets are available in Appendices I and II, for reference and IRB submission only. **They are not to be used for patient completion.**

Post-surgery booklets (month 3 and month 6) should be mailed by institutional staff to patients 1 week before the 3 and 6 month time points. Patients will be instructed to mail the booklets back to their registering site for entry into the iMedidata RAVE.

6.3 Hospital records

Submission of hospital records listed in Appendix IV will be required. Dates of admission, surgery and discharge must be included with these records. Hospital records must be de-identified by institutional staff before mailing to Dr. Benzo's staff. Site personnel MUST remove all protected health information (PHI) from the medical records (including but not limited to):

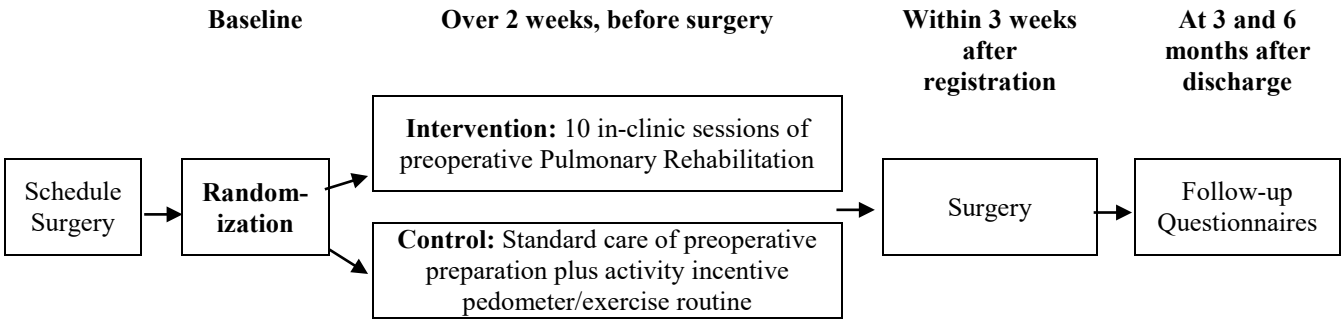
- Patient name
- Patient initials
- Date of birth
- Phone numbers
- Social security number
- Medical record number or account number
- Any unique identifying number, characteristic or code

The Alliance patient ID number **must** be included on each page. De-identified hospital records should be mailed to:

[redacted]

Dr. Benzo's staff will provide participating sites with pre-addressed postage paid envelopes.

7.0 STUDY INTERVENTION



7.1 Intervention group procedures

Patients who are randomized to the intervention group will start the Pulmonary Rehabilitation (PR) within 7 days after randomization. The PR will consist of 10 sessions with the interventionist lasting less than 2 hours each. Patients will receive a Participant Manual demonstrating and explaining the rehabilitation process. Patients will also receive a log for recording their efforts and notes for every day until the day of surgery. We will consider 6 sessions as the minimum to be deemed a complete intervention (for analysis purposes). The patients should not be asked to come only 6 times to the clinic. In case of missing sessions, the patient should be encouraged to do the sessions at home, however, they will not be counted as intervention sessions.

Using the video recording during Pulmonary Rehabilitation sessions:

A video recording of the intervention from start to finish will be provided to all patients in the intervention arm. The recording will be an mp3 file that can be played from any device (e.g., phone, computer). Alternatively a CD that has the breathing practice may be used. Patients may keep the DVD/CD. The DVD should be used during the intervention with the participant. The patient and interventionist should both follow the video. This ensures that the same intervention is being delivered.

The video recording should be played in all 10 sessions at the registering site. Following the video recording will add uniformity to the intervention across sites. The interventionist can stop the video recording any time during the session to give instructions or answer questions.

Modifications may be made if needed. For example, if the patient has shoulder injury and cannot lift arms over head, then the exercise may be modified to accommodate the patient.

PR sessions will include the following components:

The patient will document in a log that they completed each component of the rehabilitation. The patients will be asked to return the log to the registering site at the end of their last PR session.

7.1.1 Breathing Awareness (in clinic): Before and after each session, the patient will do a 3-minute mindful breathing awareness exercise guided by an audio recording provided either as a CD or mp3 file. We provided also an ultra-short 10 Breath Practice that can be used during the day and at times when there are worsening symptoms (i.e. pain after surgery).

7.1.2 Upper and lower extremity exercise (in clinic): Strength and stretching exercises (goal of at least 20 minutes per session), treadmill or hallway walking (preferred) with a goal of total 24 minutes per session (not less than 18 minutes). The sites and patients will be provided a DVD that demonstrates the rehabilitation session from start to finish.

It is acknowledged that it could be "boring to have a recording" or follow a movie every time but that will provide consistency of the intervention across sites. Patients are expected to engage in walking once daily and complete the IMT routine and upper extremity exercises.

7.1.3 Instructions for Inspiratory Muscle Training (IMT) performed using the PFlex valve (Philips Healthcare Andover, MA) (in clinic): Patients will be instructed to inhale deeply and forcefully for 2 seconds and exhale normally. Repeat for one minute and rest for 30 seconds for a total of 10 complete cycles (training plus resting time). Patients are asked to adjust their trainer (there is a selector with different levels of effort) to a level of perceived exertion of "Somewhat Hard to Hard" (11-13 on the 6-20 BORG scale) when they breathe through the device. When patients note perceived exertion less than "Somewhat Hard", the next IMT setting is increased to achieve the desired effort. The rationale to include routine use of inspiratory muscle training, not recommended as a routine in the current PR guidelines, is based primarily on a recent large randomized study which showed decreased postoperative complications.[20-22]

The table below lists the exercises that are part of the PR sessions.

Exercise	Time	Description
Breathing Awareness	3 Minutes	3 minute breathing practice at start of session
Upper Extremity	20 Minutes	Neck, Shoulder, Arm Movements
Lower Extremity	18-24 Minutes	Goal is 4 six Minute Walks, but not less than 3
P-Flex	15 Minutes	10 one minute repetitions with 30 second breaks in-between
Breathing Awareness	10 Breaths	10 Breath practice at end of session

7.1.4 Practice at home:

One-on-one revision of the IMT technique will be completed every session in the lab, and patients will be asked to do 10 repetitions of IMT twice a day when not in the lab, which includes the weekend. Twice a day training is the minimum required.

Upper and lower extremity training: Once a day training of one set of ten repetitions of upper extremity exercises, and two 6 minute walks in a safe place in the home is the minimum required.

This is a critical step in the process. Patients will be encouraged to practice every day and record their practice into a log that will be reviewed by the interventionist every session.

7.1.5 Goal setting

The patients are encouraged to set goals, a post-operative goal and post hospital discharge goal. The patients do not record the goals.

Post-operative goals will be to do at least one six minute walk, one upper arm series every day while still in the hospital. Patients will also be asked to set a goal to practice the breathing awareness, ten breaths, at least two times a day, particularly when in pain or stressed.

Post hospital discharge goals the same as post-operative goals.

7.2 Control Group Procedures

Patients randomized to the control arm will receive a pedometer to monitor their daily steps and a pamphlet with exercises plus the standard course of care for patients undergoing lung resection

surgery. The patients will not be asked to return the pedometer. The local institutional coordinator (not the rehabilitation interventionist) will go over the use of the pedometer and the exercise materials with the patient. The patients will be asked to keep a log of their pre-operative steps and mail the log to the registering site. The pedometers will be provided to the site prior to enrollment.

8.0 ADVERSE EVENTS

We do not anticipate any adverse events related to participation in this study. PR has no reported risks based on 3000 patients with severe COPD in the National Emphysema treatment trial that underwent exercise training in more intensity compared to the one planned in this study.[23]

9.0 MEASURES

9.1 Chronic Respiratory Questionnaire (CRQ):

A 20-question inventory assessing the areas of dyspnea, fatigue, emotion, and feelings of mastery. The fatigue, emotion, and mastery subscales ask the patient to rate how often in the last two weeks they have been afflicted with a particular feeling or experience on a scale of 1 to 7, with higher ratings indicating less symptom impairment. The dyspnea subscale gives an additional option of indicating that a particular activity has not been done.[24-27] The CRQ takes approximately 10 minutes to complete.

9.2 MRC: Medical Research Council Dyspnea Score (MRC):

A 5 statement questionnaire where the patient selects the answer that most closely describes the level of physical activity that precipitates their shortness of breath. The highest selected statement (more severe) is the score. The MRC Dyspnea Scale takes less than 5 minutes to complete.

9.3 Linear Analog Self-Assessment (LASA):

A 5 question inventory measuring well-being on a scale of 1 (as bad as it can be) to 10 (as good as it can be). The LASA takes less than 5 minutes to complete.

10.0 END OF INTERVENTION

10.1 Duration of Treatment

Patients in the intervention group will be scheduled for 10 sessions of mindful rehabilitation. Six sessions is the minimum requirement. Patients will be followed until 6 months following surgery.

10.2 Managing ineligible patients and registered patients who never receive protocol intervention

Definition of ineligible patient: A study participant who is registered to the trial but does not meet all of the eligibility criteria is deemed to be ineligible.

Follow-up for ineligible patients who continue with protocol treatment

Patients who are deemed ineligible after registering may continue protocol intervention, provided the treating physician, study chair, and executive officer agree there are no safety concerns if the patient continues protocol intervention. All scans, tests, and data submission are to continue as if the patient were eligible. Notification of the local IRB may be necessary per local IRB policies.

Follow-up for ineligible patients who discontinue protocol treatment

For patients who are deemed ineligible after registering to the trial, who start treatment, but then discontinue study treatment, the same data submission requirements are to be followed as for those patients who are eligible and who discontinue study treatment.

Follow-up for patients who are registered, but who never start study treatment

If surgery is cancelled after registration, the participant will be considered a screen failure.

For all study participants who are registered to the trial but who never receive study intervention (regardless of eligibility), baseline and off-treatment notice data submission is required. See the Data Submission Schedule accompanying the All Forms Packet.

11.0 STATISTICAL CONSIDERATIONS

11.1 Study Overview

Prospectively, 194 patients will be randomized to either ten sessions of preoperative pulmonary rehabilitation vs. standard care at a number of healthcare centers throughout the United States.

11.2 Sample Size, Accrual Time, and Study Duration

11.2.1 Sample Size

A total of 194 patients (97 in each group) will be accrued to this study. This sample size includes a 10% adjustment to account for attrition and will provide at least 80% power for testing each aim of the study. Based on estimates from the pilot study, this sample size will provide 80% power to detect a 25% difference in complication rates, a 3-day difference in chest tube days, 3 day difference in length of stay, and a half standard deviation difference in QOL endpoints.

11.2.2 Accrual Rate and Accrual Duration

This study will be open for 36 months. We expect to close the study to accrual at month 30 to allow time for statistical analysis and publication. About 7 patients a month need to be recruited to meet the 30 month proposed time line.

11.2.3 Primary Endpoint Completion Date for ClinicalTrials.gov Reporting

For purposes of ClinicalTrials.gov reporting, the Primary Endpoint Completion Date (PECD) for this study is the time the last patient registered has been followed for at least 6 months.

11.3 Statistical Design and Analysis for the Primary Endpoint

11.3.1 Primary Endpoint

End point that will address AIM 1: hospital length of stay. The coordinator at each site will be responsible for sending complete de-identified hospital records from each patient to Dr. Benzo's staff, where a nurse blinded to the study arm will abstract the main outcome (length of stay and postoperative complications). See Section 6.3.

The primary endpoint will be assessed at Dr. Benzo's office (Mayo Clinic) with the complete admission hospital records in order to extract the length of stay. The records will be mailed from the sites to [redacted] in a pre-stamped envelope. See Section 6.3.

11.3.2 Analysis Plan

Differences in length of stay between arms will be tested using a two-sample, two-sided t-test. Wilcoxon nonparametric testing will be used for analyzing continuous outcomes that are skewed and not approximately normally distributed. Fisher's exact tests will be used to test for differences in categorical variables between arms. All tests will be two-sided with a 0.05 significance level. Linear models will be created to test the effects of treatment after adjusting for the baseline characteristics of age, gender, and lung function.

11.4 Supplementary Analysis Plans

11.4.1 Secondary Endpoints

End points that will address AIM 2 (baseline and at 3 and 6 months after hospital discharge):

Post-Operative Pulmonary Complications: The following events will be considered post-operative pulmonary complications: pneumonia (new infiltrate + either fever (>38.5 C) and white cell count >11,000 or fever and purulent secretions), severe atelectasis (requiring bronchoscopy), prolonged chest tubes (>6 days), and respiratory failure (intubation or prolonged mechanical ventilation (>24 hours). These outcomes will be obtained by chart review by a nurse trained in the abstraction of the desired outcomes from the medical records and blinded to treatment assignment.

Chronic Respiratory Questionnaire (CRQ) (four domains: dyspnea, fatigue, emotional function and mastery). This instrument will be the primary tool to assess QoL given that it was specifically designed for COPD. Specifically, the CRQ represents one of the most well-known, widely-applied, and psychometrically-sound patient reported outcomes for use in clinical trials involving patients with COPD. The CRQ has been validated and has demonstrated a reliable quality of life measures for patients with chronic airflow limitations. .A 0.5 point will be considered significant and was considered in the sample size calculation as that difference as is the well-established MCID (minimally clinically important difference) for the instrument. Analysis for the QOL outcomes will be identical to that for the primary endpoint. We include the scores from the dyspnea questionnaire under the generic umbrella term as a domain of QOL.

LASA (single-item numerical analogue quality of life Questionnaire) individual QOL domain scores. All of these questionnaires have been validated previously for lung cancer patient populations and for assessment of patient-reported outcomes in similar trials. LASA items have been validated as general measures of global QOL dimensional constructs in numerous settings and have been constructed and validated at Mayo Clinic for use in cancer patients. These single-item assessments have become the most used assessments in all NCI-sponsored cancer control studies.[28]

11.4.2 Secondary Analysis

Longitudinal analysis for the relationship between QOL and the intervention will be handled by repeated measures analysis of variance modeling and multiple regressions. Finally, a logistic regression model will be used to identify which variables are most closely associated with the dependent variable of patients who experience either clinically significant deficits in QOL (one regression model). The modeling processes will include the aforementioned covariates to control for spurious correlations.

11.5 Study Monitoring

11.5.1 Adverse Event Stopping Rule

Not applicable.

11.5.2 Accrual Monitoring Stopping Rule

Slow Accrual: Patient accrual will be closely monitored by the investigators and secondary statistician on a monthly basis. If the accrual rate falls below 50% of expected accrual rate, investigators will carefully review feedback from sites and consider taking measures to encourage patient enrollment.

11.5.3 This study will be monitored by the Alliance Data Safety Monitoring Board (DSMB), an NCI-approved functioning body. Reports containing efficacy, adverse event, and administrative information will be provided to the DSMB every month as per NCI guidelines.

11.6 Study Reporting

At study activation, this study will have been registered within the "ClinicialTrials.gov" web site. The Primary and Secondary Endpoints (i.e., "Outcome Measures") along with other required information for this study will be reported on ClinicalTrials.gov.

11.7 Descriptive Factors

None.

11.8 Inclusion of Women and Minorities

Inclusion of Women: Based upon the gender distribution of patients from past studies and the gender distribution with ICD-9 codes for COPD/ lung cancer, we anticipate a female to male ratio of 5/6 ratio.

DOMESTIC PLANNED ENROLLMENT REPORT					
Racial Categories	**Ethnic Categories**				**Total**
	Not Hispanic or Latino		**Hispanic or Latino**		
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	1	1	0	0	2
Asian	5	3	1	1	10
Native Hawaiian or Other Pacific Islander	1	1	0	0	2
Black or African American	14	9	1	1	25
White	80	57	4	4	145
More Than One Race	4	3	2	1	10
Total	105	74	8	7	194

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13.0 MODEL CONSENT FORM

Study Title for Study Participants:

Alliance A221502: Breathing Exercises Before Lung Cancer Surgery

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

Pulmonary Rehabilitation before Lung Cancer Resection

This research study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

What is the usual approach to preparing for lung cancer surgery?

You are being asked to take part in this study because you have or are suspected of having non-small cell lung cancer (NSCLC) and Chronic Obstructive Pulmonary Disease (COPD) and your doctor is recommending surgery. Lung cancer surgery for people with COPD can cause complications such as pneumonia and prolonged hospital stays. Asking patients to quit smoking is the usual approach to prepare patients for lung cancer surgery.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to not do anything prior to surgery
- You may choose to take part in a different study, if one is available

Why is this study being done?

You will have surgery to remove your lung cancer. The purpose of this study is to test whether a breathing exercise program before lung resection is helpful on the recovery from surgery in patients with NSCLC and COPD. The effects of the pulmonary rehabilitation will be compared to usual approach.

There will be about *194* people taking part in this study.

What are the study groups?

This study has two study groups.

- Group 1 will participate in ten pulmonary rehabilitation sessions at the clinic with additional exercises to be done at home.
- Group 2 will receive a pedometer and exercise routine to use at home along with usual care

A computer will by chance assign you to treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others.

Before Surgery:

Group 1: If you are in this group, you will receive ten sessions of pulmonary rehabilitation in clinic lasting a little less than two hours per session. You will be asked to complete a log of your activities during the pulmonary rehabilitation. Pulmonary rehabilitation will include the following components:

- Upper and lower extremity (arms and legs) exercises
- Inspiratory muscle training, which is breathing through a device to strengthen the breathing muscles
- Slow breathing training using a CD or mp3 file

You will also be asked to complete 3 brief questionnaires related to your health. The questionnaires should take about 20 minutes to complete.

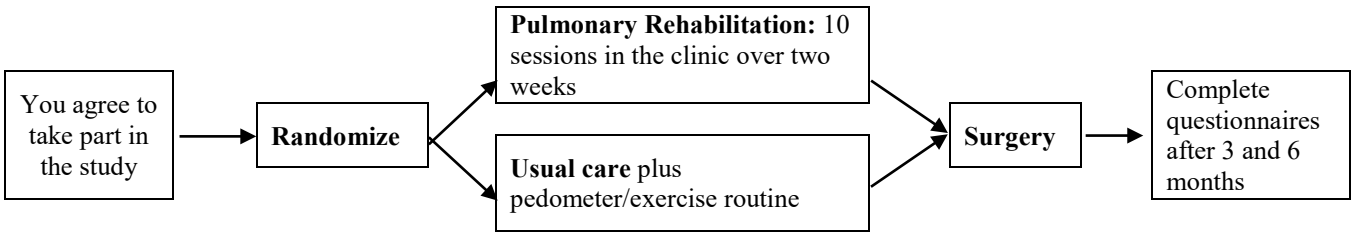
If you experience any emotional discomfort when completing the questionnaires, you may choose not to complete them. You should tell your doctor if you are having any physical or psychological symptoms such as extreme sadness or physical pain related to your treatment.

Group 2: If you are in this group, you will be asked to complete brief questionnaires related to your health. The questionnaires take about 20 minutes to complete. You will also receive a pedometer to track your steps and a booklet demonstrating exercises for people who have undergone a lung surgery. You will be asked to complete a log of your activities during the two weeks prior to your surgery.

After Surgery:

Group 1 and Group 2: You will be asked to complete brief questionnaires related to your physical activity and health after surgery, 3 months and 6 months after surgery. The questionnaires take about 20 minutes to complete.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will I be in this study?

You will participate either in the pulmonary rehabilitation or usual care for two weeks before your surgery. After your surgery, you will participate in this study for about 6 months.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss. You may choose not to answer any questions that make you feel uncomfortable.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.

Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect. The study doctor may be able to treat some side effects.

- While unlikely, you may experience muscle or joint pain due to increased exercise.
- There is the risk of developing cardiac ischemia (chest pain) due to not enough oxygen going to the heart during exercise.

What possible benefits can I expect from taking part in this study?

This study may not make your health better. By educating you on healthy behavior and promoting a more active lifestyle, the study team hopes you will see improvement in your health no matter the group to which are assigned. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

The pulmonary rehabilitation (for Group 1 participants) and pedometer (for Group 2 participants) will be provided at no charge while you take part in this study.

You and/or your health plan/insurance company will need to pay for all of the other costs of *treating* your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your health care provider will mail a copy of your hospital records from the time you were admitted for your surgery until you are discharged. This will include X-ray reports, lab results, progress notes, operative report, discharge summary and the dates when they occur. These records will be sent to Alliance researchers at the Mayo Clinic where a care provider will review the records for length of stay and any complication you may have. You may be asked to sign a form that will allow your health care provider to send these records.

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Alliance for Clinical Trials in Oncology
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s]*) at _____ (*insert telephone number*).

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study.

You must be willing to attend 10 sessions over two weeks of pulmonary rehabilitation if you are randomized to Group 1.

Participant's signature_____

Date of signature_____

APPENDIX I

LINEAR ANALOGUE SELF ASSESSMENT

Directions: Please circle the number (0-10) best reflecting your response to the following that describes your feelings **during the past week, including today**.

How would you describe:

1. **Your overall Quality of Life?**

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

2. **Your overall mental (intellectual) well being?**

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

3. **Your overall physical well being?**

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

4. **Your overall emotional well being?**

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

5. **Your level of social activity?**

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

6. **Your overall spiritual well being?**

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

Medical Research Council (MRC) Breathlessness Scale

INSTRUCTIONS: Please read each statement carefully. If you agree with the statement please circle **YES.** If you disagree with the statement please circle **NO**. Please be sure to answer all the questions. Only circle 1 answer for each question. If you make a mistake, place an **X** over the incorrect answer and be sure to circle the correct answer.

		Description
YES	**NO**	Are you ever troubled by breathlessness except on strenuous exertion?
YES	**NO**	(If yes) Are you short of breath when hurrying on the level or walking up a slight hill?
YES	**NO**	(If yes) do you have to walk slower than most people on the level? Do you have to stop after a mile or so (or after ¼ hour) on the level at your own pace?
YES	**NO**	(If yes) Do you have to stop for breath after walking about 100 yds. (or after a few minutes) on the level?
YES	**NO**	(If yes) Are you too breathless to leave the house, or breathless after undressing?

http://www.mrc.ac.uk/research/facilities/mrc-scales/mrc-dyspnoea-scale-mrc-breathlessness-scale/

Chronic Respiratory Questionnaire (CRQ-SAS)

First Administration

McMaster University
Canada

Chronic Respiratory Questionnaire

Self-Administered Standardized Format (CRQ-SAS)

First Administration

CHRONIC RESPIRATORY QUESTIONNAIRE - SELF ADMINISTERED - STANDARDIZED ACTIVITIES - "CRQ-SAS"

Participant ID:

Date ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

CHRONIC RESPIRATORY QUESTIONNAIRE -SAS- FIRST ADMINISTRATION 1(10)

This questionnaire is designed to find out how you have been feeling during the last 2 weeks. In the first section, you will be asked to answer questions about activities which make some people feel short of breath. In the next section, you will answer questions about your mood and how you have been feeling.

Please read these instructions for completing this questionnaire:

- Please read each question carefully and then place an "x" in the box beside the answer that best describes you.
- If you are unsure about how to answer a question, please give the best answer you can.
- If you would like to change an answer, put a line through the box you want to change. Place an "x" in the box beside the option you would like to choose instead.
- There are no right or wrong answers.
- Your answers to this questionnaire will be kept confidential.

Please continue on the next page.

CHRONIC RESPIRATORY QUESTIONNAIRE - SELF ADMINISTERED - STANDARDIZED ACTIVITIES - "CRQ-SAS"

Date ☐☐ DAY ☐☐ MONTH ☐☐☐☐ YEAR

CRQ-SAS- 1ST ADMINISTRATION

Below is a list of activities which make some people with lung problems feel short of breath.

For each of the activities below, place an "x" in the box that best describes how much shortness of breath you have had while doing that activity during the **LAST 2 WEEKS**.

The last column has been provided for you to indicate if you have **NOT DONE** an activity during the last two weeks.

(Place an "x" in one box on each line)

	ACTIVITIES:	Extremely short of breath	Very short of breath	Quite a bit short of breath	Moderate shortness of breath	Some shortness of breath	A little shortness of breath	Not at all short of breath	Not Done
1	**Feeling emotional such as angry or upset**	1	2	3	4	5	6	7	8
2	**Taking care of your basic needs (bathing, showering, eating or dressing)**	1	2	3	4	5	6	7	8
3	**Walking**	1	2	3	4	5	6	7	8
4	**Performing chores (such as housework, shopping groceries)**	1	2	3	4	5	6	7	8
5	**Participating in social activities**	1	2	3	4	5	6	7	8

Please continue to the next page.

These next questions ask you about your energy in general and how your mood has been during the **LAST 2 WEEKS**. Please put an "x" in a box, from 1 to 7, that best describes how you have felt.

6. In general, how much of the time during the **LAST 2 WEEKS** have you felt frustrated or impatient?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

7. How often during the **LAST 2 WEEKS** did you have a feeling of fear or panic when you had difficulty getting your breath?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

8. What about fatigue? How tired have you felt over the **LAST 2 WEEKS?**

1.	Extremely tired	☐
2.	Very tired	☐
3.	Quite a bit of tiredness	☐
4.	Moderately tired	☐
5.	Somewhat tired	☐
6.	A little tired	☐
7.	Not at all tired	☐

(Place an "x" in one box only)

9. How often during the **LAST 2 WEEKS** have you felt embarrassed by your coughing or heavy breathing?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

10. In the **LAST 2 WEEKS**, how much of the time did you feel very confident and sure that you could deal with your illness?

1.	None of the time	☐
2.	A little of the time	☐
3.	Some of the time	☐
4.	A good bit of the time	☐
5.	Most of the time	☐
6.	Almost all of the time	☐
7.	All of the time	☐

(Place an "x" in one box only)

11. How much energy have you had in the **LAST 2 WEEKS**?

1.	No energy at all	☐
2.	A little energy	☐
3.	Some energy	☐
4.	Moderately energetic	☐
5.	Quite a bit of energy	☐
6.	Very energetic	☐
7.	Full of energy	☐

(Place an "x" in one box only)

Please continue to the next page

12. In general, how much of the time did you feel upset, worried, or depressed during the **LAST 2 WEEKS**?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

13. How often during the **LAST 2 WEEKS** did you feel you had complete control of your breathing problems?

1.	None of the time	☐
2.	A little of the time	☐
3.	Some of the time	☐
4.	A good bit of the time	☐
5.	Most of the time	☐
6.	Almost all of the time	☐
7.	All of the time	☐

(Place an "x" in one box only)

Please continue to the next page

14. How much of the time during the **LAST 2 WEEKS** did you feel relaxed and free of tension?

1.	None of the time	☐
2.	A little of the time	☐
3.	Some of the time	☐
4.	A good bit of the time	☐
5.	Most of the time	☐
6.	Almost all of the time	☐
7.	All of the time	☐

(Place an "x" in one box only)

15. How often during the **LAST 2 WEEKS** have you felt low in energy?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

16. In general, how often during the **LAST 2 WEEKS** have you felt discouraged or down in the dumps?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐ (Place an "x" in one box only)
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

17. How often during the **LAST 2 WEEKS** have you felt worn out or sluggish?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐ (Place an "x" in one box only)
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

Please continue to the next page

18. How happy, satisfied, or pleased have you been with your personal life during the **LAST 2 WEEKS**?

1.	Very dissatisfied, unhappy most of the time	☐
2.	Generally dissatisfied, unhappy	☐
3.	Somewhat dissatisfied, unhappy	☐
4.	Generally satisfied, pleased	☐
5.	Happy most of the time	☐
6.	Very happy most of the time	☐
7.	Extremely happy, could not be more satisfied or pleased	☐

(Place an "x" in one box only)

19. How often during the **LAST 2 WEEKS** did you feel upset or scared when you had difficulty getting your breath?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

20. In general, how often during the **LAST 2 WEEKS** have you felt restless, tense, or uptight?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

THANK YOU

APPENDIX II: FOLLOW UP BOOKLET

LINEAR ANALOGUE SELF ASSESSMENT

Directions: Please circle the number (0-10) best reflecting your response to the following that describes your feelings **during the past week, including today**.

How would you describe:

1. Your overall Quality of Life?

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

2. Your overall mental (intellectual) well being?

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

3. Your overall physical well being?

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

4. Your overall emotional well being?

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

5. Your level of social activity?

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

6. Your overall spiritual well being?

As bad as it can be										As good as it can be
0	1	2	3	4	5	6	7	8	9	10

Medical Research Council (MRC) Breathlessness Scale

INSTRUCTIONS: Please read each statement carefully. If you agree with the statement please circle **YES.** If you disagree with the statement please circle **NO**. Please be sure to answer all the questions. Only circle 1 answer for each question. If you make a mistake, place an **X** over the incorrect answer and be sure to circle the correct answer.

		Description
YES	**NO**	**Are you ever troubled by breathlessness except on strenuous exertion?** Grade 1
YES	**NO**	**(If yes) Are you short of breath when hurrying on the level or walking up a slight hill?** Grade 2
YES	**NO**	**(If yes) Do you have to walk slower than most people on the level? Do you have to stop after a mile or so (or after ¼ hour) on the level at your own pace?** Grade 3
YES	**NO**	**(If yes to either) Do you have to stop for breath after walking about 100 yards (or after a few minutes) on the level?** Grade 4
YES	**NO**	**(If yes) Are you too breathless to leave the house, or breathless after undressing?**Grade 5

http://www.mrc.ac.uk/research/facilities/mrc-scales/mrc-dyspnoea-scale-mrc-breathlessness-scale/

Chronic Respiratory Questionnaire

Self-Administered Standardized Format (CRQ-SAS)

Follow-up Administration

CHRONIC RESPIRATORY QUESTIONNAIRE - SELF ADMINISTERED - STANDARDIZED ACTIVITIES - "CRQ-SAS"
FOLLOW-UP - ADMINISTRATION

Participant ID:

Date ☐☐ ☐☐ ☐☐☐☐
DAY MONTH YEAR

CHRONIC RESPIRATORY QUESTIONNAIRE -SAS- FOLLOW-UP ADMINISTRATION

You have previously completed a questionnaire containing questions on how you have been feeling and how your lung disease was affecting your life. This is a follow up questionnaire designed to ask you how you have been since that time.

Please read these instructions for completing this questionnaire:

- Please read each question carefully and then place an "x" in the box beside the answer that best describes you.
- If you are unsure about how to answer a question, please give the best answer you can.
- If you would like to change an answer, put a line through the box you want to change. Place an "x" in the box beside the option you would like to choose instead.
- Remember there are no right or wrong answers.
- Your answers to this questionnaire will be kept confidential.

Please continue on the next page.

CHRONIC RESPIRATORY QUESTIONNAIRE - SELF ADMINISTERED - STANDARDIZED ACTIVITIES - "CRQ-SAS"

FOLLOW-UP - ADMINISTRATION

Date ☐☐ DAY ☐☐ MONTH ☐☐☐☐ YEAR

CRQ-SAS- FOLLOW-UP ADMINISTRATION

This questionnaire is designed to find out how you have been getting along since the last time you saw us. You previously completed this questionnaire telling us how short of breath you were while performing the following activities.

For each of the activities below, place an "x" in the box that best describes how much shortness of breath you have had while doing that activity during the **LAST 2 WEEKS**.

The last column has been provided for you to indicate if you have **NOT DONE** an activity during the last two weeks.

(Place an "x" in one box on each line)

	ACTIVITIES:	Extremely short of breath	Very short of breath	Quite a bit short of breath	Moderate shortness of breath	Some shortness of breath	A little shortness of breath	Not at all short of breath	Not Done
1	**Feeling emotional such as angry or upset**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
2	**Taking care of your basic needs (bathing, showering, eating or dressing)**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
3	**Walking**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
4	**Performing chores (such as housework, shopping groceries)**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8
5	**Participating in social activities**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8

Please continue to the next page.

These next questions ask you about your energy in general and how your mood has been during the **LAST 2 WEEKS**. Please put an "x" in a box, from 1 to 7, that best describes how you have felt.

6. In general, how much of the time during the **LAST 2 WEEKS** have you felt frustrated or impatient?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

7. How often during the **LAST 2 WEEKS** did you have a feeling of fear or panic when you had difficulty getting your breath?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

8. What about fatigue? How tired have you felt over the **LAST 2 WEEKS?**

1. Extremely tired ☐

2. Very tired ☐

3. Quite a bit of tiredness ☐

4. Moderately tired ☐ (Place an "x" in one box only)

5. Somewhat tired ☐

6. A little tired ☐

7. Not at all tired ☐

9. How often during the **LAST 2 WEEKS** have you felt embarrassed by your coughing or heavy breathing?

1. All of the time ☐

2. Most of the time ☐

3. A good bit of the time ☐

4. Some of the time ☐ (Place an "x" in one box only)

5. A little of the time ☐

6. Hardly any of the time ☐

7. None of the time ☐

Please continue to the next page

10. In the **LAST 2 WEEKS**, how much of the time did you feel very confident and sure that you could deal with your illness?

1.	None of the time	☐
2.	A little of the time	☐
3.	Some of the time	☐
4.	A good bit of the time	☐
5.	Most of the time	☐
6.	Almost all of the time	☐
7.	All of the time	☐

(Place an "x" in one box only)

11. How much energy have you had in the **LAST 2 WEEKS**?

1.	No energy at all	☐
2.	A little energy	☐
3.	Some energy	☐
4.	Moderately energetic	☐
5.	Quite a bit of energy	☐
6.	Very energetic	☐
7.	Full of energy	☐

(Place an "x" in one box only)

Please continue to the next page

12. In general, how much of the time did you feel upset, worried, or depressed during the **LAST 2 WEEKS**?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

13. How often during the **LAST 2 WEEKS** did you feel you had complete control of your breathing problems?

1.	None of the time	☐
2.	A little of the time	☐
3.	Some of the time	☐
4.	A good bit of the time	☐
5.	Most of the time	☐
6.	Almost all of the time	☐
7.	All of the time	☐

(Place an "x" in one box only)

Please continue to the next page

14. How much of the time during the **LAST 2 WEEKS** did you feel relaxed and free of tension?

1.	None of the time	☐
2.	A little of the time	☐
3.	Some of the time	☐
4.	A good bit of the time	☐
5.	Most of the time	☐
6.	Almost all of the time	☐
7.	All of the time	☐

(Place an "x" in one box only)

15. How often during the **LAST 2 WEEKS** have you felt low in energy?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

16. In general, how often during the **LAST 2 WEEKS** have you felt discouraged or down in the dumps?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐ (Place an "x" in one box only)
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

17. How often during the **LAST 2 WEEKS** have you felt worn out or sluggish?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐ (Place an "x" in one box only)
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

Please continue to the next page

18. How happy, satisfied, or pleased have you been with your personal life during the **LAST 2 WEEKS**?

1.	Very dissatisfied, unhappy most of the time	☐
2.	Generally dissatisfied, unhappy	☐
3.	Somewhat dissatisfied, unhappy	☐
4.	Generally satisfied, pleased	☐
5.	Happy most of the time	☐
6.	Very happy most of the time	☐
7.	Extremely happy, could not be more satisfied or pleased	☐

(Place an "x" in one box only)

19. How often during the **LAST 2 WEEKS** did you feel upset or scared when you had difficulty getting your breath?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

Please continue to the next page

20. In general, how often during the **LAST 2 WEEKS** have you felt restless, tense, or uptight?

1.	All of the time	☐
2.	Most of the time	☐
3.	A good bit of the time	☐
4.	Some of the time	☐
5.	A little of the time	☐
6.	Hardly any of the time	☐
7.	None of the time	☐

(Place an "x" in one box only)

THANK YOU

APPENDIX III: PAIN SCALE & HOSPITAL EXPERIENCE

Patient Initials: _____ Date: _____

Patient Number: _____

Directions: Please circle the answer that best reflects the level of pain that you experienced after you were discharged from the hospital.

1. Please rate your pain by using the number that best describes your pain at its worst in the last two weeks?

   0 1 2 3 4 5 6 7 8 9 10
   None As bad as I can imagine

2. Please rate your pain by using the number that best describes your pain at its least in the last two weeks?

   0 1 2 3 4 5 6 7 8 9 10
   None As bad as I can imagine

3. How would you rate your hospital experience?

   Poor fair good very good or excellent

APPENDIX IV: CHECKLIST FOR MEDICAL RECORDS

PULMONARY REHABILITATION BEFORE LUNG CANCER RESECTION

Admission Date: _____ Discharge Date: _____ ID Number:_____

Please provide the following documents related to the Lung Surgical Resection for this study.

	YES	NO
Admission Report (Admitting history and Physical Exam)		
Operative Report (Description of procedure performed and Number of chest tubes placed)		
Discharge Summary (Dismissal information including location Subject dismissed to i.e. home, rehab facility, etc.)		
Progress Report (Daily notes including description of any complications)		
Reports of results from: Radiology (Report only, images not needed)		
Blood/Lab Draws		