

**Research Protocol**  
**Lung Institute Dallas**

**TITLE: AUTOLOGOUS STEM CELL TREATMENT FOR CHRONIC LUNG DISEASE STUDY INVESTIGATOR(S)**

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## 1. INTRODUCTION

The purpose of the Lung Institute is to collect and process a patient's own stem cells and platelet rich plasma (PRP) and deliver them back to the patient same-day through an intravenous catheter and sometimes by nebulizer. Lung Institute's treatment is limited to self-funded patients with chronic lung diseases – chronic obstructive pulmonary disease (COPD) and interstitial lung disease (ILD). The patient's stem cells and platelet rich plasma are collected through venous, adipose or bone marrow harvesting techniques. After the stem cells and platelet rich plasma have been isolated they are administered back to the patient. An inhaled antioxidant, glutathione, is administered during treatment to help mobilize lung secretions.

Researchers have demonstrated that using autologous stem cells (those derived from the patient) with minimal manipulation is safe and effective to promote the healing of lung tissue affected by COPD and ILD. The administration of glutathione to mobilize secretions in the lung has been determined a safe and effective addition to treatment (Jones, 2011).

In a pilot study conducted by Dr. Jack Coleman at Lung Institute Nashville, after following approximately 100 treated patients, Dr. Coleman discovered that within three months of treatment, 84 percent of patients reported improvement in their quality of life (Coleman, 2016). For millions of people suffering from COPD, a natural decline in pulmonary health is a harsh reality. Based on these results, stem cell therapy gives promise to improving their quality of life and slowing down the progression of disease.

At this time, autologous stem cell collection and administration is not commercially available and therefore is considered an investigational agent under the standards of the Texas Medical Board.

Lung Institute's collection and administration of stem cells as investigational agents in the state of Texas is part of a systematic program monitored under the strict oversight of Lung Institute's business associate and medical management services company, Regenerative Medical Solutions (RMS). Lung Institute and RMS are committed to the highest level of concern and caution for the welfare, safety and comfort of the patient to whom the cell therapy treatment is administered.

The hypothesized outcomes of Lung Institute therapy are safety and minimization of adverse events, a perceived improvement in the patient's lung condition (to be determined by their ability to be more physically active; walking greater distances with or without oxygen and improved quality of life scales), an improvement in their FEV1 5-10% or more, the ability to reduce their use of oxygen and possibly to stop it., the ability to function well without the use of rescue inhalers, reduction or ceasing of secondary pulmonary infections, reduction in emergency room visits and hospitalizations related to their disease, and an improvement in their six minute walk test.

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## 2. BACKGROUND

Currently, literature on the outcomes of autologous stem cell treatment for COPD is lacking.

- A white paper released by the Medical Director at Lung Institute Nashville found an 84 percent response rate in improved quality of life indicators among 100 patients followed after treatment (Coleman, 2016).

- The Lung Institute is a leader in the field of regenerative medicine with strong clinical protocols and a solid understanding of the safety and efficacy of stem cell treatment for chronic lung disease.

## **2a. Situating the Researcher**

Melissa Rubio is a doctorally-prepared Family Nurse Practitioner certified by the American Nurses Credentialing Center and licensed to practice in the state of Texas. A member of the Southern Nursing Research Association, Dr. Rubio has experience designing and conducting qualitative and quantitative research and mixed-methods studies. Her doctoral dissertation was a qualitative study involving a marginalized population of drug-addicted women (Rubio, 2013). She has also done pilot work on a population of incarcerated women using quantitative methods. Dr. Rubio has a current manuscript pending review on using the interpretive phenomenological inquiry method for qualitative research. Dr. Rubio is well-experienced in the protection of human research subjects. She is an expert in the promoting rigor in qualitative research design and situating its importance in medical research.

Dr. Rubio is a nationally certified and practicing Family Nurse Practitioner. In addition to her research role, Melissa will be the primary clinician at the research site, providing physical assessments, reviewing patient medical records and formulating the patient plan of care. Because each patient of the Lung Institute is treated using the same protocols (there are no control groups), this minimizes the conflict of interest, randomization and blinding that must occur with experimental studies.

## **3. AIM(S) OF STUDY**

Through the collection of qualitative and quantitative data, Lung Institute aims to explore and describe the safety and efficacy of autologous stem cell treatment for chronic lung disease with dissemination to the public and to the medical community for the advancement of regenerative medicine. The study aims to confirm the safety of autologous cell therapy, explore the effect of autologous cell therapy treatment on pulmonary function, and to describe the anecdotal quality of life changes of patients following treatment using both quantitative and qualitative measures.

## **4. RESEARCH QUESTIONS**

The research questions to be informed by this investigation are as follows:

1. Is the collection and administration of autologous stem cells for the treatment of chronic lung disease safe?
2. Does treatment with autologous stem cells for chronic lung disease improve measurements of pulmonary function (specifically FEV1)?
3. Does treatment with autologous stem cells for chronic lung disease improve the patient's perceived quality of life?

## **5. HYPOTHESES**

### **5a. Primary Hypothesis/Quantitative Arm**

Null hypothesis: Following autologous stem cell treatment for chronic lung disease, patients will have no improvement in pulmonary function (measured by FEV1) at six months

Alternative hypothesis: Following autologous stem cell treatment for chronic lung disease, patients will have an increase in pulmonary function (measured by FEV1) of 5 to 10% or more

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### **5b. Secondary Hypothesis/Quantitative Arm**

There will be no adverse events reported following autologous stem cell treatment for chronic lung disease.

### **5c. Qualitative Arm**

An assumption of qualitative research is that no pre-determined hypothesis is made. Following autologous stem cell treatment for chronic lung disease, patients will report improvement in at least one of several quality of life indicators.

## 6. STUDY DESIGN

This study uses a concurrent mixed-methods approach to collect and analyze both qualitative and quantitative data. The *quantitative* arm will use a non-experimental, descriptive approach to measure and analyze pre- and post-stem cell treatment pulmonary function test results of treated patients. Measurement of the occurrence of adverse events will also be part of the quantitative arm.

Pre-treatment pulmonary function test results (measured by FEV1) will be compared with a six-month post-treatment pulmonary function test result (FEV1) for each patient. The aim of this method is to generalize an improvement in pulmonary function (measured by FEV1) among the general population of all individuals treated by autologous cell therapy for chronic lung disease.

The *qualitative* arm of the study uses an interpretive phenomenological approach to collect and analyze pre- and post- cell therapy anecdotal data regarding perceived quality of life among treated patients. Phenomenological research involves investigating the lived experience.

Qualitative research has several assumptions (D. Nicholls, 2009; Ritchie & Lewis, 2003). Primarily, there is no predetermined theoretical framework- rather the theory, if any, is derived from the data. Secondly, qualitative research is context-driven. Finally, qualitative researchers focus on the *emic* perspective that concerns itself with the view, perspectives and descriptions of others.

This study uses an *interpretive phenomenological analysis* (IPA) approach throughout the study from planning to data collection to analysis. This methodology is used to illuminate each participant's variation of the same general phenomenon (in this case, COPD) (Reissman, 2008; Ritchie & Lewis, 2003).

Data from both arms of the study will be combined following data collection for analysis, discussion and presentation. Safety data on adverse outcomes will be tracked and reported separately as a descriptive, quantitative analysis.

## 7. STUDY SETTING/LOCATION

The study will be conducted at:

## 8. STUDY POPULATION

Lung Institute Dallas  
8140 Walnut Hill Lane, Suite 570  
Dallas, TX 75231

Populations that may participate vary by selected treatment of those offered by the Lung Institute. Candidates are eligible for treatment if they are diagnosed with Chronic Obstructive Pulmonary Disease and are not excluded by one or more of several disqualifiers that vary by treatment type offered by the Lung institute.

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Populations diagnosed with COPD were estimated in 2012 to be:

- Nationally: 15,340,484
- Texas: 984,708
- Dallas County: 87,305
- Denton County: 24,614

- Collin County : 30,285

## 9. ELIGIBILITY CRITERIA

Inclusion and exclusion criteria are standards that have been set to determine whether a person may or may not be allowed to enter our study. They are used to identify appropriate participants and to ensure their safety.

### 9a. Inclusion criteria

The community eligible for treatment with the Lung Institute are those diagnosed with COPD and ILD. Populations diagnosed with COPD were estimated by the American Lung Association in 2012 to be:

- US: 15,340,484
- Texas : 984,708
- Dallas County : 87,305
- Denton County : 24,614
- Collin County: 30,285

### 9b. Exclusion criteria

Exclusions from **ALL** Procedures:

- Populations
  - Inability to give informed consent (a diminished understanding or comprehension);
  - Inability to travel to Outpatient Facility;
  - Pregnant women;
  - Prisoners; and
  - Children, under the age of 16 years old
- Active Smoker - Active smoking prevalence has been estimated at:
  - Nationally: 17.8 %
  - Texas: 15.9 %
  - Dallas County: 15.3 %
  - Denton County: 10.1 %
  - Collin County: 9.7 %
- Currently diagnosed with cancer or have had cancer within the past 5 years.
  - Current cancer prevalence is estimated by the National Cancer Institute at 3.7% for males in Texas and 3.9% for females in Texas. National cancer cases were estimated in 2010 to be 13,772,000 nationally for a prevalence rate of 4.5% of the estimated national population of 309,300,000.
- Identification of new nodules/masses per chest x-ray/CT scan report that have not been noted as stable.
  - Documentation of stability must be received for confirmation prior to treatment.
- Active Infection (pulmonary or other);
- Active Tuberculosis
- A History of Recent Hospitalization (requiring mechanical ventilation in a period of one month before treatment);
- End Stage Kidney Failure;
- Acute Heart Failure; and/or
- Other Condition(s) the Provider or Principal Investigator feels would interfere with treatment protocols.

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Additional Exclusion Criteria for **ADIPOSE** Procedure

- Body Mass Index (BMI) less than 24  
*On a case-by-case basis, Provider may approve exceptions.*
- History of abdominal surgery with mesh;
- History of multiple abdominal surgeries;
- History of total abdominal liposuction and/or tummy tuck;
- History of Stents and Angioplasty;
- Atrial Fibrillation/Any Heart Arrhythmia;

- Congenital Heart Disease;
- Congestive Heart Failure (CHF)
- Cardiomyopathy
- History of heart attack (MI)
- History of stroke
- Coronary Artery Disease (CAD)

*On a case-by-case basis, Provider may approve exceptions.*

The Centers for Disease Control and Prevention has estimated National cardiovascular disease prevalence between 2011 to present at 4.1 %. The Texas Department of State Health Services has estimated the prevalence of Cardiovascular Disease and Stroke among adults to be:

- Texas 2010: 8.3 %
  - Dallas – Plano – Irving Primary Metropolitan Statistical Area 2007: 7.7 %
  - Denton 2007: 4.6 %
    - Collin County: 5.7 %
- History of blood clot (DVT & PE) on daily blood thinner
- Uncontrolled Diabetes;
- Neurodegenerative Diseases;
- Medication Rule Outs as follows:
  - Must be off Anticoagulation Drugs and other medications and/or substances that cause bleeding. (Must be held for an allotted time with prior approval from PCP/Prescribing Physician-specific hold times are subject to medication/substance type.)
  - Methotrexate (if unable to hold for 1 week prior to treatment)

#### Additional Exclusion Criteria for **BONE MARROW** Procedure

- Current blood thinner for any type of existing heart condition;
- Osteoporosis;
- Bilateral hip replacement;
- Radiation of pelvis area (including prostate seed implants)
- Uncontrolled Diabetes;
- Medication Rule Outs as follows:
  - Must be off Anticoagulation Drugs and other medications and/or substances that cause bleeding. (Must be held for an allotted time with prior approval from PCP/Prescribing Physician-specific hold times are subject to medication/substance type.)
  - Methotrexate (if unable to hold for 1 week prior to treatment)

## 10. STUDY OUTCOMES

The anticipated outcomes of this study are a minimization of adverse events, an improvement in pulmonary function testing (measured by FEV1), and an improvement in self-reported quality of life indicators.

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## 11. STUDY PROCEDURES

Informed Consent Form is obtained. Consent form must be complete, signed, and dated without forgeries or alterations. Information should be delivered in a manner in which the Patient and/or the patient's legal representative could reasonably be expected to understand.

A review of the patient's medical record will be conducted to approve for treatment. Approved treatment plans will be documented in the patient's electronic medical record. Medical records obtained from external providers will be kept in the patient's medical record and must include recent laboratory data, results of any outside office notes, chest x-ray results and any relevant information as required per treatment inclusions and exclusions protocol.

Prior to Bone Marrow aspiration, Adipose extraction, and Venous stem cell administration, the clinician will perform a physical assessment. Attached are the following Standard Operating Procedures (SOPs) for each type of cell therapy that Lung Institute provides to qualified candidates:

- Venous Procedure
- Adipose Extraction Procedure
- Bone Marrow Aspirate Procedure

Patient follow-up may be conducted at the Lung Institute facility or may be completed by telephone at 2 weeks, 3 months and 6 months post-treatment to measure adverse events and quality of life. Patient participation in these phone calls is voluntary. Data collected at these time points will be entered into password-protected database for data management and reporting. Patients will be issued a journal during their treatment to record quality of life indicators from the time they are discharged from the clinic until they are called for follow-up. This allows the patients to better recall how they felt/are feeling to better communicate progress during follow-up appointments/calls.

Patients will have pulmonary function testing 6 months post-treatment. This will be done at the Lung Institute facility, or by their primary care physician, or pulmonologist.

All adverse events are reported to the Principal Investigator. The Medical Director and Compliance Department are notified within 24 hours for appropriate follow-up. These events are documented in the patient's medical record. Additionally, adverse events will be reported to the Quality Improvement & Risk Management (QI&RM) Committee for interdepartmental transparency and to meet internal and external reporting requirements. Per MaGil IRB Investigators Handbook §5- Investigator Responsibilities, the IRB will be notified within 5 days from the PI becoming aware of any adverse events requiring immediate intervention to prevent serious harm, and within 10 days for any problem or unanticipated occurrence.

#### **11a. Recruitment of participants**

Patients are included in treatment by self-referral. Patient coordinators conduct a series of questions with prospective patients to determine initial candidacy. If prospective patients are found to meet candidacy criteria, records are obtained to be reviewed by the mid-level provider and/or physician to determine final eligibility and approval for treatment.

#### **11b. Randomization**

Neither the participants, nor the investigator, or those assessing/analyzing the outcome(s), will be blind (or masked) to group assignment; all patients will receive treatment.

#### **11c. Measurement tools used**

Pulmonary function test (FEV1)

Quality of life questionnaire (*see attached*)

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#### **11e. Safety considerations/Patient safety**

The safety of research participants is foremost. Strict policies and procedures and standard operating procedures have been developed to ensure the safety of patients during the stem cell retrieving and administration procedures. Adverse events, as well as near-miss events are reported to the Principal Investigator, Medical Director, Compliance Department, and the Quality Improvement & Risk Management (QI&RM) Committee. The Lung Institute's management services company, Regenerative Medicine Solutions (RMS) provides continuous oversight and closely monitors the adherence to regulatory standards and policies and procedures. The Compliance Program ensures that all staff are trained on the appropriate identification and reporting of adverse events and near-misses, including potential breaches in protocols or patient safety and privacy standards.

Patient safety and risk management protocols are incorporated throughout our Policies & Procedures (P&Ps) and the oversight and trending of our protocols, as well as their effectiveness and adherence is monitored by and reported to the Quality Improvement & Risk Management (QI&RM) Committee.

Patient's protected health information is also strictly protected; adherence to HIPAA & HITECH standards are continuously monitored by the Compliance Department. Staff is trained on protection of patient health information protocols within the first 30 days from hire, and annually thereafter.

All Lung Institute Dallas clinical staff are trained in the protection of human subjects for research. Additionally, each clinical staff member is trained on job functions and assessed for competency on an annual basis.

### **11f. Data monitoring and Storage**

The Compliance department of Regenerative Medicine Solutions will oversee the conduct of research and data management.

Although identifying information will not be used for the final presentation of findings, data *will not* be de-identified at the point of collection or storage. Texas Medical Board code requires that full contact information be kept on all stem-cell treated patients and available for presentation to the Board within 14 days if requested.

## **12. STATISTICAL CONSIDERATIONS AND DATA ANALYSIS**

### **12a. Sample size**

The anticipated sample size for this study is two hundred patients.

### **12b. Statistical methods**

For the quantitative, descriptive arm of this study, sample characteristics will be collected to include age, sex and diagnosis. Pre- and post-treatment FEV1 measurements will be collected on each patient and evaluated by simple measures of central tendency (mean, median and mode). Sufficient descriptive data will be collected and reported to encourage replication of our study.

For the qualitative, anecdotal arm of the study, Lung Institute utilizes CCQ, the Clinical COPD Questionnaire to document patient's perceptions on improved quality of life. The information will be collected and interpreted by evaluating for common themes within the anecdotes. As a note regarding the rigor of qualitative research: is important in qualitative research to ensure that the study is credible and trustworthy (Smith, Flowers and Larkin, 2009). A number of guidelines for assessing this quality look toward establishing credibility. Psychologist Lucy Yardley's work in 2000 provides the principles for assessing the quality of qualitative research and how the interpretive phenomenological method can address them. First, the study must provide good *sensitivity to context*. In this study, the immersion in the clinic through field experience, the existing literature on COPD and stem cell treatment, and the anecdotes obtained

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from the participants will contribute to building an awareness of the phenomena. Awareness of the patient, empathy, active listening, and providing comfort to the participants will be used (Smith et al., 2009).

Yardley's second broad principle is *commitment*. Commitment comes from the degree of attentiveness to the participant during the interview, the thoughtfulness of the work, and the completeness of the analysis undertaken. As described, the analysis needs to be conducted systematically and also be sufficiently interpretative- rather than simply describing, the analysis must also be interpretive and reflective. The third broad principle is *transparency* and how clearly the stages of the study are presented to the reader. This principle suggests a careful description of how the participants were selected, how the interview was conducted and the steps used to analyze the data. Also the study must provide cohesiveness, and the themes need to mesh together logically. With this, the foundational steps of the IPA method need to be clearly demonstrated (Smith et al., 2009). In this study, each stage of the study will be defined in the presentation of data. This will allow another researcher to replicate the study if desired.

Yardley's fourth principle, *impact and importance*, relates to the study's ability to tell the researcher something interesting, important or useful" (Smith et al., 2009). This study will inform the public and medical community on the safety and efficacy of autologous stem cell treatment for chronic lung disease.

### 13. RISK AND BENEFIT ANALYSIS

All measures are taken to minimize or mitigate risks to the patient. The following lists the potential risks as indicated on the patient informed consent:

- **Adverse reaction to stem cells** - There is a possibility of an adverse reaction to the application of stem cells. This risk is minimized by using autologous (your own) unaltered stem cells.
- **Anemia** - There have been reports of anemia with harvesting of stem cells from the circulation. This risk is low. To minimize this risk we request blood work (CBC).
- **Embolus development** - An embolus is a clot that may be from blood or cells such as fat or bone marrow. There is a chance that an embolus or emboli (plural) may develop with stem cell procedures. This risk is low and is minimized due to our stem cells processing protocols.
- **Failure of the procedure** - There is a chance that undergoing stem cell application will not alleviate symptoms, resolve inflammation, or assist in regenerating tissue.
- **Fever** - Fever associated with stem cell harvesting usually responds to acetaminophen. If fevers persist, a work-up for infection must be completed.
- **Infection** - Infection may occur at the donor site where the bone marrow or fat was harvested or at the IV site and recipient site of application. To minimize risk infection prevention protocols are maintained and followed during the treatment process and patient education is provided on post treatment cleaning and wound care.
- **Pain** - Any procedure can result in pain. To minimize this risk we ask that our patients communicate any discomfort so that we can reduce or mitigate.
- **Numbness/tingling** – Although a low risk, this has been reported with leukapheresis (the process of separating stem cells from peripheral blood in the vein). Laboratory analysis may be required along with calcium infusion.
- **Respiratory difficulties** - Breathing difficulties (which are usually temporary) or post-operative pneumonia, may occur as a result of any procedure or surgery. Pulmonary embolus, a blood clot causing blockage of an artery in the lungs may occur as a result of any procedure or surgery. Pulmonary embolus may be fatal.
- **Stroke** - Though a low risk and unlikely, there is a possibility that a stroke will occur during the procedure or in the recovery period.
- **Transfers of undiagnosed cancer** – There is a risk that undiagnosed cancer in the area where the stem cells are harvested may be transferred to the recipients area of transplantation. To minimize risks, stem cells will not be altered in any way, thereby reducing the risk of tumor induction by carcinogens.

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- **Administration of incorrect stem cells** – The stem cells administered are the recipients own stem cells. There is a low risk of administration errors. Materials are clearly marked before they leave the procedure room, eliminating the risk of a recipient receiving someone else's stem cells in error.
- **Unintended differentiation** - The unintended differentiation of stem cells was found in a single study in which extensive intra-myocardial calcification after unselected bone-marrow cells transplantation was seen in the peri-infarct and infarct areas in rats. Though a low risk, unintended differentiation could occur in areas of stem cell implantation.

The following lists the potential benefits of treatment:

- **Increased Activity** - Ability to be more physically active; walking greater distances.
- **PFT** - Improvement in their FEV1 5-10% or more.
- **Oxygen** - Ability to reduce their use of oxygen and possibly to stop it.
- **Reduction in Medications** - Ability to function well without the use of their bronchodilator inhalers and Prednisone.
- **Increased Pulmonary Health** - Reduction or ceasing of secondary pulmonary infections

## 14. ETHICAL CONSIDERATIONS

This study will be conducted in full conformance with principles of Good Clinical Practice (GCP) and within the laws and regulations of the state of Texas and the United States regarding stem cell treatment. It is the priority of the participants' interests over those of science or of society that will be safeguarded.

Informed consent for treatment is paramount. This ensures that participants can read and understand the information they need to make an informed decision about their voluntary treatment. *A copy of the informed consent is attached to this protocol.*

Patients are treated by the Lung Institute on a fee-for-service basis. This introduces an ethical consideration that the treatment is available only to those patients who can afford treatment. Therefore, results of our study and the experiences of our patients may not be generalizable to those who cannot pay for treatment. To mitigate the risk of ethical implications, patients will never be coerced into treatment, promised that they will see a definite improvement in their condition, or will be compensated for their treatment.

## 15. REFERENCES

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<b>Department:</b> Clinical	<b>Number:</b> CL-005
<b>Title:</b> A-ASC Procedures	
<b>Original Effective Date:</b> 11/20/2015	<b>Latest Revision Date:</b> 3/8/2016
<b>Review/Revision History:</b> 2/5/16-Merged P&Ps CL-005 and CL-006, and generalized Medication Rule-Outs to capture all substances that impact bleeding tendencies; 3/8/16 Removed Adipose and Growth Factor related language, and added QOL under Follow-Up section H.	
<b>Applicable To:</b> All Departments	
<b>Approved By/Signature, Title &amp; Date</b>	
Medical Director/Clinical Operations Director Date	
Compliance Director Signature Date	
<b>Compliance Committee Review &amp; Approval Date:</b>	

**PURPOSE:**

TO ENSURE THAT ALL LUNG INSTITUTE (LI) AUTOLOGOUS-ADULT STEM CELL (A-ASC) PROCEDURES ARE ADMINISTERED IN A WAY THAT IS CONSISTENT WITH QUALITY STANDARDS AND APPLICABLE REGULATORY REQUIREMENTS.

**DEFINITIONS:**

**A-ASC PROCEDURE/TREATMENT:** AN AUTOLOGOUS-ADULT STEM CELL MEDICAL PROCEDURE.

**CLINICAL STAFF:** A LICENSED PHYSICIAN OR PRACTITIONER, AND EMPLOYEE(S) WORKING BY DELEGATION THEREOF.

**EMPLOYEE (STAFF):** PERSON(S) EMPLOYED BY LUNG INSTITUTE (LI) AND/OR ITS ADMINISTRATOR AND MANAGING AFFILIATE REGENERATIVE MEDICINE SOLUTIONS (RMS). AN EMPLOYEE INCLUDES FULL-TIME, PART-TIME, TEMPORARY, VOLUNTEERS, TRAINEES, CONTRACTED/CONSULTING INDIVIDUALS, AND OTHER INDIVIDUALS WHOSE CONDUCT IS UNDER THE DIRECT CONTROL OF LI (WHETHER OR NOT THEY ARE PAID BY LI).

**EQUIPMENT:** A CLINICAL INSTRUMENT USED IN A CLINICAL SETTING.

**FACILITY:** A LUNG INSTITUTE (LI) PRACTICE LOCATION/CLINICAL SITE.

**PROVIDER/PRACTITIONER:** AN LI EMPLOYED PHYSICIAN, NURSE PRACTITIONER, OR ANY OTHER LICENSED CLINICAL STAFF MEMBER WHICH RENDERS CARE TO AN LI PATIENT; THIS INCLUDES PHYSICIAN EXTENDERS AND TEMPORARY PROVIDERS THAT HAVE BEEN APPROVED TO RENDER SERVICES AT AN LI FACILITY.

**POLICY STATEMENT:**

THE LUNG INSTITUTE (LI) WILL SET AND MAINTAIN PRACTICE STANDARDS FOR ALL A-ASC TREATMENTS ADMINISTERED TO QUALIFYING PATIENTS DIAGNOSED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) OR INTERSTITIAL LUNG DISEASE (ILD), OR DIAGNOSED UNDER ONE OF THE VARIOUS ILD DISORDERS/DISEASES.

A-ASC TREATMENTS:

- a. VENOUS

**PROCEDURES:**

**A. PROCEDURE INCLUSION CRITERIA**

**1. FOR ALL PROCEDURES**

- a) DIAGNOSIS OF COPD; OR
  
- b) DIAGNOSIS OF ILD AND/OR A DIAGNOSIS THAT FALLS UNDER THE VARIOUS ILD DISORDER/DISEASES; AND ILD DISORDERS/DISEASES INCLUDE, BUT ARE NOT LIMITED TO:
  - i. INTERSTITIAL PNEUMONIA
  - ii. IDIOPATHIC PULMONARY FIBROSIS AND/OR OTHER PULMONARY FIBROSIS
  - iii. SARCOIDOSIS
  - iv. NONSPECIFIC INTERSTITIAL PNEUMONITIS: INTERSTITIAL LUNG DISEASE THAT'S OFTEN PRESENT WITH AUTOIMMUNE CONDITIONS (SUCH AS RHEUMATOID ARTHRITIS OR SCLERODERMA).
  - v. HYPERSENSITIVITY PNEUMONITIS
  - vi. ASBESTOSIS
- c) MEET AGE REQUIREMENT (16 YEARS OR OLDER); AND
- d) CHEST X-RAY OR CT SCAN OF LUNGS SHOWING FIBROSIS AND/OR CHRONIC INFLAMMATION
  - i. DOCUMENTATION OF DIAGNOSIS MAY BE CAPTURED IN OTHER NOTES IF SCAN X-RAY OR SCAN IS NOT AS DESCRIPTIVE.

**B. PROCEDURE EXCLUSIONS/RULE-OUTS**

**1. POPULATIONS EXCLUDED FROM ALL PROCEDURES:**

- a) INABILITY TO GIVE INFORMED CONSENT (A DIMINISHED UNDERSTANDING OR COMPREHENSION);
- b) INABILITY TO TRAVEL TO OUTPATIENT FACILITY;
- c) PREGNANT WOMEN;
- d) PRISONERS; AND
- e) CHILDREN, UNDER THE AGE OF 16 YEARS OLD.

**2. RULE-OUTS FOR *VENOUS* PROCEDURE**

- a) ACTIVE TUBERCULOSIS;
- b) HISTORY OF CANCER (WITHIN THE PAST 5 YEARS);
  - i. ON A CASE-BY-CASE BASIS, PROVIDER MAY APPROVE PROCEDURE(S) FOR NON-AGGRESSIVE/NON-ACTIVE CASE(S).
- c) IDENTIFICATION OF NEW NODULES/MASSES PER CHEST X-RAY/CT SCAN REPORT THAT HAVE NOT BEEN NOTED AS STABLE.
  - i. DOCUMENTATION OF STABILITY MUST BE RECEIVED FOR CONFIRMATION PRIOR TO TREATMENT.
- d) ACTIVE INFECTION (PULMONARY OR OTHER);
- e) A HISTORY OF RECENT HOSPITALIZATION (REQUIRING MECHANICAL VENTILATION IN A PERIOD OF ONE MONTH BEFORE TREATMENT);
- f) END STAGE KIDNEY FAILURE;
- g) ACUTE HEART FAILURE; AND/OR
- h) OTHER CONDITION(S) THE PROVIDER OR PRINCIPAL INVESTIGATOR FEELS WOULD INTERFERE WITH TREATMENT PROTOCOLS.

**3. RULE OUTS FOR *BONE MARROW* PROCEDURE**

- a) CURRENT BLOOD THINNER FOR ANY TYPE OF EXISTING HEART CONDITION;
- b) OSTEOPOROSIS;
- c) BILATERAL HIP REPLACEMENT;
- d) RADIATION OF PELVIS AREA (INCLUDING PROSTATE SEED IMPLANTS)
- e) ACTIVE TUBERCULOSIS;
- f) HISTORY OF CANCER (WITHIN THE PAST 5 YEARS);
  - i. ON A CASE-BY-CASE BASIS, PROVIDER MAY APPROVE PROCEDURE(S) FOR NON-AGGRESSIVE/NON-ACTIVE CASE.

- g) IDENTIFICATION OF NEW NODULES/MASSES PER CHEST X-RAY/CT SCAN REPORT THAT HAVE NOT BEEN NOTED AS STABLE.
  - i. DOCUMENTATION OF STABILITY MUST BE RECEIVED FOR CONFIRMATION PRIOR TO TREATMENT.
- h) ACTIVE INFECTION (PULMONARY OR OTHER);
- i) A HISTORY OF RECENT HOSPITALIZATION (REQUIRING MECHANICAL VENTILATION IN A PERIOD OF ONE MONTH BEFORE TREATMENT);
- j) END STAGE KIDNEY FAILURE;

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- k) ACUTE HEART FAILURE;
- l) UNCONTROLLED DIABETES;
- m) OTHER CONDITION(S) THE PROVIDER OR PRINCIPAL INVESTIGATOR FEELS WOULD INTERFERE WITH TREATMENT PROTOCOLS; AND/OR
- n) MEDICATION RULE-OUTS AS FOLLOWS:
  - i. MUST BE OFF ANTICOAGULATION DRUGS AND OTHER MEDICATIONS AND/OR SUBSTANCES THAT CAUSE BLEEDING. (MUST BE HELD FOR AN ALLOTTED TIME WITH PRIOR APPROVAL FROM PCP/PRESCRIBING PHYSICIAN-SPECIFIC HOLD TIMES ARE SUBJECT TO MEDICATION/SUBSTANCE TYPE.)
  - ii. METHOTREXATE (IF UNABLE TO HOLD FOR 1 WEEK PRIOR TO TREATMENT)

**C. ELEMENTS OF INFORMED CONSENT**

1. A SIGNED CONSENT FORM WITH THE FOLLOWING ELEMENTS CONSTITUTES PRIMA FACIE EVIDENCE THAT THE PATIENT OR THE PATIENT'S LEGAL REPRESENTATIVE GAVE INFORMED CONSENT TO THE HEALTH CARE PROVIDER.
2. INFORMATION SHOULD BE DELIVERED IN A MANNER IN WHICH THE PATIENT AND/OR THE PATIENT'S LEGAL REPRESENTATIVE COULD REASONABLY BE EXPECTED TO UNDERSTAND.
3. PATIENT MUST BE PROVIDED A MINIMUM OF:
  - a) THE NATURE AND CHARACTER OF THE PROPOSED TREATMENT;
  - b) THE ANTICIPATED RESULTS OF THE PROPOSED TREATMENT, WITH 'NO GUARANTEES' MADE BY LI;
  - c) ANY AVAILABLE ALTERNATIVE FORMS OF TREATMENT INCLUDING NON-TREATMENT;
  - d) THE RECOGNIZED RISKS AND COMPLICATIONS; AND
  - e) THE ANTICIPATED BENEFITS INVOLVED IN THE TREATMENT.

**D. PATIENT PAPERWORK & DISCLOSURES**

1. LI PROVIDERS WILL PRACTICE APPROPRIATELY UNDER THEIR LICENSED AND/OR THEIR CERTIFIED SCOPE.
2. DELEGATION OF CLINICAL FUNCTIONS ARE ONLY PERMITTED TO TRAINED AND QUALIFIED INDIVIDUALS.

**E. ATTENDING PROVIDER**

1. ONLY PROVIDERS WHO'S CREDENTIALS HAVE BEEN VERIFIED AND HAVE BEEN GRANTED PRIVILEGING MAY RENDER TREATMENT AND SERVICES AT LI FACILITIES. (REFER TO PROVIDER QUALIFICATIONS & PRIVILEGING P&P No.: HR-001)
  - a) THE TREATING LICENSED PROFESSIONAL(S)
    - i. PHYSICIAN
    - ii. NURSE PRACTITIONER (ARNP/CRNP/APRN; APN)
    - iii. PHYSICIAN ASSISTANT (PA)
    - iv. REGISTERED NURSE (RN)
    - v. LICENSED PRACTICAL NURSE (LPN/LVN)
    - vi. MEDICAL ASSISTANT (CMA/MA)
2. LI PROVIDERS WILL PRACTICE APPROPRIATELY UNDER THEIR VALID LICENSE(S) AND/OR THEIR CERTIFIED SCOPE OF SERVICES.
  - a) DELEGATION OF CLINICAL FUNCTIONS ARE PERMITTED TO INDIVIDUALS QUALIFIED AND/OR TRAINED TO PERFORM SAID DELEGATED FUNCTIONS.

3. IT IS THE RESPONSIBILITY OF THE ATTENDING PROVIDER TO ASSURE THAT THE PATIENT AND/OR THE LEGAL REPRESENTATIVE HAS BEEN INFORMED OF RISKS, BENEFITS, AND ALTERNATIVES OF PROCEDURE AND HAS CONSENTED TO TREATMENT WITHOUT COERCION, GIVING THEIR INFORMED CONSENT, AND TO DOCUMENT THE PROCESS IN PATIENT'S MEDICAL RECORD.
4. PROCUREMENT OF CELLS ARE CONDUCTED USING STERILE TECHNIQUES AND UNIVERSAL PRECAUTIONS TO MINIMIZE RISK OF CONTAMINATION AND INFECTION. (REFER TO MEDICAL EQUIPMENT MAINTENANCE AND MANAGEMENT P&P No.: CL-001)
5. TREATMENT PROTOCOLS INCLUDES A CLEAR, TIMELY, AND EFFECTIVE PLAN FOR REPORTING ADVERSE OCCURRENCES. (REFER TO INCIDENT REPORTING P&P No.: OP-004)

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## **F. LIFE-THREATENING EMERGENCIES**

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1. IMPLIED CONSENT EXISTS FOR ALL LIFE-THREATENING EMERGENCIES. HEALTH CARE PROVIDERS WHO ACT IN GOOD FAITH RECEIVE IMMUNITY WHEN RENDERING EMERGENCY CARE. IF A LIFE-THREATENING CARE EMERGENCY EXISTS AND THE PATIENT IS NOT CAPABLE OF GIVING INFORMED CONSENT OR A LEGALLY AUTHORIZED PERSON IS UNAVAILABLE, CONSENT WILL BE IMPLIED. A LIFE-THREATENING EMERGENCY IMPLIES THAT IMMEDIATE TREATMENT IS NECESSARY TO PRESERVE LIFE, OR TO PREVENT SERIOUS DETERIORATION OR AGGRAVATION OF THE PATIENT'S CONDITION. IMPLIED CONSENT IS FOR TREATMENT OF THE EMERGENCY ONLY.
  - a) A MINIMUM OF ONE PROVIDER IS TRAINED AND CERTIFIED FOR EMERGENCY RESPONSE AND IS ON-SITE DURING THE RENDERING OF PATIENT TREATMENT(S):
    - i. BASIC LIFE SUPPORT (BLS) CERTIFICATION/CPR CERTIFICATION
    - ii. ADVANCED CARDIO LIFE SUPPORT (ACLS) CERTIFICATION

## **G. POST TREATMENT**

1. PATIENTS ARE PRESCRIBED AND/OR RECOMMENDED TO FOLLOW A COMPREHENSIVE FOLLOW-UP PROTOCOL, INCLUDING THE FOLLOWING:
  - a) NEBULIZER AND/OR NEBULIZER SOLUTIONS;
  - b) SUPPLEMENTS;
  - c) PULMONARY REHABILITATION RECOMMENDED TO BE ORDERED BY PRIMARY CARE PHYSICIAN OR PULMONOLOGIST; AND
  - d) INCENTIVE SPIROMETER AND INSTRUCTIONS FOR USE.

## **H. FOLLOW-UPS**

1. LI CONDUCTS A FOLLOW-UP EVALUATION VIA A TELEPHONE CALL AT 2 WEEKS.
  - a) TWO CALL ATTEMPTS ARE MADE.
2. LI CONDUCTS AN ADDITIONAL FOLLOW UP PHONE CALL CONDUCTED AT 12 WEEKS.
  - a) TWO CALL ATTEMPTS ARE MADE.
3. PATIENT IS ADVISED TO RETURN TO CLINIC AT 6 MONTHS FOR EVALUATION, LABS, PULMONARY FUNCTION, PULSE OXIMETRY AND SIX MINUTE WALK TEST.
  - a) IF RETURN TO CLINIC IS NOT POSSIBLE DUE TO DISTANCE, THE PATIENT IS ADVISED TO GO TO A LOCAL PHYSICIAN FOR EXAMINATION, LABS, PULMONARY FUNCTION, PULSE OXIMETRY, AND SIX-MINUTE WALK TEST AT 6 MONTHS.
  - b) TWO CALL ATTEMPTS ARE MADE TO OBTAIN PATIENT PROGRESS VIA A QUALITY OF LIFE SURVEY.

### **ATTACHMENT(S):**

**A-1:** VENOUS PROCEDURE (CLINICAL - SOP)

**A-2:** BONE MARROW ASPIRATE PROCEDURE (CLINICAL - SOP)

**A-3:** DISCHARGE TREATMENT DAY PROCEDURE (CLINICAL-

**SOP) A-4:** OFFICE MANAGER PROCEDURE (CLINICAL-SOP)

**STATUTORY REFERENCE(S):**

**CONTRACT REFERENCE(S):**

**ELEMENT REFERENCE(S):**

**RELATED POLICY(S):**

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<b><u>Lung Institute</u></b> <i>Clinical Procedure</i>	<b><i>Standard Operating Procedure (SOP)</i></b> <b>Venous Procedure</b>
<b>Issue Date:</b> <b>Last Revision Date:</b> <b>Owner:</b> <b>Document Author:</b> <b>Approved By:</b>	11/20/2015 3/8/2016 Clinical Department Jessica Reed, ARNP – Lung Institute Operations Medical Director
<b>Purpose:</b>	To outline the clinical Venous Procedure; to ensure Patient and employee safety and minimize risk of exposure or incident.
<b>Primary User:</b> <b>Other department(s) Affected:</b>	LI-Clinical Department RMS-Records Department
<b>Systems Used:</b>	EMR; ZOHO

These instructions encompass the process for the preparation and completion of the A-ASC Venous Procedure treatment days. Steps must be completed in sequential order unless instructed to skip steps in the procedure work flow.

<b>1.</b>	Is today the first treatment day for the Patient? ➤ <b>If NO</b> > Proceed to Step 6 of this SOP ➤ <b>If YES</b> > Proceed to Step 2 of this SOP
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<b>2.</b>	<p>Has the Practitioner reviewed the required records prior to procedure and completed the required Pre-Op evaluation and documentation?</p> <ul style="list-style-type: none"> <li>• Signed Patient Consent Form</li> <li>• Patient Diagnostics: <ul style="list-style-type: none"> <li><b><i>Within 6 months from first DOS (Date of Service) is Preferred for Venous &amp; 3 months for Bone Marrow</i></b></li> <li>✓ Labs <ul style="list-style-type: none"> <li>a) Complete Blood Count with Differential (CBC w/ Diff)</li> <li>b) Comprehensive Metabolic Panel (CMP) - Basic Metabolic Panel (BMP) may be acceptable</li> <li>c) <i>For Bone Marrow Only:</i> Prothrombin Time-International Normalized Ratio (PT-INR)</li> </ul> </li> <li>✓ Diagnostic Imaging/Testing <ul style="list-style-type: none"> <li>a) Chest X-Ray; or</li> <li>b) CT Scan of Chest</li> <li>c) <i>For Bone Marrow Only:</i> EKG</li> </ul> </li> </ul> </li> <li>• Patient History: <ul style="list-style-type: none"> <li>✓ Previous Serious Illness;</li> <li>✓ Current and Chronic Illness;</li> <li>✓ Surgical History; and</li> <li>✓ Treating Physician Reports</li> </ul> </li> <li>• Allergies <ul style="list-style-type: none"> <li>✓ If Allergies Present - MUST use Suitable Alternative(s): <ul style="list-style-type: none"> <li>a) Latex Allergy - Non-Latex Gloves</li> <li>b) Betadine Allergy – Use Chlorhexidine</li> <li>c) Antibiotics Allergy - If allergic to Penicillin use Lincocin</li> <li>d) Lidocaine Allergy - Use Marcaine or Diphenhydramine</li> <li>e) Medication Allergies - Use suitable substitutes</li> </ul> </li> </ul> </li> <li>• Medications <ul style="list-style-type: none"> <li>✓ If Patient is on Blood Thinners or Anti-arrhythmics – Patient is only Suitable for Venous TX</li> </ul> </li> <li>• Bleeding Tendencies</li> </ul> <p>➤ <b><i>If NO &gt; Assess missing documentation and obtain prior to moving forward with procedure.</i></b></p>
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	<p>➤ <b><i>If YES &gt; Proceed to Step 3 of this SOP</i></b></p>
<b>3.</b>	<p>Has the Clinic Staff properly disposed of all materials associated with previous Patients and thoroughly cleaned all surface areas with Caviwipes per disinfection protocols?</p> <p>➤ <b><i>If NO &gt; Procedure Room must be cleaned per protocols prior to proceeding.</i></b></p> <p>➤ <b><i>If YES &gt; Proceed to Step 4 of this SOP</i></b></p>
<b>4.</b>	<p>Clinic Staff must properly prepare and label syringes and supplies for Patient procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff completed the following in the lab area? <ul style="list-style-type: none"> <li>✓ Open Harvest PRP (PC-60) Kit;</li> <li>✓ Label syringes and supplies w/ Patient Name and D/O/B;</li> <li>✓ Draws 8ml ACD-A into 60ml syringe;</li> <li>✓ Transfer 2ml ACD-A from syringe into white port of Process Disposable (PD) Cup; and</li> <li>✓ Spike 100ml normal saline IV bag with 15ggt IV tubing.</li> </ul> </li> </ul> <p>➤ <b><i>If NO &gt; Step must be completed prior to proceeding.</i></b></p> <p>➤ <b><i>If YES &gt; Proceed to Step 5 of this SOP</i></b></p>

5.	<p>Clinic Staff must properly prepare mayo stand under a clean technique for Patient procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff prepared the mayo stand by covering with underpad and ensuring all the following is made available? <ul style="list-style-type: none"> <li>✓ 60ml Syringe with ACD-A</li> <li>✓ 20g or 22g IV Catheter</li> <li>✓ Alcohol Prep Pad(s)</li> <li>✓ 2x2 Gauze</li> <li>✓ IV Starter Kit</li> </ul> </li> <li>• Has the Clinic Staff hung the IV bag in the exam room on the IV pole? <ul style="list-style-type: none"> <li>✓ Previously spiked 100ml Normal Saline (NS) IV Bag</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.  ➤ <b>If YES</b> &gt; Proceed to Step 9 of this SOP</p>
6.	<p>Has the Clinic Staff properly disposed of all materials associated with previous Patients and thoroughly cleaned all surface areas with Caviwipes per disinfection protocols?</p> <p>➤ <b>If NO</b> &gt; Procedure Room must be cleaned per protocols prior to proceeding.  ➤ <b>If YES</b> &gt; Proceed to Step 7 of this SOP</p>
7.	<p>Clinic Staff must properly prepare and label syringes and supplies for Patient procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff completed the following in the lab area? <ul style="list-style-type: none"> <li>✓ Open Harvest PRP (PC-30) Kit;</li> <li>✓ Label syringes and supplies w/ Patient Name and D/O/B;</li> <li>✓ Draws 6ml ACD-A into 30ml syringe;</li> <li>✓ Transfer 2ml ACD-A from syringe into white port of Process Disposable (PD) Cup; and</li> <li>✓ Spike 100ml normal saline IV bag with 15ggt IV tubing.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.  ➤ <b>If YES</b> &gt; Proceed to Step 8 of this SOP</p>

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8.	<p>Clinic Staff must properly prepare mayo stand under a clean technique for Patient procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff prepared the mayo stand by covering with underpad and ensuring all the following is made available? <ul style="list-style-type: none"> <li>✓ 35ml Syringe with ACD-A</li> <li>✓ 20g or 22g IV Catheter</li> <li>✓ Alcohol Prep Pad(s)</li> <li>✓ 2x2 Gauze</li> <li>✓ IV Starter Kit</li> </ul> </li> <li>• Has the Clinic Staff hung the IV bag in the exam room on the IV pole? <ul style="list-style-type: none"> <li>✓ Previously spiked 100ml Normal Saline (NS) IV Bag</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.  ➤ <b>If YES</b> &gt; Proceed to Step 9 of this SOP</p>
9.	<p>Clinic Staff assumes responsibility of Patient and Patient care from the Office Manager.</p> <ul style="list-style-type: none"> <li>• If Patient is on O<sup>2</sup>, has Patient been transferred to clinic's oxygen concentrator for the remainder of the day's visit?</li> </ul> <p>➤ <b>If applicable, and NO</b> &gt; Transfer Patient as required prior to moving forward with SOP.  ➤ <b>If not applicable; or applicable, and YES</b> &gt; Proceed to Step 10 of this SOP</p>

<p><b>10.</b></p>	<p>Clinic Staff conducts introductions, reviews process, and checks for Patient readiness.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff introduced themselves? <ul style="list-style-type: none"> <li>✓ Name and Roles</li> </ul> </li> <li>• Has Clinic Staff reviewed the procedure process for the day? <ul style="list-style-type: none"> <li>✓ Go over what the Patient can expect during the days procedure</li> </ul> </li> <li>• Has Clinic Staff ensured Patient readiness? <ul style="list-style-type: none"> <li>✓ Answer any questions the Patient may have; and</li> <li>✓ Check to see if Patient needs to use the restroom prior to procedure.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 11 of this SOP</p>
<p><b>11.</b></p>	<p>Clinic Staff obtains vitals.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff obtained the following vitals? <ul style="list-style-type: none"> <li>✓ Blood Pressure;</li> <li>✓ Pulse;</li> <li>✓ Heart Rate;</li> <li>✓ Respiratory Levels;</li> <li>✓ SaO<sup>2</sup> Levels;</li> <li>✓ EKG (If required, per Practitioner's judgement); and</li> <li>✓ PFT (May be obtained within the 3 days of scheduled treatment)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Obtaining Patient vitals is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 12 of this SOP</p>
<p><b>12.</b></p>	<p>Clinic Staff completed the subjective/chief complaint.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the Subjective/Chief Complaint? <ul style="list-style-type: none"> <li>✓ Patient Complaint/Primary Reason for Visit (i.e.: Patient here for shortness of breath, second day of procedure, COPD Treatment, etc.)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 13 of this SOP</p>

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<p><b>13.</b></p>	<p>Is today the first treatment day for the Patient?</p> <p>➤ <b>If NO</b> &gt; Proceed to Step 16 of this SOP</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 14 of this SOP</p>
<p><b>14.</b></p>	<p>Clinic Staff completed initial evaluation, including medical history.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following Patient History? <ul style="list-style-type: none"> <li>✓ Patient Complaint/Primary Reason for Visit</li> <li>✓ Social;</li> <li>✓ Medical;</li> <li>✓ Allergies;</li> <li>✓ Medications;</li> <li>✓ Surgical;</li> <li>✓ Family; and</li> <li>✓ Review of Systems</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 15 of this SOP</p>

15.	<p>Clinic Staff draws blood and affixes IV line to catheter.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ IV site is prepped and disinfected;</li> <li>✓ Affix tourniquet to upper arm;</li> <li>✓ Insert IV catheter into desired site;</li> <li>✓ Remove needle from catheter;</li> <li>✓ Affix Harvest PRP kit 60ml syringe to catheter and draw approximately 55ml of blood;</li> <li>✓ Remove syringe and affix IV drip line to catheter;</li> <li>✓ Wrap with Coban bandage to hold catheter in place;</li> <li>✓ Check the patency and flow to make sure it is correct;</li> <li>✓ Once correct, close off IV drip line until reinfusion; and</li> <li>✓ Dispose of supplies in designated biohazard/sharps containers.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 17 of this SOP</p>
16.	<p>Clinic Staff draws blood and affixes IV line to catheter.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ IV site is prepped and disinfected;</li> <li>✓ Affix tourniquet to upper arm;</li> <li>✓ Insert IV catheter into desired site;</li> <li>✓ Remove needle from catheter;</li> <li>✓ Affix Harvest PRP kit 35ml syringe to catheter and draw approximately 30ml of blood;</li> <li>✓ Remove syringe and affix IV drip line to catheter;</li> <li>✓ Wrap with Coban bandage to hold catheter in place;</li> <li>✓ Check the patency and flow to make sure it is correct;</li> <li>✓ Once correct, close off IV drip line until reinfusion; and</li> <li>✓ Dispose of supplies in designated biohazard/sharps containers.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 17 of this SOP</p>

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17.	<p>Clinic Staff takes blood supply to lab for processing and notifies Practitioner of Patient readiness.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Notified Practitioner of Patient readiness;</li> <li>✓ Transfer blood drawn to the correctly labeled Harvest PRP cup for centrifuging; and</li> <li>✓ Place PD Cup in centrifuge and press green start button or PRP start button.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 18 of this SOP</p>
18.	<p>Practitioner reviews and conducts required pre-procedural protocols and renders physical exam.</p> <ul style="list-style-type: none"> <li>• Has Practitioner reviewed the following prior to procedure and conducted the required? <ul style="list-style-type: none"> <li>✓ Has Practitioner conducted and noted H&amp;P or SOAP (Subjective; Objective; Assessment; Plan) on the Patient record; and</li> <li>✓ Reviewed all required pre-procedural documentation?</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward with procedure.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 19 of this SOP</p>

19.	<p>Clinic Staff will extract venous final product.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Draw PRP from the side compartment of PRP cup, identified by the white port.</li> <li>✓ Use PRP to wash walls of PD Cup at least twice; and</li> <li>✓ Extract into a 20ml syringe</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 20 of this SOP</p>
20.	<p>Clinic Staff administers final product.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Place venous final product (injected via the 20ml syringe referenced above) into the IV bag; and</li> <li>✓ Open IV line (checking for sufficient flow and drip rate)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 21 of this SOP</p>
21.	<p>Clinic Staff conducts on-going oversight of Patient during administration.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff confirmed the patency and flow are correct?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 22 of this SOP</p>
22.	<p>Clinic Staff starts nebulizer treatment.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Place glutathione and saline into nebulizer medicine cup and provide Patient with instructions to begin nebulizing treatment; and</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 23 of this SOP</p>

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23.	<p>Clinic Staff discontinues IV line and nebulizer; and provide post care instructions.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Turn off nebulizer when treatment completed;</li> <li>✓ When final product has emptied IV bag, use normal saline flush to flush entire contents of IV line;</li> <li>✓ Remove IV catheter;</li> <li>✓ Place 2x2 gauze pad over site, affix coban bandage;</li> <li>✓ Instruct Patient to remove gauze and coban after 20 to 30 minutes; and</li> <li>✓ Dispose of supplies in designated biohazard containers.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 24 of this SOP</p>
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<b>24.</b>	<p>Has Clinic Staff provides Patient with discharge folder and post-care instructions and answered any Patient questions or concerns?</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff advised the Patient of the below post-care instructions and ensured that they understand said instructions; answering any questions or concerns? <ul style="list-style-type: none"> <li>✓ Briefly review and explain the discharge folder contents to Patient;</li> <li>✓ Review LI follow-up procedures; and</li> <li>✓ Review Patient Journals for quality of life outcome data.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.  ➤ <b>If YES</b> &gt; Proceed to Step 25 of this SOP</p>
<b>25.</b>	<p>Has Clinic Staff updated EMR as required?</p> <ul style="list-style-type: none"> <li>• Capture procedure as required in the EMR: <ul style="list-style-type: none"> <li>✓ Vitals</li> <li>✓ Testing Conducted</li> <li>✓ Medications Administered</li> <li>✓ Lot Numbers and expirations (As Applicable);</li> <li>✓ Dosage(s)</li> <li>✓ Site(s) of Procedure and/or Administrations (Left vs Right, and location)</li> <li>✓ Route (PO, SubQ, IM, IV, Etc.); and</li> <li>✓ Any additional notation or documentation required (e.g.: Checklists and/or Flowsheets).</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed to complete SOP.  ➤ <b>If YES</b> &gt; SOP Complete</p>
<b>Notes:</b>	
<b>Related Documents:</b> P&P CL-005	

<p><b><u>Lung Institute</u></b>  <b><i>Clinical Procedure</i></b></p>	<p><b><i>Standard Operating Procedure (SOP)</i></b>  <b>Bone Marrow Aspirate Procedure</b></p>
<p><b>Issue Date:</b> 11/20/2015  <b>Last Revision Date:</b> 3/7/2016  <b>Owner:</b> Clinical Department  <b>Document Author:</b> Jessica Reed, ARNP – Lung Institute Operations  <b>Approved By:</b> Medical Director</p>	
<p><b>Purpose:</b></p>	<p>To outline the clinical treatment day for the Bone Marrow Aspirate Procedure; to ensure Patient and employee safety and minimize risk of exposure or incident.</p>
<p><b>Primary User:</b>  <b>Other department(s) Affected:</b></p>	<p>LI-Clinical Department  RMS-Records Department</p>
<p><b>Systems Used:</b></p>	<p>EMR; ZOHO</p>

These instructions encompass the process for the preparation and completion of the A-ASC Bone Marrow Procedure treatment day. Steps must be completed in sequential order unless instructed to skip steps in the procedure work flow.

<b>1.</b>	<p>Is today the first treatment day for the Patient?</p> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Proceed to Step 3 of this SOP</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 2 of this SOP</li> </ul>
<b>2.</b>	<p>Has the Practitioner reviewed the required records prior to procedure and completed the required Pre-Op evaluation and documentation?</p> <ul style="list-style-type: none"> <li>• Signed Patient Consent Form</li> <li>• Patient Diagnostics: <i>Obtained within 3 months from first DOS (Date of Service) is Preferred</i> <ul style="list-style-type: none"> <li>✓ Labs <ul style="list-style-type: none"> <li>a) Complete Blood Count with Differential (CBC w/ Diff)</li> <li>b) Comprehensive Metabolic Panel (CMP) - Basic Metabolic Panel (BMP) may be acceptable</li> <li>c) Prothrombin Time-International Normalized Ratio (PT-INR)</li> </ul> </li> <li>✓ Diagnostic Imaging/Testing <ul style="list-style-type: none"> <li>a) Chest X-Ray; or</li> <li>b) CT Scan of Chest</li> <li>c) EKG</li> </ul> </li> </ul> </li> <li>• Patient History: <ul style="list-style-type: none"> <li>✓ Previous Serious Illness;</li> <li>✓ Current and Chronic Illness;</li> <li>✓ Surgical History; and</li> <li>✓ Treating Physician Reports</li> </ul> </li> <li>• Allergies <ul style="list-style-type: none"> <li>✓ If Allergies Present - MUST use Suitable Alternative(s): <ul style="list-style-type: none"> <li>a) Latex Allergy - Non-Latex Gloves</li> <li>b) Betadine Allergy – Use Chlorhexidine</li> <li>c) Antibiotics Allergy - If allergic to Penicillin use Lincocin</li> <li>d) Lidocaine Allergy - Use Marcaine/Bupivacaine or Diphenhydramine</li> <li>e) Medication Allergies - Use suitable substitutes</li> </ul> </li> </ul> </li> <li>• Medications <ul style="list-style-type: none"> <li>✓ If Patient is on Blood Thinners or Anti-arrhythmics – Patient is only Suitable for Venous TX</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>• Bleeding Tendencies</li> <li>➤ <b>If NO</b> &gt; Assess missing documentation and obtain prior to moving forward with procedure.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 3 of this SOP</li> </ul>
<b>3.</b>	<p>Has the Clinic Staff properly disposed of all materials associated with previous Patients and thoroughly cleaned all surface areas with Caviwipes per disinfection protocols?</p> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Procedure Room must be cleaned per protocols prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 4 of this SOP</li> </ul>

4.	<p>Clinic Staff must properly prepare and label syringes and supplies for Patient procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff completed the following in the lab area? <ul style="list-style-type: none"> <li>✓ Open Harvest PRP (PC-60) Kit;</li> <li>✓ Label syringes and supplies w/ Patient Name and D/O/B;</li> <li>✓ Draws 8ml ACD-A into 60ml syringe; and</li> <li>✓ Spike 100ml IV bag with filter tubing to be used for administration of final product.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 5 of this SOP</p>
5.	<p>Clinic Staff must properly prepare mayo stand under aseptic technique for Patient <i>Bone Marrow</i> procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff prepared the mayo stand and procedure room with Harvest BMAC kit and by ensuring all the following is made available? <ul style="list-style-type: none"> <li>✓ Harvest BMAC kit</li> <li>✓ Marcaine/Bupivacaine 0.25%</li> <li>✓ Heparin 1,000units/ml</li> <li>✓ Anesthesia Syringe</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 6 of this SOP</p>
6.	<p>Clinic Staff must properly prepare mayo stand under a clean technique for Patient <i>Venous</i> procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff prepared the mayo stand by covering with underpad and ensuring all the following is made available? <ul style="list-style-type: none"> <li>✓ 60ml Syringe with ACD-A</li> <li>✓ 20g or 22g IV Catheter</li> <li>✓ IV Catheter Hep-Lock</li> <li>✓ Alcohol Prep Pad(s)</li> <li>✓ 2x2 Gauze</li> <li>✓ IV Starter Kit</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 7 of this SOP</p>
7.	<p>Clinic Staff assumes responsibility of Patient and Patient care from the Office Manager.</p> <ul style="list-style-type: none"> <li>• If Patient is on O<sup>2</sup>, has Patient been transferred to clinic's oxygen concentrator for the remainder of the day's visit?</li> </ul> <p>➤ <b>If applicable, and NO</b> &gt; Transfer Patient as required prior to moving forward with SOP.</p> <p>➤ <b>If not applicable; or applicable, and YES</b> &gt; Proceed to Step 8 of this SOP</p>

8.	<p>Has Clinic Staff conducted introductions, review process, and checks for readiness?</p> <ul style="list-style-type: none"> <li>• Clinic Staff introduces themselves; <ul style="list-style-type: none"> <li>✓ Name and Roles</li> </ul> </li> <li>• Reviews the procedure process for the day; and <ul style="list-style-type: none"> <li>✓ Go over what the Patient can expect during the days procedure</li> </ul> </li> <li>• Ensure Patient readiness <ul style="list-style-type: none"> <li>✓ Answer any questions the Patient may have; and</li> <li>✓ Check to see if Patient needs to use the restroom prior to procedure.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 9 of this SOP</p>
9.	<p>Clinic Staff obtains vitals.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff obtained Patient Vitals? <ul style="list-style-type: none"> <li>✓ Blood Pressure;</li> <li>✓ Pulse;</li> <li>✓ Heart Rate;</li> <li>✓ Respiratory Levels;</li> <li>✓ SaO<sup>2</sup> Levels;</li> <li>✓ EKG (Required to be obtained prior to Bone Marrow Procedure); and</li> <li>✓ PFT (May be obtained within the 3 days of scheduled treatment)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Obtaining Patient vitals is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 10 of this SOP</p>
10.	<p>Clinic Staff completed the subjective/chief complaint.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the Subjective/Chief Complaint? <ul style="list-style-type: none"> <li>✓ Patient Complaint/Primary Reason for Visit (i.e.: Patient here for shortness of breath, second day of procedure, COPD Treatment, etc.)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 11 of this SOP</p>
11.	<p>Is today the first treatment day for the Patient?</p> <p>➤ <b>If NO</b> &gt; Proceed to Step 13 of this SOP</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 12 of this SOP</p>
12.	<p>Clinic Staff completed initial evaluation, including medical history.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following Patient History? <ul style="list-style-type: none"> <li>✓ Patient Complaint/Primary Reason for Visit</li> <li>✓ Social;</li> <li>✓ Medical;</li> <li>✓ Allergies</li> <li>✓ Surgical;</li> <li>✓ Family; and</li> <li>✓ Review of Systems</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 13 of this SOP</p>

<b>13.</b>	<p>Clinic Staff draws blood and affixes Hep-lock to catheter.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ IV site is prepped and disinfected;</li> <li>✓ Apply tourniquet to upper arm;</li> <li>✓ Insert IV catheter into desired site;</li> <li>✓ Remove needle from catheter;</li> <li>✓ Affix Harvest PRP kit 60ml syringe to catheter and draw approximately 60ml of blood;</li> <li>✓ Remove syringe and affix Hep-lock to catheter;</li> <li>✓ Flush with Heparin syringe;</li> <li>✓ Wrap with Coban bandage to hold catheter in place; and</li> <li>✓ Dispose of supplies in designated biohazard/sharps containers.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 14 of this SOP</p>
<b>14.</b>	<p>Clinic Staff takes blood sample to lab to processing and notifies Practitioner of Patient readiness.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff processed blood in lab as required? <ul style="list-style-type: none"> <li>✓ Notified Practitioner of Patient readiness;</li> <li>✓ Transfer blood drawn to the correctly labeled Harvest PRP cup into the red port for centrifuging;</li> <li>✓ Place PD Cup in centrifuge and press green start button or PRP start button; and</li> <li>✓ Verify centrifuge is running properly.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 15 of this SOP</p>
<b>15.</b>	<p>Practitioner reviews and conducts required pre-procedural protocols and renders physical exam.</p> <ul style="list-style-type: none"> <li>• Has Practitioner reviewed the following prior to procedure and conducted the required? <ul style="list-style-type: none"> <li>✓ Has Practitioner conducted and noted H&amp;P or SOAP (Subjective; Objective; Assessment; Plan) on the Patient record; and</li> <li>✓ Reviewed all required pre-procedural documentation?</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward with procedure.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 16 of this SOP</p>
<b>16.</b>	<p>Clinic Staff will extract venous final product.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Remove approximately 10-15ml plasma from white port of PD Cup using Harvest kit syringe with yellow stoppers and discard to appropriate biohazard container;</li> <li>✓ Draw PRP from the side compartment of PRP cup, identified by the white port.</li> <li>✓ Use PRP to wash walls of PD Cup at least twice; and</li> <li>✓ Extract into a 20ml syringe and place labeled syringe on top of clean box for re-infusion once bone marrow extraction is complete.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 17 of this SOP</p>

MATERIAL	Amount Required
BMAC Harvest kit (BMAC – 60-07)	1

<p><b>17.</b></p>	<p>Has Practitioner ensured all of the following Reagents and Materials availability and prepare for procedure?</p> <ul style="list-style-type: none"> <li>• Has Practitioner washed hands according to hand washing hygiene protocol?</li> <li>• Has Practitioner dressed in appropriate PPE (Personal Protective Equipment)? <ul style="list-style-type: none"> <li>✓ Gown</li> <li>✓ Shoe Covers</li> <li>✓ Hair/Head Cover</li> <li>✓ Mask</li> <li>✓ Gloves (to be donned upon right before commencement of procedure)</li> </ul> </li> <li>• Has Practitioner ensured all of the following Reagents and Materials availability and prepare lab space for procedure?</li> </ul> <p>REAGENTS:</p> <ul style="list-style-type: none"> <li>✓ Marcaine/Bupivacaine 0.25%</li> <li>✓ Heparin 1,000units/ml</li> </ul> <p>MATERIALS:</p> <p>➤ <b>If NO</b> &gt; <i>Materials required must be available and prepared prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 18 of this SOP</i></p>
<p><b>18.</b></p>	<p>Practitioner and an additional member of Clinic Staff (minimum of 2) will conduct and document on the Medical Record a “Time-Out”.</p> <ul style="list-style-type: none"> <li>• Has the procedure team conducted pre-op verification check-point with an alert and aware Patient? <ul style="list-style-type: none"> <li>✓ Patient Name</li> <li>✓ DOB (Date of Birth)</li> <li>✓ Procedure Type</li> <li>✓ Allergies</li> <li>✓ Anesthesia</li> <li>✓ Procedure Site/Side &amp; Process</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Time-Out must be completed and documented prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 19 of this SOP</i></p>
<p><b>19.</b></p>	<p>Clinic Staff administers prophylactic antibiotic injection.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff administered Rocephin? <ul style="list-style-type: none"> <li>✓ Inject Rocephin 1g IM (Intra Muscular) via gluteus maximus; or</li> <li>✓ In event of Penicillin (PCN) allergy, administer Lincocin 600mg IM via gluteus maximus.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Step must be completed prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 20 of this SOP</i></p>
<p><b>20.</b></p>	<p>Practitioner instructs Patient on safety protocol.</p> <ul style="list-style-type: none"> <li>• Has Practitioner instructed Patient of lateral decubitus positioning? <ul style="list-style-type: none"> <li>✓ Patient is placed on right or left side-lying position depending on patient preference; if applicable.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Instruct Patient on safety protocol prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 21 of this SOP</i></p>

21.	<p>Has Practitioner checked on Patient readiness in the procedure room and noted Start-Time of Procedure once ready to commence procedure?</p> <ul style="list-style-type: none"> <li>• Patient Readiness <ul style="list-style-type: none"> <li>✓ Is Patient comfortable?</li> <li>✓ Does Patient need anything?</li> <li>✓ If Applicable, do we have Patient preferred music playing?</li> <li>✓ If Applicable, is their O<sup>2</sup> on?</li> </ul> </li> <li>• Start-Time <ul style="list-style-type: none"> <li>✓ Note the Start-Time of Procedure</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 22 of this SOP</p>
22.	<p>Practitioner prepares the BMAC kit.</p> <ul style="list-style-type: none"> <li>• Has the Practitioner completed the following on the mayo stand in the procedure room with assistance of the Clinic Staff? <ul style="list-style-type: none"> <li>✓ Close off filter bag clamp;</li> <li>✓ Prepare 8ml ACD-A into filter bag;</li> <li>✓ Prepare 8ml Heparin into cup for washing;</li> <li>✓ Wash two 30ml locking syringes with Heparin;</li> <li>✓ Wash Trocar with Heparin;</li> <li>✓ Wash Blunt tip end of Trocar with Heparin; and</li> <li>✓ Prepare 10ml Marcaine/Bupivacaine into syringe with 25g needle;</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Preparation is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 23 of this SOP</p>
23.	<p>Practitioner preps and disinfects area of procedure site point.</p> <ul style="list-style-type: none"> <li>• Has the Practitioner disinfected the procedure area; mid axillary line to spinal processes; and lower ribcage to buttocks? <ul style="list-style-type: none"> <li>✓ Using betadine swabs or 4x4 gauze saturated with Betadine (use Chlorhexidine if allergy).</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 24 of this SOP</p>
24.	<p>Practitioner marks procedure site point.</p> <ul style="list-style-type: none"> <li>• Using palpation and landmarks of iliac crest and SI (sacroiliac) joint to find the PSIS (posterior superior iliac spine); and marked with marking pen?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 25 of this SOP</p>
25.	<p>Practitioner injects local anesthetic at site of port.</p> <ul style="list-style-type: none"> <li>• Has Practitioner injected, using Marcaine/Bupivacaine 0.25%, 4ml via a 25 gauge needle from superficial skin down to cortical bone and then “pepper” area of cortical bone? May need to change to spinal needle as appropriate to body habitus?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 26 of this SOP</p>

<p><b>26.</b></p>	<p>Practitioner makes incision at site.</p> <ul style="list-style-type: none"> <li>• Has Practitioner used 11 blade scalpel to make incision?</li> </ul> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 27 of this SOP</li> </ul>
<p><b>27.</b></p>	<p>Practitioner inserts trocar into marrow space.</p> <ul style="list-style-type: none"> <li>• Using sharp end trocar, has Practitioner used drilling motion to go through cortical bone and into marrow space (at loss of resistance)?</li> </ul> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 28 of this SOP</li> </ul>
<p><b>28.</b></p>	<p>Practitioner advances in marrow space.</p> <ul style="list-style-type: none"> <li>• Has Practitioner removed sharp end trocar and replaces with blunt tip in following manner? <ul style="list-style-type: none"> <li>✓ Removes sharp end trocar very slowly;</li> <li>✓ Replaces with blunt tip trocar; then</li> <li>✓ Inserts entire trocar another 1/2cm deeper into marrow space</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 29 of this SOP</li> </ul>
<p><b>29.</b></p>	<p>Practitioner extracts bone marrow from site.</p> <ul style="list-style-type: none"> <li>• Has Practitioner removed blunt end and replaces with locking syringe in following manner? <ul style="list-style-type: none"> <li>✓ Removes blunt end trocar very slowly;</li> <li>✓ Replaces with 30ml Harvest locking syringe and withdraws 30ml of bone marrow aspirate ; then</li> <li>✓ Replaces with second 30ml Harvest locking syringe and withdraws second 30ml of bone marrow aspirate</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 30 of this SOP</li> </ul>
<p><b>30.</b></p>	<p>Practitioner removes trocar from procedure port.</p> <ul style="list-style-type: none"> <li>• Has Practitioner removed blunt end trocar from procedure port site? <ul style="list-style-type: none"> <li>✓ Removes filled Harvest locking syringe;</li> <li>✓ Replaces with blunt tip trocar; and</li> <li>✓ Removes entire trocar and applies steady pressure to incision port site using 4x4 gauze.</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 31 of this SOP</li> </ul>
<p><b>31.</b></p>	<p>Practitioner filters bone marrow aspirate.</p> <ul style="list-style-type: none"> <li>• Has Practitioner filtered bone marrow aspirate for processing? <ul style="list-style-type: none"> <li>✓ Injects 30ml Harvest locking syringe into filter bag port;</li> <li>✓ Injects second 30ml Harvest locking syringe into filter bag;</li> <li>✓ Agitates entire filter bag to mix with ACD-A;</li> <li>✓ Attaches 60 ml syringe to filter bag;</li> <li>✓ Releases white filter clamp; and</li> <li>✓ Removes bone marrow aspirate into 60ml syringe; and</li> <li>✓ Attaches blunt tip needle to 60ml syringe.</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</li> <li>➤ <b>If YES</b> &gt; Proceed to Step 32 of this SOP</li> </ul>

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32.	<p>Clinic Staff cleans procedure area and applies bandage.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff appropriately cleaned procedure area and applied bandage as per below instructions? <ul style="list-style-type: none"> <li>✓ Use 4x4 gauze with Normal Saline (NS) to remove excess betadine from procedure area;</li> <li>✓ Wipe dry with clean 4x4 gauze;</li> <li>✓ Apply 3 steri-strips over incision site;</li> <li>✓ Apply new 4x4 gauze; by folding each gauze in half and then folding them in half again; then</li> <li>✓ Cover port site with folded gauze; and</li> <li>✓ Cover with 4x4 Tegaderm over folded gauze.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 33 of this SOP</p>
33.	<p>Practitioner takes harvested bone marrow aspirate to Lab area for processing.</p> <ul style="list-style-type: none"> <li>• Has Practitioner made sure that processing area is clean and free from other samples, clutter, and any other risk of contamination?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 34 of this SOP</p>
34.	<p>Practitioner transfers bone marrow aspirate to Harvest processing cup for centrifuge.</p> <ul style="list-style-type: none"> <li>• Has practitioner placed bone marrow aspirate from 60ml syringe into blood chamber (red port) of process disposable (PD)?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 35 of this SOP</p>
35.	<p>Practitioner inserts PD cup into centrifuge.</p> <ul style="list-style-type: none"> <li>• Has Practitioner completed the following? <ul style="list-style-type: none"> <li>✓ Practitioner places PD into Harvest centrifuge; and</li> <li>✓ Presses "BMAC" button for processing</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 36 of this SOP</p>
36.	<p>Has Practitioner removed bone marrow concentrate from centrifuge?</p> <ul style="list-style-type: none"> <li>• Practitioner withdraws excess plasma from white port of PD cup with syringe containing yellow spacers; <ul style="list-style-type: none"> <li>✓ Draws off excess plasma until bubbles appear in syringe;</li> <li>✓ Properly discard excess plasma syringe; and</li> <li>✓ Use 20ml syringe to draw remaining PRP from the side compartment of PD cup, identified by the white port.</li> <li>✓ Use PRP to wash walls of PD Cup at least twice; and</li> <li>✓ Extract into a 20ml syringe.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 37 of this SOP</p>

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37.	<p>Practitioner utilizes light system.</p> <ul style="list-style-type: none"> <li>• Has Practitioner completed the following? <ul style="list-style-type: none"> <li>✓ Place 20ml syringe of bone marrow aspirate final product in Adi-Light for 20 min.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 38 of this SOP</p>
38.	<p>Clinic Staff prepares final product for administration via IV bag.</p> <ul style="list-style-type: none"> <li>• Has Practitioner completed the following? <ul style="list-style-type: none"> <li>✓ Remove 20ml syringe of bone marrow final product from Adi-Light;</li> <li>✓ Inject bone marrow final product into 100ml normal saline IV bag; and</li> <li>✓ Inject 20ml PRP syringe from top of clean box into same 100ml normal saline IV bag.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 39 of this SOP</p>
39.	<p>Clinic Staff administers final product via IV.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Clean Hep-Lock site with alcohol prep pad;</li> <li>✓ Affix IV tubing of final product contents to Hep-Lock catheter;</li> <li>✓ Open IV line (checking for proper flow and drip rate).</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 40 of this SOP</p>
40.	<p>Clinic Staff conducts on-going oversight of Patient during administration.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff confirmed the patency and flow are correct?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 41 of this SOP</p>
41.	<p>Clinic Staff discontinues IV line.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ When final product has emptied IV bag, use NS (normal saline) flush to flush entire contents of IV line;</li> <li>✓ Remove IV catheter;</li> <li>✓ Place 2x2 gauze pad over site, affix coban bandage</li> <li>✓ Instruct Patient to remove gauze and coban after 20 to 30mins; and</li> <li>✓ Dispose of supplies in designated biohazard containers.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 42 of this SOP</p>

<b>42.</b>	<p>Clinic Staff gives Patient post-op instructions.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff advised the Patient of the below post-op care instructions and ensured that they understand said instructions; answering any questions or concerns? <ul style="list-style-type: none"> <li>✓ Do not shower until after next-day clinic visit; only sponge bath and avoid water to bandaged area;</li> <li>✓ Avoid excessive lifting and bending for the next seven days; and</li> <li>✓ To use ice for 15 minute sessions at least twice within the day.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 43 of this SOP</p>
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<b>43.</b>	<p>Has Clinic Staff updated EMR as required?</p> <ul style="list-style-type: none"> <li>• Capture procedure as required in the EMR: <ul style="list-style-type: none"> <li>✓ Vitals</li> <li>✓ Testing Conducted</li> <li>✓ Medications Administered</li> <li>✓ Lot Numbers and expirations (As Applicable);</li> <li>✓ Dosage(s)</li> <li>✓ Site(s) of Procedure and/or Administrations (Left vs Right, and location)</li> <li>✓ Route (PO, SubQ, IM, IV, Etc.); and</li> <li>✓ Any additional notation or documentation required (e.g.: Checklists and/or Flowsheets).</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed to complete SOP.</p> <p>➤ <b>If YES</b> &gt; SOP Complete</p>
<b>Notes:</b>	
<b>Related Documents:</b> P&P CL-005	

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<p><b><u>Lung Institute</u></b> <i>Clinical Procedure</i></p>	<p><b>Standard Operating Procedure (SOP)</b> <b>Discharge Treatment Day Procedure</b></p>
<p><b>Issue Date:</b> 11/20/2015  <b>Last Revision Date:</b> 3/7/2016  <b>Date:</b> Clinical Department  <b>Owner:</b> Jessica Reed, ARNP – Lung Institute Operations  <b>Document Author:</b> Medical Director  <b>Approved By:</b></p>	
<p><b>Purpose:</b></p>	To outline the clinical Discharge Treatment Procedure, to ensure Patient and employee safety and minimize risk of exposure or incident.
<p><b>Primary User:</b>  <b>Other department(s) Affected:</b></p>	LI-Clinical Department RMS-Records Department

**Systems Used:** EMR; ZOHO

These instructions encompass the process for the preparation and completion of the Discharge Procedure. Steps must be completed in sequential order unless instructed to skip steps in procedure work flow.

1.	Has the Clinic Staff properly disposed of all materials associated with previous Patients and thoroughly cleaned all surface areas with Caviwipes per disinfection protocols? <input type="checkbox"/> <b>If NO</b> > Procedure Room must be cleaned per protocols prior to proceeding. <input type="checkbox"/> <b>If YES</b> > Proceed to Step 2 of this SOP
2.	Clinic Staff assumes responsibility of Patient and Patient care from Office Manager. <ul style="list-style-type: none"><li>• If Patient is on O<sub>2</sub>, has Patient been transferred to clinic's oxygen concentrator for the remainder of the day's visit?</li></ul> <p>➤ <b>If applicable, and NO</b> &gt; Transfer Patient as required prior to moving forward with SOP. ➤ <b>If not applicable; or applicable, and YES</b> &gt; Proceed to Step 3 of this SOP</p>
3.	Clinic Staff conducts introductions, reviews process, and checks for Patient readiness. <ul style="list-style-type: none"><li>• Clinic Staff introduces themselves;<ul style="list-style-type: none"><li>✓ Name and Roles</li></ul></li><li>• Reviews the procedure process for the day; and<ul style="list-style-type: none"><li>✓ Go over what the Patient can expect during the days procedure</li></ul></li><li>• Ensure Patient readiness<ul style="list-style-type: none"><li>✓ Answer any questions the Patient may have; and</li><li>✓ Check to see if Patient needs to use the restroom prior to procedure.</li></ul></li></ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding. ➤ <b>If YES</b> &gt; Proceed to Step 4 of this SOP</p>
4.	Is this a Venous Treatment Discharge day? <p>➤ <b>If NO</b> &gt; Proceed to Step 15 of this SOP ➤ <b>If YES</b> &gt; Proceed to Step 5 of this SOP</p>

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5.	Clinic Staff must properly prepare and label syringes and supplies for Patient procedure. <ul style="list-style-type: none"><li>• The Clinic Staff will complete the following in the lab area:<ul style="list-style-type: none"><li>✓ Open Harvest PRP (PC-30) Kit;</li><li>✓ Label syringes and supplies w/ Patient Name and D/O/B;</li><li>✓ Draws 6ml ACD-A into 60ml syringe;</li><li>✓ Transfer 2ml ACD-A from syringe into white port of Process Disposable (PD) Cup; and</li><li>✓ Spike 100ml normal saline IV bag with 15ggt IV tubing.</li></ul></li></ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding. ➤ <b>If YES</b> &gt; Proceed to Step 6 of this SOP</p>
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6.	<p>Clinic Staff must properly prepare mayo stand under a clean technique for Patient procedure.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff prepared the mayo stand by covering with underpad and ensuring all the following is made available? <ul style="list-style-type: none"> <li>✓ 30ml Syringe with ACD-A</li> <li>✓ 20g or 22g IV Catheter</li> <li>✓ Alcohol Prep Pad(s)</li> <li>✓ 2x2 Gauze</li> <li>✓ IV Starter Kit</li> </ul> </li> <li>• Has the Clinic Staff hung the IV bag in the exam room on the IV pole? <ul style="list-style-type: none"> <li>✓ Previously spiked 100ml Normal Saline (NS) IV Bag</li> </ul> </li> </ul> <p><input type="checkbox"/> <b>If NO</b> &gt; Preparation is required prior to proceeding.</p> <p><input type="checkbox"/> <b>If YES</b> &gt; Proceed to Step 7 of this SOP</p>
7.	<p>Clinic Staff obtains vitals.</p> <ul style="list-style-type: none"> <li>• Vitals: <ul style="list-style-type: none"> <li>✓ Blood Pressure;</li> <li>✓ Pulse;</li> <li>✓ Heart Rate;</li> <li>✓ Respiratory Levels;</li> <li>✓ SaO<sup>2</sup> Levels;</li> <li>✓ EKG (If required, per Practitioner's judgement); and</li> <li>✓ PFT (May be obtained within the 3 days of scheduled treatment)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Obtaining Patient vitals is required prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 8 of this SOP</p>
8.	<p>Clinician draws blood and affixes IV line to catheter.</p> <ul style="list-style-type: none"> <li>• IV site is prepped and disinfected;</li> <li>• Affix tourniquet to upper arm;</li> <li>• Insert IV catheter into desired site;</li> <li>• Remove needle from catheter;</li> <li>• Affix Harvest PRP kit 30ml syringe to catheter and draw approximately 30ml of blood;</li> <li>• Remove syringe and affix IV drip line to catheter;</li> <li>• Check the patency and flow to make sure it is correct;</li> <li>• Once correct, close off IV drip line until reinfusion; and</li> <li>• Dispose of supplies in designated biohazard/sharps containers.</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 9 of this SOP</p>

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9.	<p>Clinic Staff takes blood supply to lab for processing and notifies Practitioner of Patient readiness.</p> <ul style="list-style-type: none"> <li>• Transfer blood drawn to the correctly labeled Harvest PRP cup for centrifuging;</li> <li>• Place PD Cup in centrifuge and press green start button or PRP start button;</li> <li>• Clinic Staff notifies Practitioner that Patient is ready to be seen.</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 10 of this SOP</p>
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10.	<p>Clinic Staff will extract venous final product.</p> <ul style="list-style-type: none"> <li>• Draw PRP from the side compartment of PRP cup, identified by the white port.</li> <li>• Use PRP to wash walls of PD Cup at least twice; and</li> <li>• Extract into a 20ml syringe</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 11 of this SOP</p>
11.	<p>Clinic Staff administers final product.</p> <ul style="list-style-type: none"> <li>• Place venous final product (injected via the 20ml syringe referenced above) into the IV bag; and</li> <li>• Open IV line (checking for sufficient flow and drip rate)</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 12 of this SOP</p>
12.	<p>Clinic Staff starts nebulizer treatment.</p> <ul style="list-style-type: none"> <li>• Place glutathione and saline into nebulizer medicine cup and provide Patient with instructions to begin nebulizing treatment.</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 13 of this SOP</p>
13.	<p>Clinic Staff conducts on-going oversight of Patient during administration.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff confirmed the patency and flow are correct?</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 14 of this SOP</p>
14.	<p>Clinic Staff discontinues IV line and nebulizer; and provide post care instructions.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Turn off nebulizer when treatment completed;</li> <li>✓ Remove IV catheter;</li> <li>✓ Place 2x2 gauze pad over site, affix coban bandage;</li> <li>✓ Instruct Patient to remove gauze and coban after 20 to 30 minutes;</li> <li>✓ Dispose of supplies in designated biohazard containers; and</li> <li>✓ Was Practitioner made available to Patient for additional education and questions?</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 19 of this SOP</p>

15.	<p>Clinic Staff obtains vitals.</p> <ul style="list-style-type: none"> <li>• Has the Clinic Staff obtained Patient Vitals? <ul style="list-style-type: none"> <li>✓ Blood Pressure;</li> <li>✓ Pulse;</li> <li>✓ Heart Rate;</li> <li>✓ Respiratory Levels;</li> <li>✓ SaO<sup>2</sup> Levels;</li> <li>✓ EKG (If required, per Practitioner's judgement); and</li> <li>✓ PFT (May be obtained within the 3 days of scheduled treatment)</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Obtaining Patient vitals is required prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 16 of this SOP</i></p>
16.	<p>Clinic Staff to undress bandage at incision site and notifies Practitioner that Patient is ready to be seen.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Remove Tegaderm and 4x4 gauze;</li> <li>✓ Examine incision site for any signs of infection; and</li> <li>✓ Notify Practitioner to examine site.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Step must be completed prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 17 of this SOP</i></p>
17.	<p>Clinic Staff to apply bandage to incision site.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff completed the following? <ul style="list-style-type: none"> <li>✓ Apply 2x3 Tegaderm bandage to incision site; and</li> <li>✓ Provide Patient with instructions to replace bandage as needed at home for next 5-7 days.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Step must be completed prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 18 of this SOP</i></p>
18.	<p>Clinic Staff gives Patient post-op instructions.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff advised the Patient of the below post-op care instructions and ensured that they understand said instructions; answering any questions or concerns? <ul style="list-style-type: none"> <li>✓ Practitioner made available to Patient for additional education and questions;</li> <li>✓ Advised of no submerging of incision site in pools, hot tubs, bath, etc. for 7 days post-op;</li> <li>✓ Advised to avoid excessive lifting and bending for the next seven days; and</li> <li>✓ Advised to use ice as needed for 15 minutes per session for pain or swelling.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Step must be completed prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 19 of this SOP</i></p>
19.	<p>Clinic Staff to review all discharge paperwork provided and answer any questions pertaining to treatment and discharge.</p> <ul style="list-style-type: none"> <li>• Has Clinic Staff advised the Patient of the below post-care instructions and ensured that they understand said instructions; answering any questions or concerns? <ul style="list-style-type: none"> <li>✓ Briefly review and explain the discharge folder contents to Patient;</li> <li>✓ Review LI follow-up procedures; and</li> <li>✓ Review Patient Journals for quality of life outcome data.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; <i>Step must be completed prior to proceeding.</i></p> <p>➤ <b>If YES</b> &gt; <i>Proceed to Step 20 of this SOP</i></p>

20.	<p>Has Clinic Staff updated EMR as required?</p> <ul style="list-style-type: none"> <li>• Capture procedure as required in the EMR: <ul style="list-style-type: none"> <li>✓ Vitals</li> <li>✓ Testing Conducted</li> <li>✓ Medications Administered</li> <li>✓ Lot Numbers and expirations (As Applicable);</li> <li>✓ Dosage(s)</li> <li>✓ Site(s) of Procedure and/or Administrations (Left vs Right, and location)</li> <li>✓ Route (PO, SubQ, IM, IV, Etc.); and</li> <li>✓ Any additional notation required.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward.  ➤ <b>If YES</b> &gt; Proceed to Step 21 of this SOP</p>
21.	<p>Office Manager provides Patient with Satisfaction Survey and Doctor's letter of treatment.</p> <ul style="list-style-type: none"> <li>• Patient is given instructions to complete Satisfaction Survey and hand back to Office Manager prior to departure; and</li> <li>• Is provided with correct Doctor's letter of LI treatment completed;</li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward.  ➤ <b>If YES</b> &gt; Proceed to Step 22 of this SOP</p>
22.	<p>Office Manager updates EMR with Patient check-out.</p> <ul style="list-style-type: none"> <li>• Office Manager completes the following EMR step: <ul style="list-style-type: none"> <li>✓ Patient Check-Out</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to proceeding.  ➤ <b>If YES</b> &gt; SOP complete</p>
<b>Notes:</b>	
<b>Related Documents:</b> P&P CL-005	

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<p><b><u>Lung Institute</u></b>  <i>Clinical Procedure</i></p>	<p><b>Standard Operating Procedure (SOP)</b>  <b>Office Manager Procedure</b></p>
<p><b>Issue Date:</b> 11/20/2015  <b>Last Revision</b> 3/7/2016  <b>Date:</b> Clinical Department  <b>Owner:</b> Jessica Reed, ARNP – Lung Institute Operations  <b>Document Author:</b> Medical Director  <b>Approved By:</b></p>	
<p><b>Purpose:</b></p>	<p>To outline the Office Managers patient care responsibilities and procedures, to ensure Patient and employee safety and minimize risk of exposure or incident.</p>
<p><b>Primary User:</b>  <b>Other department(s) Affected:</b></p>	<p>LI-Clinical Department  RMS-Records Department</p>

**Systems Used:** EMR; ZOHO

These instructions encompass the process for the preparation and completion of the Office Manager's Patient Check-In, Processing, and Check-Out Procedures. Steps must be completed in sequential order unless instructed to skip steps in the procedure work flow.

1. Has Office Manger thoroughly cleaned Patient waiting areas; wiping all chairs and surfaces, and disposing of any trash or materials associated with previous Patients per disinfection and HIPAA protocols at end of previous work day?
- **If NO** > Step 1 MUST be completed prior to moving forward.
  - **If YES** > Proceed to Step 2 of this SOP

**PATIENT CHECK-IN**

2. Is today the first treatment day for the Patient?
- **If NO** > Skip to Step 5 of this SOP
  - **If YES** > Proceed to Step 3 of this SOP

3. Office Manager receives Patient and processes paperwork and completes Patient Flow Chart as required.
- Has Office Manager reviewed and collected the required registration paperwork below, as well as assists the Patient with any remaining paperwork required for processing?
    - ✓ New Patient Packet (If NPP completed via Portal; OM must obtain hard copies of forms e and f)
      - a) Personal Information;
      - b) Emergency Contact Information;
      - c) Referral Source;
      - d) Medical History;
      - e) Authorization to Verbally Discuss Health Information;
      - f) Patient Bill of Rights;
      - g) How to File a Complaint; and
    - ✓ Provided the Patient with LI Privacy and Security Practices Notice
    - ✓ Consent Form Review and Completion; and
    - ✓ Quality of Life Survey
- **If NO** > Must complete this Step prior to moving forward.
  - **If YES** > Proceed to Step 4 of this SOP

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4. Office Manager processes payment.
- Has Office Manager collected and processed payment by completing the following?:
    - ✓ Obtaining a signed Payment Agreement;
    - ✓ Providing invoice and copy of payment agreement to Patient; and
    - ✓ Note payment in required systems (both EMR and CRM)
- **If NO** > Must complete this Step prior to moving forward.
  - **If YES** > Proceed to Step 5 of this SOP

5.	<p>Office Manager updates EMR as required.</p> <ul style="list-style-type: none"> <li>• Has Office Manager scanned any required paperwork (e.g.: Registration, Payment Agreement) into the EMR chart; and</li> <li>• Completed the following EMR steps? <ul style="list-style-type: none"> <li>✓ Patient Check-In</li> <li>✓ Exam Room</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Must complete this Step prior to moving forward.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 6 of this SOP</p>
6.	<p>Office Manager completes Patient Flow Chart and transfers Patient to Clinical Staff.</p> <ul style="list-style-type: none"> <li>• Has Office Manager completed the following? <ul style="list-style-type: none"> <li>✓ Signed-off on the Patient Flow Chart; and</li> <li>✓ Brought the Patient back to assigned exam room?</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Must complete this Step prior to moving forward.</p> <p>➤ <b>If YES</b> &gt; Patient Check-In Process completed; pick-up on Step 7 to complete Check-Out Process.</p>
<b>PATIENT CHECK-OUT</b>	
7.	<p>Is today the Patient's discharge day?</p> <p>➤ <b>If NO</b> &gt; Skip to Step 11 of this SOP</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 8 of this SOP</p>
8.	<p>Office Manager provides Patient with Satisfaction Survey and Doctor's letter of treatment.</p> <ul style="list-style-type: none"> <li>• Has Office Manger completed the following discharge steps? <ul style="list-style-type: none"> <li>✓ Patient is given instructions to complete Satisfaction Survey and Media Release to hand back to Office Manager prior to departure;</li> <li>✓ Is provided with correct Doctor's letter of LI treatment completed; and</li> <li>✓ Completed Patient Flow Chart &amp; Scan into EMR.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 9 of this SOP</p>
9.	<p>Office Manager obtains Media Release and Patient photo, if Patient is in agreement.</p> <ul style="list-style-type: none"> <li>• Has the Office Manager obtained the following? <ul style="list-style-type: none"> <li>✓ Patient Testimonial Authorization Form (if Patient is in agreement); and</li> <li>✓ Taken a photo of Patient for approved use.</li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 10 of this SOP</p>

<b>10.</b>	<p>Office Manager updates systems to record Patient treatment status, PFT results, and survey responses.</p> <ul style="list-style-type: none"> <li>• Has Office Manger completed the following steps in the CRM System? <ul style="list-style-type: none"> <li>✓ Review and complete missing demographic information in the “Contacts” module;</li> <li>✓ Update “Potentials” Module with Patient Treatment Status (e.g.: Completed);</li> <li>✓ Updated the “Treatment Complete Date”</li> <li>✓ Create a “Case” <ul style="list-style-type: none"> <li>a) Search Patient/Select Correct Patient</li> <li>b) Enter Subject (Should match the selected “Survey Subject” data field below)</li> <li>c) Enter Case Origin (In Person)</li> <li>d) Status</li> </ul> </li> </ul> </li> </ul> <p>➤ <b>If NO</b> &gt; Step must be completed prior to moving forward.</p> <p>➤ <b>If YES</b> &gt; Proceed to Step 11 of this SOP</p>
<b>11.</b>	<p>Office Manager updates EMR with Patient check-out.</p> <ul style="list-style-type: none"> <li>✓ Has Office Manager checked-out Patient in EMR system?</li> </ul> <p>➤ <b>If NO</b> &gt; Office Manager must update EMR as required to complete this SOP.</p> <p>➤ <b>If YES</b> &gt; SOP is complete.</p>
<b>Notes:</b>	
<b>Related Documents:</b> P&P CL-005	

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## CONSENT TO PARTICIPATE IN RESEARCH

**General Information** Please read this form carefully. To be in a research study you must give your informed consent. **“Informed consent” includes:**

- Having the study doctor or staff explain the research study to you
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This give you time to think about it and talk to family or friends before you make your decision.

**You should not join this research study until all of your questions are answered.**

**Things to know before deciding to take part in a research study:**

- The main goal of regular medical care is to help each patient.
- No one can promise that this treatment or research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- During your treatment you will receive standard medical care. Standard care is the treatment normally given for a certain condition, such as a medical emergency.

- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

**After reading and discussing the information in this consent form you should know:**

- Why this research study is being done and why this consent is required
- What will happen during the research
- What treatment procedures will be used
- Any possible benefits to you
- The possible risks to you
- The other medical procedures, drugs or devices that could be used instead of being in this research study
- How potential problems will be treated during the study and after the study is over.

If you are pregnant, or have reason to believe that you may be pregnant, you must notify the Lung Institute Principle Investigator immediately.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

Any significant new findings developed during the course of the research which may relate to your willingness participate will be provided to you.

## **Study Description**

This study involves exploring the outcomes of treatment using your body's own, unaltered stem cells to promote repair of damaged lung tissue from chronic lung disease. The aim of the study is an improvement in your pulmonary function and quality of life after treatment.

### ***This Study Involves Research***

Because this study uses cells from your own body, we are exempt from Food and Drug Administration (FDA) oversight. In the state of Texas, whenever stem cell treatment is used it is considered investigative and strict procedures and oversight of your treatment are required and ensured. In addition, we will be tracking data on the outcomes of all of our treated patients in order to inform future patients and the future of stem cell medical therapy.

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LI-001

## **Study Procedures**

### **How many participants will be enrolled in the study?**

Approximately 200 patients will be enrolled in the study.

### **What will I be asked to do if I participate in the study?**

The application of autologous (patient's own) stem cells is performed to diminish inflammation and improve pulmonary function. The application of stem cells can be utilized as a stand-alone procedure or as an adjunct to other procedures.

### **What is the purpose of this study?**

The purpose of this study is to obtain information regarding the efficacy of stem cell treatments for treating COPD and ILD. The application of autologous (patient's own) stem cells is performed to diminish inflammation and improve pulmonary function. The application of stem cells can be utilized as a stand-alone procedure or as an adjunct to other procedures.

## How long will I be asked to participate in this study?

Treatments are conducted over the course of three days; thereafter, you will be expected to provide Lung Institute with feedback regarding your progress, specifically as it relates to your quality of life improvements and PFT results. Feedback will be obtained over the course of six months, and up to a year. Outreach to obtain results will be conducted at a minimum of 2 weeks, 3 months, and 6 months.

## Consent

I understand that LI will perform the following type(s) of study procedures (please check one):

### Harvesting of Bone Marrow

- Aspiration of bone marrow from hip
- Processing aspirate to isolate stem cells
- Administration of autologous stem cells to patient
- Venous Treatment (see procedure details below)

### Venous

- Drawing of blood
- Processing blood to separate stem cells
- Administration of PRP (Platelet Rich Plasma) to patient

Data will be collected on your medical diagnosis, pulmonary function test results before and after treatment, and your perceived quality of life scores before and after treatment. We will follow up with you by phone two weeks, three months and six months after your treatment to collect this information.

## Risks and Minimizing Risks

### What risks will I face by participating in this study?

Although there are risks associated with the application of stem cell treatments, the risks are minimized by applying autologous stem cells same day and additional risk factors may be mitigated with appropriate protocols focused on patient safety; therefore the overall risk to benefit relationship results in a treatment with minimal risks which can improve a patient's quality of life.

- **Abdominal or pelvic organ perforation** - Stem cells harvested from bone marrow are obtained from the pelvis (posterior iliac crest). There is a small risk of organ (bowel, bladder, ureter, urethral) perforation when obtaining the bone marrow from the pelvis. Perforations may not be diagnosed immediately. This risk is low. All perforations require surgical repair. This risk is minimized by careful introduction of the harvesting needle into the bone marrow and by extensive training of the providers.
- **Adverse reaction to stem cells** - There is a possibility of an adverse reaction to the application of stem cells. This risk is minimized by using autologous (your own) unaltered stem cells.
- **Anemia** - There have been reports of anemia with harvesting of stem cells from the circulation. This risk is low. To minimize this risk we request blood work (CBC).
- **Bleeding** - It's possible, though unusual, to experience an episode of bleeding, which may be excessive, during or after a procedure or treatment. Bleeding may require additional treatment

or transfusion of blood or blood products. Certain medications, such as aspirin, anti-inflammatory drugs, or blood thinners may increase the risk of bleeding. This risk will be minimized by a review of your medical history and medications prior to your procedure as well as the application of appropriate pressure to the treatment site whenever bleeding could occur.

- **Blood clot development** - Blood clots may occur with any type of procedure or treatment. Clots can block blood flow and cause complications, including pain, swelling, inflammation, tissue damage, pulmonary emboli, or death. We will minimize this risk by utilizing safe and appropriate treatment modalities.
- **Cardiac complications** - There is a small chance that having the procedure could cause an irregular heartbeat or a heart attack. To minimize this risk we obtain EKG.
- **Death** - Although the risk is remote, death may occur during or soon after any procedure or surgical procedure. We will minimize this risk by using safe and appropriate treatment modalities.
- **Dizziness** - Dizziness after blood donation may occur. It has also been reported after harvesting of stem cells from the bone marrow. It usually responds to IV fluids. You can minimize this risk by ensuring that you are well-hydrated and have eaten the day of your procedure.
- **Embolus development** - An embolus is a clot that can be from blood or cells such as bone marrow. There is a chance that an embolus or emboli (plural) may develop with stem cell procedures. This risk is low and is minimized due to our stem cells processing protocols.
- **Failure of the procedure** - There is a chance that undergoing stem cell application will not alleviate symptoms, reduce inflammation or improve lung function. Recurrence of pulmonary symptoms may recur.
- **Fever** - Fever associated with stem cell harvesting usually responds to acetaminophen. If fevers persist, a work-up for infection must be completed.
- **Fracture** - Fracture of the bone where the bone marrow is harvested can lead to significant pain and possibly the need for surgery. This complication is not common and will likely heal with simple activity modification. This risk will be minimized by careful introduction and removal of the harvesting needle into and out of the bone and only after extensive training of the provider.
- **Hypotension** - Hypotension or low blood pressure has been reported after harvesting of stem cells from the bone marrow. It usually responds to IV fluids. This risk can be minimized by ensuring that you are well-hydrated and have eaten the day of the procedure.

- **Infection** - Infection may occur at the donor site where the bone marrow was harvested or at the IV site and recipient site of application. To minimize risk infection prevention protocols are maintained and followed during the treatment process and patient education is provided on post treatment cleaning and wound care.
- **Pain** - Any procedure can result in pain. To minimize this risk we ask that our patients communicate any discomfort so that we can reduce or mitigate.
- **Nausea/vomiting** - Nausea and vomiting have been reported with bone marrow harvesting. This is usually temporary and responds to supportive care. Again, this can be minimized with good hydration and nutrition the day of the procedure.
- **Numbness/tingling** - Although a low risk, this has been reported with leukapheresis (the process of separating stem cells from peripheral blood in the vein). Laboratory analysis may be required along with calcium infusion.
- **Respiratory difficulties** - Breathing difficulties (which are usually temporary) or post-operative pneumonia, may occur as a result of any procedure or surgery. Pulmonary embolus, a blood clot causing blockage of an artery in the lungs may occur as a result of any procedure or surgery. Pulmonary embolus may be fatal.

- **Scar Formation** - Scar tissue forms as a part of the natural healing process after any procedure, surgery, or injury. In rare circumstances, some patients can form excessive amounts of scar tissue that can be a source of pain. Scarring can be minimized by massage and applying vitamin E oil to the site after the incision has healed completely. Unfortunately, not all scarring can be prevented.
- **Soreness** - Pain at the site of stem cell harvesting or site of application will occur. It is unlikely to be permanent. We will minimize this risk using local anesthetic during the procedure.
- **Stroke** - Though a low risk and unlikely, there is a possibility that a stroke will occur during the procedure or in the recovery period.
- **Transfers of undiagnosed cancer** - There is a risk that undiagnosed cancer in the area where the stem cells are harvested may be transferred to the recipient's area of transplantation. To minimize risks, stem cells will not be altered in any way, thereby reducing the risk of tumor induction by carcinogens.
- **Administration of incorrect stem cells** - The stem cells administered are the recipient's own stem cells. There is a low risk of administration errors. Materials are clearly marked before they leave the procedure room, eliminating the risk of a recipient receiving someone else's stem cells in error.
- **Tumorigenicity** - There is no evidence that point-of-care adult stem cells cause tumors. Initial concerns on tumorigenicity (formation of tumors) after adult stem cell therapy decreased as experimental and clinical data have revealed no such complication reported to date. Human mesenchymal stem cells can undergo spontaneous transformation following long-term in vitro (out of the body) culture of approximately 4-5 months. Your stem cells will not be cultured and will be used immediately during the procedure, thereby minimizing this risk.
- **Unintended differentiation** - Stem cells are cells that have the ability to develop into one of several different types of cells. The cells may transplant into an area of the body and start to grow into certain types of cells that we do not want them to grow into. Although rare, in a single study it was found that bone-marrow harvested stem cells transplanted into rats caused a calcification, or hardening, of the cells of the rat's heart that was not intended. Though a low risk, unintended differentiation could occur in areas of stem cell implantation.
- **If Pregnant** - Or may become pregnant, there may be risks to you, the embryo, or fetus that are unforeseeable. *If you are pregnant, or have reason to believe that you may be pregnant, you must notify the Lung Institute Principle Investigator immediately.*

## Benefits

- **Increased Activity** - Ability to be more physically active; walking greater distances.
- **PFT** - Improvement in their FEV1 5-10% or more.
- **Oxygen** - Ability to reduce their use of oxygen and possibly to stop it.
- **Reduction in Medications** - Ability to function well without the use of their bronchodilator inhalers and Prednisone.
- **Increased Pulmonary Health** - Reduction or ceasing of secondary pulmonary infections

## Source of Fundy for the Study

### Will I be charged anything for participating in this study?

There is no cost to you to participate in the data collection and investigation of your response to treatment.

At this time, insurance companies are not covering the cost of stem cell therapy therefore the cost of treatment is the responsibility of the patient. It will likely be a few more years

before insurance covers the cost of stem cell treatment. If you have questions about this, a patient coordinator will be able to help.

**Are subjects paid or given anything for being in the study?**

No. You are not given any payments for your participation during or after the study.

**Confidentiality**

**What happens to the information collected?**

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. We may decide to present what we find to others, or publish our results in scientific journals or at scientific conferences. Only the Principal Investigator and clinic staff will have immediate access to the information. However, the Institutional Review Board or appropriate federal agencies like the Office for Human Research Protections may review your records.

**Why is my information collected?**

It is important to us and to the future of stem cell therapy that we track your response to treatment over time. This information will be used to inform future patients and the medical community of the results of stem cell treatment for chronic lung disease.

**How is my information protected?**

The protection of confidential health information is of the highest importance. Your electronic medical record is protected by safeguards to ensure that only the staff that are required to view your records do so. Oversight of clinic staff and of your protected health information is enforced by the Compliance Department of Regenerative Medicine Solutions and by the Institutional Review Board.

**How am I protected?**

Clinic staff are trained in the protection of human subjects in research. The Compliance Department and Institutional Review Board ensure that clinic staff protects both you and your health information during your treatment.

**DHHS REQUIRED STATEMENT**

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.

**Alternatives**

**Are there alternatives to participating in the study?**

- Using medication to assist with symptoms;
- Lung Transplant/Lung Reduction Surgery
- Undergoing physical therapy (Pulmonary Rehabilitation);
- Acupuncture;
- Mind-body medicine;
- Chiropractic treatment;
- Lifestyle modification;
- Nutritional modification/supplements;
- Hypnosis; and
- Interactive guided imagery.

## **Voluntary Participation and Withdrawal**

### **What happens if I decide not to be in this study?**

Your participation in this study is entirely voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. If you decide not to participate in the study, it will not affect the resources available to you, your care received at the clinic nor your relationship with the clinic.

## **Involuntary Withdrawal**

### **Under what circumstances would my participation in the study be withdrawn without my consent?**

If you decide not to participate in the feedback portion of this study, your participation may be terminated due to Lung Institute's inability to gather information regarding your progress which would be necessary to gather results data and to identify the efficacy of our treatments.

## **Questions**

### **Who do I contact for questions about this study?**

For more information about the study or the study procedures or treatments, or to withdraw from the study, please contact:

Melissa Rubio, PhD,  
FNP Principal  
Investigator Lung  
Institute  
(Phone number email etc)

**Who do I contact for complaints about Lung Institute and my stem cell treatment?** At the Lung Institute, you may contact our Compliance Department at (855) 469-5864. *By law, you cannot be penalized for filing a complaint.*

### **Who do I contact for questions about my rights or complaints towards my treatment as a research subject?**

*The Institutional Review Board may ask your name, but all complaints are kept in confidence.*

#### **MaGil IRB Contact Information**

Phone: 731-624-4584  
Email: subjects@magilirb.com  
Address: Chairperson  
MaGil IRB, Inc.  
2275 Research Blvd., Suite 700  
Rockville, MD 20850

## **Signatures**

### **Research Subject's Consent to Participate in Research:**

*To voluntarily agree to take part in this study, you must sign on the line below. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read or had read to you this entire consent form, including the risks and benefits, and have had all of your questions answered, and that you are 18 years of age or older.*

\_\_\_\_\_ Printed Name of  
Subject/Legally Authorized Representative

\_\_\_\_\_  
Signature of  
Subject/Legally Authorized Representative Date **Principal Investigator (or Designee)**  
*I have given this research subject information on the study that is accurate and sufficient for the subject to fully understand the nature, risks and benefits of the study.*

\_\_\_\_\_  
Printed Name of Person  
Obtaining Consent Study Role

\_\_\_\_\_  
Signature of Person  
Obtaining Consent Date



**Study Sponsor:** Lung Institute

8140 Walnut Hill, Suite 570  
Dallas, TX 75231 USA

**PI:** Melissa Rubio, PhD, APRN, FNP  
Lung Institute  
8140 Walnut Hill, Suite 570  
Dallas, TX 75231 USA

**Protocol Number:** LI-001

**Study Title:** Autologous Stem Cell Treatment For Chronic Lung Disease Study

**Date:** 12Feb2016

MaGil IRB reviewed the study named above via **Full Board Review** on **12Feb2016**. This letter serves as proof the study meets all criteria for approval and was approved, at that time, with no additional restrictions on the conduct of the study. This study has been approved to be conducted **in English only** at the following site:

***Lung Institute***

***8140 Walnut Hill, Suite 570***

***Dallas, TX 75231***

***USA***

As a condition of MaGil IRB's approval, you are required to use and abide by the enclosed, approved documents stamped with "Approved MaGil IRB."

- ***LI-001 - Lung Institute Research Protocol\_Rev 2-5-16 - Version 1.0 - APPROVED - 12Feb2016***
- ***LI-001 - Adipose Extraction Procedure (SOP\_2016)\_Rev 1-7-16 - APPROVED - 12Feb2016***
- ***LI-001 - Bone Marrow Aspirate Procedure (SOP\_2016)\_Rev 1-7-16 - APPROVED - 12Feb2016***
- ***LI-001 - Venous Procedure (SOP\_2016)\_Rev 1-7-16 - Version 1.0 - APPROVED - 12Feb2016***
- ***LI-001 - CL-005 - A-ASC Procedures\_Rev 2-5-16 - Version 1.0 - APPROVED - 12Feb2016***
- ***LI-001 - CONSENT TO PARTICIPATE IN RESEARCH FORM-Rev 2-12-16 - Version 1.0 - APPROVED - 12Feb2016***

- **LI-001 - 10082015\_Privacy&SecurityNotice - APPROVED - 12Feb2016**
- **LI-001 - 090815\_TestimonialAut&MediaRelease - Version 1.0 - APPROVED - 12Feb2016**
- **LI-001 - Web-Contact Submittal Thank You Page - Version 1.0 - APPROVED - 12Feb2016**
- **LI-001 - PC Script\_Rev 1-11-16 - Version 1.0 - APPROVED - 12Feb2016**

The IRB has determined that your study is of **Greater Than Minimal Risk** and has been assigned an approval period of **12 months (365 days)**. Please be aware that this study's IRB approval will therefore expire on **04Feb2017**. As a reminder, you will receive a Continuing Review Report Form (CRRF) approximately sixty days before the study's IRB approval period ends. The sponsor and/or designee is responsible for completing the CRRF and returning it to MaGil IRB along with the necessary materials for a continuing review re-approval prior to the due date printed on the CRRF.

**Note: The IRB reviewed the following documents;**

- **LI-001 - OP-002 - Emergency Preparedness\_final**
- **LI-001 - OP-004 - Incident Reporting\_TX**
- **LI-001 - OP-005 - Patient Consent\_Rev 1-11-16 (IRB)**
- **LI-001 - OP-006 - Privacy and Security Practices\_final**
- **LI-001 - OP-007 - Patient Grievance Process\_TX**
- **LI-001 - OP-009 - Patient Media and Referral, Consent and Use\_final**
- **LI-001 - OP-011 - Corrective Action Plan\_final**
- **LI-001 - OP-012 - Quality Improvement & Risk Management Program\_final**
- **LI-001 - OP-013 - Compliance Program\_final**

**PLEASE NOTE:**

- ***The CRRF must be received by the due date printed on your form to allow sufficient time for our IRB panels to review your study for continuing review approval before your initial or most recent approval expires.***
- ***If the CRRF is not received and reviewed before the study's approval expiration date, your study's approval will have expired, barring continuation of the study until a new approval is issued.***
- ***Continuing research after expiration of IRB approval is a violation of federal law.***
- ***Missed CRRF submission deadlines are the sole responsibility of the Sponsor and/or designee regardless of whether or not the IRB notifies you.***

You are obligated to notify MaGil IRB of the following occurrences:

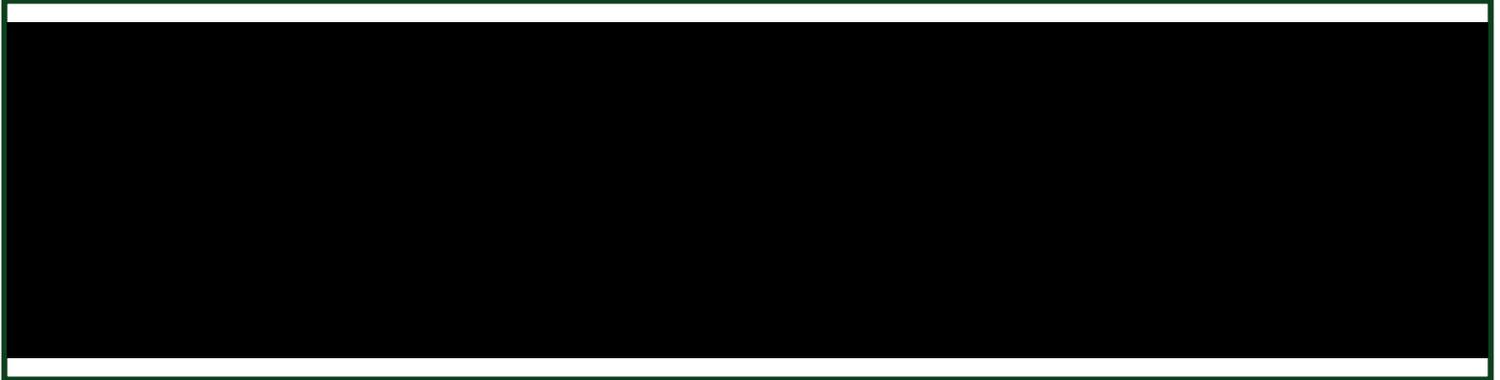
- Any and all amendments or changes to the protocol, investigator guide, or consent/assent scripts (all changes must receive IRB approval before implementation).
- Any and all changes to the protocol that are implemented without prior IRB approval to eliminate an apparent immediate hazard to subjects – *must be reported within 24 business hours of implementation*
- Related (Possible, Probable or Likely) Serious Adverse Events and unexpected and related Adverse Events – *must be reported within 5 business days from the date of discovery*
- Significant Protocol Deviations/Violations – *must be reported within 5 business days from the date of discovery*
- Unanticipated Problems involving risks to subjects or others – *within 5 business days of discovery*
- All materials used to recruit study subjects – *these items must receive IRB approval before being used*
- Any and all changes in the research activity

The Principle Investigator (PI) is bared from making any changes in research, without prior approval of MaGil IRB, except when it is necessary to eliminate immediate risk to study subjects. In addition, it is the responsibility of the

PI to uphold the following three ethical principles outlined in the Belmont Report throughout the entire conduct of this study:

- **Respect for Persons** – individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- **Beneficence** – maximize possible benefits and minimize possible harms.
- **Justice** – benefits and burdens of research should be distributed equally.

MaGil IRB is a resource to assist you in protecting research subjects and carrying out ethical research. Please don't hesitate to contact us for help.



Signature: Pia Mikkelsen Lynch

Pia Mikkelsen Lynch (Feb 14, 2016)

**Email: Title: Company:**

