PARTICIPANT INITIALS _____

Consent to Participate in Research

Sponsor / Study Title:	**Lung Institute Dallas / "An Observational Outcomes Study For Autologous Cell Therapy Among Patients With COPD And Interstitial Lung Disease: Cohort B Study Investigator(s)"**
Protocol Number:	**LI-002**
Principal Investigator: **Co-Principal Investigator:** **Co-Principal Investigator:**	**Melissa Rubio, PhD, FNP** **Thomas Stauss, MD** **Theodore Piliszek, MD**
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Site:	☐ **Lung Health Institute Dallas** **8140 Walnut Hill Lane, Suite 570 Dallas, TX 75231** ☐ **Dr. Thomas Stauss** **1239 Corporate Center Dr. Oconomowoc, WI 53066** ☐ **Advanced Health and Wellness** **13661 Vermarion Houston, TX 77070**

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 investigator or study staff explain the research study to you
- Asking questions about anything that is not clear, and
- Taking home a copy of this consent form. **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:**
- No one can promise that this study 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 study 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 study treatment procedures will be used
- Any possible benefits and risks
- 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 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 study which may relate to your willingness to participate will be provided to you.

Study Description

Sponsor: Lung Health Institute **Protocol Number:** LI-002

Title: An Observational Outcomes Study for Autologous Cell Therapy Among Patients with COPD and Interstitial Lung Disease

This study involves exploring the outcomes of study treatment using your body's own, minimally manipulated cells to promote repair of damaged lung tissue from chronic lung disease. The aim of the study is an improvement in your pulmonary (lung) function and quality of life after study 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 study treatment are required and ensured. In addition, we will be tracking data on the outcomes of all of our treated participants in order to inform future patients and the future of cellular medical therapy.

Study Procedures

WHAT WILL I BE ASKED TO DO IF I PARTICIPATE IN THE STUDY?

Participants in this study are asked to provide Lung Health Institute with feedback regarding progress, specifically as it relates to quality of life improvements and PFT (lung function test) results. Feedback will be obtained over the course of six months, and up to a year. Data will be collected on your medical diagnosis and pulmonary function test results before and after study treatment, and your perceived quality of life scores before and after study treatment. Study treatments are conducted over the course of 2 days. Thereafter, we will follow up with you by phone at a minimum of two weeks, three months and six months after your study treatment to collect this information.

Consent

I understand that Lung Health Institute (LHI) will perform the following type(s) of study procedure:

VENOUS STUDY TREATMENT

- Drawing of blood
- Processing blood to separate cells
- Administration of PRP-PC (Platelet Rich Plasma-Platelet Concentrate) to participant

Data will be collected on your medical diagnosis, pulmonary function test results before and after study treatment, and your perceived quality of life scores before and after study treatment. We will follow up with you by phone two weeks, 3 months, 6 months, 12 months, 2 years, 4 years and 5 years after your study 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 cell treatments, the risks are minimized by applying your autologous cells in the same day that they are extracted and minimally processed and through safety protocols.

Common Risks:

- **Bleeding** - It's possible, though unusual, to experience an episode of bleeding, which may be excessive, during or after a procedure or study treatment. 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 procedures during your study treatment.
- **Dizziness** - Dizziness may occur after harvesting of cells. 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.
- **Hypotension** - Hypotension or low blood pressure has been reported after harvesting of cells. 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.
- **Nausea/vomiting** - Nausea and vomiting have been reported with cell 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.
- **Soreness** - Pain at the site of cell harvesting or site of application will occur. It is unlikely to be permanent.

Rare Risks

- **Adverse reaction to cells** - There is a possibility of an adverse reaction to the application of cells. This risk is minimized by using autologous (your own) minimally manipulated cells.
- **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 treatments.
- **Embolus/blood clot development** - An embolus is a clot that can be from blood or cells. There is a chance that an embolus or emboli (plural) may develop with cell procedures. Clots can block blood flow and cause complications, including pain, swelling, inflammation, tissue damage, pulmonary emboli (a blood clot causing blockage of an artery in the lungs) or death. This risk is low and is minimized due to our cell processing protocols.
- **Failure of the procedure** - There is a chance that undergoing cell application will not alleviate symptoms, reduce inflammation or improve lung function. Recurrence of pulmonary (lung) symptoms may recur.
- **Fever** - Fever associated with cell harvesting usually responds to acetaminophen (for example, Tylenol). If fevers persist, a work-up for infection must be completed.
- **Infection** - Infection may occur at the IV site and the site of application of your cells. To minimize risk infection prevention protocols are maintained and followed during the study treatment process.
- **Pain** - Any procedure can result in pain. To minimize this risk, we ask that our participants communicate any discomfort so that we can reduce or mitigate (lessen).
- **Numbness/tingling** - Although a low risk, this has been reported with leukapheresis (the process of separating 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 cells are harvested may be transferred to the participant's area of transplantation. To minimize risks, cells will not be altered in any way, thereby reducing the risk of tumor induction by carcinogens.

- **Tumorigenicity** - There is no evidence that point-of-care adult cellular therapy causes tumors. Your cells will not be cultured and will be used immediately during the procedure, thereby minimizing this risk.
- **Unintended differentiation** – Stem cells and progenitor cells are cells that can 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.

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

Potential Benefits

You may or may not benefit as a result of your participation in this study.

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

Source of Funding 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 study treatment.

Currently, insurance companies are not covering the cost of cellular therapy for chronic pulmonary diagnosis; therefore, the cost of study treatment is the responsibility of the participant. If you have questions about this, a patient coordinator will be able to help.

WHAT SERVICES ARE COVERED UNDER PAYMENT OF INVESTIGATIVE CELLULAR THERAPY?

Payment in full for investigative cellular therapy accounts for medical, surgical, facility, and office services rendered by Lung Health Institute (LHI) for consented procedures. Additional medical services rendered by external providers and facilities are not covered under your investigative cell therapy payment, and therefore fall under participant's financial responsibility. Should additional medical services be required due to injury sustained at an LHI facility, LHI will agree to review the case and decide for possible reimbursement of related, reasonable, and necessary medical expenses not routinely covered by insurance for the required tests and study treatments; however, participants should assume they will not receive reimbursement for study-related injuries. To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You will not lose any of your legal rights or release the sponsor, the Investigator, the study staff, or study site from liability for mistakes by signing this consent document.

ARE PARTICIPANTS PAID OR GIVEN ANYTHING FOR BEING IN THE STUDY?

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

Alternatives

ARE THERE ALTERNATIVES TO PARTICIPATING IN THE STUDY?

- Not having the procedure; Conservative Treatments and Medications
- Lung Transplant/Lung Reduction Surgery;
- Undergoing physical therapy (Pulmonary Rehabilitation)

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 study 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 cellular therapy that we track your response to study treatment over time. This information will be used to inform future patients and the medical community of the results of cellular 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 study staff that are required to view your records do so. Oversight of clinic study 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 study staff are trained in the protection of human participants in research. The Compliance Department and Institutional Review Board ensure that clinic study staff protects both you and your health information during your study treatment.

WHAT ARE MY RIGHTS?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision to stop participation in follow-up activities. Choosing to stop participation in follow-up will not result in any penalty to you or loss of benefits. Specifically, your choice will not negatively affect your right to any present or future participation.

Department of Health and Human Services (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.

The study investigator will discuss the risks and benefits of alternate treatments with you.

Questions

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document or pidallas@thelunghealthinstitute.com.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00022039.

WHO DO I CONTACT FOR COMPLAINTS ABOUT LUNG INSTITUTE AND MY CELLULAR THERAPY 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.

Signatures

RESEARCH PARTICIPANT'S CONSENT TO PARTICIPATE IN RESEARCH:

To voluntarily agree to take part in this study, you must sign and date 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 Participant

_____ _____

Signature of Participant Date

PRINCIPAL INVESTIGATOR (OR Study DESIGNEE)

I have given this research participant information on the study that is accurate and sufficient for the participant 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