UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

(For Healthy Volunteers)

Study Title: Fibroblast specific inhibition of LOXL2 and TGFbeta1 signaling in patients with pulmonary fibrosis.

Protocol Number:	17-23008
Version Date:	01/30/2018
Investigational Product:	Epigallocatechin-3-gallate (EGCG)
IND Number:	144120
NCT Number:	NCT03928847

Research Project Director:	Harold A. Chapman, M.D., Professor of Medicine. UCSF, Room 201, 513 Parnassus Ave, San Francisco, CA. Phone: 415.514.1210; e-mail: hal.chapman@ucsf.edu

Study Coordinator:	Ying Wei, Phone: 415.514.1209 ying.wei@ucsf.edu Fizaa Ahmed, Phone: 415.502.1958 fizaa.ahmed@ucsf.edu

This is a clinical research study. Your study doctor(s), Harold Chapman [MD], Harold Collard [MD], Jasleen Kukreja [MD] from the UCSF Department of Medicine, will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are a healthy adult between 40-70 years old and you have responded to our flyer advertisement. The investigators want to figure out the best oral dose of epigallocatechin gallate (EGCG) to reach optimal blood level in healthy people. Then they will give that dose to patients with lung fibrosis (scarring on lungs) and test if EGCG which can reduce lung scarring on animals can do the same on patients with this disease. EGCG is a principal component of Green Tea and can be obtained online as a food supplement.

Why is this study being done?

Studies from UCSF show that EGCG can block lung scarring (fibrosis) in experimental animals. The purpose of this study is to get to know if EGCG will also block lung scarring in humans if

EGCG is given before scheduled diagnostic surgery of patients with signs of lung scarring on X-rays. EGCG is a widely used, and commercially available, dietary supplement enriched in green tea. It is hoped that the information gained from these studies will lead to the development of a new treatment approach and a larger scale true clinical trial of EGCG in lung fibrosis.

This study is being supported by federal funding from the National Institute of Health and a gift from Three Lakes Partners, a foundation devoted to developing new drugs to treat lung fibrosis disease. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.

How many people will take part in this study?

About 15 people will take part in this study.

What will happen if I take part in this research study?

Procedure	Screen	Treatment Period (hours)			
		0	0.5	2	4
Informed Consent	x				
Eligibility Assessment	x				
Age	x				
EGCG Administration		x			
Blood Collection		x	x	x	x

If you agree to participate in this study, you will be asked not to eat or drink anything other than water after midnight the night before your study visit. You will be giving EGCG pills at 8 AM and will be allowed to eat and drink at 10 AM after 2-hour blood draw. You must not drink green tea or eat green tea or cocoa product. The following will happen:

Schedule of Study for Healthy Volunteers

- **EGCG administration**: If you agree, 3-5 capsules of EGCG (total 450 mg, 600 mg, or 750 mg) will be given to you orally one time, blood specimens will be drawn at 0 hour, 1/2 hour post dose, 2 hours post dose, and 4 hours post dose (see Schedule of Study).

- **Blood drawing (venipuncture):** Blood sample will be drawn at ILD clinic by inserting a needle into a vein in your arm. Each sample will be approximately 3 teaspoons; there will be a total of 12 teaspoons drawn for this study.

- **Specimen storage**: Your specimens will be labeled with a unique identifying number and stored in a locked freezer located in the Health Science East Building at 513 Parnassus Avenue.

- **Experimental research**: Blood samples will be processed and blood level of EGCG will be measured. Reports about any research will not be given to you. Your specimen will be kept until it is used up or destroyed at the end of the study and it will not be used for commercial purposes without your express consent.

How long will I be in the study?

You will be asked to take EGCG once early in the day and stay for 4 hours until the last blood drawn.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from EGCG can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- **Adverse effects from EGCG**: There is potential risk for adverse effects from oral ingestion of EGCG. Previous trials taking 800 mg EGCG per day and lasting 6 months to a year in patients noted no adverse effects. It appears mild liver transaminitis (elevated levels of liver enzymes, can be an indicator of liver disorders) may occur but this is rare.

  You should talk to your study doctor about any side effects you experience while taking part in the study.

- The following are the risks of your participation in the study. If you have questions regarding these risks, the investigators or other designated research personnel will answer these questions:

  Physical risks: The risks of venipuncture (obtaining blood with a needle) include temporary discomfort from the needle stick, bruising, and rarely, infection.

  Confidentiality: Donating specimens may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your name will not be used in any published reports from research performed using your specimen. The manager of the tissue bank and select tissue bank staff members will have access to information about

you but they will not release any identifying information about you to researchers using your specimen. The UCSF Committee on Human Research may see information about you to check on the tissue bank. The tissue bank staff will protect your personally identifiable health information as described in this consent form.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

There is no direct benefit at present for you individually. There is the potential for improved therapy of pulmonary fibrosis progression if EGCG has the predicted biological impact and for a new non-invasive biomarker (a measurable substance indicative of disease) to track drug responses that may benefit future subjects with IPF.

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

If you choose not to participate this study, your blood specimens will be thrown away.

How will information about me be kept confidential?

All records will be coded and permanently kept in locked files with access limited to the study investigators. All collected specimens will be assigned a corresponding code number by the study investigators and will then be processed without knowledge of your identity. Only the UCSF investigators who are part of this study have access to the records that link this coded ID number to you during the study.

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

Will any research-related procedures be billed to me?

No. The sponsor has agreed to pay for EGCG capsules and all procedures associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

You will be paid $200 for participating this study. If any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

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

It is important that you tell your study doctor, Dr. Harold Chapman, Dr. Harold Collard, or Dr. Jasleen Kukreja, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call Drs. Chapman, Collard, and Kukreja at 415-514-1210.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to Dr. Harold Chapman about any questions or concerns you have about this study. You may call Dr. Chapman at 415-514-1210.

For questions about your rights while taking part in this study, call the office of the **Committee on Human Research**, UCSF's Institutional Review Board (a group of people who review the research to protect your rights) at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will also be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent