

TARGETING PRO-INFLAMMATORY CELLS IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF)

Informed Consent Form to Participate in Research
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INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have idiopathic pulmonary fibrosis (IPF), are age 50 or older and have expressed interest in the study. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

Medical scientists have found that most cells in your body turn over rapidly, but with age some cells become inflamed. This means the cells no longer turn over and can become destructive to nearby cells, creating more inflamed cells and releasing signals that can increase inflammation in the rest of the body. Patients with IPF have even greater numbers of inflamed cells than other older people, but researchers are not sure how this affects their disease.

Researchers have found ways to eliminate the cells in the body that have become inflamed and destructive; the most effective way to target these cells in animals is to use a combination therapy of dasatinib and quercetin. Dasatinib is a chemotherapy drug currently used to treat leukemia. Dasatinib has been approved by the US Food and Drug Administration (FDA), but it has not been approved for use in IPF or for use to reduce the number of inflamed cells. Quercetin is a flavonoid found in black currants, cilantro, red onion, watercress, cranberries and other fruits and herbs, and is “generally recognized as safe” by the Food and Drug Administration (FDA).

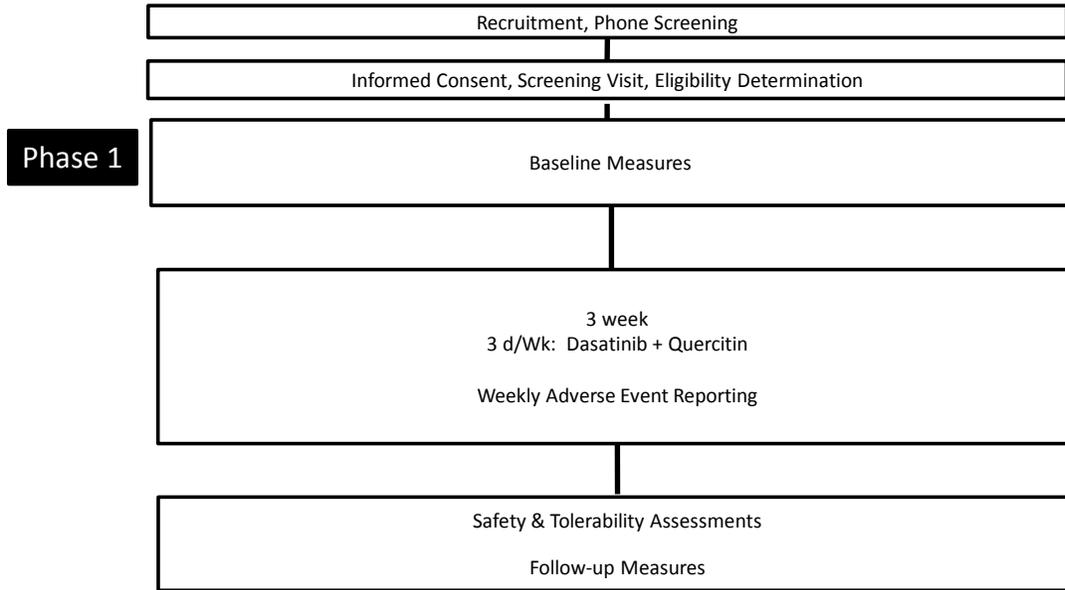
In animal models of IPF and aging, dasatinib and quercetin can reduce the number of inflamed cells and improve endurance, but the combination treatment has never been studied in people. The purpose of this research study is to test the safety of dasatinib and quercetin and see what effects (good and bad) it has on you, the number of inflamed cells you have and your IPF.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

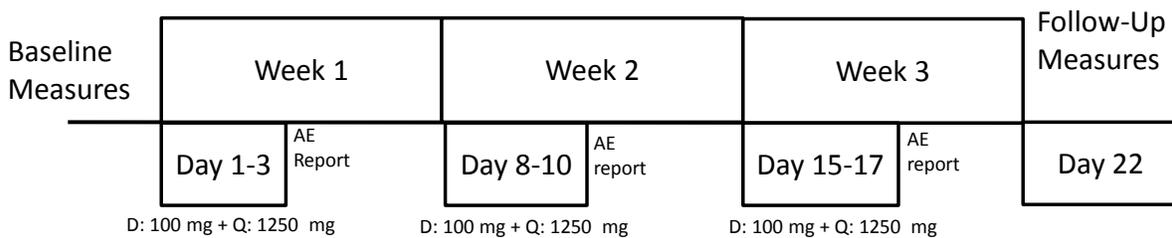
A total of 20 people at 2 research sites (Winston-Salem, NC and San Antonio, TX) will take part in the study, including approximately 5 people at Wake Forest Baptist Medical Center. In order to identify the 5 subjects needed, we may need to screen as many as 40 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study by signing this consent form, you will be asked to complete screening visit to see if you qualify for the study. You will then complete a baseline visit before beginning the intervention. You will then complete three weeks of drug intervention. After the drug intervention period the tests conducted at baseline will be repeated in a follow-up visit. An overview of the study is below:



During the dasatinib (D) and quercetin (Q) intervention period, you will take your required doses for three consecutive days on three consecutive weeks. After your third day of taking the study drugs each week we will ask you about any side effects, or adverse events (AE) you may experience. An overview of the drug intervention strategy is shown below:



The details about all study visits and procedures are provided below. We will make every effort to follow the visit procedures in the order they are outlined below; however, it may be necessary at times to make changes to accommodate different schedules. If you take part in this study, you will have the following tests and procedures:

Screening Visit (SV)

We will ask that you come to the Sticht Center having fasted for at least 8 hours prior to your appointment time, with nothing to eat or drink except water. You will learn all the details of the study and you will be given time to ask any questions and get satisfactory answers. Then, you will be asked to sign this informed consent form if you qualify for the study. After signing the consent form, we will:

- Draw blood (approximately 1.5 tablespoons) from a vein in your arm to collect measurement of lipids (cholesterol), blood counts and chemistries, average blood sugar levels, and liver, heart, and kidney function for screening purposes
- Provide you with a light snack
- Measure your blood pressure, pulse, height, and weight
- Measure the electrical activity of your heart
- Ask you questions about your memory
- Ask you questions about your background, medical history, review of medications and dietary supplements
- Ask you to do a series of physical performance tests that include balance tests, chair rise (stand up from a seated position in a chair 5 times), a short walk test (4 meters) and a narrow walk test.

This visit will take approximately 1 – 1 ½ hours to complete. We will call you within a week to let you know if you qualify to continue for a Baseline Visit. If you do not qualify we will send you a letter with the results of your lab work so that you may share with your doctor, if you would like.

Baseline Visit (BV)

Approximately one week later you will come to the Sticht Center having fasted for at least 8 hours prior with nothing to eat or drink except water. We will:

- Draw blood (approximately 2 tablespoons) to measure your cells response to dasatinib and quercetin as well as the inflammation signals in your blood. Some of this blood may be stored for later use.
- Obtain a fasting urine sample.
- Do a brief physical exam and check your vitals.
- Perform a skin biopsy, or a surgical removal of a small bit of skin from your body a few inches under your armpit. For this procedure, we will use a small amount of lidocaine to numb the area, then use a tool to remove a small piece of skin (~1/8 to ¼ inch). One or two stitches may be used to close the skin, if needed. Pressure will be applied to the site until any bleeding stops, then the wound will be covered with a bandage.
- Provide you a light snack
- Ask you to walk for six minutes on our indoor walking course
- Test your grip strength by asking you to squeeze a hand held device
- Ask to complete some lung and breathing tests that require you breathe into a device while filling your lungs completely and blowing out until your lungs are completely empty.
- Ask you to answer some questions on how much difficulty you have doing different

- physical tasks and how tired or fatigued you feel
- Ask you to answer some questions about your IPF symptoms and shortness of breath
- Administer your first dose of dasatinib and quercetin and receive instructions for taking the drug combination
- Receive guidance on filling out weekly adverse event reporting and symptom questionnaire and completing weekly call-in

This visit will take approximately 2 hours to complete.

Follow-up Visit One (FV1)

Approximately one week after your final dose of dasatinib and quercetin (week 4) you will come to the Sticht Center having fasted for at least 8 hours prior with nothing to eat or drink except water. This visit will repeat all measures from the baseline visit. We will:

- Draw blood (approximately 4 tablespoons) to collect measurement of lipids (cholesterol), blood counts and chemistries, average blood sugar levels, and liver, heart, and kidney function. We will also measure your cells response to dasatinib and quercetin as well as the inflammation signals in your blood. Some of this blood may be stored for later use.
- Obtain a fasting urine sample.
- Do a brief physical exam and check your vitals.
- Test your grip strength.
- Perform a skin biopsy, or a surgical removal of a small bit of skin from your body a few inches under your armpit. After a local anesthetic is injected, a small sharp tool that looks like a cookie cutter (punch) is placed over the lesion, pushed down and slowly rotated to remove a small piece of skin (~1/8 to 1/4 inch). One or two stitches may be used to close the skin, if needed. Pressure will be applied to the site until any bleeding stops, then the wound will be covered with a bandage.
- Take a picture of the biopsy site.
- Provide you a light snack
- Ask you to walk for six minutes on our indoor walking test
- Ask to complete some lung and breathing tests that require you breathe into a device while filling your lungs completely and blowing out until your lungs are completely empty.
- Ask you to answer some questions on how much difficulty you have doing different physical tasks and how tired or fatigued you feel
- Ask you to answer some questions about your IPF symptoms and shortness of breath

This visit will take approximately 2 hours to complete.

Follow-Up Visit Two (FV2)

We will ask that you return approximately one week after your follow-up visit so we can take an additional photo of your biopsy site so we can document how well it has healed. At this visit we will also ask you to repeat the following performance tests: balance tests, chair rise (stand up from a seated position in a chair 5 times), a short walk test (4 meters) and a narrow walk test. This visit will take approximately 30 minutes to complete.

Weekly Check-In Calls

Within 24 hours of your 3rd dasatinib and quercetin dosing day of the week, we will arrange a telephone call for a brief check-in to review potential events or symptoms related to your IPF, ensure the study medication is tolerable, and to assess potential side effects.

You will have blood withdrawn from a vein at a total of 3 study visits. The total amount of blood withdrawn during the study will be approximately (5 tablespoons).

Storage of Biological Tissue

If you agree to participate in this study, we will draw approximately 7.5 tablespoons of blood, collect urine and take 2 skin biopsies; of this ~ 2 tablespoons of blood, ~ 2 tablespoons of urine, and a very small amount of skin is to be used for future research. These samples will be kept and may be used in future research to learn more about other diseases. Your samples will be obtained in the Geriatrics Clinical Research Unit at Wake Forest University Baptist Medical Center. The samples will be stored in the Geriatrics Laboratory temporarily and then shipped to the Mayo Clinic where they will be analyzed and stored. An Institutional Review Board (IRB) must also approve any future research study using your tissue samples. In order to participate in this study, you must be willing to provide this sample for future research.

Your blood, urine, and skin samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the samples.

The research that may be performed with your blood, urine, and skin samples are not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood, urine, and skin will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood, urine, and skin samples will not affect your care.

Your blood, urine, and skin samples will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 5 weeks. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures and drugs we are studying include:

1. Study Medications

Dasatinib. Dasatinib is indicated for use in cancer (chronic myeloid leukemia and lymphoblastic leukemia). While there are no safety data available for this drug in persons with IPF, there are some side effects reported in trials for cancer when given daily. The most common and frequently reported side effects are pulmonary hypertension (type of high blood pressure in the blood vessels of the lungs or right side of the heart) and fluid retention, which can be severe in some cases [pleural and pericardial effusion (fluid around the heart and lungs), and pulmonary edema (fluid in the lungs)]. Also common are headache, rash and gastrointestinal effects, including diarrhea, abdominal pain, nausea, vomiting, indigestion and loss of appetite. Less common is mild hypoglycemia (low blood sugar) in people with uncontrolled Type II Diabetes Mellitus, changes in heart rhythm (QTc prolongation), particularly in patients using antiarrhythmic medication or with congenital long QT syndrome. Myelosuppression, a condition in which bone marrow activity is decreased resulting in fewer red blood cells, white blood cells and platelets, has also been reported. Though very rare, the most serious side effects are cardiac events, including death from myocardial infarction (heart attack).

Dasatinib drug and food interactions.

Nintedanib: Dasatinib is a similar type of drug to a nintedanib (Ofev) which may be prescribed for IPF. Though there are no known risks of taking the two drugs together, if you are currently prescribed nintedanib, we will ask you to refrain from taking it on the days you take the study drug, dasatinib. There are no known additional risks to IPF symptoms or increased risk of death with brief interruption in nintedanib dosing, but we will ask you to obtain permission from your physician acknowledging the interruption in nintedanib use.

Acid reflux treatments: Dasatinib is best absorbed in the presence of stomach acid; please avoid taking medications that reduce or neutralize stomach acids (e.g. Tums, Maalox, Mylanta, Alka-Seltzer) for two hours before and two hours after taking dasatinib. There may be interactions with daily over the counter and prescribed medications taken to relieve stomach acid reflux, such as proton-pump inhibitors (e.g. Prilosec, Nexium, Prevacid, AcipHex, Protonix, Dexilant and Zegerid) or H2 blockers (e.g. Tagament, Pepcid, Axid or Zantac), and these should be avoided if possible. Since you will be holding acid reflux medications you might temporarily have heartburn and you can take over the counter (calcium carbonate or Tums) as directed for relief two hours after taking dasatinib.

Other drugs: Other medicines are metabolized in similar ways to dasatinib, and could increase or decrease the amount of dasatinib in your blood stream. These include some anti-fungal medicines (ketoconazole, itraconazole), antibiotics (erythromycin, clarithromycin, rifampicin), some types of steroid medications (dexamethasone), anti-seizure medicines (phenytoin, carbamazepine, phenobarbital). Dasatinib could also interact to increase the levels of other drugs you may take in your blood stream, such as some medicines that decrease the

activity of your immune system (cyclosporine) or lower cholesterol levels (simvastatin). No current information suggests that these interactions are known to be dangerous, but nevertheless there is always potential for risk and possible symptoms will be monitored (see below).

Grapefruit: There are also some reports of food-drug interactions between dasatinib and grapefruit; please avoid eating grapefruit or drinking grapefruit juice on the days you take dasatinib.

Quercetin is generally considered safe, even at the doses being given in this study. To date, there are no known risks of toxicity or side effects associated with quercetin administration, but if toxicity should occur you could experience headache, tingling, or kidney toxicity. Though critical reviews support the safety of quercetin when taken orally, some basic research in bacteria and yeast or quercetin injections in mice suggest potential for quercetin to be mutagenic, or to increase the rate of change in genes. For this reason we will ask men to use contraceptives to avoid risk of possible gene changes in the sperm while taking quercetin (see below).

Quercetin can interact with some drugs and foods, and quinolone antibiotics and warfarin (an anti-coagulant used to prevent heart attack, stroke or blood clots) should be avoided. It is possible that quercetin may interact with antihypertensive drugs to lower blood pressure, and we may ask you about and monitor your blood pressure if you take antihypertensive medication. Interactions may also occur if you are currently taking nintedanib; possible risks will be monitored.

Drug-drug Interaction Monitoring: As stated above, there are suspected drug-drug interactions for dasatinib and quercetin. We will try to identify any possible drug-drug interactions by having both investigators and the pharmacy staff review all prescribed medications and over-the-counter medicines and supplements you take. We will review these on a comprehensive and regularly updated computerized database. You will be notified of any potential interactions, and if needed we may ask you to discuss with your physician, and, if deemed appropriate, obtain a letter from your physician allowing you to possibly refrain from certain medications during the 3-week intervention period (e.g. acid reflux drugs or warfarin) or on drug-dosing days (e.g. nintedanib). Possible symptoms from drug-drug interactions will be monitored on weekly check-in calls, and if symptoms are detected we may ask you to come to the clinic for a check-in with medical and study staff.

2. Skin Biopsy

This procedure is rarely associated with discomfort, and the anesthesia to the area should make the procedure relatively painless. Common risk includes minor bleeding. Although unlikely, there is a slight risk of infection and a slight risk of persistent bleeding. If you usually form scars after skin injuries or surgery, you could develop a scar at the biopsy site. The biopsy site may be sore or bleed slightly for several days. The study team should be contacted immediately if you have excessive bleeding or drainage through the bandage, increased tenderness, pain or redness at the biopsy site, or develop a fever.

3. Blood Sampling

You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally, some people become dizzy, lightheaded or feel faint. Infection may occur on rare

occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia). You should not donate blood for at least 8 weeks after completing this study.

4. Physical Function Tests

Your ability to perform certain physical activities will be measured before and after the intervention. There is a slight risk of falls while participating in the balance test. However, you will be positioned beside a step or wall that can be reached immediately if you feel that you are going to lose your balance. Additionally, the person conducting the test will stand next to you at all times. There is a small possibility that you may stumble, fall or aggravate one of your joints/muscles during the walking test. You may have slight hand discomfort during the grip the strength test, but this usually stops once the test is over.

5. Pulmonary Function Tests

Pulmonary function tests are non-invasive tests that show how well your lungs are working. Though generally safe and quick for most people, there are some risks because the test may require you to breathe in and out quickly. These risks may include dizziness during the tests, feeling short of breath, coughing, or an asthma attack brought on by deep inhalation. In very rare cases these tests could cause a collapsed lung.

6. Questionnaires

During the clinic visits we will ask you a variety of questions that you may feel are boring or wonder why we need this information. Please know that we only collect information that we feel may be useful to know when studying the effects of dasatinib and quercetin. You may become tired during the questionnaires and if this occurs, we can take a break until you are ready to continue.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

Reproductive Risks and other Issues to Participating in Research

Contraceptive Measures for Males

Your participation in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to

be in this study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. Since these medications do not last in your system very long, you can stop using these contraceptives, if you wish, about 30 days after taking the last dose. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

What About My Health Information?

In this research study, any information we collect from you and/or information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: health history, how you respond to study drugs, and study activities or procedures, laboratory and other test results, and information from study visits, phone calls, surveys and physical examinations.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

- 1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research
- 2) Other people or laboratories (Mayo Clinic and The University of Texas Health Science Center at San Antonio) providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center
- 3) Representatives from government agencies such as the US Food and Drug Administration (FDA), and the Department of Health and Human Services (DHHS).

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completed and finished.

You can tell Dr. Stephen Kritchevsky that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Stephen Kritchevsky



However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

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

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even

de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety of dasatinib and quercetin; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid \$150 if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid \$75 for each complete study visit (baseline and follow-up).

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences and the National Institute on Aging. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of \$25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of \$25,000 coverage for each claim and is limited to a total of

\$250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [REDACTED].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Stephen Kritchevsky at [REDACTED] or [REDACTED] after hours and identify yourself as an IPF study participant.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because

- it is in your best medical interest,
- your condition worsened,
- new information becomes available,
- you had an unexpected reaction,
- you failed to follow instructions,
- or because the entire study has been stopped

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Stephen Kritchevsky at [REDACTED] or [REDACTED] after hours and identify yourself as an IPF study participant.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [REDACTED].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm