UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO DONATE SPECIMENS FOR FUTURE RESEARCH

Study Title: Tacrolimus assessment by NFAT-related gene expression in lung allograft recipients

This is a request that you donate specimens for medical research. The researchers, including Jon Singer, MD, Jasleen Kukreja, MD, and John Greenland MD, PhD from the UCSF Lung Transplantation Program (Departments of Medicine and Surgery) will explain this research to you.

Medical research includes only people who choose to take part. 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 the researchers.

You are being asked to take part in this study because you have had or may have a lung transplant at UCSF and you have been treated or are likely to be treated with tacrolimus as part of a regimen to prevent rejection of the new lung.

Why is this research being done?

The purpose of this study is to examine a new test to determine the appropriate dose of a critical immunosuppressive drug tacrolimus. This drug is part of the standard immunosuppression regimen for all lung transplant recipients, but has some side effects. We suspect that a different dose may be needed for different people and that this test may help us personalize medication regimens to individuals. We are looking to see if this new test can reliably determine when the dose is too high or too low.

Astellas manufactures Prograf, which is one formulation of tacrolimus, and pays for the conduct of this study, including part of the investigators salary. Participation in this study will not affect the how tacrolimus is prescribed for you. You can participate if you are taking tacrolimus from any manufacturer.

How many people will take part in this research?

About 50 people will be asked to donate specimens for this research.

What will happen if I agree to donate my specimens?

Participation in this study will not affect the medications you will receive. If your doctors determine that tacrolimus is not an appropriate medication for you, we will stop collecting blood samples for this study. No additional visits to UCSF will be required to participate in this study.

If you agree to let researchers collect and store your specimens for future research, the following will happen:

- During scheduled clinical visits to UCSF, you will be asked to bring your immune suppression medications with you. Before taking your tacrolimus medication, a doctor, nurse or phlebotomist will draw a blood sample (approximately 15 ml or 3 teaspoons). Generally, this blood draw will be done at the same time (same puncture) as routine labs that are done with every clinic visits. Ninety minutes after taking your tacrolimus medication, we will draw another blood sample. You will proceed with your scheduled clinical activities in the meantime. We will not collect the extra blood if we think it will cause

any additional risk, discomfort, or pain beyond what we normally expect from post-transplantation surveillance.

- After all routine tests required for your care are finished, instead of discarding your leftover specimens we will save them in what is called a "tissue bank" for possible future research. We also will collect and save information from your medical record, including things like results of biopsies, microbiology data, breathing tests, and clinical outcomes. We do not know for sure if your specimens or medical record will be used, but they might be used in research about lung transplantation.

- We also will collect and save information from your medical record for an indefinite period of time, including things results from your physical examinations, diagnostic tests, diagnoses, and treatments that are already being done for your regular clinical care. Information from your medical record will be entered into a clinical-research database to evaluate your clinical condition over time and included for future statistical analysis.

- We may give your specimens and certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a government health research database, but we will not give them your name, address, phone number, or any other information that would identify you. Reports about any research will not be given to you or your doctor.

- Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if we use the specimen for genetic research, we will not put the results in your medical record. The research will not change the care you receive. Your specimen and any information about you will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances these may have potential commercial value. Your personal health information cannot be used for additional research without additional approval from either you or a review committee.
- Your specimens will be kept for an indefinite period of time. If you decide later that you do not want your specimens and information to be used for future research, you can notify the investigator in writing at 505 Parnassus Ave, Room HSE-520, San Francisco, CA, 94143, and we will destroy any remaining identifiable specimens and information if they are no longer needed for your care. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies.

What risks are involved with donating specimens for research?

1. Blood draw: The side effects associated with a blood draw are minor and include pain and bruising. You may experience some mild muscle soreness from physical assessments. This soreness should get better within one day. Less than 1% of the blood donor population can experience fainting or light-headedness, and rarely an infection.
2. Confidentiality: Donating specimens may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Your name will not be used in any published reports from research performed using your specimen. The managers of tissue bank (Drs. Greenland and Wolters) 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 and other University of California personnel also may see information about you to check on the tissue bank.

3. Genetic information: Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as your age or transplant history. These facts are important because they will help us learn if the factors that cause any subsequent health problems, such as transplant rejection or skin cancer, are the same or different based on these facts. Thus it is possible that study findings could one day help people of the same race, ethnicity, or sex as you.

   However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

4. Other minimal risks include loss of privacy or confidentiality and the inconvenience of the time needed to participate in the study. For more information about risks and side effects, ask your study doctor.

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

It is important that you tell your study doctor, Dr. Greenland, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at 415-476-0789.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor Astellas, depending on a number of factors. The University and the study sponsor do 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 the benefits of donating specimens for research?

There will be no direct benefit to you from allowing your specimens to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease.

What financial issues should I consider before donating?

You will not be charged for donating your specimens. You will not be paid for donating your specimens. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. UCSF may receive payment from researchers requesting specimens in order to cover the costs of collecting and storing the specimens.

What alternatives do I have?

If you choose not to donate your specimens, any leftover blood and/or tissue removed during your surgery that is not needed for diagnosis will be thrown away and no additional normal tissue or blood will be removed for research purposes. Your post-transplantation care will not be affected based on whether you participate in this study or choose not to.

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. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

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 with the study researcher about any questions, concerns or complaints you have about this study. Contact the study researcher, Dr. John Greenland at 415-476-0789.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

Consent

Please read each sentence below and think about your choice. After reading each sentence, put your initials in the "Yes" or "No" box. If you have any questions about this study, please talk to the study doctor or nurse.

No matter what you decide to do, it will not affect your care.

1. My specimens may be kept for use in research to learn about, prevent, or treat problems associated with lung transplantation or other health problems.

YES	*NO*

2. Someone may contact me in the future to ask me to take part in more research.

YES	*NO*

3. Additional blood may be taken for this research, as described in the What Will Happen If I Agree… section above.

YES	*NO*

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

Date Person Obtaining Consent

Date Witness – Only required if the participant is a non-English speaker

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S

BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told of the other choices I have and how they may be better or worse than being in the study,

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,

9) To receive a copy of the signed and dated consent form,

10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Call 476-1814 for information on translations.

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IRB Approval Number **14-13221**

University of California
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):
Tacrolimus adjustment by NFAT-related gene expression in lung allograft recipients

Principal Investigator:
John Greenland, MD, PhD

Sponsor/Funding Agency (if funded):
Astellas Scientific and Medical Affairs

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California San Francisco (UCSF) or your health care provider cannot release your health information to the research team unless you give your permission. The research team includes the researchers and people hired by the University or the sponsor to do the research. If you decide to give your permission and to participate in the study, you must sign this form, as well as the Consent Form. This form describes the different ways that the researcher, research team and research sponsor may use your health information for the research study. The research team will use and protect your information as described in the attached Consent Form. Once your health information is released it may not be protected by these privacy laws and might be shared with others. However, other laws protecting your confidentiality may still apply. If you have questions, please ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing UCSF to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

☒ Entire Medical Record	☐ Radiology Reports	☐ Laboratory Reports
☐ Outpatient Clinic Records	☐ Radiology Images	☐ Psychological Tests
☐ Progress Notes	☐ Diagnostic Imaging Reports	☐ Dental Records
☐ Consultations	☐ Operative Reports	☐ Discharge Summaries
☐ History & Physical Exams	☐ Pathology Reports	☐ Health Care Billing
☐ EKG	☐ Emergency Medicine Center Reports	

☐ Other: _____

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

____ I agree to the release of HIV/AIDS testing information.

____ I agree to the release of genetic testing information.

____ I agree to the release of information pertaining to mental health diagnosis or treatment as follows:

_____

D. How will my Personal Health Information be used?

Your Personal Health Information may be released to these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC who are required by law to review the research;
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration, the research sponsor or the sponsor's representatives, or government agencies in other countries. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

E. How will my Personal Health Information be used in a research report?

If you agree to be in this study, the research team may fill out a research report. (This is sometimes called a "case report".) The research report will ***not*** include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care, and a tracking code. The research report will also include information the research team collects in the study. The research team and the research sponsor may use the research report and share it with others in the following ways:

1. To perform more research;
2. Share it with researchers in the U.S. or other countries;
3. Place it into research databases;
4. Use it to improve the design of future studies;
5. Use it to publish articles or for presentations to other researchers;
6. Share it with business partners of the sponsor; or
7. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over. Research reports can be used forever.

G. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used. Also, if the law requires it, the sponsor and government agencies may look at your medical records to review the quality or safety of the study.

H. Signature

If you agree to the release and use of your Personal Health Information, please sign below. You will be given a signed copy of this form**.**

_____

Name of Subject (print)

_____ _____

Signature of Subject Date

Note: if the subject is a minor, an individual signing with an "X", an adult incapable of giving consent, or is unable to read the authorization, fill out and attach the "special signatures" page (sections "I" and "J").