UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT

Study Title: Cardiopulmonary Effects of Secondhand Smoke Exposure on Flight Attendants

This is a research study. Your study doctors Rita Redberg, MD and Eveline O. Stock, MD from the UCSF Department of Cardiology 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 of your experience working as a flight attendant for at least one year during the pre-tobacco ban years. You are a candidate for the study because of your exposure to secondhand smoke.

Why is this study being done?

The purpose of this study is to test whether exposure to secondhand tobacco smoke causes negative effects on your health. In particular, the investigators wish to find out whether secondhand tobacco smoke exposure causes heart or lung problems. The purpose of collecting bio-specimens, like blood, is to perform a cholesterol test and other tests that can help us assess your cardiovascular risk. Part of the specimen will be saved for future research to identify new markers of cardiovascular risk and of secondhand smoke exposure, known as “biomarkers.” Biomarkers in the blood may enable the researchers to quantify flight attendants’ exposure to tobacco smoke.

This study is being partly funded by a grant from the Flight Attendant Medical Research Institute (FAMRI), a private non-profit organization founded to study the health effects of exposure to secondhand tobacco smoke.

How many people will take part in this study?

About 2000 people will be asked to donate specimens for this research. If you choose not have your blood drawn or donate your specimens, you may still participate in the research study. The specimen collection component is optional and your choice will not affect any part of your care.

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

Before you begin the main part of the study…

You will complete a brief questionnaire on your smoke exposure and medical history to find out if you can be in the main part of the study.

If you are participating in the vascular study we will provide additional instructions to prepare for testing.
During the main part of the study…

If the questionnaire shows that you can be in the main part of the study, and you choose to take part, then you will need the following tests and procedures.

- A 12 lead EKG (electrocardiogram) will be preformed
- A spirometry test to measure lung function will be administered
- A single blood sample of up to 45 mL (about eight teaspoons) will be drawn from a vein in your arm to identify biomarkers of secondhand smoke. Part of the blood will be sent for analysis of your cholesterol levels and the rest of the blood will be processed and stored for research purposes to identify biomarkers of cardiovascular risk and secondhand smoke
- You will undergo a physical examination including assessment of blood pressure, heart rate, temperature, weight, height
- Perform noninvasive assessment of vascular function (for example: blood pressure, pulse wave measurements) which require you to lay for an hour as blood pressure is measured at different times to gage the flow of the arteries to respond the when the blood pressure cuff is released and the ability for the blood vessel to dilate. At this time you will be measured on the speed of waves that travel using a probe by the neck and the groin.
- If you agree to have your blood drawn, part of the blood will be sent to a laboratory for analysis of cholesterol levels. The remainder of the blood specimen will be processed and saved for research purposes.

The study doctor will review the results of your EKG, spirometry, vascular assessment, and medical examination with you during the appointment. If any concerns are identified you will be instructed to share the results with your primary doctor. At the end of the appointment, you will be given a copy of the results. The laboratory results of your cholesterol levels will become available following your appointment. The results will be sent to you approximately 1 month after your study visit by either letter or secure email according to your preference.

When you are finished with the main part of the study…

The questionnaire, interview, physical examination, EKG, vascular study, and spirometry test will take approximately 3 hours.

**Study location:** All procedures will be performed at the UCSF Mission Bay Cardiovascular Care Clinic or San Francisco General Hospital.

**Storage and future use of blood plasma:** This is a continuing search for secondhand smoke biomarkers and DNA analysis. At the end of this consent form you will be asked if you are willing to allow Dr. Redberg and Dr. Stock and their collaborators to store and to continue to examine the samples that they obtain from your blood for such risk factors as long into the future as is necessary to identify them. You may still participate in the study if you choose not to allow your specimens to be kept. It is possible that commercial products will be developed
from the samples. We may give your specimens and certain medical information about you to scientists at other universities, foundations or collaborating industries but we will not give them your name, address, phone number, or any other information that would identify you. If you decide later that you do not want your specimens and information to be used for future research, you can tell us, 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 will happen if I agree to donate my specimens?

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

- Results of your cholesterol levels will be shared with you via your preferred method of contact, either mail or secure email. You can choose to share these results with your physician for clinical purposes.

- The rest of the sample will be saved 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 blood pressure, EKG results, spirometry results, reproductive information, and other medical history information included in your questionnaire. We do not know for sure if your specimens or medical record will be used, but they might be used in research about cardiovascular or heart disease. Genetic information taken from the DNA specimens (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in coded form.

- We may give your specimens and certain medical information about you (for example, diagnosis, blood pressure, age) to other scientists or companies not at UCSF, but we will not give them your name, address, phone number, or any other information that would identify you. Your identifying data will be coded and never connected with your blood sample. Reports about blood specimen results are only for research purposes and will not be shared with you or your doctor.

- DNA specimens may be used for genetic research (about diseases that are passed on in families). This blood will be used to make some chemical measurements and to extract DNA and RNA. DNA is the substance which includes hereditary factors (genes), and RNA carries information from the genes to the cellular machinery that creates proteins. My genes will be examined for hereditary changes (mutations) that could contribute to heart disease, stroke, metabolic disorders or related illnesses, and RNA studies can reveal how the expression of genes is regulated in my body. Because the gene studies are under development and are not yet certified under federal regulations (CLIA, or Clinical Laboratory Improvement Act), the results are of a research nature and should not be considered a diagnosis on which to base my treatment. 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 indefinitely. 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 [Dr. Rita Redberg, 555 Mission Bay Blvd. South, San Francisco, CA 94158] 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 side effects or risks can I expect from being in the study?

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

Risks and side effects related to the study include:

- The risk associated with completing the questionnaire, with making chemical measurements, and genetic testing is the loss of privacy.
- The risks associated with blood drawing are temporary discomfort from the needle stick and bruising.
- The tests associated with the vascular assessment require that you lie still and hold your hands still. There may be mild discomfort and tingling when the blood pressure cuff is inflated which will be temporary.
- The adhesive stickers used for the EKG can cause some people minor skin irritation upon removal.
- Results produced by this study may predict health problems that you could have in the future. If insurance companies were to find out that you have high cholesterol or carry genes related to high blood pressure, diabetes, obesity, strokes, heart problems, or other diseases, you, or your relatives, may have difficulty getting insurance or employment. UCSF Researchers will not release any information to insurance companies or employers. Cholesterol levels will be recorded in my clinical chart.
- Rarely, infection is a risk associated with blood drawing.
- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

You will not benefit directly from participation in this study besides the possibility of early identification of heart and lung conditions. The cholesterol panel may provide you with information about your health and cardiovascular risk. The investigators hope that information gained from this study will provide important information about the health effects of second-hand smoke exposure. Future patients and their physicians may benefit from this study due to improved understanding of the effects of second-hand smoke. In addition, findings from this study may contribute to public policy decisions to further limit smoking in public areas in the future.

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

Spirometry, electrocardiograms, and blood draws are all standard medical procedures. Your doctor can order these tests, if they are clinically appropriate, without requiring your participation in a research study. If you choose not to participate in this study, you will continue to receive standard medical care. You are under no obligation to participate. If you choose not to donate your specimens, your healthcare at UCSF or elsewhere will not be affected in any way.

Please talk to your doctor about your choices before deciding if you will take part in this study.
How will information about me be kept confidential?

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. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. 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.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- The Flight Attendant Medical Research Institute

What are the costs of taking part in this study?

There will be no cost to you if you participate in this study. The study sponsor (FAMRI) will pay for the clinic visits and all standard laboratory tests (e.g., electrocardiogram, exercise, breathing tests, blood tests) that are considered part of the research study. 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.

Will I be paid for taking part in this study?

If you are eligible to participate in this study, you will be paid $100 for your participation. We will provide you with accommodation at a hotel near San Francisco or Oakland airports location. The accommodation costs are about $100 - $200 depending on hotel seasonal prices. You are responsible for any additional charges beyond the room cost at the hotel including valet, meals, and room service. In addition to a hotel, we will also provide you with round trip transportation from the accommodation site or airport to UCSF through shuttle and/or taxi. If you choose to drive, you will be reimbursed for parking at UCSF Medical Center for the duration of your participation. Lastly, if you refer a friend to the study who completes a visit you will receive a $5 Starbucks gift card.

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

It is important that you tell your study doctor, Dr. Rita Redberg, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at (415) 476-6874.
**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 [FAMRI], 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 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. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

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 your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor Dr. Rita Redberg at (415) 476-6874.

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**

You have been given copies of this consent form and the Experimental Subjects Bill of Rights to keep. You will be asked to sign a separate HIPAA Authorization Form authorizing access, use, creation, or disclosure of your health information.

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 coordinator.

No matter what you decide to do, it will not affect your care. If you have any questions about this study, please talk to the study coordinators.
1. My specimens (blood or saliva) may be kept for use in future research (optional tissue banking for future research).

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<th>YES</th>
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2. Do you wish to be contacted in the future regarding the possibility to participate in future research at UCSF, and to ask about your health status?

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3. If you answer yes to the question above, do you prefer to be contacted using email or phone? Please indicate your answer by circling your choice below.

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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