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

Study Title: DECAF (Does Eliminating Coffee Avoid Fibrillation?)

This is a medical research study. Your study doctor(s), Gregory Marcus, MD or Christopher X. Wong, MD, or one of their associates from the Division of Cardiology at UCSF, will explain this study to you.

Medical research studies include 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 your study doctor.

You are being asked to take part in this study because you are scheduled to have a cardioversion for your atrial fibrillation.

Why is this study being done?

We want to see how coffee consumptions affects whether you have atrial fibrillation (AF) after your scheduled electrical cardioversion.

Coffee is one of the world's most consumed beverages. Because an increasing number of people have AF, and many drink coffee, it is important for doctors and patients to learn whether coffee affects AF.

This study will compare coffee drinkers who have AF and stop drinking coffee, with those who continue drinking coffee. If you choose to participate in the study, after your cardioversion you will be randomized to either stop drinking coffee and caffeine in general, or to continue consumption. If you do not participate in this study, you will still get your cardioversion and can decide afterwards if you want to continue drinking coffee.

How many people will take part in this study?

About 200 people will take part in this study. 100 people will be randomized to continue to consume coffee over the study period, and 100 people will be randomized to stop consuming coffee over the study period.

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

If you choose to take part in this study and are eligible, you will still have the medical procedure (called cardioversion), which you are already planning to have, to help convert you back to normal sinus rhythm. If the cardioversion is successful, you will be put into one of two study groups by chance, where you will either be instructed to continue to consume coffee as usual, or to discontinue coffee consumption for the study period. You will be in this study for up to 6 months in total and will need to visit the clinical site only once, the day of your cardioversion (which you are already coming in for). The follow-up visits will be at 1 day, 1 month, 3 months, and 6 months post-cardioversion. These visits will be done remotely over the phone. The study is completed once you have documented AF recurrence or at 6 months post cardioversion, whichever occurs first.

Documented AF recurrence includes evidence of AF (on an ECG strip) from any of the options below:

- Personally owned wearable or handheld devices (such as an Apple watch or Kardia device)
- 12 lead ECG reviewed by a provider
- Wearable monitor ordered by a healthcare provider (Zio patch, Biotel device, or Holter)
- Implantable loop recorder (overread and confirmed by a physician)
- Pacemaker or ICD (from a device check)

If you believe you have symptoms suggesting that your AF has recurred, but there is no documented evidence, we will refer you to your usual cardiologist to decide if additional investigations are required.

Before you begin the main part of the study...

You will need to have the following "screening" exams to find out if you can be in the main part of the study.

Medical chart review: Your medical chart will be reviewed by the study doctors to look at your medical history. We will ask you a series of questions to ensure you are eligible for the study.

It is expected that completion of the screening exams will take around 10 minutes.

During the main part of the study...

If the screening exams show that you can continue to be in the study, and if you choose to take part, then you will have the following tests and procedures done.

Initial Remote Visit: Consent and Enrollment
During this first visit (which may be done at the same time as your screening visit) you will be asked study questions, including those regarding your health history, coffee habits, and demographics. The study coordinator will review the consent form with you.

This visit will take 15-20 minutes.

Baseline Visit (Day of Your Cardioversion):
After enrollment, you will have your scheduled cardioversion, which should take 1-2 hours in total, including the time needed to prepare for the procedure. This time is expected to be the same whether you participate in the study or not.

If cardioversion is successful and you are back in sinus rhythm, you will be randomized into one of the two study groups described below. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in group 1 or group 2.

- If you are in group 1, you will be instructed to abstain from coffee and other caffeinated products (tea, cola, energy drinks), until your first documented AF episode after your cardioversion or up to 6 months post cardioversion, whichever comes first. As some decaffeinated coffee can also contain caffeine, you will be encouraged to abstain from decaffeinated coffee as well.
- If you are in group 2, you will be instructed to consume coffee and other caffeinated

products as you normally do, until your first documented AF episode after your cardioversion or up to 6 months post cardioversion, whichever comes first. You will be encouraged to drink at least one cup of caffeinated coffee or one espresso shot daily and other caffeine- containing products as per your usual lifestyle. It will be recommended that you do not intentionally increase or decrease consumption of these products.

This visit will take 2-3 hours, depending on length of cardioversion.

First Remote Visit (Day 1 after Study Ablation):
The study team will check in with you to remind you of which group you are randomized to and answer any questions you may have about the study.

This should take 5-10 minutes.

Second Remote Visit (1 Month after Study Ablation):
The study team will once again check in with you to ask some questions about your compliance with the allocated treatment, coffee and caffeine habits since cardioversion, and AF events since the cardioversion over the phone or if they meet with you during a visit to see your doctor. You also have the option to answer these questions in-person at UCSF. If you have documented evidence of AF (see above for examples of documented evidence) before this visit, this will be your last visit for the study.

This visit will take 10-15 minutes.

Third Remote Visit (3 Months after Study Ablation):
During this visit, the study team will check in with you and ask the same questions asked at the 1 month follow up over the phone or if they meet with you during a visit to see your doctor. You also have the option to answer these questions in-person at UCSF.

This visit will take 10-15 minutes.

Fourth Remote Visit (6 months after Study Ablation):
During this final visit, the study team will check in with you and ask the same questions asked at the 3 month follow up over the phone or if they meet with you during a visit to see your doctor. You also have the option to answer these questions in-person at UCSF.

This visit will take 10-15 minutes.

You will be provided with telephone and email contact information for both the study doctors and study coordinators.

How long will I be in the study?

Once you are randomized, you will be in the study for the next 6 months or until there is evidence that your AF has come back, whichever comes first. The three follow-up visits will take place at 1 Month, 3 Months, and 6 Months after your cardioversion. The three follow-up visits can all be done remotely or during a regularly scheduled doctor's visit. If you have recurrent, documented AF before any of these follow up visits, you will be considered to have completed the study and will not need to attend any remaining follow ups.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctors if you are thinking about stopping or decide to stop.

The study doctors may stop you from taking part in this study at any time if they believe 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?
The cardioversion procedure used in this study involves several risks. Because you are already scheduled to undergo this procedure with your doctor, you will be exposed to these potential risks whether you participate in this study or not.

The known risks of cardioversion have been shown to occur in less than 1% of cases and include: adverse reaction from administered medications for sedation/anesthesia, lack of success, induction of another arrhythmia, skin burn, or stroke/TIA.

Abstinence from coffee and other caffeine-related products may result in caffeine-withdrawal, symptoms of which can include: headache, fatigue, anxiety, difficulty concentrating, depressed mood, irritability, tremors, and low energy.

Unknown risks:

- It is not clear what effect, if any, coffee has on AF and AF recurrence; this forms the rationale for the present study. It may be possible that coffee consumption is beneficial and abstinence may result in a greater likelihood of AF recurrence or vice versa.
- The methods of the cardioversion procedure may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study

Are there benefits to taking part in the study?
You will have the same potential benefits of the cardioversion procedure to treat your abnormal heart rhythm, whether (1) you have the procedure as part of this study or (2) if you have the procedure and are not in the study (because you are already scheduled to do this procedure).

Potential benefits of coffee abstention may include a reduction in AF recurrence.

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

Your other choices may include:

- Getting cardioversion treatment without being in the study.
- Taking part in another study.
- Getting no cardioversion treatment.

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 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:

- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

What are the costs of taking part in this study?

You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

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

It is important that you tell your study doctors, Gregory Marcus, MD or Christopher X Wong, MD, if you feel that you have been injured because of taking part in this study. You can tell the doctors in person or call them at (415) 353-2554.

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, depending on a number of factors. The University and the study do not normally provide any other form of compensation for injury.
For further information about this, you may call the office of the Institutional Review Board 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. Your study doctors, Gregory Marcus, MD or Christopher X. Wong, MD, can be reached at (415) 353-2554. The study coordinator is Gabby Montenegro (415) 502-3053.

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 Institutional Review Board 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 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.

Participant	Signature of Participant.	Date and Time
Person Obtaining Consent.	Signature	Date and Time