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

**Study Title:** The effect of sodium lauryl sulfate on the oral absorption of fexofenadine in humans.

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This is a clinical research study. Katherine Yang, PharmD, MPH, or other team members from the Department of Clinical Pharmacy at UCSF, or your study doctor, research nurses from Clinical Research Services at UCSF, and/or other research personnel will explain the study to you.

## STUDY SUMMARY

**Introduction:**
We are asking you to consider taking part in a research study being done by Katherine Yang and her colleagues at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether you want to take part in this study. Please take your time to decide about participating. You can discuss your decision with your family, friends, and health care team.

**Purpose of the study:**
The researchers want to find out if sodium lauryl sulfate (an ingredient commonly added to medicines) reduces levels of the drug fexofenadine (a medicine used to treat allergies) in the body.

**Study Procedures:**
Before choosing to participate in this study, a member of the study staff will go over this Informed Consent Form with you via Zoom. If you choose to be in this study, you will then go through an on-site screening visit to determine your eligibility for study participation. Your screening visit will occur within 30 days prior to first drug dosing in the study. If your visit procedures fall outside of the 30-day screening window, you will be reconsented, the screening visit repeated, and your eligibility to participate re-determined. If you are eligible, you will be asked to come to the clinic to receive the study drug (fexofenadine) with and without sodium lauryl sulfate (SLS). There will be 3 periods in the study, each including a 9-hour visit in the clinic and two follow-up visits. Your study participation will typically last 21 to 45 days. You will be on the study for a minimum of 17 days to a maximum of 75 days.

You will be asked to remain in the clinic (outpatient) for blood sampling during the first 9 hours after you take the study drug. You will then come back to the clinic at 24 hours and 48 hours after you received the drug for additional blood draws. Your blood will be drawn at several time points over 48 hours to measure the drug levels after you have swallowed the pill. Samples of your stools will also be collected to measure the drug quantities within the 48 hours. There will be 3 periods, and you will provide approximately 360 mL (12 oz) of blood in total.

In addition, you will visit the research site to repeat this process two more times, one to three weeks after each previous period.

From the first subject to the last subject, the total duration of the study is expected to be 6 months to 1 year.

Fexofenadine (120 mg) and SLS (3 mg or 30 mg) used in this trial have been administered to humans at the same doses or lower. For fexofenadine, the highest dosage form is 180 mg (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20786se8-014,20872se8-011,20625se8-012_allegra_lbl.pdf). For SLS, the amounts used in this study are lower than what have been used in capsule (147.6 mg) and suspension (705 mg) (https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm?event=BasicSearch.page).

**Possible Risks:**
There are risks to taking fexofenadine and sodium lauryl sulfate. Some of the most likely risks of participation in this study include: headache (5% to 11%), drowsiness (1% to 3%), diarrhea (3% to 4%), viral infection (3%), and upper respiratory tract infection (3% to 4%). Insertion site bruising due to the IV catheter is a possible risk. There are also rare but serious risks of participation, and please refer to the section "**What side effects or risks can I expect from being in the study?**" for more detailed information.

**Possible Benefits**:
There will be no direct benefit to you from taking part in this study. However, the benefit of participating in this study is that you can add to our knowledge about the impact of ingredients that are commonly added in drug products on drug safety and toxicity. In addition, the information gained may be used to improve drug formulation and dosing strategies in the future.

**Your Other Options:**
This is not a treatment study. You do not have to participate in this study. Please talk to your study doctor about your choices before agreeing to take part in this study.

Below is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for your future reference.

## DETAILED STUDY INFORMATION

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/or with your primary care physician team. If you have any questions, you may ask the study doctor.

### Why is this study being done?

The purpose of this study is to determine if sodium lauryl sulfate, an inactive ingredient commonly added in drug products, decreases drug absorption. Investigators want to find out if drug absorption is different in people taking the drug alone compared to in people taking the drug with low or high amounts of sodium lauryl sulfate at the same time.

The blood and stool samples may also be used for, but not limited to, genomic, epigenomic, metabolomic, proteomic, and transcriptomic follow-up studies. For example, an exploratory objective is to study the effect of genetic variants of fexofenadine transporters on fexofenadine absorption. In addition, a metabolomics study may be done to determine endogenous biomarkers for transporters. Please refer to the complete definitions of the technical names later in the document. We will acquire consent from you for these exploratory analyses in the end of this form.

This study is being funded by the Office of Generic Drugs at the Food and Drug Administration (FDA).

### How many people will take part in this study?

We anticipate that about 12 people will take part in this study.

## Study location:

All study procedures will be done at:

UCSF Clinical Research Center at Parnassus
400 Parnassus Avenue, A101
San Francisco, CA 94143

**Parking***
500 Parnassus Avenue
San Francisco, CA 94143

*Parking validation stickers will be provided.

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

If you consent to participate and are deemed eligible after reviewing your health questionnaire, you will be asked to come for a screening visit. This screening visit will be at the UCSF Parnassus Clinical Research Services (CRS) site. Your blood will be drawn (about 2 teaspoons) for baseline clinical labs to determine if you are eligible to participate in the study. The screening visit will be an outpatient visit that lasts approximately 30 minutes.

There are three periods in this study that will be conducted at UCSF Parnassus. For each of these periods, you will be asked to arrive in the morning and stay for approximately 9 hours. During each of these 9-hour visits, you will be given fexofenadine with or without sodium lauryl sulfate, after which, the research nurse will draw blood from you at several time points. You will also be asked to return for outpatient blood draws at approximately 24 hours (+/- 30 minutes) and 48 hours (+/- 30 minutes) after your dose. You will also be asked to collect your stool any time from taking the pill until 48 hours. The three periods will be at least a week apart from each other and your entire study participation will last about 17 days to 45 days.

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

After you have provided your consent, you will go through the following exams, tests, or procedures to find out if you can be in the main part of the study.

**Initial Screening:**

- **Demographics/Health Questionnaire:** You will complete an online questionnaire to determine if you are eligible for this study. The information gathered will include medical questions about your general health and medication history, as well as the medical health of your family members. Information from this questionnaire may be stored in a database for future research; however, it will be maintained as confidential as possible. The data will be coded with a number, and your name and other individual identifiers will not be used. If you choose not to sign this consent form, the investigator cannot use information that you have provided, and you cannot participate in this study.

**Follow Up Screening:**
If you are eligible based on the results of the Initial Screening, you will go through a Follow Up Screening. You will be asked to report to the UCSF Parnassus CRS (400 Parnassus Avenue, A101) for your screening visit.

- **Height, weight, and body temperature measurement.** Your height, weight, and vital signs will be measured by a UCSF Parnassus staff member at the time of arrival for the Follow Up Screening.

- **Blood drawing (needle stick):** You will be asked to provide a blood sample for laboratory tests. Approximately 10 mL or 2 teaspoons of blood will be collected to measure your blood cell counts (to check for anemia), liver, and kidney functions. The outcome of the laboratory tests will help determine if you are eligible to continue the study.

- **Urine collection:** You will be asked to provide a urine sample for laboratory tests for checking your overall kidney health.

- **Pregnancy Test (women only):** Because the inactive ingredient and drug in this study (sodium lauryl sulfate and fexofenadine) may affect a fetus, pregnant women are not eligible and may not participate in this study. If you are a female of child-bearing age, a urine test will be done before each period to make sure you are not pregnant.

**During the main part of the study...**

If your questionnaires, exams, tests, and procedures show that you can be in the main part of the study, and you choose to take part, then you will need to undergo the following tests and procedures:

- **Diet and supplement restriction:** You must avoid ingestion of fruit juices (grapefruit juice, orange juice, apple juice) and citrus bioflavonoids, such as grapefruit extract, hesperidin supplement, and naringin supplement, one week before the study until completion. The reason is that these drinks and supplements have been shown to affect fexofenadine absorption. You will also be contacted before your scheduled study visits to be reminded about avoiding these food/supplements.

- **Randomization:** Because this is a 3-period crossover study, you will be "randomized" into one of the three study groups described below. Randomization means that you are put into a group by chance, like flipping a coin. Neither you nor your study doctor can choose the group you will be in. You will not know which group you have been assigned to or which study drug you will be receiving. You will have an equal chance of being placed in any of the three groups.

    - If you are in Group 1, you will receive:
        - Fexofenadine only in Period 1,
        - Fexofenadine and 3 mg sodium lauryl sulfate in Period 2,
        - Fexofenadine and 30 mg sodium lauryl sulfate in Period 3.

- If you are in Group 2, you will receive:
  - Fexofenadine and 3 mg sodium lauryl sulfate in Period 1,
  - Fexofenadine and 30 mg sodium lauryl sulfate in Period 2,
  - Fexofenadine only in Period 3.

- If you are in Group 3, you will receive:
  - Fexofenadine and 30 mg sodium lauryl sulfate in Period 1
  - Fexofenadine only in Period 2,
  - Fexofenadine and 3 mg sodium lauryl sulfate in Period 3.

**Study Period**

- You will go through the same procedures for Periods 1, 2, and 3. Reminders for your study visit as well as procedures for the day will be given at least 24 hours before the visit day.
- You will be asked to report to the UCSF CRS (400 Parnassus Avenue, A101) to begin your first study day. You will be asked to fast (water is okay) around 11 pm prior to your visit. Please stop drinking water 1 hour before administration of the pill.
- Lunch and water during your stay will be provided. The same meal will be provided during each period. If you require a special diet or food restrictions, including allergies, this study may not be for you.
- Pre-menopausal female subjects will be asked to provide a small urine sample at the beginning of each stay to make sure pregnancy status has not changed.
- Your vital signs and weight will be recorded.
- Before the start of the study, one intravenous (IV) catheter (tube used to draw blood samples during the first 9-hour confinement only) will be placed in a vein of your forearm (alternatively, your hand may be used if they are unable to locate a vein in your arm).
- You will receive your assigned pill between 8 AM and 9 AM. No water should be consumed 1 hour before until 1 hour after taking the pill. No food will be allowed until 4 hours after taking the pill. Small blood samples will be taken via IV catheter over the next 8 hours to determine your blood levels of fexofenadine as well as sodium lauryl sulfate. Stool samples will be collected throughout the entire stay in specimen cups provided by the CRS Research Center.
- You will be confined to the UCSF CRS until the 8-hour post-dose sample is collected.
- In case the IV catheter stops working, another IV catheter may be placed.
- **One** blood sample will be collected before, and **seven** blood samples will be collected in the 8 hours after your dose. Then, your IV catheter will be removed.
- You will then be asked to leave the clinic and return the next morning for an outpatient blood draw (needle stick) at 24 hours from your dose (between 8 AM and 9 AM).
- You will also be asked to return for another outpatient blood draw (needle stick) at 48 hours from your dose (between 8 AM and 9 AM).
- **Stool Collection:** Before being discharged from your 9-hour stay at the study site, you will receive instructions, along with a stool collection kit, labeled with your unique study identification number. You will collect your bowel movements (at home) for 24 hours and 48 hours post-drug administration. This kit will include stool collection baskets, specimen containers, zip-lock bags, thermal storage containers, disposable gloves, and cold gel packs. After the stool is placed into the specimen container, the container will be sealed in a plastic

zip-lock bag and placed into the thermal storage container along with the cold gel packs. You will bring your stool sample containers back to the study site at the 24-hour and 48-hour visits.
- You will then be discharged from the clinic.

24- and 48-hour Post-Medication Administration In-Clinic Visits:
- You will return the next morning for an outpatient blood draw (needle stick) at 24 hours from your dose (between 8 AM and 9 AM). Please bring stool samples if available for the 24-hour time period.
- You will also be asked to return for outpatient blood draw (needle stick) at 48 hours from your dose (between 8AM and 9 AM). Please bring stool samples if available for the period between 24-hour time point and the 48-hour time point.

## Study Chart

In this study, you will receive fexofenadine with or without sodium lauryl sulfate on the first day of a three-day Period. The Period will be repeated three times. There will be one to three weeks between each Period. Each Period is numbered in order. The chart below shows what will happen to you during Period 1 and future treatment Periods. The left-hand column shows the study day, and the right-hand column tells you what will be done on that day.

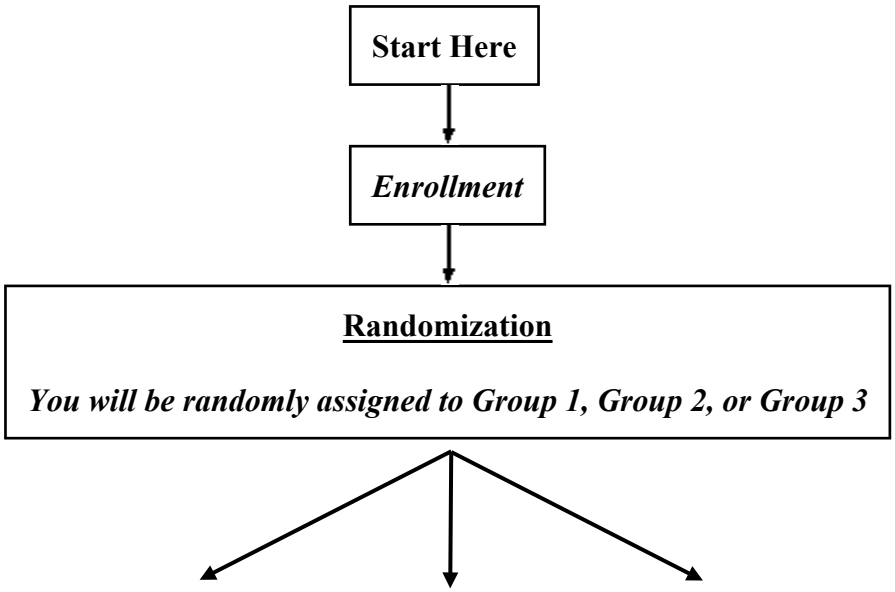
**Period 1, Period 2, and Period 3**

| Day | Time | What will happen |
|---|---|---|
| *Day 1 (approx. 9 hours)* | *Early morning* | • *Check-in to the UCSF Clinical Research Services site at 8:00 AM.*<br>• *Record vital signs and weight.*<br>• *For female subjects, urine sample will be collected for pregnancy test.*<br>• *A nurse will provide you with the period drug and water. You will be asked to drink a limited amount of water and no food for the next 4 hours.*<br>• *Blood draw before dosing.*<br>• *You will be asked to begin collecting your stool.* |
| *Day 1* | *30 minutes (+/- 10 minutes) post drug* | • *Blood draw* |
| *Day 1* | *1 hour (+/- 10 minutes) post drug* | • *Blood draw* |
| *Day 1* | *2 hours (+/- 10 minutes) post drug* | • *Blood draw* |
| *Day 1* | *3 hours (+/- 10 minutes) post drug* | • *Blood draw* |

| | | |
|---|---|---|
| *Day 1* | *4 hours (+/- 10 minutes) post drug* | • *Blood draw* |
| *Day 1* | *6 hours (+/- 10 minutes) post drug* | • *Blood draw* |
| *Day 1* | *8 hours (+/- 10 minutes) post drug* | • *Blood draw*<br>• *Take stool collection kit and instructions.*<br>• *Leave the clinic.* |
| *Day 2 (approx. 30 minutes)* | *24 hours (+/- 30 minutes) post drug* | • *Arrive at the clinic at 8:00 AM.*<br>• *Bring your stool sample container.*<br>• *Blood draw*<br>• *Leave the clinic.* |
| *Day 3 (approx. 30 minutes)* | *48 hours (+/- 30 minutes) post drug* | • *Arrive at the clinic at 8:00 AM.*<br>• *Bring your stool sample container.*<br>• *Blood draw*<br>• *Leave the clinic.* |

## Study Plan

Another way to find out what you will undergo during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.




| | Group 1 | Group 2 | Group 3 |
|---|---|---|---|
| Period 1 | Fexofenadine | Fexofenadine + 3 mg sodium lauryl sulfate | Fexofenadine + 30 mg sodium lauryl sulfate |
| Period 2 | Fexofenadine + 3 mg sodium lauryl sulfate | Fexofenadine + 30 mg sodium lauryl sulfate | Fexofenadine |
| Period 3 | Fexofenadine + 30 mg sodium lauryl sulfate | Fexofenadine | Fexofenadine + 3 mg sodium lauryl sulfate |

## How long will I be in the study?

Participation in the study will take a total of 3 days per period during the study, plus one screening visit.

- Initial screening and follow up screening, approx. 1 hour
- Study Day 1, approx. 9 hours
- Study Day 2, 24-hour blood draw, approx. 30 minutes
- Study Day 3, 48-hour blood draw, approx. 30 minutes

The following period of study will be scheduled at least 7 days, but no longer than 3 weeks, after the dosing. Each subject will participate in three periods to complete the study.

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor or nurses 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 fexofenadine or sodium lauryl sulfate can be evaluated by the study doctor. Another reason to tell the study 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 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?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, study doctors do not know all the side effects that may happen. Side effects may be mild or very serious. Your study team may give you over-the-counter medicines to help lessen side effects. Many side effects go away soon after you stop taking fexofenadine or sodium lauryl sulfate. In some cases, side effects can be serious, long-lasting, or may never go away.

However, not everyone who takes the drug will experience side effects. In fact, most people tolerate fexofenadine quite well. If side effects do occur, in most cases, they are minor and either require no treatment or can be treated by your healthcare provider or you.

Serious side effects are less common. You should talk to the study doctor/researcher about any side effects you may experience while taking part in the study.

**Risks and side effects (uptodate.com) related to fexofenadine (oral administration, up to 180 mg per day) include:**

- More than 10%
    - Headache (5% to 11%)
- 1% to 10%
    - Drowsiness (1% to 3%), fatigue (1% to 3%), dizziness (2%), pain (2%)
    - Diarrhea (3% to 4%), nausea (2%), indigestion (1% to 2%)
    - Menstrual cramps (2%)
    - Viral infection (3%)
    - Muscle pain (3%), back pain (2% to 3%), limb pain (2%)
    - Middle ear infection (2% to 4%)
    - Upper respiratory tract infection (3% to 4%), cough (2% to 4%), runny nose (1% to 2%)
    - Fever (2%)
- Less than 1%
    - Allergic reaction (including trouble breathing, shortness of breath, chest tightness, changes in blood pressure, dizziness/lightheadedness, flushing, swelling, rashes, hives, itchiness, stomach cramps, vomiting, and/or diarrhea), insomnia, nervousness, nightmares, sleep disorder

**Risks and side effects related to sodium lauryl sulfate include:**

- Oral ulcers
- Stomatitis (painful swelling and sores inside the mouth)
- Skin irritant

**Other side effects related to procedures, interventions and participation include:**

- **Blood drawing risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting. Additionally, you may experience some discomfort or inconvenience with having an IV line in the arm or hand.

- **Blood loss:** The estimated total amount of blood that you will have drawn during the entire study is approximately 360 mL (about 12 oz or 1.5 cups). Loss of this amount of blood is less than a blood donation (approximately 500 mL) and is considered safe.

- **Questionnaire:** Some of the questions may make you feel uncomfortable. You are free to decline to answer any questions you do not wish to answer.

- **Reproductive risks:** You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important to understand that if you take hormonal birth control

medications while on this study, you must take your medication 6-8 hours before taking the study drug. Some methods might not be approved for use in this study.

- **Unknown Risks:** The experimental treatments 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.

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

## Are there benefits to taking part in the study?

There will be no direct benefit to you from taking part in this study. However, the benefit of participating in this study is that you are able to add to our knowledge about the rate and extent of fexofenadine absorption. In addition, the information gained may be used to improve drug formulation and dosing strategies in the future.

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

This is not a treatment study. Your other choices include not participating. Please talk to the study doctor as well as your primary care physician about your choices before deciding if you will take part in this study.

### How will my specimens and information be used?

Researchers will use your specimens (blood and stool samples) and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for, but not limited to, genomic, epigenomic, metabolomic, proteomic, and transcriptomic follow-up studies. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Brief definitions:

Genomic – Study of all of a person's genes (the genome) including interactions of those genes with each other and the person's environment.

Epigenomic – Chemical compounds and proteins that can attach to DNA and direct such actions as turning genes on and off, controlling the production of proteins in particular cells.

Metabolomic – Scientific study and analysis of metabolites (substances or byproducts produced during metabolism) produced by a cell, tissue, or organism.

Proteomic – Study of the entire/complete set of proteins that is produced/expressed or modified by an organism.

Transcriptomic – Study of the RNA present in a cell or tissue and related technologies used to study it.

## How will my genetic information be shared?

Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give 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 public government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you.

Donating data 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. Genetic information that results from this study does not have medical or treatment importance currently. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research 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.

There will be no direct benefit to you from allowing your data 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. 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. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing to the address below:

Dr. Katherine Yang
University of California, San Francisco
School of Pharmacy, Department of Clinical Pharmacy
521 Parnassus Avenue, Rm 3302
UCSF Box 0622
San Francisco, CA 94143

and any remaining data will be destroyed. However, we cannot retract any data that has been shared with other researchers.

**Research results:** There may be times when researchers using your information and/or specimens may learn new information. The researchers may or may not share these results with you, depending on several factors.

**Commercial Use:** Your specimens may be used for commercial use. If this happens, you will not share in any profits.

## 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 because 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.

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 University of California
- Representatives and/or designees of the U.S. Food and Drug Administration (FDA)

This research is covered by a Certificate of Confidentiality from the FDA. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the FDA. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

## Are there any costs to me for taking part in this study?

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

## Will I be paid for taking part in this study?

In return for your time, effort, and travel expenses, you may be paid up to $750 for taking part in this study and will be paid in the form of a check for the screening visit and for all subsequent periods. If you cannot complete the required procedures for each period, the amount will be prorated. Below is a description of the payment schedule.

- Screening: $20
- Study Period 1 (about 11 hours and stool samples): $200
- Study Period 2 (about 11 hours and stool samples): $200
- Study Period 3 (about 11 hours and stool samples): $200
- Completion bonus: $130

Parking stickers will also be provided if you will be parking at the study site. You will receive a $130 bonus at the end of the study if you complete all study visits and comply with all requirements. This payment will be to offset your time and inconvenience, and only if you complete the entire period and comply with all aspects of the study, including the scheduled blood draws and stool collection, will you be paid the entire amount. If you fail to comply with procedures relating to the study, including the scheduled blood draws and stool collection, then you will only receive a partial payment that will be prorated.

Payments will be paid in the form of a check according to the payment schedule above. Payments are made approximately 10 days after receipt of the properly completed paperwork. You must provide researchers with your Social Security number and current home address so the payments can be processed. This information will be shared with the UCSF Accounts Payable office. According to law, you must pay taxes on payment for research participation more than $600 per calendar year. You need to keep the study team informed of any address change to receive your tax form.

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

It is important that you tell Katherine Yang, PharmD, MPH or the study doctor, Beth Apsel Winger, MD, or the research nurses if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call her at (415) 502-1994.

**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, depending on a number of factors. The University of California 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 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 the study doctor about any questions, concerns, or complaints you have about this study. Contact the study doctor, or Katherine Yang or their associates at (415) 502-6511.

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.

A description of this clinical trial is 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 website at any time by searching "NCT04534153".

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## OPTIONAL RESEARCH

**Please note: This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these optional studies.**

**You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.**

## Broad Sharing of Genomic Data

### *How will my genetic information be shared?*

*Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give 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 (public or controlled access) government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you.*

*Donating data 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. 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. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research 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.*

*There will be no direct benefit to you from allowing your data 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. 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. If you decide later that you do not want your information to be used for future research, you can notify the investigator, Dr. Katherine Yang, in writing at University of California, San Francisco 1550 4th Street San Francisco, CA, 94158 and any remaining data will be destroyed. However, we cannot retract any data that has been shared with other researchers.*

*Please put **your initials** in the "YES" or "NO" box to indicate your answer.*

*1. My specimens and associated data may be kept for use in research to learn about fexofenadine, sodium lauryl sulfate and the study of the way the body absorbs, distributes, and gets rid of the drug of fexofenadine and sodium lauryl sulfate, and prevention, or treatment of allergies.*

| *YES* | *NO* |
|---|---|

*2. My specimens and associated data may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease) unrelated to this study.*

| *YES* | *NO* |
|---|---|

**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.

_____ _____

Date Participant's Printed Name for Consent

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent