

**UC Davis and UC Davis Health  
Consent to Participate in Research**

**Title of study:** Flavanol Intake in Davis (FID) study: biomarker-estimated habitual (-)-epicatechin and flavanol intake in adults

**Principal Investigator:** Francene M. Steinberg

**Experimental Subject's Bill of Rights**

Someone will explain this research study to you, including:

- The nature and purpose of the research study.
- The procedures to be followed.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

**What are my rights when signing this consent electronically?**

- California law provides specific rights when you are asked to provide electronic consent:
  - You have the right to a paper copy of the consent document
  - You have the right to give consent by signing a paper version of this form instead.
  - If you change your mind about electronic consent, you have the right to ask for your electronic consent to be withdrawn and then you can give consent using a paper form. A copy of your electronic consent will be kept for regulatory purposes. If you wish to withdraw your electronic consent please tell the study team
- Your electronic consent on this form applies only to this research study.

**Introduction and Purpose**

You are being invited to join a research study. The purpose of this study is to see if we can learn more about the types and amounts of flavanols people are eating as part of their usual diet. Flavanols are compounds found in plants and are commonly present in foods and beverages. Previous research has shown that these compounds are absorbed and broken down into metabolites after they are eaten. Certain metabolites are then excreted in urine. In this study, we hope to collect urine and examine the metabolites to learn more about the types and amounts of flavanols people who live in Davis or the greater Sacramento area of California are eating.

If you agree to be in this research, you will be asked to give one spot urine and one 24-hour urine sample. You will also be asked for a small amount of blood (2 2/3 tablespoons) via blood draw by a trained phlebotomist for this research. In addition, you may have the option to extend your

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participation by joining a group of sub-cohort volunteers who will be asked to give one additional spot urine and one additional 24-hour urine sample. This form will call the samples we collect from you “specimens.”

We expect that your participation will be completed within 2 weeks of determining eligibility. The duration of study-related activities includes the time required to complete an Online Screening Questionnaire (0.5 h), Informed Consent (0.5 h), Online Participant Characterization Questionnaires (1.5 h), Urine Collection Materials Pick-Up (15 min), Spot Urine Collection (30 min), 24-Hour Urine Collection (24 hr), and In-Person Study Visit (1 hr). In addition, you may have the option to extend your participation by joining a group of sub-cohort volunteers who will be asked to do additional activities and/or provide additional measurements.

If you decide to participate in this research, you will complete questionnaires about your health, diet, and lifestyle and collect a spot urine and 24-hour urine sample. You will be asked to schedule an in-person study visit at the Department of Nutrition’s Ragle Facility (located on the UC Davis campus). A member of the research team will measure your height, weight, and blood pressure. The health of your arteries will also be measured. You will also be asked for a small amount of blood via blood draw by a trained phlebotomist. If you choose to, you may also participate in additional urine collections and diet questionnaires in a smaller group known as a sub-cohort as detailed below.

**1. Participant Characterization Questionnaires (1.5 hr)**

You will be asked to complete three online questionnaires asking about your health, usual diet, and lifestyle habits. These questionnaires will help us to better understand the characteristics of volunteers participating in the study. Questionnaires to be completed include:

- A Food Frequency Questionnaire (Diet History Questionnaire III (DHQIII)). ~1 hour
- A Physical Activity Questionnaire (International Physical Activity Questionnaire (IPAQ)). ~15 min
- A Health and Habits Questionnaire. ~15 min

**2. Urine Collection Materials Pick-Up (15 min)**

You will be provided with spot and 24-hour urine collection containers and instructions for collection. You can choose to pick up these materials in-person at the UC Davis Department of Nutrition’s Ragle Facility or from a secure lockbox nearby at Meyer Hall or another accessible location.

**3. 24-Hour Urine Collection (24 hr) and Dietary Recall Questionnaire (30 min)**

You will be asked to collect your urine in the 24 hours prior to your scheduled in-person visit. When collection is complete, you will be asked to return your urine sample to the research team at your in-person study visit.

Additionally, you will be asked to complete a questionnaire detailing everything you ate and drank during the 24-hour period that you collected your urine. This questionnaire is a ‘recall’ and so is designed to be completed retrospectively, or the day after your urine collection. It is called the Automated Self-Administered 24-hour Dietary Assessment Tool (ASA-24)).

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**4. Spot Urine Collection (30 min)**

In addition to your 24-hour urine collection, you will be asked to collect a small amount of urine on a different day from your 24-hour collection. This can be done at any time throughout the day. You will be asked to record date and time of collection.

You may choose to return this sample at your scheduled in-person study visit, in person at the Ragle Facility at a time other than your scheduled study visit, or to a secure lockbox at Meyer Hall or another accessible location.

**5. In-Person Study Visit (1 hr)**

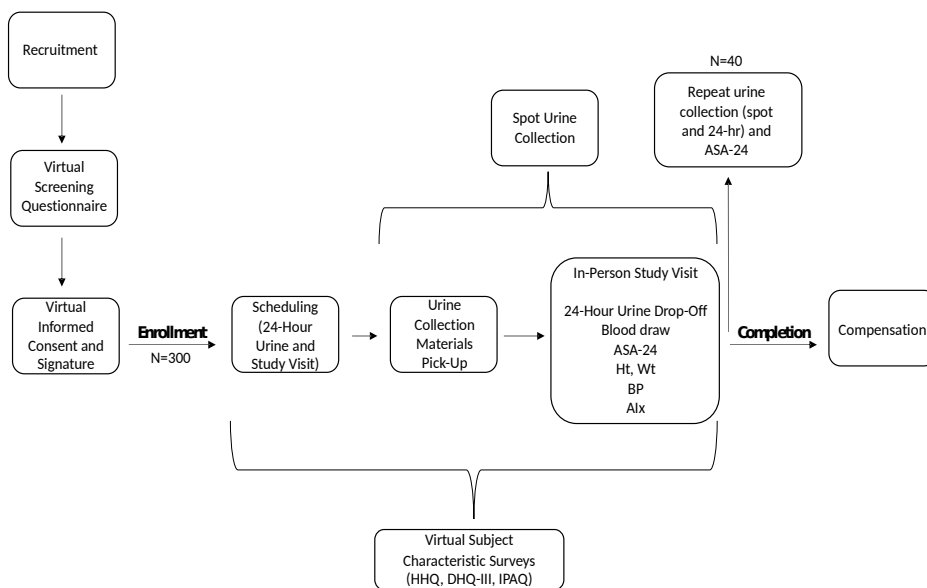
You will be asked to schedule an in-person study visit at the Department of Nutrition’s Ragle Facility (located on the UC Davis campus). You will be asked to come in following an overnight fast and to bring your 24-hour urine collection from the day before.

At the study visit, a member of the research team will measure your height, weight, and blood pressure. The health of your arteries will also be measured (Aix). This measure is noninvasive and is similar to a common blood pressure measurement.

You will also be asked for a small amount of blood (40 ml (2 2/3 tablespoons)) via blood draw by a trained phlebotomist. We will send your blood to the UC Davis Medical Center for comprehensive metabolic panel (CMP), lipid panel, complete blood count (CBC), and HbA1c measurements. Your blood sample will also be used by our researchers to measure nutritional biomarkers, including those for flavanol intake.

**6. Repeat Spot (30 min) and 24-Hour Urine Collections (24 hr) (optional)**

You may choose to repeat the 24-hour urine collection and associated dietary recall questionnaire and spot urine collection as described above in Steps 3 and 4, respectively, 3-10 days after the first collection day.



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Figure 1. Study Timeline

**Here are some issues to think about before you decide whether to join this research:**

We will use your biospecimens and information to conduct this study. Leftover biospecimens and data collected for this research may also be used for future research studies. We will not share any personally identifiable information. Our goal is to make more research possible. These studies may be done by researchers at this institution or other institutions, including commercial entities. Data may be placed in one or more external scientific databases for access and use. Biospecimens may be placed in research repositories. We will not ask you for additional permission to share de-identified information or biospecimens.

You will not receive the results of any of the tests run on your specimens. You will also not receive any commercial value or income that may result from the use of your specimens and data.

Being in research is completely voluntary. You can choose to take part now and change your mind in the future. Whatever you decide, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

You will not receive any direct benefit if you take part in this study. We hope this research will help us to learn more about the types and amounts of flavanols people are eating as part of their usual diet.

The physical risks of this research are minimal. You might feel minor discomfort and there is a slight risk of infection when blood is collected from you.

Genetic and Genomic Research

Researchers will not use your specimens for genetic or genomic testing.

**Confidentiality**

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. Instead, we will record a code on the specimen and information, and we will keep a link between the code and your identity in a different location.

People from UC Davis who oversee and monitor research to see if it is done properly may look at the information we collect about you.

**Compensation**

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If you agree to take part in this research study, we will pay you for your time and effort in completing the study. Compensation will be prorated as follows: \$10 per in-person visit, \$5 per spot urine collection, \$5 for each lifestyle questionnaire (Health and Habits Questionnaire and International Physical Activity Questionnaire (IPAQ)), \$10 for each dietary questionnaire (Diet History Questionnaire III (DHQIII) and Automated Self-Administered 24-hour Dietary Assessment Tool (ASA-24)), \$15 per blood draw, \$15 per blood pressure-Aix measurement and \$25 per 24-hour urine collection. You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

**Questions**

If you have any questions about this research, please feel free to contact the investigators Javier Ottaviani (530-752-3548) or Jodi Ensunsa (530-752-0502)

If you have any questions about your rights or treatment as a research participant in this study, please contact the UC Davis, Institutional Review Board by phone: 916-703-9158 or by email: [HS-IRBEducation@ucdavis.edu](mailto:HS-IRBEducation@ucdavis.edu).

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**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research.

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Signature of subject

\_\_\_\_\_  
Date

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Printed name of subject

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Signature of person obtaining consent

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Date

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