



SCHOOL OF PUBLIC HEALTH

BERKELEY, CALIFORNIA 94720-7360  
140 Warren Hall

## **CONSENT TO PARTICIPATE IN RESEARCH**

### **Name of the Study:**

UC Berkeley Vitamin Study.

### **Purpose of the study:**

The purpose of this research is to examine the effect of supplemental antioxidant vitamins C and E on measures of inflammation and oxidative stress. Recent research has found that compounds found in the blood that are associated with inflammation and oxidative stress, may increase risk of heart disease. Antioxidant nutrients like vitamins C and E may reduce the levels of these compounds in the blood, which in turn may reduce risk of heart disease.

### **Sponsorship:**

The research is funded by the National Institute of Diabetes, Digestive and Kidney Diseases, NIH. The principal investigator is Gladys Block, PhD, Professor of Epidemiology at the School of Public Health, 426 Warren Hall, University of California, Berkeley, CA 94720-7360. Dr. Block can be contacted at 510-643-7896 or [gblock@berkeley.edu](mailto:gblock@berkeley.edu). The principal investigator at Children's Hospital & Research Center, Oakland, CA is Paul Harmatz, MD. Dr. Harmatz can be contacted at 510-428-3076 or [pharmatz@mail.cho.org](mailto:pharmatz@mail.cho.org).

### **Conflicts of Interest:**

Neither the principal investigator nor coinvestigators have any financial ties related to the study that would constitute a conflict of interest.

### **Procedures:**

If you agree to take part in the research, you will be asked to come to the Outpatient Clinic at Children's Hospital & Research Center at Oakland (hereafter referred to as the "Outpatient Clinic"), on a weekday morning for a total of two clinic visits. The first clinic visit will take about 90-120 minutes and the second will take about 30-45 minutes. The first and second clinic visits will be scheduled about 60 days apart. For both visits you will be asked to arrive at the Outpatient Clinic after having fasted from food and beverages, other than water, for 12 hours.

This consent form, and a very similar one from Children's Hospital & Research Center at Oakland, is being sent to you in the mail before your clinic appointment. Please take time to read the consent forms prior to your first clinic visit. You will also receive in the mail questionnaires related to your diet and physical activity, and personal information. You can complete them at home in about 45 minutes. Please bring your two consent forms and three completed questionnaires to your first clinic visit. If you drive to the Outpatient Clinic, you will be given a voucher to pay for your parking at the hospital garage. The Outpatient Clinic is located in the building adjacent to the hospital parking garage.

At your first clinic visit the staff will register you at the Outpatient Clinic, have you sign the two consent forms, and ask you questions related to your recent diet, medication use, and health history. If you are female, before drawing blood you will be asked to provide a urine sample which will be tested for evidence of pregnancy. You will not be eligible to participate in the study if the pregnancy test is positive. Next, a nurse will measure your weight, height, waist and hip circumference, blood pressure, pulse, and temperature, and draw about 45 milliliters of blood from your arm (approximately three to four tablespoons).

During your first clinic visit a nurse will also review with you your completed diet, physical activity, and personal information questionnaires. You will also be assigned to take two pills by mouth each day, with food, for 60 consecutive days. The pills contain either 1000 mg of vitamin C, or 800 IU of vitamin E, or inactive materials. Pills with inactive materials are called placebo pills. Which pills you receive will be decided completely by chance, and neither you nor the study staff will know which pills you receive until the study is completed and analyzed. You will also be asked to refrain from taking any other vitamin C, vitamin E, iron, or multivitamin supplements that contain vitamin C, vitamin E, or iron for the duration of the study, other than those supplied by the study team during the research.

The final step in your first clinic visit will be to have your abdominal diameter, bone density, and percent body fat measured. The location for this test is the Children's Hospital of Oakland Research Institute which is about three blocks north from the Outpatient Clinic. You can either take the free hospital shuttle round trip, or drive your car. Parking at the Children's Hospital of Oakland Research Institute is free.

Bone density and percent body fat will be measured by a dual energy x-ray absorptiometry scanner. Your abdominal diameter will be measured using abdominal calipers. You will be asked to lie still on a padded table. Please wear street clothes without metal buttons or zippers, such as sweat pants and sweat shirt. If this is not possible, you will be provided with paper shorts and t-shirt for wearing during testing. This scan involves a minor amount of radiation exposure, 9.18 mRad total. This is about the amount of radiation you would be exposed to if you flew on an airplane from San Francisco to New York. The scan itself takes about 15 minutes. Calcium supplements may interfere with your results, so please do not take a calcium supplement on the morning of your exam.

Certain medications can interfere with the tests we will perform on your blood samples. If you are occasionally taking over-the-counter medications for pain or inflammation, such as aspirin, ibuprofen (Advil, Motrin), or naproxen (Aleve, Naprosyn), you will be asked to use the pain reliever acetaminophen (Tylenol) instead during the study. Acetaminophen functions as a pain reliever but not as an anti-inflammatory medication. Therefore, before changing any medications you are advised to consult with a physician.

If you wish to participate in the study, but have been taking medications that interfere with blood tests, you will be asked to stop using these medications for a 30-day "washout period" prior to your first clinic visit. If you require a washout, your participation in the study would span 90 days including 30 days of washout and 60 days of taking study supplements. If you are taking an aspirin regularly to prevent heart attacks you can continue to take a single low-dose (81 mg) aspirin each day. However, if during the study you have need for an over-the-counter medication for pain, you will be asked to use acetaminophen (Tylenol) instead of taking extra aspirin. Again, you are advised to consult with a physician if you have questions about your medications.

If you are regularly taking or require over-the-counter pain or anti-inflammatory medications, other than a baby aspirin for your heart, you will not be able to participate in the study.

If because of injury or other reason you need to start regular use of pain or anti-inflammatory medications, other than Tylenol, during the study, you should consult with your own physician or the study physician and probably drop out of the study.

You will also be asked to refrain from changing your diet or exercise patterns during the two-month study. Continue to eat your usual diet and maintain your usual level of physical activity.

During your second appointment, we will again obtain a fasting blood sample from you, measure your weight and blood pressure, and ask you to fill out questionnaires related to your recent diet, medication use, and health history. You will also be asked to return the pill bottles with any remaining pills. The second visit will take about 30-45 minutes. If you drive to the Outpatient Clinic, you will be given a voucher to pay for your parking at the hospital garage.

Your blood samples will be tested for the amounts of certain nutrients and clinical indicators, as well as measures of inflammation and oxidation. We may use your blood sample for possible future testing, including how genes may be associated with dietary factors, inflammation, oxidation, or other markers of disease. This may involve making your blood samples available to other researchers. You have the option of participating in the present study and electing not to have your blood sample saved for future research. Please check the appropriate box below and write your initials on the line next to your selection:

I do want my blood sample saved for future research      Participant Initials: \_\_\_\_\_

I do not want my blood sample saved for future research      Participant Initials: \_\_\_\_\_

### **Safety, Risks and Discomforts:**

There are no significant health risks associated with participating in this study. The risk in drawing blood is temporary discomfort from the needle stick, bruising, and discoloration of your arm; rarely there may be a clot or infection. For healthy individuals there is no physical risk in taking the study vitamins. At much higher doses some people may experience loose stools, but that is not expected at the dose you would receive.

### **Benefits:**

You will not receive any personal benefit from participating in this study. It is hoped that the information learned from this study will benefit society by showing a way to reduce risk of heart attacks. In addition, at the end of the second clinic visit we will provide you with a nutritional analysis of your diet and the results of your bone density, body fat, and blood pressure tests.

### **Confidentiality:**

All of the information obtained about you during the research will be kept confidential. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of the University of California, Berkeley School of Public Health or Children's Hospital & Research Center at Oakland. For records disclosed outside of the University of California, Berkeley School of Public Health or Children's Hospital & Research Center at Oakland, you will be

assigned a unique code number. The key to the code will be kept in a locked file in the principal investigators office. Neither your name nor identifying information will be used in any reports of the research. If you agree to have your blood saved for future research, the same precautions will be taken to preserve your identity from disclosure.

### **Financial:**

At the end of your second clinic visit you will be given a check in the amount of \$70 for the time and travel associated with your participation in the study. Payment will not be prorated if you are only able to participate in part of the study. There will be no charge to you or your insurance company for any of the costs directly related to this study.

The Outpatient Clinic has a parking garage, and if you drive to your appointments, you will be given parking vouchers that will pay for your parking. Parking at the Children's Hospital of Oakland Research Institute, where bone density and percent body fat will be measured, is free.

### **Injuries:**

In the rare event that you are injured as a result of being in this study, the study physician, Paul Harmatz, MD should be notified immediately. If this occurs at Children's Hospital or an associated location we will notify your doctors. If this occurs elsewhere, please notify one of the study investigators directly (Paul Harmatz, MD, or Gladys Block, PhD). You will be treated at the Outpatient Clinic; however, there will be no compensation, and treatment will not be provided free of charge. The costs of this care may be covered by the University of California depending on a number of factors. If you have any questions regarding this assurance, you may consult the Committee for Protection of Human Subjects, 101 Wheeler Hall, University of California, Berkeley, CA 94720-1340.

### **Contact Information**

Paul Harmatz, MD: 510-428-3076 (study physician and co-principal investigator)

Gladys Block, PhD: 510-643-7896 (principal investigator)

Committee for Protection of Human Subjects: 510-642-7461

### **Questions:**

If you have any questions, either before deciding whether to participate or during the course of this study, please direct your questions to Gladys Block, PhD, who may be reached at 510-643-7896, or Paul Harmatz, MD, who may be reached at 510-428-3076.

If you have any questions about your rights or treatment as a participant in this research project, please contact either:

The University of California at Berkeley, Committee for Protection of Human Subjects at (510) 642-7461, or email: [subjects@berkeley.edu](mailto:subjects@berkeley.edu).

IRB Administrator, Children's Hospital & Research Center at Oakland, 747 52<sup>nd</sup> Street, Oakland, CA 94609 at (510) 428-3754.

### **Participation in Research is Voluntary:**

Your participation in this research is voluntary. You have the right to refuse to take part in this study. You may withdraw at any time without jeopardizing your medical care at Children's Hospital & Research Center at Oakland. If any significant new findings are developed during

the course of the research which may affect your willingness to continue involvement, we will notify you as quickly as possible.

**Consent to be a research participant and list of rights:**

Your signature below indicates that you consent to participate in this study. You will be given a copy of this consent form and a copy of the 'List of Rights of a Participant in a Medical Experiment' to keep. Please sign only after you've read and signed the attached "List of Rights."

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature

**Statement of Investigator or Study Nurse:**

The undersigned hereby certifies that he or she has discussed the research project with the participant, and has explained all of the information contained in the consent form including any adverse reactions that may reasonably be expected to occur. The undersigned further certifies that all those participating in the discussion were encouraged to ask questions and that all questions were answered.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator or Study Nurse

## LIST OF RIGHTS OF A PARTICIPANT IN A MEDICAL EXPERIMENT

Under California law, if you are a person participating in a medical study, you must be told:

- ◆ The purpose of the study
- ◆ The procedures which will be followed in the study, and the drugs or devices which will be used
- ◆ If there are any other possible treatment, procedures, drugs or devices which can be given (instead of those offered in the study), and the risks or benefits of those other possibilities
- ◆ If there are any discomforts or risks you may expect from participating in the study
- ◆ If any medical treatment will be available to you if complications happen during or after the study
- ◆ If you might benefit by taking part in the study
- ◆ That you may ask any questions about the study and that you may receive answers
- ◆ That you may leave the study at any time, without affecting the quality of care you would receive outside the study.
- ◆ That you may freely decide if you want to take part in the study and not be pressured into your decision
- ◆ That you will be given a copy of the written, signed, and dated "Consent to be a Research Participant" form.

Dated: \_\_\_\_\_, 20\_\_\_\_

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Participant Signature

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Participant Name