

**Title of research study:** The independent effects of level of kidney function and body composition on establishing HDL cholesterol levels.

**Investigator:** George A. Kaysen, M.D., Ph.D

**Why am I being invited to take part in a research study?**

We invite you to take part in a research study because you have kidney failure or you are a normal control subject. Approximately 20 million people in the United States have some form of kidney failure. People with kidney failure have an increased chance of having low levels of HDL, so called “good cholesterol.” Patients who are overweight or obese also have low levels of HDL. We are trying to find out whether causes of low HDL are the same in people who are overweight and in patients with kidney failure so that we can better treat low HDL cholesterol levels. People with low levels of HDL are more likely to have heart attacks and strokes and are more likely to lose kidney function. We hope to learn more about how kidney failure causes low HDL cholesterol levels. You must be between the ages of 18 and 75 years, not have diabetes and not be taking a lipid lowering medicine. In order to participate in this study, it will be necessary to give your written consent.

**What should I know about a research study?**

The main goal of a research study is to learn things to help patients in the future. No one can guarantee that a research study will help you.

Participating in research is voluntary. You have the right to know about the procedures, risks, and benefits of the research study. If you decide to take part, you can change your mind later and leave the study. To participate in this study, you will need to give your written consent by signing this form. Please take your time to make your decision and discuss it with your family, friends, and caregivers.

About 90 people will take part in this study at UC Davis. Twenty patients will be on dialysis. Forty patients will have moderate to advanced kidney failure and thirty normal, non-diabetic subjects will take part.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Investigator: George Kaysen, MD at phone number: (916)734-3774

Co-investigator: Shubha Ananthakrishnan, MD at phone number: (916) 734-3774

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Information to help you understand research is on-line at <http://www.research.ucdavis.edu/IRBAdmin>. You may talk to

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a IRB staff member at (916) 703-9151, [IRBAdmin@ucdmc.ucdavis.edu](mailto:IRBAdmin@ucdmc.ucdavis.edu), or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

## ***Why is this research being done?***

The purpose of this study is to examine the lipids (fats) and proteins in your blood to find out whether the levels are changed because of your kidney function. We will also measure the amount of fat in your body so that we can see whether the lipid levels that are caused by how much fat there is in your body are changed by your kidney function.

This is a research study. Research studies only include subjects who choose to participate. As a study participant, you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is to make you better informed so that you may give or withhold your consent to participate in this research study. Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you have kidney failure or you are a normal control subject. Approximately 20 million people in the United States have some form of kidney failure. People with kidney failure have an increased change of having low levels of HDL, so called “good cholesterol.” Patients who are overweight or obese also have low levels of HDL. We are trying to find out whether the causes of low HDL are the same in people who are overweight and in patients with kidney failure so that we can better treat low HDL cholesterol levels. People with low levels of HDL are more likely to have heart attacks and strokes and are more likely to lose kidney function. We hope to learn more about how kidney failure causes low HDL cholesterol levels. You must be between the ages of 18 and 75 years, not have diabetes and not be taking a lipid lowering medicine. In order to participate in this study, it will be necessary to give your written consent.

## ***How long will the research last?***

We expect that you will be in this research study for about an hour and the study will be conducted at the CCRC located in the Cypress Building, 2221 Stockton Blvd. Suite D, Sacramento, CA 95817. After you are finished providing blood sample(s), the investigator will continue to test your donated samples but you will not be asked again to give blood samples or participate further in this study.

## ***How many people will be studied?***

We expect about 90 people to be in this research study.

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***What happens if I say yes, I want to be in this research?***

You will need to give a medical history of the medications that you are taking and to provide health information. If you have diabetes, hepatitis, liver disease, receiving treatment for HIV/AIDS, or are pregnant, taking birth control or hormone replacement therapy you cannot be in the study. If you are taking medications to treat diabetes, or taking medicines to treat high cholesterol or low HDL, you cannot be in the study.

If you are a dialysis patient, you will also need to be your red cell count measured within one month and your serum iron measured within 3 months of the start of this study. We will also check your blood for possible infections such as hepatitis. These tests are routinely done in your dialysis clinic, so no extra testing will be done.

***What are my responsibilities if I take part in this research?***

If you decide to participate in this study, you will be asked to do the following: You will be asked to provide a urine sample to measure protein, a substance called creatinine in the urine to see if your kidneys are leaking protein into the urine. We may also draw a blood sample of about a teaspoonful of blood to measure sugar. If you are leaking protein and/or have high blood sugar you cannot be in the study. We will give you the result(s) for you to share with your doctor.

You may suffer some discomfort from needle sticks associated with the blood tests.

Parts of this study may involve standard medical care. Standard care is what is normally done to prevent, diagnose, or treat a certain condition or illness. No experimental clinical procedures are part of this study.

<p><b>The following procedures are part of standard of care and may be done even if you do not join the study:</b> None.</p>	<p><b>The following procedures WILL ONLY BE DONE IF YOU JOIN THE STUDY:</b> Experiments will only be done on your blood sample after it is drawn from you as noted below.  There will be two tests to measure your body composition (body fat) as described below.</p>
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If you are eligible for the study, you will be asked not to eat for 12 hours before your blood is drawn. We will place a small intravenous catheter into a vein in your hand or your arm. We will draw 2 tablespoons of blood, then inject an anticoagulant called heparin into the vein. After 15 minutes we will draw about 1 teaspoon of blood. This will conclude the blood draw section of this study.

For dialysis patients, your blood sample will be drawn in the dialysis clinic. We will draw the blood just before we put you on dialysis using your normal dialysis access. You will still need to go to the CCRC for the body fat measurements but you do not need to fast for that part of the study.

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**Bioimpedance Spectroscopy Analysis (BIS):** Bioimpedance (BIS) uses a weak, harmless electric current. The current is passed through your body. The current is so weak that you will not feel it. By measuring how much current passes through your body we can tell how much fat and muscle is in your body. With the exception of patients who have a pacemaker there is no known risk. Whole body BIS measurements will be performed using two different devices in all patients while patients are in the supine position. The BIS tests take about 5 minutes each, taken after a 15 minute rest. Each device uses two electrodes that are placed on your ankle and two that are placed on your wrist. The measurements are made with each machine attached to the electrodes.

**Dual energy X-Ray Adsorptiometry (DEXA) scans.** You will undergo a whole body DEXA scan for assessment of your total body fat, lean tissue and bone density. The study requires that you lie still on the canning table for no longer than 6 minutes while an image head measuring X-ray transmission scans from side to side, moving over your body from head to foot. Also, for maximum safety, pregnant women should not have a DEXA scan and should not participate in this part of the study.

These tests will measure your body composition and blood fats. They are not a treatment and cannot improve your current health. Should any abnormalities be detected in the course of the tests, you will be informed.

***What happens if I do not want to be in this research?***

You may decide not to take part in the research and it will not be held against you.

Your alternative is not to take part in this study. If you choose not to take part in this study, your future care will not be affected.

Please talk to your doctor about your choices before deciding if you will take part in this study.

***What happens if I say yes, but I change my mind later?***

You can leave the research at any time and it will not be held against you.

Taking part in this study is your choice and completely voluntary.

If you decide to take part in this study, you can decide to stop at any time. Leaving the study will not affect your medical care here at UC Davis. Tell the Researcher if you are thinking about stopping or decide to stop so any risks from the blood sampling can be evaluated by the Investigator.

The Researcher may withdraw you from this research if circumstances arise which warrant doing so even if you would like to continue.

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

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***Is there any way being in this study could be bad for me?***

You may have side effects while on this study. Everyone taking part in the study will be watched carefully for any side effects. However, the Investigator does not know all the side effects that may happen. Side effects may be mild or very serious. Many side effects go away soon after you stop giving blood samples. In some cases, side effects can be serious, long lasting, or may never go away.

Risks and side effects related to drawing blood samples in this study include:

**Likely (for both dialysis patients and controls)**

- Red cell loss (no expected symptoms)
- Iron loss (no expected symptoms)

**Less Likely**

- For control patients, pain from the needle stick is usually minimal.
- For control patients slight bruising can occur at the needle puncture site.
- For control patients, fainting sometimes occurs during or after blood sampling.

**Rare But Serious**

- For dialysis patients, air embolism , from air introduced into you blood tubing during blood sampling. This is a theoretical complication that is prevented by several air trapping safeguards in the blood lines.
- For both dialysis patients and controls, infection caused by bacteria or viruses entering the blood during blood sampling. Sterile techniques are used to prevent this complication.

The DEXA scan in this study involves a low radiation exposure that is less than other diagnostic tests using ionizing radiation. The amount of radiation exposure received in this study is below the levels that are thought to result in a significant risk of harmful effects.

There may also be risks to your privacy. The Researchers will store study records and other information about you in a secure location and will gran access only to those with a need to know. However, just like with other personal information kept by your health care providers, your banks, and others, even these safeguards cannot guarantee absolute protection of the data. If private information gets into the wrong hands, it can cause harm. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance of employment.

For more information about risks and side effects, ask the Researcher.

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**Will being in this study help me in any way?**

You may not benefit from taking part in this research. No immediate direct benefit is anticipated. The information we get from this study may help us to understand lipid levels (low HDL) in hemodialysis patients and suggest better methods for preventing or treating it.

**What happens to the information collected for the research?**

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

We will do our best to make sure that your personal information will be kept confidential. However, we cannot guarantee total privacy. Your personal information may be released if required by law.

We will disclose your information if it is necessary to protect your rights or welfare. For example, you are injured and are in need of emergency care. We will disclose your information if the researchers becomes aware that you may be a danger to yourself or to others. We will disclose your information if the researcher becomes aware that acts of child, elder, or dependent adult abuse or neglect may have occurred.

If the information from the study is published or presented at scientific meetings, your name and other personal information will not be used. Your blood samples and personal information will be labeled with code numbers so that research people and those writing papers will not know that you are providing blood samples for this study. Your records will be stored in a locked room in a locked file accessible only by Dr. Kaysen or his assistant.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission.

Designated University officials, including the Institutional Review Board, and the research sponsor, DCI, Inc. have the authority to review research records.

If information from the study is published or presented at scientific meetings, your name and other personal information will not be used.

**What else do I need to know?**

This is a research study conducted by George A. Kaysen, M.D., Ph.D. from the Department of Internal Medicine and funded by Dialysis Clinics Inc., (DCI). This means that the DCI is giving money to the University of California, Davis so that the study doctor can conduct the study. The Investigator does not have any personal or financial interest in this study.

The only cost to the subject is that of travel to the CCRC for the measurements.

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There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury.

If you agree to take part in this research study, we will pay you \$50 for your time and effort.

The results of this study, including specimens collected, may have commercial value to the sponsors, UC Davis, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

We will inform you in writing of your body composition (percent fat) and HDL levels at the conclusion of the study.

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**Signature Block for Capable Adult**

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

\_\_\_\_\_  
Signature of subject Date

\_\_\_\_\_  
Printed name of subject

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Signature of person obtaining consent Date

\_\_\_\_\_  
Printed name of person obtaining consent

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