

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

**Study Title:** The Blood Pressure Lowering in Dialysis Trial (BOLD trial)

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This is a clinical research study. Your study doctor, Chi-yuan Hsu, M.D., from the UCSF Department of Medicine, Division of Nephrology and/or his research team, will explain the study to you.

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 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 have kidney disease and require chronic hemodialysis treatment.

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

The purpose of this pilot study is to test if it is possible to adjust dry weight target and blood pressure medication to achieve systolic blood pressure <140 mmHg among hemodialysis patients measured in two different settings--at the dialysis unit (before dialysis treatment) or at home. We hope this pilot study will lead to a larger scale study to examine whether such different blood pressure management will improve clinical outcomes.

As many dialysis patients know, the conventional concept for “dry weight” is your normal weight without any extra fluid in your body.

### **Who pays for this study?**

This study is being paid for by research grants from the U.S. Federal Government (National Institutes of Health) and by Satellite Healthcare, a not-for-profit dialysis company.

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

About 50 people will take part in this study total (counting both San Francisco and Seattle study participants). In San Francisco, this study will take place at the dialysis centers where UCSF doctors see patients.

In Seattle, this study will take place at the dialysis centers where our collaborating University of Washington doctors see patients.

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

You will be selected randomly (i.e. by chance only) to be in one of two groups.

In Group 1, we will aim to keep the systolic blood pressure (upper reading) measured at the dialysis unit (before the start of dialysis) below 140 mmHg. In Group 2, we will aim to keep the systolic blood pressure (upper reading) measured at home below 140 mmHg.

In both groups, dry weight target and blood pressure medication adjustment will be made to achieve target blood pressure.

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

You will be asked a series of questions about your health and your symptoms related to blood pressure. We will also review your medical record for additional information to see if you qualify for the study.

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

If you qualify and choose to take part, then you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

**If you are in group 1:** Your blood pressure measured at the dialysis unit before the start of dialysis will be targeted for treatment. This is the current approach many doctors take and it is supported by guidelines and opinion leaders (although most acknowledge the evidence supporting this approach is not strong). The target will be systolic blood pressure <140 mmHg. The study team and your regular nephrologist/health care providers will work together to adjust your dry weight target or blood pressure medications.

**If you are in group 2:** Your blood pressure measured outside of the dialysis unit will be targeted for treatment. This is based on new research that blood pressure measured outside of the dialysis unit is likely more important than blood pressure measured at the dialysis unit. You will be given a blood pressure monitor and asked to measure your blood pressure at home and transmit the readings to the study team (potentially via Bluetooth and a smart phone). You will take your

blood pressure at home morning and evening on one non-dialysis day every 2 weeks (the machine automatically averages 3 readings per sitting). The target is also systolic blood pressure <140 mmHg. The study team and your regular nephrologist/health care providers will work together to adjust your dry weight target or blood pressure medications.

In both groups, you will check in with the study staff every 2 weeks, either by phone or at the dialysis unit, to answer a series of questions about symptoms related to dialysis and blood pressure such as cramping or dizziness.

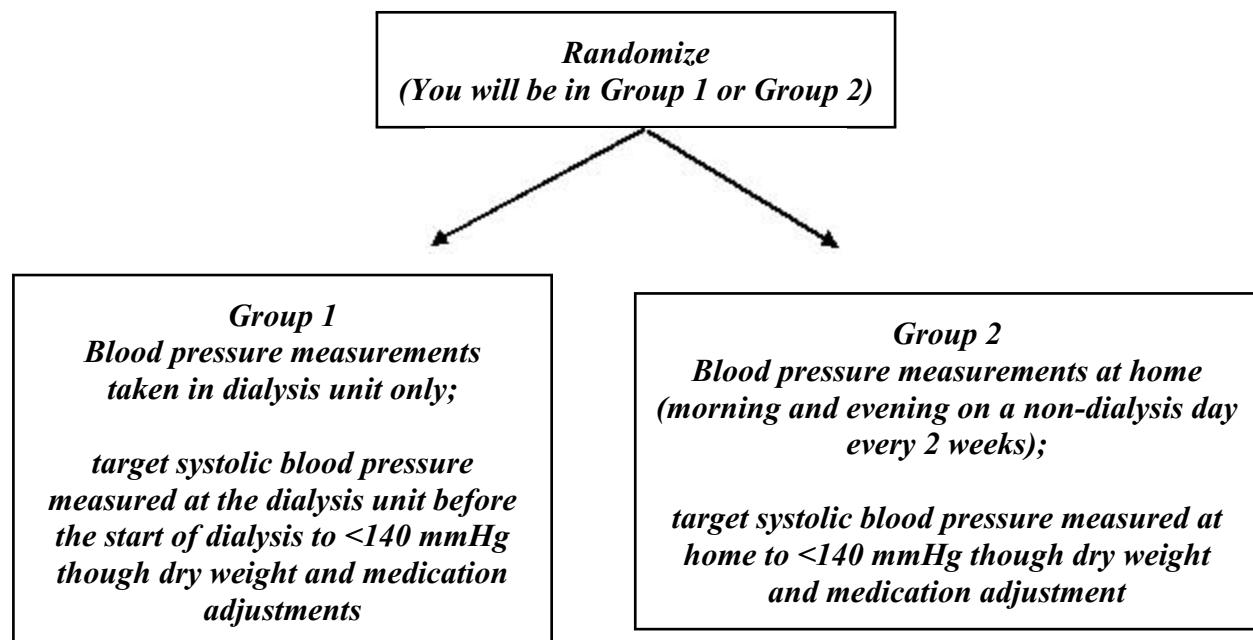
Optional for either group: At the beginning and at the end of the study, you can choose to wear a blood pressure monitor for 44 hours. It will take your blood pressure at regular intervals during this time. Changes in 44-hour averaged blood pressure from beginning to end of the study will give us more information about the impact of being in group 1 or group 2.

All other aspects of your care will remain unaffected.

**Study location:** All study procedures will be done at your regular dialysis unit or at home.

### Study Plan

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



As you may know, adjustment of dry weight target and blood pressure medication dose are the two main ways by which doctors can influence blood pressure levels in patients on hemodialysis. Extra fluid in the body is an important reason patients have high blood pressure.

In either group, if your blood pressure is above goal (i.e. too high), we will gently try to remove more fluid while you are on dialysis and encourage less intake of salt and water (i.e. targeting a lower dry weight). Your dry weight target will be adjusted by small amounts (e.g. by 0.5 to 1 lb every other week). If this is not enough, we will increase your blood pressure medications, also not more frequently than every other week. The changes in blood pressure medication dosage will be within standard clinical practice dose changes. Your dry weight target and blood pressure medications will not be adjusted at the same time. We will only do one or the other.

In either group, if your blood pressure is below goal (i.e. too low), we will gently try to remove less fluid while you are on dialysis (i.e. targeting a higher dry weight) if the study team and your nephrologist think you do not have enough fluid in your body. This will also occur by small amounts (e.g. 0.5 to 1 lb each time). Otherwise, your blood pressure medications will be decreased.

The study chart below summarizes the procedures:

	<b>VISIT 0 Screening Visit</b>	<b>VISIT 1 Baseline Visit</b>	<b>VISITS 2-8 (in person during regularly scheduled dialysis or phone call) 14 (+/-7) days apart</b>	<b>VISIT 9</b>
Informed Consent	<b>X</b>			
Research team review of medical/dialysis records	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Questionnaires on episodes and symptoms of high or low blood pressure	<b>X</b>		<b>X</b>	<b>X</b>
Randomization		<b>X</b>		
Teaching of home BP monitor (if applicable)		<b>X</b>		
Review home BP readings (if applicable)			<b>X</b>	<b>X</b>
Administer home BP monitor experience questionnaire (if applicable)				<b>X</b>
Adjust dry weight or blood pressure medications			<b>X</b>	<b>X</b>
44-hour ambulatory blood pressure monitor (optional) and administer 44-hour ambulatory blood pressure monitor experience questionnaire (if applicable)		<b>X</b>		<b>X</b>

## How long will I be in the study?

You will be in this study for 5 months. We would like to keep track of your medical condition for up to one month after the end of the study. We would like to do this by calling you on the telephone to see how you are doing to help us look at the long-term effects of the study.

## **Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell the study team (Dr. Hsu and his colleagues) if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes 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, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to the changes in dry weight and blood pressure medications include those which are:

### **Likely**

- Dizziness/lightheadedness
- Fatigue
- Cramping during dialysis

### **Possible**

- Erectile dysfunction

### **Rare but serious**

- Passing out/loss of consciousness due to excessively low blood pressure
- Trouble breathing due to excessively high blood pressure

**Unknown Risks:** The new approach to blood pressure management 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 your study doctor.

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

If you are in the group that receives the home blood pressure monitor and it proves to treat your blood pressure with fewer side effects than standard therapy, you may benefit from participating in the study, but this cannot be guaranteed.

If you are in the group whose blood pressure is being managed based on blood pressure measured at the dialysis unit, you are getting standard therapy that the other group is not.

In both groups, you will learn more about blood pressure treatment. You will get a better understanding of how your blood pressure changes over time if you choose to wear the blood pressure monitor for 44 hours.

This study will help doctors learn more about how to best manage blood pressure among hemodialysis patients and it is hoped that this information will help in the treatment of future patients with kidney failure.

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

If you do not take part in this study, you will receive medical care as usual. Participation in this study is completely voluntary.

### **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 as a result of your participation. 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 National Institutes of Health
- Representatives of the Satellite Healthcare
- Representatives of the University of California

### **Will any research-related procedures be billed to me?**

No. The sponsor has agreed to pay for all procedures associated with this research study (e.g. cost of home blood pressure device, cost of 44-hour blood pressure monitor); you or your insurer will not be billed.

You will continue to pay for your blood pressure medications as you were doing before participating in the study. We will be adjusting the dosages of the medications you are already on and if new medications are added, we will work with your nephrologist to select ones with favorable coverage by your insurance.

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

In return for your time, effort and travel expenses, you will be paid \$30 for each month you are in the study, through until Visit 9 in study chart above.

If you choose to also wear the blood pressure monitor for 44 hours at the beginning and at the end of the study, you will receive an additional \$30 the first time and \$30 the second time.

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

It is important that you tell your study doctor, Dr. Hsu, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at (415) 353-2379.

**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 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 and physicians.

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. Contact your study doctor, Chi-yuan Hsu, MD at 415-353-2379.

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 will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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## 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 Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent