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Document:

Informed Consent Form

Official Study Title:

Mi Puente: My Bridge to Better Cardiometabolic Health and Well-Being

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Mi Puente: My Bridge to Better Cardiometabolic Health and Well-Being

Scripps Health & San Diego State University

INFORMED CONSENT

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Research Sites:
Scripps Mercy Hospital, Chula Vista: 435 H Street, Chula Vista, CA 91910
Scripps Whittier Diabetes Institute: 10140 Campus Point Drive, Suite 200, San Diego, CA 92121 San Diego State University: 780 Bay Boulevard, Suite 200, Chula Vista, CA 91910

Sponsor:
National Institutes of Health/National Institutes of Nursing Research (NIH/NINR)

We are asking you to be a part of the *Mi Puente* study. *Mi Puente* is a clinical trial, a type of health research study. Clinical trials include only patients who choose to take part. Before you give your consent to volunteer, please take your time to make your decision. It is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Before you start reading about this research, please read the California Experimental Subjects' Bill of Rights, which is page 9 of this form.

This study is being done by Scripps Health and San Diego State University.

Why is this research study being done?
This research study will try a new way to discharge patients from the hospital to their home. Its purpose is:

- To test how well this new procedure works to keep patients from being readmitted to the hospital or visiting the Emergency Department and
- To see if we can improve the way patients feel physically and emotionally.

We will invite 560 patients to join this study over five years. Patients must be

hospitalized at Scripps Mercy Hospital in Chula Vista and have certain conditions, which are described below.

Who is eligible to participate?

You can participate in this research study if you:

- Consider yourself Hispanic/Latino (and/or Mexican, or Chicano), of any race
- Are in the hospital as a patient at Scripps Mercy Hospital Chula Vista
- Are 18 years of age or older
- Have two or more chronic cardiovascular-metabolic conditions, such as obesity, diabetes, hypertension, dyslipidemia, ischemic heart disease, congestive heart failure, or other chronic coronary conditions.
- Have one or more behavioral health concerns such as feeling depressed, anxious, stressed, smoking, drinking too much alcohol, or having difficulty taking all your medications; and
- Have access to a telephone.

You cannot participate if you:

- Are pregnant
- Have a serious life-threatening condition
- Have a severe psychiatric or neurological/memory condition
- Are going to be discharged to inpatient rehabilitation or nursing care; or
- Do not speak Spanish or English.

What happens in this research study?

If you agree to participate in *Mi Puente* study, you will be asked to sign this consent form. A copy of the signed form will be given to you for your records. You will then be randomly assigned (like a flip of a coin) to be part of the study group *Mi Puente*, or the group that receives usual care. The study and follow-up period will last six months.

How will each group be treated?

Usual Care Group: If you are in the Usual Care group, your healthcare providers will follow all the usual discharge procedures. You will continue to receive medical care, have your medication reviewed, and receive care instructions while you are in the hospital. A team of healthcare professionals will help you with a discharge plan to follow once you leave the hospital.

Mi Puente Study Group: If you are in the *Mi Puente* study group, you will receive both usual care and support from a Behavioral Health Nurse and a Community Mentor.

The Behavioral Health Nurse will:

- Meet with you at least once while you are in the hospital.
- Find out about any language, social, or financial needs you may have.

- Help you manage your behavioral health concerns, such as:
    - Help you identify stress or other issues that may interfere with how you manage your health.
    - Discuss what to expect and what might motivate you to follow through with your discharge plan.
    - Create an action plan that takes your personal strengths and barriers into account.
    - Advise you on how to overcome problems and barriers while you seek help after leaving the hospital.

The Behavioral Health Nurse will review your "Personal Health Record" with you before you leave the hospital. She (or he) will telephone you within three days of leaving the hospital to make sure that you had a successful return home and to answer questions about your medications, symptoms, or referrals.

Before you leave the hospital, the Behavioral Health Nurse will try to introduce you to your "Community Mentor". Your Community Mentor will be your resource for up to 30 days after leaving the hospital. During your first meeting, the Behavioral Health Nurse will give you and your Community Mentor a copy of a form that outlines your action plan. The Community Mentor will schedule weekly follow-up telephone calls during the first and second week after you leave the hospital. If needed, they will call you again three and four weeks after you leave the hospital. If your Community Mentor believes you need medical advice, they will refer you to the Behavioral Health Nurse or to 911, if urgent.

What type of follow-up will I have?

All patients, both in the Usual Care group and in the Mi Puente group, will have the same surveys.

There will be three surveys, lasting about 20-30 minutes each, given by our bilingual research staff. The first survey will be done in person, before you leave the hospital, by a research staff member. After that, we will ask you to complete two more surveys by telephone at 3 and 6 months after you leave the hospital.

During these surveys, you will be asked questions about:

- Your background, such as where you were born, your employment status, and education
- Your quality of your life
- Any barriers to healthcare access
- Your knowledge, skill and confidence in managing your health and healthcare
- Resources you use to manage your chronic conditions

Medical Record Review

We will review your medical record for the next 6 months. We will check if you visit your doctor, go to the emergency department, or are admitted to the hospital again. If you

need to see your doctor, we will review your health problems and your medications. We will also find out how long you stay in the hospital if you are admitted. We will review your medical records three times during the study:

- When you first agree to participate;
- At one month and;
- At six months after you leave the hospital.

How will my information be used?

The information we collect from you and the other people who take part in this study will be combined into one file. Members of the Mi Puente research team will then review this information to see:

- How often patients visited the Emergency Department or were admitted to the hospital;
- How often they sought other healthcare (routine or follow-up appointments);
- How they managed their health; and
- The quality of life patients had.

These results will be compared between the two groups, Usual Care and Mi Puente. We wish to find out if the program has any effect on how patients use healthcare and how they feel physically and emotionally. The results may be published in medical journals, but your name and personal information will never be shown in any report.

What if you cannot reach me on the phone?

If we cannot reach you, we will contact the relatives or others you name when you enroll in the study to help locate you. We will also attempt to search for your information through public directories.

Is anything experimental in this study?

All of the study techniques are well known and routinely used. None of the questionnaires or practices in this research is experimental. What is considered experimental is that we combine these techniques in a new way, to see whether this will be helpful to patients.

Could I face any risks or discomforts?
All of the techniques used in *Mi Puente* study are routine at doctors' offices and are considered safe. You may feel uncomfortable or embarrassed when you are asked sensitive questions or when you discuss your behavioral health needs or how you deal with your chronic condition. Well-trained research staff will make sure that you are as comfortable as possible. You are encouraged to complete all items and measures. You may refuse, however, to answer any question or participate in any surveys that makes you feel uncomfortable.

You may find it hard to give your time to our study. We know that your time is valuable and we will keep all the surveys as short as possible and conduct the follow-up surveys by phone at a time suitable to you. We will also give you reminder calls and send reminder letters to make communication easier and more successful.

Is there a cost for participating in the study?
There is no cost in money for participating in this study. The only cost is your time during contact with our research team.

Depending on your answers to the questions, our research staff may refer you to your healthcare provider for further examination, diagnosis, or treatment. Any cost related to diagnosis or treatment by your healthcare provider will be covered by either you or your health insurance. The *Mi Puente study* has no funds to pay for diagnostic procedures or treatment. This does not take away any of your legal rights.

Will I be paid for participating?
You will receive a $20 gift card when you complete each of the baseline and 3-month survey. You will receive a $25 gift card after you complete the 6-month survey. You can receive up to $65 in gift cards if you complete all of the surveys in the study.

What if I refuse to participate in the study or wish to withdraw early?
Taking part in this study is voluntary. You may decide not to join or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits and it will have no effect on the quality of medical care you get. It will not affect your ability to get health care from Scripps Mercy Hospital Chula Vista. It will not affect any healthcare compensation or enrollment in any health plan. Taking part is completely up to you and if you choose to do so, you have the right to quit at any time.

If you decide to leave the study, we may still use the information collected about you unless you ask that we remove your records from the study files. If you choose to leave the study, you should call the *Mi Puente* Project Manager at the telephone number at the top of this form.

Taking part in this study may be stopped at any time by the investigators without your

consent. This may happen if it is considered best for your health or safety, if funding for the study ends, or for any other reason.

What are my alternatives to joining the study?
You may decide not to join this research study. You will then be offered the best-practice discharging procedures that are already in use. Your treatment will not be affected. Not joining is your alternative.

What are my rights if I join?

- You may call the Project Manager to ask any questions about this study. The telephone number is listed at the top of this form.
- You may decide not to take part in the study or you can decide to quit at any time after starting. Whatever you do, your medical care at Scripps Mercy Hospital Chula Vista or the community clinics will not be affected.
- For any questions about your rights, you may call the Scripps Office for the Protection of Research Subjects at (858) 678-6402. You should also read the *Experimental Subject's Bill of Rights*, which is on page 9 of this form.
- You retain all your legal rights whether you join this research study or not.
- You have the right to be told about any new information that might make you change your mind about participating in this study.

What are my responsibilities if I join?
If you join this study, you are expected to:

- Cooperate with the research staff.
- Keep or reschedule your study appointments.

What if new information becomes available?
If we have new information that may change your mind about taking part in the study, we will let you know as soon as possible. We will then ask you to tell us if you wish to continue or not.

May I participate in other research studies, while taking part in *Mi Puente*?
If you qualify for another research study, you are welcome to go on with whichever study you feel is better for you.

You may participate in any unrelated research study and may freely contact other study coordinators.

What about confidentiality?
Protecting your privacy is a top priority for *Mi Puente.* Any information we receive about you during this study will be treated as strictly confidential to the extent permitted by law. To make sure that the information you share is protected, a code number will be

assigned to you and your private information. This number will only be given to research staff and investigators of *Mi Puente*. Files linking names and other identifying information will be saved on a secure computer. We will use technology that prevents unauthorized individuals from accessing and reading this information. If your information is printed, it will be kept locked and accessible only to *Mi Puente* personnel.

When study results are published, your name and other identifying information will not be revealed. Results from this study and from your records may be reviewed and photocopied by federal regulatory agencies, such as the Office of Human Research Protection and the Institutional Review Boards of Scripps and/or San Diego State University. The researchers can share information without consent only in very special instances (for example, in case they believe that a person taking part in the study or some other individual is in serious danger of harm).

For more information, please read the ***Authorization to use your Private Health Information*** at the end of this form.

Will Scripps Health, San Diego State University or the research investigators benefit from this study?

Scripps Health, San Diego State University and the research investigators and staff will be paid to do this research under a research grant from the National Institutes of Health (NIH). Findings from this research study will also help to guide the care and treatment that is delivered to future patients.

Questions and/or more information regarding this study:

If you have any questions or would like more information at this moment about this research study, please ask. If you get to have any questions or concerns at any time while you are taking part in the study, please contact the Project Manager -- contact details are listed at the top of this form.

If you have questions regarding your rights as a participant in this study, you may contact the *Scripps Office for the Protection of Research Subjects* at (858) 678-6402.

I agree to participate.

I have read and understood the explanation of the study. The study has also been explained to me by_____. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel obligated to take part.

I have read the attached ***Experimental Subject's Bill of Rights*** and the ***Authorization to use my Private Health Information*** *that contain some important information about research studies. I must sign this consent form, the* ***Experimental Subject's Bill of Rights*** *and the* ***Authorization to use my Private Health Information****. I will be given a signed copy of each to keep.*

Printed Name of Subject	*Signature of Subject*	*Date*

Signature of person conducting the informed consent discussion	Date

Role of person named above in the research project

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS*

If I am asked to consent to be a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:

Learn the nature and purpose of the experiment (also called "study" or "clinical trial").

Receive an explanation of the procedures to be followed in the study, and any drug or device to be used.

Receive a description of any discomforts and risks that I could experience from the study.

Receive an explanation of any benefits I might expect from the study.

Learn about the risks and benefits of any other available procedures, drugs, or devices that might be helpful to me.

Learn what medical treatment will be made available to me if I should be injured because of the study.

Ask any questions about the study or the procedures involved.

Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment.

Receive a copy of the signed and dated consent form.

Decide to consent or not to consent to a study without feeling forced or obligated.

If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Scripps Office for the Protection of Research Subjects, which protects volunteers in research studies. I may telephone the Office at **(858) 678-6402**, 8:00 a.m. to 4:00pm weekdays, or I may write to the Scripps Office for the Protection of Research Subjects, 4275 Campus Point Ct., CPB200, San Diego, CA 92121.

By signing this document, I agree that I have read and received a copy of this Bill of Rights.

_____ _____

Signature of Subject or Legal Representative Date

**California Health & Safety Code, Section 24172*

Authorization to use your Private Health Information

Name of Study: *Mi Puente: My Bridge to Better Cardiometabolic Health and Well-Being*

Principal Investigator: *Athena Philis-Tsimikas, MD*

What is private health information?

Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- Your age, where you live, and how to contact you
- Information from your hospital and clinic records
- Answers to questions about your mental and physical health

Who else will see my information?

- Only the investigators named in the consent form and research staff that receives training in confidentiality procedures will see your information. In addition, Scripps committees that overview research to help protect people who join research studies may review your data if needed. Your name will not be used in any report that is written.
- If ***you*** share your information with people outside the research team, it will no longer be private.

How long will Scripps use and share my information?

Your information will be used and shared via reports and publications in aggregate (group) form (i.e., with no names or identifying information) for several years after the research is completed in 2020.

What if I change my mind about sharing my research information?

If you decide not to share your information anymore:

- The sponsor and the research team can continue to use any of the private information that they already have.
- You will no longer be a part of the research study.
- You will still get the same medical care that you have always had.

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- You must write to the investigator and tell her that you no longer want to share your information. Write to the investigator at:

Athena Philis-Tsimikas, MD
10140 Campus Point Drive, Suite
200 San Diego, CA 92121

Do I have the right to see and copy my research information?
You cannot see your research information while the study is going on, unless it is also being used for your health care. Once the study is over, you can ask to see any research information that is in your Medical Record that is kept at Scripps Whittier Diabetes Institute.

If you agree to share your information, you should sign this form below. You will be given a copy of this form.

****

I agree to share my information as described in this form

_____
Print your name

_____ _____
Sign your name Date

If you have questions or concerns about your privacy and the use of your personal medical information, contact the investigator at the telephone number listed in the consent form.