UNIVERSITY OF CALIFORNIA, IRVINE

CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Sponsor / Study Title:	**Brigham and Women's Hospital/TIMI Study Group / "A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Trial to Evaluate the Effect of In-Hospital Initiation of Dapagliflozin on Clinical Outcomes in Patients Who Have Been Stabilized During Hospitalization for Acute Heart Failure"**
Protocol Number:	**D1690C00078**
Principal Investigator: (Study Doctor)	Dawn Lombardo, DO
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Section 1 Introduction

You are being invited to join a clinical research study (also known as a trial). Before you agree to participate in this study, you need to know the risks and benefits to help you make an informed decision. This process is known as "informed consent".

This informed consent form tells you about the study in which you are being asked to participate. Please read the information carefully and discuss it with anyone you want. If you have questions, please ask the study doctor or study staff to answer them.

Your decision to participate in this study is voluntary. This means:

- You are free to decide to participate in this study or not.
- You are free to stop study treatment and study-related activities at any time and without any reason.
- If you do not want to participate in this study, then this decision will not affect your medical care.

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.

Your study doctor is a researcher for this study. As a researcher, he/she is interested both in your health and how this study is carried out. The study doctor is being paid by Brigham and Women's Hospital ('the study sponsor') to carry out this study.

You may ask for a second opinion about your care at any time. You can get this opinion from a doctor who is not connected with this study.

If you agree to participate in this study, your primary care physician (PCP)/treating physician will be informed that you are taking part.

Read this information carefully and please ask the study doctor or the study staff if you have any questions.

Section 2 What is the background and purpose of the study?

This study will test whether the drug dapagliflozin is safe and has beneficial effects when added to conventional heart failure therapy in patients who have been admitted to the hospital for acute heart failure.

Dapagliflozin is a drug that has been approved by the US Food and Drug Administration (FDA) to improve blood sugar control in patients with type 2 diabetes and to reduce the risk of hospitalization for heart failure in patients with type 2 diabetes and either cardiovascular disease or cardiovascular risk factors. Dapagliflozin has also been approved by the FDA to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure regardless of whether they have diabetes. It has not, however, been studied in patients hospitalized for acute heart failure. The use of dapagliflozin in this study is investigational. An investigational use is one that is not approved by the FDA. This trial will determine if it is safe and beneficial to start dapagliflozin during hospital admission for acute heart failure.

Approximately 2400 other people like you will take part at approximately 150-250 study sites in the United States, Canada, and Europe. The study is led by the TIMI Study Group, an academic research organization at Brigham and Women's Hospital and Harvard Medical School (Boston, MA USA).

Section 3 What will happen if I take part, and what do I have to do?

You will be asked to take part in this study for 2 months. If you decide to join this study, you will have a screening visit and 4 study visits. Screening and Visit 1 (also called randomization) will take place while you are still in the hospital and may occur on the same day. After you have been randomized, you will be asked to return to the study center at one (1) week ("Visit 2"), one (1) month ("Visit 3"), and two (2) months ("Visit 4") after randomization. At these visits, the study procedures outlined below will be performed.

During the study you will be asked to take study drug once a day. You will either receive dapagliflozin 10 mg or an identical-looking placebo daily. Which study drug you will receive throughout the study is decided at random by a computer (purely by chance, like flipping a coin). You have a 50% chance of receiving dapagliflozin and a 50% chance of receiving placebo. You and your study doctor will not know which study drug you will receive; however, the study doctor can get this information in case of an emergency. To keep you and the study doctor from knowing which study drug you are taking, this study uses placebo pills. A placebo pill is a tablet that looks like the study drug but has no medicine.

In this consent form, both dapagliflozin and placebo are described as "**study drug**".

You cannot participate in any other research studies that involve investigational drugs or devices while participating in this study.

What will happen at each visit during your participation in the study is detailed below.

Screening visit

Your first visit (called your Screening Visit) will take place in the hospital. The study team will explain the study to you and answer any of your questions. If you want to continue, you will be asked to sign and date this Consent Form agreeing to take part in the study.

As part of standard care in the hospital, your height, weight, blood pressure and heart rate will be measured, and blood and urine samples will be collected. If some of these tests are not done as part of your medical care in the hospital, the study doctor may do them to see if you qualify for this study. If you are a female of childbearing potential, you will be tested to see if you are pregnant.

The study team will ask you about your health and your medical history including any medications you have been taking. The study doctor will review the results of the screening procedures and will tell you if you meet the requirements to continue participation in the study. If that is not the case, your participation will end after the screening period.

Visit 1 (Randomization): prior to hospital discharge

- This visit will take place while you are still in the hospital. It may be the same day as the screening visit or up to 14 days after the screening visit.
- Your blood pressure, pulse, height and body weight may be measured again.
- You may have another blood test.

- The study team will ask you about any medications and about your medical history.
- You will be asked to fill out questions about your health and quality of life.
- You will be given a 2-month supply (2 bottles) of study drug to be taken once daily starting at this visit. Study tablets should be taken at approximately the same time of day each day.
- The next visit will be scheduled.

Visit 2 (occurs 1 week after randomization)

- Attend visit at study center.
- Bring your bottles of study drug to study visit.
- You will be asked about additional medical history, current medications you are taking and if you have had any medical problems since your last visit.
- Your blood pressure, pulse, and body weight will be measured.
- Blood samples will be taken to check on your health.
- The study team will review whether you have taken the study drug as directed and they will review any new relevant information since Visit 1.
- You will continue to take the study drug once daily at approximately the same time of day throughout the study period.
- The next visit will be scheduled.

Visit 3 (occurs 1 month after randomization)

- Attend visit at study center.
- Bring your bottles of study drug to study visit, even if empty.
- You will be asked about additional medical history, current medications you are taking and if you have had any medical problems since your last visit.
- Your blood pressure, pulse, and body weight will be measured.
- Blood samples will be taken to check on your health.
- The study team will review whether you have taken the study drug as directed and they will review any new relevant information since Visit 2.
- You will continue to take the study drug once daily at approximately the same time of day.
- The next visit will be scheduled.

Visit 4: End of study visit (occurs 2 months after randomization)

- Attend visit at study center.
- Bring your bottles of study drug to study visit, even if empty.
- You will be asked about additional medical history, current medications you are taking and if you have had any medical problems since your last visit.

- Your blood pressure, pulse, and body weight will be measured.
- Blood samples will be taken to check on your health.
- The study team will review whether you have taken the study drug as directed and they will review any new relevant information since Visit 3.
- You will be asked to fill out questions about your health and quality of life.
- You will return any unused study drug that you have not taken.

End of study treatment visit (completed for participants who prematurely discontinue study drug)

If, during the study, you permanently stop taking study drug for any reason, we will ask you to return for an End of Study Treatment Visit as soon as possible after the last dose of study drug. At this visit, you will have a full assessment completed. This will include all items that would have been completed at the End of Study Visit, except for the questions about your health and quality of life.

Following End of Study Treatment assessments, you will continue to be followed at your regularly scheduled visits until the study end. You will be asked to continue all study visits as planned and participate in the study as if you are still receiving study drug. You will be asked about your overall health and whether you have had any problems or discomfort since your last study contact. Your blood pressure, pulse and body weight will be measured, information on or changes to the medications you take will be recorded.

If discontinuing study drug was your choice, you may be asked by the study doctor to consider re-starting study drug at later study visits. If the discontinuation of study drug was your study doctor's decision, the study doctor may suggest that you begin taking it again if the reason for discontinuation is no longer there. You are not obliged to accept the suggestion and you may choose to not re-start taking study drug. Either way you will be asked to continue with all other study activities as planned.

Completion of the study

After completing the End of Study Visit at 2 months, your participation in the study is ended. You will return to your normal medical care.

The study sponsor may find it necessary to stop the study for safety reasons. In addition, the study sponsor may stop the study for administrative reasons unrelated to the purpose of the study. Your withdrawal by either the sponsor or the study doctor may be done without your consent.

Contact during the study

At each visit, the study doctor or staff will review your contact information and update if necessary. If during the study, your study doctor loses contact with you (for example, study appointments are missed or the study doctor needs follow-up information from you and the study team has been unable to reach you), the study doctor will try to obtain updated contact information for you. They may do this by contacting the individuals whose details you provided, your primary care physician, or search publicly available sources, such as information available from voting registries. If updated contact information is not available, your personal information (name, address, telephone, and date of birth) may be given to a participant finder service or other representative of the study doctor to help contact you (as permitted by local regulations). No other party will receive this information.

If you have withdrawn your consent from the study, your contact information will not be forwarded to these organizations.

Unscheduled visits

Phone contacts or unscheduled visits may also be done any time during the study if the study doctor deems it necessary.

Section 4 What are the possible side effects, risks and discomforts of taking part?

Dapagliflozin may cause some side effects. You may experience none, some, or all of those listed below. There may be risks involved in taking dapagliflozin that have not been identified in the studies performed so far. There is always a risk involved in taking a new drug, and you are encouraged to report anything that is troubling you.

The safety profile of dapagliflozin has been evaluated in clinical studies and development programs for type 2 diabetes mellitus, type 1 diabetes mellitus and heart failure. In these studies, dapagliflozin was generally safe and well tolerated.

Common side effects (greater than or equal to 1 in 100 people, to less than 1 in 10 people) are:

- **Urinary tract infection (UTIs)** where symptoms may include discomfort with urination, increased urge to urinate, or fever.
- **Genital infections** as yeast infections of the vagina, vulva or penis (thrush) are more common in women and in people with a history of such infections. Symptoms may include irritation or pain, itching, unusual discharge or odor, or a rash.
- **Back pain**
- **Increased urine volume** due to higher levels of sugar into the urine, may lead to larger amounts of urine or increase in urination frequency. Signs of losing too much body fluid could be low blood pressure or dizziness.

A rare side effect (greater than or equal to 1 in 10,000 people, to less than 1 in 1,000 people) is:

- **Diabetic ketoacidosis**
  In rare cases, people with type 2 diabetes can develop diabetic ketoacidosis. This is a serious condition that may require hospitalization. Symptoms of diabetic ketoacidosis could include nausea, vomiting, abdominal pain, excessive thirst, frequent urination, weakness or fatigue/tiredness shortness of breath, fruity-scented breath and confusion. More specific signs of diabetic ketoacidosis include high ketone levels in your blood or urine and most often high blood sugar level (hyperglycemia). It is important to know that you may develop diabetic ketoacidosis even though your blood sugar values are normal or near normal (less than 14 mmol/L [250 mg/dL]. Study staff will instruct you on steps to prevent and how to recognize signs and symptoms of diabetic ketoacidosis. Contact your study doctor, and seek medical attention, if you experience any of the symptoms listed above.

Side effects from post marketing reports of unknown frequency

- **Rash**

Additional information:

As the study drug may contain lactose, you may feel some discomfort in your stomach and bowels if you are lactose intolerant.

Allergic reaction

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- having a hard time breathing
- wheezing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- a fast pulse
- sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Loss of confidentiality

There is a risk of loss of confidentiality of your information that is used in this study. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Study tests

Drawing blood may result in pain, irritation, bruising, bleeding, or irritation at the site of the needle stick. There is also a possibility of fainting or infection.

New information

Your study doctor may receive new information about the study drug. If the study doctor believes it may affect your decision to take part in the study, you will be told in a timely manner. If this changes your decision to take part in the study, please talk with your study doctor about your decision.

Women of childbearing potential

If you are a woman of child-bearing potential:

There might be unknown risks to the unborn baby if you are or if you become pregnant during the study. Due to these risks, you must not take part in this study if you are pregnant, plan to become pregnant during the research study period, or if you are breast-feeding a baby.

By signing and dating this consent form, you confirm to the best of your knowledge that you are not pregnant now and you do not intend to become pregnant during this study. A pregnancy test will be done to confirm that you are not pregnant before you take part in this study. Some methods of birth control will not work when you are taking certain drugs.

You must use a reliable birth control method throughout the study and 4 weeks after your last dose of study drug. Your study doctor will explain effective methods of birth control.

If at any time during this study you think you might be pregnant, or later learn that you became pregnant during the study, you must contact the study doctor immediately for further instructions about your participation in this study. If you or your study doctor suspect that you may be pregnant, you should stop taking study drug immediately. If pregnancy is not found, you may re-start your study drug. If you do become pregnant, you will be followed until the end of your pregnancy.

Your health information will become part of the research study records. It will be shared with the study sponsor and the Advarra Review Board (a group of people who review research studies to protect the rights and welfare of research participants). With this information, the study sponsor may be able to determine if there are any effects of the study drug upon unborn children.

Section 5 What are the possible benefits of taking part?

It is possible, but not guaranteed, that the study drug might help your condition. However, it may also be possible that your condition will not improve while you are in this study. You will continue to receive your other background heart failure medications during the study.

You will receive study-related visits, procedures, tests, and the study drug at no cost to you.

Information gained from this study may help to develop new treatments for patients in the future.

Section 6 What other treatments are available?

You do not need to participate in this study to receive treatment for your condition.

Participation in this study does not replace your usual ongoing medical care by your regular doctor or specialist.

Section 7 WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the study doctor if you believe that you have been injured because of taking part in this study. You can tell the study doctor in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, Brigham and Women's Hospital/TIMI Study Group, or billed to you or your insurer just like other medical costs, depending on a number of factors.

The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

For any side effects, adverse reaction, illness or injury resulting from a defect in the study drug, the study funder, AstraZeneca, LP, may pay for the reasonable costs of medical treatment.

If the study funder covers these costs they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. This information will not be used for any other purpose.

Section 8 Will there be payment for taking part in this study?

You will not receive any monetary compensation for your participation in this study.

Section 9 What are the costs of taking part in this study?

The study sponsor will supply the study drug at no cost while you take part in the study. Any additional research-related tests, procedures or visits will also be provided at no cost while you take part in this study:

- Study visits
- Study procedures
- Study laboratory tests

You and /or your health plan/insurance will be billed for the costs of any routine medical care you receive to diagnose and/or treat any medical condition(s) within the scope of this study. You and /or your health plan/insurance will need to pay for this routine care. You will also be billed for any co-payments or deductibles required by your insurance. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs. Financial counselling and itemized cost estimates are available upon request.

Section 10 Do I have to take part?

Taking part in this study is voluntary. It is up to you whether or not to take part in this study. You may refuse to take part or stop taking part in this study at any time. If you choose to refuse to join or stop taking part later, there will be no penalty or loss of benefits that you are already receiving. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

What if I work for the study center? What if I am a family member of someone who works for the study center?

Study center employees and their family members may not participate in this study.

Section 11 WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, the study sponsor, the Institutional Review Board, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Your Health Information and Identification

The part of your health information sent by the study doctor to the study sponsor usually does not directly identify you (for example, by name, address, or social security number). Instead, the study doctor uses a code number on the information sent to the study sponsor. The study sponsor, people who work with the sponsor on the study, and government agencies and other groups that watch over research studies like this one may look at all your health information. Regulatory authorities such as the FDA may also require that the study doctor turn over to them copies of all your health information. The reason these people may look at your health information is to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

Possible Transfer of Your Health Information Out of the Country

As explained above, the study sponsor may send your study data (with a code number, but not your name) outside of the United States for the reasons described in this form. Please know that the laws in other countries may not provide the same level of data protection and may not stop your study data from being disclosed to others.

Notice on Redisclosure of Your Health Information and Confidentiality

The researchers conducting this research can disclose your protected information only to the persons whom you have permitted to see it, and only in the ways you have permitted. However, if you sign and date this form it is possible that those persons may share your protected information with other persons. Federal law does not protect you against this, but the laws of your state may provide additional protection.

Publication of Study Results

Your health information will be kept confidential at all times, except when disclosure is required by law. The results from this study may also be presented at meetings or in articles. However, your name, or initials that could identify you, will not be used in those meetings or articles.

Your Right to See and/or Copy Your Study-Related Health Information

You may see and copy your study-related health information as long as the study doctor keeps this information. You may also, under data protection laws, have the right to ask that any mistakes in your study-related health information be corrected. However, you may not be able to see, or copy, your study-related health information until after the study has been completed, otherwise, it could affect the study.

Cancelling Your Authorization (Withdrawing Your Permission)

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. If you withdraw your permission, the study doctor will no longer use your health information or share it with others, unless the study doctor needs to do so to protect the study data and research results. However, the study sponsor may still use or disclose information about you that was shared with the study sponsor before you cancelled your authorization, if allowed under state law. Where allowed by local law, we will collect your health status information from publicly available sources at study closure.

Section 12 Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail: Study Subject Adviser
  Advarra IRB
  6100 Merriweather Drive, Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00043552.

You may also contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697.

Section 13 Do I have the right to withdraw from the study?

You have the right to withdraw from this study at any time and still receive the same standard of care.

If you decide to completely withdraw from all participation in the study, you will be asked to indicate the reasons for your decision, to participate in the necessary withdrawal procedures, and return all unused study drug. If you withdraw, no further study related contacts or data collection would occur. Where allowed by local law, we will collect your health status information from publicly available sources at study closure.

The study doctor may choose to end your participation in this study without your consent for any of the following reasons:

- You are unable to continue in the study
- You do not follow the instructions of the study doctor
- You experience an injury related to the study, or
- For any other reason

Section 14

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)

❒**NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date

A witness signature is required on this consent form <u>only</u> if: ***(Researchers: check which one applies)***

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:

I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____

Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____

Printed Name of Witness

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Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Drive, Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00043552.

You may also contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697.

UCI IRB # 942

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Trial to Evaluate the Effect of In-Hospital Initiation of Dapagliflozin on Clinical Outcomes in Patients Who Have Been Stabilized During Hospitalization for Acute Heart Failure

Principal Investigator Name: Dawn Lombardo, DO

Sponsor/Funding Agency (if funded): Brigham and Women's Hospital/TIMI Study Group

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☐ Entire Medical Record

☐ Ambulatory Clinic Records

☐ Progress Notes

☐ Other Test Reports

☐ Other (describe): Type Here
(Description of Other Health Information)

☐ Lab & Pathology Reports

☐ Dental Records

☐ Operative Reports

☐ Discharge Summary

☐ Consultations

☐ Emergency Department Records

☐ Financial Records

☐ Imaging Reports

☐ History & Physical Exams

☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject
If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____
Subject's Name (print)—required

_____ _____
Subject's Signature Date

Parent or Legally Authorized Representative
If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____
Parent or Legally Authorized Representative's Name (print) Relationship to Subject

_____ _____
Parent or Legally Authorized Representative's Signature Date

Witness
If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____
Witness' Name (print)

_____
Witness' Signature

_____
Date