Final Informed Consent Form

Study Title: Optimizing Preeclampsia Postpartum with POCUS (PPPOCUS): A Pilot Prospective Cohort Study
Primary Investigator: Ashten Waks, MD MSPH
Identifier: 7178 (NCT not yet assigned)
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UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Optimizing Preeclampsia Postpartum with Point-of-Care Ultrasound (PPPOCUS): A Pilot Prospective Cohort Study

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STUDY SPONSOR(S):
UC Irvine School of Medicine
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Dorothy J. Marsh Small Grant Program

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
Preeclampsia, a condition characterized by high blood pressure, protein in the urine, and organ dysfunction, affects up to 9% of all pregnancies. Over 60% of patients with preeclampsia continue to experience high blood pressure after delivery, and many of these patients require blood pressure medications for up to 6 months postpartum. The purpose of this research study is to determine whether point-of-care ultrasound (POCUS) can help identify postpartum patients with preeclampsia who might benefit from diuretic medications to improve their blood pressure and other short-term health outcomes related to preeclampsia.

Study Procedures
Within 24 hours of delivery and providing informed consent, you will undergo a bedside ultrasound of the lungs and inferior vena cava (a large abdominal vein) to look for evidence of excess fluid that may contribute to elevated blood pressure. If excess fluid is identified, you will be prescribed a diuretic medication called furosemide (either orally or intravenously) to help you pass this extra fluid via the urine. Your blood pressure, urine output, certain lab results, medication requirements, and any hospital readmissions will then be followed closely by study staff.

Expected Duration
Your participation will last the duration of your postpartum hospitalization but will require only 20-30 minutes of direct interaction with study staff. This time will be allocated to a maximum of two point-of-care ultrasound (POCUS) evaluations, each lasting no more than 10-15 minutes. For all participants, the initial ultrasound evaluation will take place within 24 hours of delivery; for participants who are found to have evidence of excess fluid on the initial ultrasound evaluation and are then treated with a diuretic medication, a follow-up ultrasound evaluation will be completed approximately 24 hours from the time the diuretic medication was given. Although in-person participation will be complete at the time of your hospital discharge, we request your consent to continue reviewing your electronic medical record for other clinical and safety outcomes through 30 days postpartum.

Risks of Participation
Overall, the risks of participation are minimal, but might include discomfort associated with study ultrasounds or lab draws, medication reactions, low blood pressure, low potassium, kidney problems, excess thirst, headache, muscle aches, or abnormal heart rhythm. Also, should there be a break in confidentiality of your data, there is a slight risk that your private medical information could be shared with individuals who are not members of the study team.

Benefits to Participants
Taking part in this study may or may not make your health better. While researchers hope that using point-of-care ultrasound (POCUS) to determine which preeclamptic patients might benefit from postpartum diuretic therapy will be more effective than standard (usual) management, there is no proof of this yet.

Benefits to Others or Society
This study will help researchers learn more about point-of-care ultrasound (POCUS) and diuretic therapy in the management of postpartum preeclampsia. It is hoped that this information might explain the mechanisms underlying preeclampsia recovery in the postpartum period and inform new strategies to optimize care of future patients with preeclampsia. This has the potential to improve postpartum care protocols, decrease the use of blood pressure medications postpartum, reduce hospital readmissions and associated costs, and support the development of more personalized treatment strategies in obstetrics.

Alternative Procedures or Treatments
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

- Getting no treatment

- Getting standard treatment for your condition without being in a study.

WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to determine whether point-of-care ultrasound (POCUS) can identify signs of excess fluid that may contribute to high blood pressure in postpartum patients with preeclampsia. When signs of excess fluid are identified by ultrasound, the study will also assess whether giving a diuretic medication (furosemide) can reduce this fluid and, in turn, improve blood pressure control and reduce the chance of hospital readmission.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 96 participants will be enrolled at UCI for the prospective portion of the study. Among the first cohort (group) of 48 participants enrolled, those who are found to have evidence of volume overload on point-of-care ultrasound (POCUS) will be treated with oral furosemide 20mg daily and oral potassium chloride 40mEq daily for a total of 5-days. Among the second cohort (group) of 48 participants enrolled, those who are found to have evidence of volume overload on point-of-care ultrasound (POCUS) will be treated with a single dose of intravenous furosemide 40mg and oral potassium chloride 40mEq on postpartum day 1. An additional 48 patients with preeclampsia who delivered prior to implementation of the study protocol will be selected from the electronic medical record to serve as historical controls. In total, this means that 144 participants will be included across all study groups.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements

You can participate in this study if you:

- Are at least 18 years old
- Gave birth within the past 24 hours
- Are diagnosed with preeclampsia (with or without severe features)

Exclusion Requirements

You cannot participate in this study if you:

- Are currently taking a diuretic medication
- Are allergic to sulfa medications or furosemide
- Have a history of high blood pressure prior to pregnancy
- Have significant kidney disease
- Have electrolyte abnormalities (e.g., low potassium) that are as not easily corrected with supplementation

HOW LONG WILL THE STUDY GO ON?

Your active study participation will be limited to your postpartum hospital stay, which is anticipated to last for 2-5 days. During this time, you will have a maximum of 2 in-person ultrasound encounters with study staff, neither of which is expected to exceed 10-15 minutes. After the first encounter, some participants will receive a one-time intravenous dose or a 5-day oral course of a diuretic medication. If you are prescribed this medication, it would be administered alongside of your other postpartum medications so as to reduce time associated with study participation. Additionally, all participants will have 2 lab draws performed by nursing staff or hospital phlebotomists, neither of which is anticipated to take more than 5 minutes. Otherwise, study staff will monitor your health status during your hospital stay and review your

records 30 days postpartum to assess for hospital readmissions; this monitoring will not require any direct involvement of or contributions from participants.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

Before you can participate in the main part of the study...

You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include:

- Review of your electronic medical records to confirm your diagnosis of preeclampsia and the timing of your delivery.
- A blood test called a comprehensive metabolic panel (CMP) to check your potassium level and kidney function. This blood test is part of our routine assessment of patients with preeclampsia and will likely have been obtained at the time your diagnosis was made.

During the main part of the study...

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include:

1. **Physical examination and baseline laboratory study:** During your enrollment encounter, study staff will examine you for signs of excess fluid accumulation (e.g. distended blood vessels, crackles on lung exam, swelling). A baseline blood test called a brain natriuretic peptide (BNP), which is another marker of excess fluid accumulation, will also be drawn at this time. This blood draw will require that less than 1 tablespoon of blood be collected. Unlike the comprehensive metabolic panel mentioned above, this blood test is not always part of the routine assessment of patients with preeclampsia.

2. **Ultrasound (POCUS) assessment:** Within 24 hours of delivery, you will receive a point-of-care ultrasound of your lungs and the inferior vena cava (a large abdominal ultrasound). This non-invasive procedure takes approximately 10–15 minutes and is used to check for signs of excess fluid that may cause your blood pressure to be high. The ultrasound is performed at the level of your rib cage so will not apply pressure to your uterus or the site of a possible cesarean section incision.

3. **Treatment as indicated based on ultrasound findings:**

    a. If the ultrasound shows signs of excess fluid, you will be prescribed a diuretic medication:
        i. The first cohort (group) of 48 participants enrolled in the study will be treated with a five-day course of oral furosemide (20mg once daily) and oral potassium chloride (40mEq once daily).
        ii. The second cohort (group) of 48 participants enrolled in the study will receive a one-time dose of intravenous furosemide (40mg) and oral potassium chloride (40mEq).
    b. If the ultrasound shows no signs of excess fluid, you will be managed according to the standard of care for preeclampsia in the postpartum period. Standard management of preeclampsia involves regular blood pressure measurement and prescription of blood pressure medications if the blood pressure is persistently elevated (above 140/90 mm Hg).

4. **Repeat ultrasound (POCUS) assessment if diuretic medications were prescribed:** Participants with evidence of excess fluid accumulation on their first ultrasound assessment will have a repeat ultrasound performed within 24 hours of diuretic administration to evaluate the impact of the medication.

5. **Monitoring during your hospital stay:** While in the hospital, the following will be closely monitored by study personnel:

a. **Vital signs:** Blood pressure, temperature, heart rate, breathing rate, and oxygen level.
b. **Daily weight** to assess for changes related to fluid management.
c. **Strict intake of fluids and urine output** to assess response to diuretic therapy.
d. **Blood tests:** A small blood sample (about one tablespoon) will be taken before you are discharged from the hospital to determine if your brain natriuretic peptide level (BNP), electrolyte balance, or kidney function has changed from the time of study enrollment.

6. **Medical record review** – Researchers will access your electronic medical records for up to 30 days from the time of your delivery to review prescribed medications, blood pressure readings, lab results, any complications related to study participation, or hospital readmissions.

All study procedures except for the point-of-care ultrasound(s), BNP blood draws, and possible diuretic administration are part of your routine postpartum care. The study adds only point-of-care ultrasound evaluation and possible furosemide use based on the imaging results.

RETURN OF RESULTS
You will not receive individual research results. However, any unexpected findings from your ultrasound will be communicated to your clinical care team who will use the results to direct treatment if necessary.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
You may have side effects while enrolled in the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after the procedures are completed or you stop taking furosemide, but in some cases, side effects can be serious, long lasting, or permanent.

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the study medication (furosemide) include:
Likely
- Increased urination
- Temporary low blood pressure or increased heart rate (dizziness or lightheadedness)
- Mild drop in potassium, sodium, magnesium, or calcium levels (which can cause muscle cramps or fatigue)

Less Likely
- Dehydration or thirst
- Constipation or diarrhea
- Nausesa or vomiting
- Decrease in milk supply
- Headache
- Changes in kidney function

Rare but serious
- Allergic reaction (such as rash, itching, or difficulty breathing)
- Severe electrolyte imbalance
- Acute kidney injury
- Irregular heart rhythm

Please note that all patients with preeclampsia in the postpartum period will have their intravenous access in place until they are discharged from the hospital. This means that, if assigned to intravenous

diuretic therapy, you will not need to have intravenous access established solely for study purposes. Please also note that if you are prescribed the oral dosing, the medication will likely begin to take effect within 30 to 60 minutes. If you are prescribed the intravenous dosing, the medication will likely begin to take effect within 5 minutes. For this reason, subjects prescribed to intravenous dosing may be more likely to experience the electrolyte changes (e.g. low potassium, sodium, magnesium, or calcium) described above. On the other hand, subjects prescribed the oral dosing may be more likely to experience the gastrointestinal effects of constipation, diarrhea, nausea, or vomiting.

Additional risks and side effects related to the study procedure may include:

Ultrasound: Receiving an ultrasound may cause temporary temporary discomfort.

Blood draw: Removing blood by a needle may cause temporary pain, bruising, bleeding, swelling, dizziness, and on rare instances fainting or infection.

Psychological discomforts: Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

Incidental finding: In this study, you will receive a bedside ultrasound. This ultrasound is for research purposes only. The purpose of the scan is to look for excess fluid in your lungs and your inferior vena cava (large abdominal vein). This is not a whole-body scan. The ultrasound will be performed on your chest, back, and upper abdomen only. Whenever imaging of this type takes place, there is a chance that the imaging will show something in addition to what the research study is designed to find. We refer to any finding that is in addition to the purpose of the research study as an “unexpected finding.” Because we are not able to determine what significance, if any, there is to an unexpected finding, if there is an unexpected finding, the finding will be shared with you along with a copy of the imaging to take to your primary care physician for further review. If you do not have a primary care physician, ask the research team for a list of current UCI primary care providers.

Unknown risks: There may be risks related to the research that we don't know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

Reproductive Risks: While the use of study furosemide may harm a developing pregnancy, this medication would not be administered until after your delivery is complete. Additionally, there is no evidence to suggest that the use of study furosemide would harm a baby fed with lactated (human) milk.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation:

You will not be compensated for your participation in this research study.

Reimbursement:

You will receive reimbursement for out-of-pocket expenses related to study participation, including required medications or laboratory assessments that are not covered by your insurance provider. An itemized receipt for these expenses is required prior to approval for reimbursement.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your insurer for your participation in this study. However, there may be out-of-pocket expenses such as parking and transportation fees. You and /or your health plan/insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical

condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs.

Most of the tests, procedures, and/or drugs provided to you are routinely used to treat your illness. You would receive these tests, procedures, and/or drugs even if you were not participating in this study. You and /or your health plan/insurance will need to pay for this routine care. You will also be responsible 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 counseling and itemized cost estimates are available upon request.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
If you get injured as a direct result of being in this study, UCI will provide reasonably necessary medical treatment, if it is available at that location. You can also seek medical treatment at a non-UC facility. Who pays for the treatment depends on different factors. The costs of medically necessary treatment may be handled in one of the following ways:

1. The costs may be covered by the University of California (for example, this may occur if you receive treatment at a University of California facility),
2. The costs may be billed to you or billed to your insurer, just like other medical costs, or
3. The costs may be covered or reimbursed by the University.

The University does not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-8170 or by e-mail at IRB@uci.edu.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study, or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to complete an exit telephone interview.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
Identifiable information collected about you will be removed at the end of data collection.

Data Storage
Research data will be maintained in paper format in a secure location at UCI. Research data will also be stored electronically on a secure online database in an encrypted file with password protection.

Data Retention
In accordance with UC Office of the President policy, information will be retained for 10 years after the end of the calendar year in which the research is completed.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, 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.

Medical Care

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your records. If necessary for your care, this information will be provided to you or your physician.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY

Use of Biospecimens Biospecimens (such as blood, tissue, or saliva) collected for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent.

Investigator Financial Conflict of Interest

Dr. Edmund Hsu has financial interests in Butterfly Network, a company with interests related to this study. Edmund Hsu received income from the entity, which is in addition to his salary from the University of California, Irvine. The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee (COIOC). The COIOC has determined that the researcher's financial interests are appropriately managed as to avoid compromising the quality or reliability of the study and furthermore, the UCI Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare.

WHAT ARE MY RIGHTS WHEN PROVIDING ELECTRONIC CONSENT?

California law provides specific rights when you are asked to provide electronic consent:

- You have the right to obtain a copy of the consent document in a non-electronic format.
- You have the right to provide consent in a non-electronic format.
- If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes.
- This agreement for your electronic consent applies only to your consent to participate in this specific research study.
- If you choose to withdraw your electronic consent, please tell the study team listed at the top of this consent document.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed at the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or during weekends.

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 suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone at (949) 824-8170, by e-mail at IRB@research.uci.edu or by mail at University of California, Irvine, Office of Research, Irvine, CA 92697-7600.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

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.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

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.

Subject Signature	**Date**
Printed Name of Subject	
Signature of Person Obtaining Informed Consent	**Date**

(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

Printed Name of Person Obtaining Informed Consent

WITNESS SIGNATURE BOX

A witness signature is required on this consent form only 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).

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**

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

_____

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
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 are 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.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-8170 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us by mail at University of California, Irvine, Office of Research, Irvine, CA 92697-7600.

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):
Optimizing Preeclampsia Postpartum with Point-of-Care Ultrasound (PPPOCUS): A Pilot Prospective Cohort Study

Principal Investigator Name:
Ashten Waks, MD MSPH
Afshan B. Hameed, MD MBA

Sponsor/Funding Agency (if funded):
UC Irvine School of Medicine, Department of Obstetrics and Gynecology Dorothy J. Marsh Small Grant Program

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

☒ 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