

IRB# _____

University of California

Permission to Use Personal Health Information for Research

Study Title: _____

Principal Investigator's Name: _____

UC Location: _____

A. What is the purpose of this form?

This form is used to get your permission to allow the study team and others listed on this form to see and use your Personal Health Information (PHI) for the research study listed above.

State and federal privacy laws protect your PHI. In most cases, your PHI cannot be shared for research purposes unless you give your written permission by signing this form.

If you sign this form, your PHI will be shared with the study team and others listed on this form. They will use and protect your information as described in the Informed Consent Form.

B. Why would a study team need my PHI?

Many research questions can only be answered by looking at PHI. The study team will only look at the information needed to answer the research question.

C. What PHI will be used or shared?

The study team will access and use only the information needed for the research as described in the Informed Consent Form. PHI may include your medical records, billing and insurance records, and other records that can identify you, including your name, birth date, hospital visit dates, medical record number, and other personal identifiers. These identifiers could be used on their own or in combination with other information to identify you.

For this study, the study team may access and use this information from your medical record, including but not limited to:

- Information about you, such as your birth date
- Clinical notes from health care providers
- Medical history and diagnoses
- Current and past medications or treatments
- Physical examinations
- Laboratory and imaging test results
- Billing records

D. Will sensitive health information be used or shared?

If this study includes access to sensitive health information, the study team checks only those boxes that apply. The study team will only use this information if you give your permission by initialing on the line(s). (The study team checks only those boxes that apply.)

- HIV/AIDS testing information _____ (your initials)
- Genetic testing information _____ (your initials)
- Drug and alcohol abuse diagnosis or treatment _____ (your initials)
- Mental health diagnosis or treatment _____ (your initials)

E. Who will have access to my PHI?

Your PHI may be shared with the study team. They will use your PHI only for the research described in the Informed Consent Form.

Other people who may see your PHI are:

- UC officials who oversee research
- The research sponsor(s) and their authorized representatives, clinical research organizations, and affiliates, if needed, to assess safety of the study
- People who review the quality and safety of the research, as required by law, including U.S. government agencies, such as the Food and Drug

Administration or the Office of Human Research Protections, or government agencies in other countries when the research is conducted in another country.

F. Will my PHI be used for optional research?

If this box is checked, the research includes optional research activities, as described in the Informed Consent Form. We may need to collect additional PHI for these activities. Sharing your PHI for optional research is your decision. Your decision to share your PHI will not affect your participation in the main research study. To give your permission to share your PHI for optional research activities, please initial here: _____.

G. Do I have to sign this form?

No, you do not have to sign this form. To be in this study, you would need to sign this form. Your choice will not affect any other clinical treatment or health care at the University of California.

H. Does my permission expire?

Your permission to use and share your PHI ends when the study ends and all required follow-up and recordkeeping is complete.

I. Can I cancel my permission?

You may cancel your permission at any time by writing to study team (see the contact information on the Informed Consent Form). If you cancel, you may no longer be in the study. The study team may still keep and use PHI they have already collected. But they cannot access or share more PHI about you unless it is required by a federal agency that is monitoring the research.

Your Signature

I have read this form. I also had the opportunity to ask questions about the use of my PHI. I agree to the use of my PHI for this study. You will be given a signed copy of this form.

Participant Name *–required (print)*

Participant Signature

Today's Date

Parent or Legally Authorized Representative

If the Participant is a child aged 0-17 or if the Participant is unable to complete this form, a Parent or Legally Authorized Representative must review this form and complete this section. If you agree to share the Participant's PHI, please print the Participant's name, your name, and sign below.

Participant Name *–required (print)*

Parent or Legally Authorized Representative *(print)*

Relationship to
Participant – *required*

Parent or Legally Authorized Representative Signature

Today's Date

Witness

If this form must be read to the Participant or the Participant's Parent or Legally Authorized Representative, because they cannot read the form, a witness must be present and sign here:

Witness Name *(print)*

Witness Signature

Today's Date