

PERMISSION TO USE PERSONAL HEALTH INFORMATION FOR RESEARCH

Study Title (or IRB Approval Number if study title may breach subject's privacy):

Principal Investigator Name:

Sponsor/Funding Agency (if funded):

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 the UC San Diego Health System 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 San Diego Health System 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: UC San Diego Health System 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.

- | | | |
|--|--|---|
| <input type="checkbox"/> Entire Medical Record | <input type="checkbox"/> Lab & Pathology Reports | <input type="checkbox"/> Emergency Department Records |
| <input type="checkbox"/> Ambulatory Clinic Records | <input type="checkbox"/> Dental Records | <input type="checkbox"/> Financial records |
| <input type="checkbox"/> Progress Notes | <input type="checkbox"/> Operative Reports | <input type="checkbox"/> Imaging Reports |
| <input type="checkbox"/> Other Test Reports | <input type="checkbox"/> Discharge Summary | <input type="checkbox"/> History & Physical Exams |
| <input type="checkbox"/> Other (describe) | <input type="checkbox"/> Consultations | <input type="checkbox"/> Psychological Tests |

C. Do you have to give your 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).

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

☐ You agree to the release of HIV/AIDS testing information.

☐ You agree to the release of genetic testing information.

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

D. Who will disclose and/or receive your 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 including but not limited to _____, or government agencies in other countries.

E. How will your 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. Are you 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. You will not be able to participate in this research study if you do not sign the document.

G. Optional research activity

If the research you are 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 you in the informed consent process, you can choose to agree to have your information shared for those activities or not. You will be able to participate in this research study and/or receive the same clinical care if you do not agree to these optional research activities.

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

☐ This section does not apply to this study.

H. Does your permission expire?

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

I. Can you cancel your 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 the 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