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

Sponsor/Funding Agency (if funded):

Principal Investigator Name:

#### What is the purpose of this form?

State and federal privacy laws protect the use and release of your protected health information (“PHI”). Under these laws, the University of California or your health care provider cannot release your PHI to the research team unless you give your permission. Your PHI 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. The research team includes the researchers and people hired by the University or the sponsor to do 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 researcher, research team and research sponsor may use your PHI for the research study. The research team will use and protect your information as described in the attached Consent Form. However, once your PHI is released 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 Protected Health Information will be released?

If you give your permission and sign this form, you are allowing your health care providerto release the following medical records containing your PHI. Your Protected Health Information includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

Entire Medical Record

Radiology Reports

Pathology Reports

Laboratory Reports

Dental Records

Operative Reports

Emergency Medicine Center Reports

Progress Notes

History & Physical Exams

Discharge Summary

Consultations

Outpatient Clinic Records

EKG

Radiology images

Psychological Tests

Health Care Billing Statements

Other (describe):

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

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

\_\_\_\_ 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, including psychotherapy notes.

#### D. How will my PHI be used?

Your Protected Health Information may be released to these people for the following purposes:

To the research team for the research described in the attached Consent Form;

To others at UC who are required by law to review the research;

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 the contract research organization (CRO), or government agencies in other countries.

Your PHI used in this study will include all information which is used to determine your eligibility and collected from the procedures and tests that are carried out as part of this study. This may include, but is not limited to, the following types of medical information

[Researchers: Provide bullet point description of the PHI to be used or disclosed (identifying the information in a specific and meaningful manner]

#### E. How will my Protected Health Information be used in a research report?

If you agree to be in this study, the research team may fill out a research report. (This is sometimes called “a case report”.) The research report will **not** include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care, and a tracking code. The research report will also include information the research team collects for the study. The research team and the research sponsor may use the research report and share it with others in the following ways:

To perform more research;

Share it with researchers in the U.S. or other countries;

Place it into research databases;

Use it to improve the design of future studies;

Use it to publish articles or for presentations to other researchers;

Share it with business partners of the sponsor; or

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. Does my permission expire?

This permission to release your Protected Health Information expires when the research ends and all required study monitoring is over. Research reports can be used forever. You have the right to see and copy any of the research data gathered about you, but not until the study is complete.

You may revoke 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. 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.

#### H. Optional Research Activity

This section does not apply to this study.

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 even if you do not agree to these optional research activities. If you give your specific permission for the optional research by signing your initials on the line(s) below.

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

#### I. Signature

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

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Subject’s Name (print) - Required |  |
|  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Subject’s Signature | Date |

Note: If the subject is a minor, an individual signing with an “X”, an adult incapable of giving consent, or is unable to read the authorization, fill out and attach the “special signatures” page (sections “J” and “K”).

SPECIAL SIGNATURES PAGE

J. If the subject is a minor, or an individual signing with an “X”, or an adult incapable of giving consent (where IRB approved), the legally authorized representative or witness signs here:

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Legally Authorized Representative’s Name  or Witness to the “X” (print) | Relationship to the Subject |
|  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Representative or Witness Signature | Date |

#### K. If the subject is unable to read the authorization, the translator or reader and two witnesses sign here:

I have accurately and completely read this Authorization to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (subject’s name) in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (language), the subject’s primary language. **The subject has verbally affirmed his/her Authorization to me and to the witnesses.**

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Translator or Reader’s Name (print) |  |
|  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Translator or Reader’s Signature | Date |
|  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Witness Name (print) |  |
|  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Witness Signature | Date |