**Study Title (or IRB Approval Number if study title may compromise 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 disclosure of your health information. Under these laws, the University of California or your health care provider cannot release your health information to the research team unless you give your permission through a written authorization. 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 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?**

Your Protected Health Information includes health information in your medical records, financial records and other information that can identify you. If you give your permission and sign this form, you are allowing your health care providerto release the medical records indicated below, as indicated with the marked box.

|  |  |  |
| --- | --- | --- |
| [ ]  Entire Medical Record | [ ]  Lab & Pathology Report | [ ]  Emergency Dept. Records |
| [ ]  Ambulatory Clinic | [ ]  Dental Records | [ ]  Financial records |
| [ ]  Progress Notes | [ ]  Operative Reports | [ ]  Imaging Reports |
| [ ]  Other Test Reports | [ ]  Discharge Summary | [ ]  History & Physical Exams |
| [ ]  Other (describe): | [ ]  Consultation | [ ]  Psychological Tests |
|        |

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

Yes.

[ ]  The research team will also be collecting information from your medical record that is marked by the check box. 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. \_\_\_\_ (initials)

[ ]  I agree to the release of HIV/AIDS testing information. \_\_\_\_ (initials)

[ ]  I agree to the release of genetic testing information. \_\_\_\_ (initials)

[ ]  I agree to the release of information pertaining to mental health diagnosis or treatment, including psychotherapy notes. \_\_\_\_ (initials)

**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 who are required by law to review 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 the contract research organization (CRO), 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 more 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**

[ ] There are no optional research activities**.**

[ ] 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. \_\_\_\_ (initials)

**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 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 |
|  |  |

**Instructions for Researchers: This version clarifies Instructions for Researchers. There are no other changes to the document. Do not make any changes to this form other than the following items:**

The IRB **will not** be confirming the accuracy of the information you complete on this form. The researchers are responsible for accurately completing the HIPAA Research Authorization as follows:

1. Page 1, Item B: Mark all sources of PHI that will be released
2. Page 2, Item C:
	1. Check the first box if any of the 4 categories of sensitive information will be collected
	2. Then, check the box ***only*** for each specific type of information that will be collected for this study
	3. Obtain the participant’s initials ***only*** *for the specific types of information*
3. Page 3, Item G:
	1. Check one of the boxes indicating if there are optional research activities or not
	2. Obtain the participant’s initials ***only*** *if the study involves optional research activity, and the participant agrees to the optional research activity.*
4. Page 4, Item J: Obtain the participant’s name, signature, and date; *complete subsequent signature lines* ***if applicable***
5. Provide the subject with a signed copy of the form. Do Not Include these instructions.

***Note: The Word document of this form allows you to check the boxes electronically. You can make a ‘master version’ of this form for this study with all pertinent boxes checked.***

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