

University of California
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject’s privacy): **T01235**

Sponsor/Funding Agency: **The March of Dimes & The National Institutes of Health**

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 to the research team unless you give your permission. 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 health information for the research study. The research team will use and protect your information as described in the attached Consent Form. However, once your health information 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 Personal Health Information will be released?

If you give your permission and sign this form, you are allowing _____ to release the following medical records containing your Personal Health Information. Your Personal 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.

- | | | |
|---|--|--|
| <input type="checkbox"/> Entire Medical Record | <input type="checkbox"/> Laboratory Reports | <input type="checkbox"/> Emergency Medicine Center Reports |
| <input type="checkbox"/> Health Care Billing Statements | <input type="checkbox"/> Dental Records | <input type="checkbox"/> History & Physical Exams |
| <input type="checkbox"/> Pathology Reports | <input type="checkbox"/> Operative Reports | <input type="checkbox"/> Diagnostic Imaging Reports |
| <input type="checkbox"/> EKG | <input type="checkbox"/> Radiology Reports | <input type="checkbox"/> Consultations |
| <input type="checkbox"/> Progress Notes | <input type="checkbox"/> Radiologic & MR Scans | <input type="checkbox"/> Outpatient Clinic Records |
| | <input type="checkbox"/> Discharge Summary | <input type="checkbox"/> Psychological Tests |
| <input type="checkbox"/> Other (describe) | | |
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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 as follows:
- _____.

D. How will my Personal Health Information be used?

Your Personal Health Information may be released to 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, the research sponsor or the sponsor's representatives, or government agencies in other countries. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

E. How will my Personal 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:

1. To perform more research;
2. Share it with researchers in the U.S. or other countries;
3. Place it into research databases;
4. Use it to improve the design of future studies;
5. Use it to publish articles or for presentations to other researchers;
6. Share it with business partners of the sponsor; or
7. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over. Research reports can be used forever.

G. 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. 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. Signature

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

Subject's Name (print)

Subject's Signature

Date

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

If the subject is unable to read the authorization, the translator or reader and a witness 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 witness.**

Translator or Reader's Name (print)

Translator or Reader's Signature

Date

Witness Name (print)

Witness Signature

Date