

For the Use of Patient Health Information for Research

Research Title: [Title of research study - must be the same as the IRB application title]
Lead researcher: [Lead researcher name]
Institution of lead researcher: [Name of institution of lead researcher]

A. Purpose of this form

The purpose of this form is to give your permission to the research team to obtain and use your patient health information. Your patient information will be used to do the research named above.

[Delete this paragraph and/or the next paragraph if they do not apply to your research.]

This document is also used for parents to provide permission to obtain the patient information of their minor children, and for legally-authorized representatives of subjects (such as an appropriate family member) to provide permission to obtain patient information of individuals who are not capable themselves of providing permission. In such cases, the terms "you" and "your patient information" refer to the subject rather than the person providing permission.

A minor's signature is required to release the following information about the minor: 1. Age 14 and older – information relating to reproductive care, including but not limited, to birth control and pregnancy-related services and sexually-transmitted diseases, including HIV/AIDS and 2. Age 13 and older – substance abuse diagnosis or treatment, and mental health information.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not, you [insert the appropriate words: will not OR will still] be allowed to join the research study. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

B. The patient information that will be obtained and used

"Patient information" means the health information in your medical or other healthcare records. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, and medical record number.

1. Location of patient information

By signing this form you are giving permission to the following organization(s) to disclose your patient information for this research. [Be as specific as possible. Some examples are listed here. You and/or the subject may instead write in the name of his/her health care organization. Delete organizations from this bulleted list that are not applicable.]

- UW Medicine (includes University of Washington Medical Center & Clinics; Harborview Medical Center & Clinics; UW Medicine Neighborhood Clinics; University of Washington Sports Medicine Clinic; UW Medicine Eastside Specialty Center; Hall Health Primary Care Center; University of Washington Physicians)
- UW School of Dentistry Clinics & Dental Practice Plan (UW Dentists)
- UW Speech and Hearing Clinics
- UW MTM Pharmacy in the School of Pharmacy (Pharmacy Cares)

- UW Autism Clinic
- UW Behavioral Research & Therapy Clinics
- UW Psychology Clinics in the School of Arts and Sciences (UW Psychological Services & Training Center; The LEARN Clinic; the Faculty Clinic)
- Seattle Cancer Care Alliance]

Name of health care organization(s) or provider(s):

[insert the name or leave a space for the subject to write in the name.]

2. Patient information that will be released for research use

This permission is for the health care provided to you during the following time period: [Describe the time period. Examples: (1) January 1, 2004 through December 31, 2008; (2) the last 5 years; (3) from the time of your last heart attack until today; (4) from the time of your last heart attack until the end of this research study.]

The specific information that will be released and used for this research is described below:

[Delete information that is not applicable. **BY LAW**, the information must be limited to the minimum necessary information needed to accomplish the purpose of the research]

- All records
- Hospital discharge summary
- Radiology records
- Medical history / treatment
- Consultation
- Radiology films (like X-rays or CT scans)
- Laboratory / diagnostic tests
- EKG report
- EEG report
- Psychological testing
- Pathology reports
- Operative report (about an operation)
- Pathology specimen(s) and/or slide(s)
- Diagnostic imaging report
- Dental records
- [specify other here]

3. Use of the UW Clinical Research Center (CRC)

- If you are not using the CRC, delete this entire section.
- If you are using the CRC for any procedures and any subjects, chose one of the following two options.

[Option 1. If the CRC staff will obtain any information about/from the subjects or conduct any research procedures *other than just blood draw(s) where the sample is being held for pick-up by the researcher or is sent for testing to UW Research Testing Service (RTS)*, include this paragraph. Otherwise, delete it.]

Some of the research procedures may occur at the UW Clinical Research Center (CRC). Information from or about those procedures will be entered into your UW Medicine medical record. If you do not already have a UW medical record, one will be created for this purpose. The specific research information that will be recorded in your medical record and released to the researcher has

been described in section B.2 (above). In addition, in the unlikely event something happens to you that requires treatment while you are at the CRC, information about the event and treatment will also be released to the researcher. Examples: fainting during a blood draw, or having a reaction to a study procedure or study medication.

[Option 2. If the CRC staff will not obtain any information about/from the subjects or conduct any research procedures *other than just blood draw(s) where the sample is being held for pick-up by the researcher or is sent for testing to UW Research Testing Service (RTS)*, include this paragraph. Otherwise, delete it.]

Some of the research procedures may occur at the UW Clinical Research Center (CRC). In the unlikely event something happens to you that requires treatment while you are at the CRC, information about the event and treatment will also be released to the researcher. Examples: fainting during a blood draw or stumbling while entering the blood draw area.

C. How your patient information will be used

The researcher will use your patient information only in the ways that are described in the research consent form that you sign and as described here.

The research consent form describes who will have access to your information. It also describes how your information will be protected. You can ask questions about what the research team will do with your information and how they will protect it.

The privacy laws do not always require the receiver of your information to keep your information confidential. After your information has been given to others, there is a risk that it could be shared without your permission.

D. Expiration

[The expiration date refers to the date after which you will no longer obtain patient information (or access patient records) for your research. If you are uncertain, choose a date that provides plenty of time for your work to be completed, as it is considered noncompliance to continue to obtain patient data (or access patient records) after the expiration date you have provided to subjects on this form.]

This permission for the researchers to obtain your patient information: [Select and insert the option that applies to your research, and provide the required information. Delete the other options. If you are uncertain, **choose a date that provides plenty of time for your work to be completed. The IRB will not approve the second option listed here unless you provide (in your application) a good rationale for why you are not using a specific date.**]

ends on [insert date].

ends when the research ends and any required monitoring of the study is finished.

ends when [insert description of event or other circumstance. Examples: one year after death; one year after you reach age 50].

E. Canceling your permission

You may change your mind at any time. To take back your permission, you must send your **written** request to:

[Name of researcher or appropriate research staff person]

[Address information]

If you take back your permission, the research team may still keep and use any patient information about you that they already have. But they can't obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

If you take back your permission, you [insert the appropriate words: will OR will not] need to leave the research study. [Insert if appropriate: This means that you would not have any more research treatments or tests.] Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans or eligibility for benefits.

F. Giving permission

You give your permission to release your information by signing this form.

[Insert the following yellow-highlight section if appropriate. Delete the types of information you do not need for your research.]

To release the specific information listed below, you need to also write your initials next to the type of information. This is your specific permission for release of this information, which is required by Federal and state laws. The federal rules bar any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

	Sexually transmitted disease
	AIDS or HIV
	Behavioral or mental health/illness, including psychotherapy notes
	Drug or alcohol abuse, diagnosis, or treatment

Printed Name of Research Subject

Birthdate

Signature of Research Subject

Date of signature

[If HIPAA authorization may be obtained from a legally authorized representative (for example, a parent, legal guardian, or family member) and you have (or are requesting) approval from the IRB for doing so, the following information must be included. **Otherwise, delete this section.**]

Printed Name of Person Authorized to Give Permission

Signature of Person Authorized to Give Permission

Date of signature

Relationship to Subject and Description of Authority

(Examples: parent of a young child; sister of an individual who is in a coma; researcher who signs for a subject who is unable to physically sign the authorization but was observed by the researcher to read and otherwise agree to the authorization.)

You will receive a copy of this signed form. Please keep it with your personal records.