

# Seattle Cancer Care Alliance

## Administrative Policies and Operating Procedures

**Section:** Administration

**Policy Title:** Informed Consent: Research Consenting Guidelines

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### Purpose

The purpose of these guidelines is to describe the informed consent process for clinical trials or other research studies occurring at the SCCA.

The Cancer Consortium Research Trials Office (RTO) and the SCCA jointly created this policy and procedure. The SCCA and RTO will continue to communicate about informed consent issues including those related to research clinical trials and other research studies occurring at the SCCA.

### Policy

#### **Patients' Rights Regarding Research**

- Patients have a right to voluntary participation in medical research studies.
- A patient's medical needs take higher priority than objectives of any research study.
- Patients have the right to refuse research studies at any time.
- Provisions are made for including patients less than 18 years of age in the consenting discussion(s) (i.e., assenting).
- Research consent language is understandable to the subject.
- Records that identify the research subject are kept confidential as described in the research informed consent document.

#### **Research informed consent process required elements**

- Patients may not participate on research studies unless informed consent has been obtained and documented in the legal medical record.
- Informed consent shall be obtained only under circumstances that provide the participant or participant's legal representative sufficient opportunity to consider whether or not to participate without possibility of coercion or undue influence.
- The elements of informed consent process are followed (see "Informed Consent: Clinical Consenting Guidelines Policy and Procedure").
- For research studies that are likely to involve patients who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards should be included in the study to protect the rights and welfare of these subjects.
- Informed consent shall be obtained by the use of a written consent form approved by an Institutional Review Board (IRB). When an IRB allows, an interpreter may be used to translate during the informed consent discussion as well as the written consent form.
- The person obtaining informed consent has been approved to do so by the IRB of record.
- The person obtaining informed consent documents the research consent process in the medical record.
- The patient is informed that refusal to consent will not result in a penalty or affect availability of other treatment options.
- A copy of the written consent shall be given to the person signing the form.
- A copy of the consent is placed in the SCCA medical record.

Please refer to the Informed Consent: Substituted Consent Policy and Procedure for information about consenting of incapacitated and incompetent patients.

**Procedure**

**Research informed consent document**

Please contact the IRB that will review the research study for guidelines on required and recommended elements for the informed consent document.

**Documentation of the Informed Consent Process**

After the researcher or the Licensed Independent Practitioner (LIP) [defined as any individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual’s license and consistent with individually granted clinical privileges] has gone through the essential elements of the informed consent process with the patient or patient ‘s legal representative, the researcher or LIP is encouraged to document this process in the medical record including:

- The nature of the research
- Anticipated results;
- Risks;
- Alternative treatments.

It is recommended that documentation include a notation of the patient’s or patient’s legal representative’s response and expression of understanding and agreement. Research staff can document informed consent in lieu of the researcher or LIP when such activity is within the scope of practice of the staff member or affiliate and the staff person is listed as a research associate for the study on file at the IRB.

If the patient or patient’s legal representative chooses not to be informed of the above elements of consent, a statement to that effect should be noted in the SCCA medical record. For additional information regarding documentation in the SCCA medical record, please refer to the “Authorized Entries into the Medical Record” and “General Documentation” Policies

A copy of any consent form signed by the patient or patient’s legal representative should be provided to the patient or patient’s legal representative and filed in the patient’s SCCA medical record.

**UW, CHRMC and FHCRC have separate but similar informed consent policies.**

**Approval**

Director:	Aleana Waite	Approval Date:	11/26/08
		(this version)	
Process Owner:	Steve Johnson	Next Review Due:	10/30/11
		Revision/Review Dates:	11/26/08,11/21/05, 09/29/05
		Original Approval Date:	9/29/05

This version reviewed and approved by specialty committee or specialty individual:

Reviewer	Date Reviewed
APOP Committee	11/06/08
CST Committee	11/26/08