



Controlled Distribution of Current Clinical Research Consents

Approval

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Clinical Research Oversight Committee Chair or Designee		Date:	5/31/17
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Vice Dean, Research and Graduate Education, School of Medicine, University of Washington		Date:	6/9/17
Printed Name	John T. Slattery, PhD		

Background

All partner institutions that make up the Cancer Consortium, Fred Hutchinson Cancer Research Center (FHCRC), the University of Washington (UW), Seattle Children's (SC) and the Seattle Cancer Care Alliance (SCCA), are committed to protecting human subjects involved in clinical research. An important component of protecting participants is ensuring that they have the most current information regarding the studies in which they choose to participate.

Clinical FYI is a secured website accessible by physicians, nurses, and other authorized staff members at the SCCA, FHCRC, UW and SC's. Authorization is obtained through the Clinical Oncology Research Entrance (CORE).

This policy describes the required use of Clinical FYI to ensure the current IRB-approved version of a consent form is used to consent participants on Cancer Consortium clinical trials.

Responsible Personnel

Principal Investigator

Medical Director, Clinical Research Support

Director, Clinical Research Support

Quality and Compliance Manager, Clinical Research Support

Abbreviations and Acronyms

<p>FRED HUTCH UNIVERSITY OF WASHINGTON CANCER CONSORTIUM</p>	<p>Clinical Research Policies and Procedures Documents for Participants</p>
	<p>Controlled Distribution of Current Clinical Research Consents</p>

CORE: Clinical Oncology Research Entrance

CRS: Clinical Research Support

FHCRC: Fred Hutchinson Cancer Research Center

IRB: Institutional Review Board

PI: Principal Investigator

SC: Seattle Children’s

SCCA: Seattle Cancer Care Alliance

UW: University of Washington

Definitions

Clinical FYI: Secured website housed on the CORE website that houses current study documents

CORE: Clinical Oncology Research Entrance – a secured website for oncology related secured websites

Cancer Consortium: An NCI-designated Comprehensive Cancer Center comprised of: Fred Hutchinson Cancer Research Center (FHCRC), University of Washington (UW), Seattle Children’s (SC), and Seattle Cancer Care Alliance (SCCA)

Clinical Trial: Any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes. (ICMJE)

Policy

Personnel responsible for consenting participants on Cancer Consortium clinical trials are required to use consent forms printed from the Clinical FYI system. The consent document should be signed within three business days after it was printed, unless the consent version has been verified and documented.

Exceptions:

- The Clinical FYI System is unavailable
- NW Bio Trust
- The most up to date consent is not yet posted to the Clinical FYI system (postings occur within three business days after receipt of IRB approval)
- Another Clinical Research Support approved and documented consent management system is in place for a study/team (special circumstances only)
- Single patient studies

Procedures

Designated personnel should access the Clinical FYI site through the Clinical Oncology Research Entrance (CORE), locate the relevant study and print the relevant consent(s). Caution should be used when printing documents where system notifications indicate documents may be in the process of modification or are managed differently from most other content

in the system. In this situation, the study team should be contacted before consent forms are given to potential study participants.

The consent release date and expiration date should be verified along with the printed date to ensure that the consent form is the appropriate document for the participant to sign. If the document was printed more than three days before it was signed, the study team should verify that the signed document version was still valid on the day the consent form was signed, and this verification process should be documented in the study records. Verification can be done through the Clinical FYI system or by contacting Clinical Research Support (CRS).

Failure to comply with this policy may result in escalation to the appropriate review body for further action.

Exception Procedures

The Clinical FYI system is unavailable. Contact the Clinical Research Support for a copy of the consent during normal working hours (8:00 am – 5:00 pm, Monday through Friday, except Fred Hutchinson holidays and closures). At other times, contact the IRB of record directly.

The most up to date consent is not yet posted to the Clinical FYI system. Contact Clinical Research Support, and they will help to obtain the document as soon as it is available.

Another CRS approved and documented consent management system is available. In some cases, a document management system other than Clinical FYI can be utilized to obtain consent forms for participants. Those systems require notification and approval through Clinical Research Support, and documentation regarding the system is kept on file in CRS.

Single patient studies. Contact Clinical Research Support to obtain the document after IRB approval. Clinical FYI posting can be arranged, if time is available before the patient must be consented and treated.

Applicable Regulations & Guidelines

21 CFR 50.27 – Documentation of Informed Consent

45 CFR 46.117 – Documentation of Informed Consent

Fred Hutchinson Cancer Research Center Institutional Review Board Policy 2.11 – Informed Consent

Attachments/Related References

CRS Document: 00207 Information Sheet for the FYI System

Seattle Cancer Care Alliance Policy: Informed Consent: Research Consenting Guidelines

Version Review History	
Reviewer	Date
Frederick Appelbaum, MD, Deputy Director, FHCRC	5/20/2014
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John T. Slattery, PhD, Vice Dean for Research, University of Washington	5/31/2017