

# Seattle Cancer Care Alliance

## Administrative Policies and Operating Procedures

**Section:** Administration

**Policy Title:** Medical Record Requests for Research Purposes

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### **Policy**

Medical records of patients enrolled in a research study are made available for review by members of the Fred Hutchinson Cancer Research Center (FHCRC), Research Staff from the University of Washington Medical Center (UWMC), the Children's Hospital and Regional Medical Center (CHRMC) Research Staff Members and External Study Monitors. Agreements are in place with SCCA partner institutions to assure patient consent and Institutional Review Board (IRB) reciprocity.

### **Purpose**

To outline the process necessary to request the patient's paper and electronic medical record for research study review purposes.

### **Definitions**

**Paper Medical Record:** In November 2006, SCCA adopted the hybrid medical record keeping system and discontinued inserting electronically generated documentation into the patient's paper medical record.

**Electronic Medical Record:** The electronic medical record is stored in the UW systems entitled ORCA and Mindscape. Both systems contain the same information with minor exceptions. The location of specific data elements can be found on the SCCA O Drive:\Legal Medical Record folder and in Mindscape under Clinical Info Matrix.

**U-Link:** Provides a means for non - UW, FHCRC and SCCA users, such as community referring physicians and external study monitors, to access a particular patient's medical record in accordance with the patient's authorization as required by the IRB.

**UAA:** The UW User Access Administration (UAA) grants permission to authorized external users to access specific patients' medical records via the U-Link system for a limited time period.

**HIM Staff Member:** Member of the SCCA's Health Information Management (HIM) department who is the liaison between the study coordinator and the UAA. The HIM staff member coordinates the release of medical records with FHCRC/UW research staff members, verifies the presence of patient's consent and IRB study approval, and ensures the timely return of the paper medical record as well as access termination for the electronic medical record.

**FHCRC/UW Research Staff Member:** Liaison who coordinates study reviews of SCCA medical records with HIM (Health Information Management) staff members for external study monitors.

**External Study Monitor:** An individual who verifies research data from the SCCA medical record for SCCA patients who are enrolled in a research study.

**Review Visit Dates:** Period of time external study monitor requests access to SCCA medical records.

### **Procedure**

#### **I. Review of Electronic Medical Records**

##### **A. FHCRC/UW Research Staff Member Responsibilities**

1. Determine if the external study monitor requires review of both the electronic and paper medical record. (follow II.A for paper record request only).
2. If the electronic medical record is necessary, determine if external study monitor has an established U-link account.
3. If a U-link account needs to be established, the external study monitor's driver's license number, date of birth, and signature of agreement of the UW Medicine - Individual U-Link Privacy, Confidentiality, and Information Security Agreement are necessary. The agreement can be found in SCCA's O:\Forms folder and on the Fred Hutch Research Process and Resource Guide webpage at: [http://www.cancerconsortium.org/shared\\_resources/rto/training/resource\\_guide/](http://www.cancerconsortium.org/shared_resources/rto/training/resource_guide/).
4. Determine the on-site review dates, taking into account additional time necessary to establish a U-Link account. The UAA requires two weeks notice for an account to be established once they have received the signed agreement and identification information.
5. Upon receipt of signed agreement and identification information forward document to HIM staff member, Mailstop G7-805.
6. Notify HIM staff member of the record requests via the e-mail address [HIMChart@seattlecca](mailto:HIMChart@seattlecca) with a cc: to the Health Information Management Supervisor ([lang@seattlecca.org](mailto:lang@seattlecca.org)) and indicate the following information:
  - i. External study monitor does have a U-Link account; or
  - ii. External study monitor does not have a U-link account and date signed agreement was sent to the HIM staff member;
  - iii. Name of external study monitor;
  - iv. List of Study Participants' names; U-numbers; DOB;
  - v. Title of Research Study;
  - vi. Protocol Number (study group);
  - vii. Research staff member's contact information; and
  - viii. Dates external study monitor will require records.

#### B. HIM Staff Member Responsibilities

1. Facilitates the creation or reactivation of external study monitor's U-Link account
2. Scans all U-Link agreement for documentation purposes
3. Sends e-mail confirmation to the FHCRC/UW research staff member of external study monitor's U-Link account and provides the user log-in id to forward to the external study monitor.

#### C. FHCRC/UW Research Staff Member Responsibilities

1. Relays the information to the external study monitor and directs them to contact UW Medicine IT Help Desk at 206-543-7012 upon arrival onsite to receive their user password.
2. Informs the external study monitor that for verification purposes, they must provide UW Medicine IT Help Desk with their full name, date of birth, and last 4 digits of their state driver's license number to receive the password.
3. Instructs the external study monitor to log-in to <https://mindscape.mcis.washington.edu/login/index.cgi> when they are ready to begin reviewing records electronically.

## II. Review of Paper Medical Records

#### A. FHCRC/UW Research Staff Member

1. To request paper records follow step I.A.6.iii – I.A.6.viii above.
2. Picks up records delete the hours in the HIM Department, room G7-700A.
  - i. Please note: To gain access to the 7<sup>th</sup> floor the research staff members must check in at the main floor reception desk and have their SCCA, FHCRC, UWMC, or CHRMC badge.
3. Completes the Research Request for Access to Medical Records form at the time of pick up.

4. FHCRC Research Staff Members may review medical records off-site in Minor, Fairview (LF266) and Valley; however, records at the Valley must be returned to HIM by 4:00 pm.
  - i. Please note: For records that can be stored overnight at Minor and Fairview those records must be kept in a designated storage area. Records may not be kept in personal storage spaces in the event retrieval is necessary for patient care purposes for records stored overnight.
  - ii. Review of active transplant patients' records (not discharged from the transplant clinic system) must take place on the 6<sup>th</sup> floor at the SCCA. If space is an issue, special arrangements will be made on an individual case basis.
5. Contact the courier for the return of records to G7-700A.

**Approval**

<b>Director:</b>	Aleana Waite	<b>Approval Date: (this version)</b>	10/31/07
<b>Process Owner:</b>	Steve Johnson, Addie Price	<b>Next Review Due:</b>	09/30/09
		<b>Revision/Review Dates:</b>	10/31/07
		<b>Original Approval Date:</b>	10/31/07

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

<b>Reviewer</b>	<b>Date Reviewed</b>
APOP Committee	10/11/07
CST	10/31/07

**UW Medicine**  
**Individual U-Link Privacy, Confidentiality, and Information Security Agreement**

**As a user of UW Medicine computing resources and data, specifically, U-LINK, I understand and agree to the following responsibilities:** I will comply with federal and state statutory and regulatory requirements regarding the privacy and security of protected health information.

I understand that as a study monitor, my login and password provides access to protected health information only of research participants enrolled to a research trial with which I am associated who are receiving care at University of Washington Medical Center (UWMC), or Seattle Cancer Care Alliance (SCCA).

I understand that if an error occurs and I am given access to other patients' medical records, I agree to immediately notify the SCCA Health Information Manager (206-288-6262) and I agree not to review such medical records.

I agree to securely protect my access account, and password. I will not share my password with any other person and will not permit others to access the U-Link system through my account. I accept responsibility for all activities associated with the use of my individual user account and related access privileges.

I agree to maintain the confidentiality of information to which I am given access. I will only disclose protected health information obtained via U-LINK to individuals having the appropriate authority to receive and use such information.

I understand that the information I obtain via U-Link is only a portion of the medical record and does not contain all of the information in the participant's medical record. For example, it does not contain handwritten notes and other non-electronic information. It contains such information as dictated transcripts, laboratory, pathology, medications, procedures and demographics.

I understand that information in U-LINK is identified as having been either *verified* or *not verified* by the attending physician. I understand that the information I view that is indicated as *not verified* has not been reviewed or authenticated by the attending physician for completeness and accuracy.

I understand that my access to U-LINK will be monitored to assure appropriate use and compliance with system integrity.

I understand that access to U-LINK is a privilege granted to me by UW Medicine and I understand and acknowledge that these privileges may be terminated at any time and for any reason.

I agree to comply with periodic requests from UW Medicine or SCCA to verify or update my demographic information in order to maintain accurate records of U-Link users.

I understand that this agreement shall apply to my access to U-Link for all clinical trials that I monitor at UWMC or SCCA even if there is a change in sponsor or if I change employers or affiliations.

This agreement shall remain in effect until terminated in writing by one of the parties.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Print name: \_\_\_\_\_ Title: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Phone: \_\_\_\_\_ E-mail Address: \_\_\_\_\_

Driver's License #: \_\_\_\_\_ Expiration Date: \_\_\_\_\_ State issued: \_\_\_\_\_

Employer : \_\_\_\_\_ FAX#: \_\_\_\_\_

Address: \_\_\_\_\_

Please keep a signed copy for your records and send the original to:

Seattle Cancer Care Alliance  
Health Information Management  
825 Eastlake Avenue E, MS: G7-805  
Seattle, WA 98109-1023  
Fax: 206-288-6987