

Research

Orientation & Compliance Manual



SEATTLE
CANCER CARE
ALLIANCE

Fred Hutchinson Cancer Research Center
UW Medicine
Seattle Children's

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Notification Process

- Patients are notified of their rights regarding making a complaint in the following ways:
- The Patient Rights and Responsibilities brochure
- Patient Care Manuals
- Postings within the clinic

Patients are notified of the use of the Protected Health Information (PHI) and right to complain through the Notice of Privacy Practices.

Resolving Complaints

Patient complaints are best resolved, whenever possible, directly and promptly by those providing the care or service. The staff member or clinician involved with the issue will involve the manager or director of the department if they are not able to promptly resolve the complaint.

If the patient contacts Patient Relations or Administration directly, without first contacting the staff or clinician involved in the issue, the administrator or patient relations staff will work with the manager or director whose staff or clinician is involved in the issue to promptly resolve the complaint for the patient. The complaint is considered resolved when the patient is satisfied with the outcome and the complaint is resolved promptly.

Adverse, Unexpected or Sentinel Events

The SCCA has policies and procedures for Adverse and Sentinel Events. For more information about these policies and procedures please log onto the SCCA network and go to the following location: O:\Policies and Procedures\Risk Management.

Patient Relations/ Patient Complaints Process

Patients have the opportunity to make verbal or written complaints. Options for patient complaints include:

- Speak with their health care providers;
- Contact the manager at the point of care of service or SCCA Patient Relations;
- Contact IRB/IRO with questions or complaints about research in which they are participating. Consent forms provide contact information.
- Patients also have the right to contact the Washington State Department of Health, 1112 S.E. Quince Street, P O Box 47890, Olympia, WA 98504-7890. TOLL-FREE # 1-800-633-6828.
- Patients with complaints about the privacy of Protected Health Information (PHI) may also contact U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201, (202) 619-0257,

Introduction

The SCCA Research Orientation and Compliance Manual is intended for those individuals who will be involved in conduct of research at the SCCA. This manual provides information about doing research at the SCCA because supporting the conduct of cancer clinical research and education is part of our mission.

If you have questions or comments about this manual or require further assistance, please contact the Research Implementation Office at (206) 288-6607.

Who must be an SCCA Affiliate?

All persons conducting research at the SCCA are required to become non-employee affiliates. To determine if you are an SCCA non-employee affiliate or if you need to complete the Non-employee Affiliate Packet, please contact:

- SCCA Medical Director's Office at 288-1162 , if you are a medical staff member or;
- SCCA Human Resources at 667-4700, if you are a non-clinical staff members [e.g., research nurse, study coordinator].

Becoming an SCCA non-employee affiliate is not the same as being "credentialed." If you have credentialing questions or need information, please contact:

- SCCA Medical Director's Office, if you are a medical staff member or;
- UWMC Patient Care Services Administration, if you are a non-clinical staff member.

In general, SCCA Affiliates are:

- Researchers
- Research Staff
- Credentialed Staff
- Contract Staff
- Agency Temps
- Administrative Affiliates (*i.e. administrative staff from partner institutions who utilize the SCCA clinic as their primary work site or require access to SCCA computer applications*)

Medical Records and Health Information Management for Research Participants

A medical record is initiated and maintained for all patients or research participants assessed or treated at the SCCA. Complete and accurate medical record documentation is essential to maintain the records for continuity of care. Policies and procedures exist to help ensure that medical records are complete and accurate. Of specific note for researchers and staff are the following policies and procedures:

- General Documentation: this policy covers general principles such as all entries in the medical record shall be signed and dated, all handwritten entries in the medical record must be in black ink, and how to access medical records.
- Authorized Entries into the Medical Record: this policy outlines who is authorized to make entries in the SCCA health record.
- Error Correction: this policy provides instructions on how to make corrections to patient records.

For more information about these policies and procedures or to review other medical record related policies and procedures, please log onto the SCCA network and go to the following location: O:\Policies and Procedures\Health Information Management.

Informed Consent Process Guidelines

Federal Regulations require that the informed consent process (and preferably consent form) state:

1. That the study involves **research**; an explanation of the **purposes** of the research and the expected **duration** of the subject's participation; a description of the **procedures** to be followed; and identification of any procedures which are experimental.
2. Any reasonably foreseeable **risks or discomfort** to the subject.
3. Any **benefits** to the subject or to others, which may reasonably be expected from the research.
4. Appropriate **alternative procedures** or courses of treatment that might be advantageous to the subject.
5. The extent, if any, to which **confidentiality** of records identifying the subjects will be maintained.
6. For research involving more than minimal risk, whether any **compensation and/or medical treatments** are available if injury occurs and, if so, what they consist of or where further information may be obtained.
7. Whom to contact for answers to pertinent questions about the research and research **subjects' rights**, and whom to contact in the event of a **research-related injury** to the subject.
8. That **participation is voluntary**, that refusal to participate or withdrawing from participation will involve **no penalty or loss of benefits to which the subject is otherwise entitled**.
9. Any **additional costs** associated with participating in the study above routine care costs.

What is the SCCA

The Seattle Cancer Care Alliance (SCCA) brings together the outstanding adult and pediatric oncology patient care services of three world-renowned institutions: the Fred Hutchinson Cancer Research Center, the University of Washington, and Seattle Children's Hospital (SCH).

Through the collective research of these organizations, Alliance patients benefit from leading-edge treatments, improved outcomes, and a strong cancer prevention program. In addition, patients and their family members benefit from access to a unique array of support services. Our specialized expertise and state of the art approaches can reduce complications, speed recovery, improve long-term survival, and enhance the quality of life for cancer patients.

SCCA Mission and Vision statements

Research is an integral part of our mission and vision.

Mission Statement:

- Provide state of the art, patient-focused cancer care;
- Support the conduct of cancer clinical research and education;
- Advance the standard of cancer care regionally and beyond.

Vision Statement:

- To lead the world in translating scientific discovery into the prevention, diagnosis, treatment and cure of cancer.

Relationship of SCCA, FHCRC, UW and SCH

Fred Hutchinson Cancer Research Center (FHCRC), UW Medicine, and Seattle Children's Hospital (SCH) have long-standing affiliations that support their respective missions of research, patient care, and education. In order to enhance cancer research and advance the treatment of cancer, FHCRC, UW Medicine, and SCH have consolidated their adult and pediatric medical oncology/hematology clinical care programs into the separate, jointly governed Seattle Cancer Care Alliance (SCCA). Each of the three SCCA partners has equal ownership in the SCCA. For more information on the partners, go to our website: <http://www.seattlecca.org/>.

What is a RRR account?

It is a mechanism created to direct clinical trial charges to the research budget and not to the patient or his/her insurance. The clinical trial is registered in the UWMC registration system and gets a RS Study Code).

Role of Study Coordinator in Research Billing

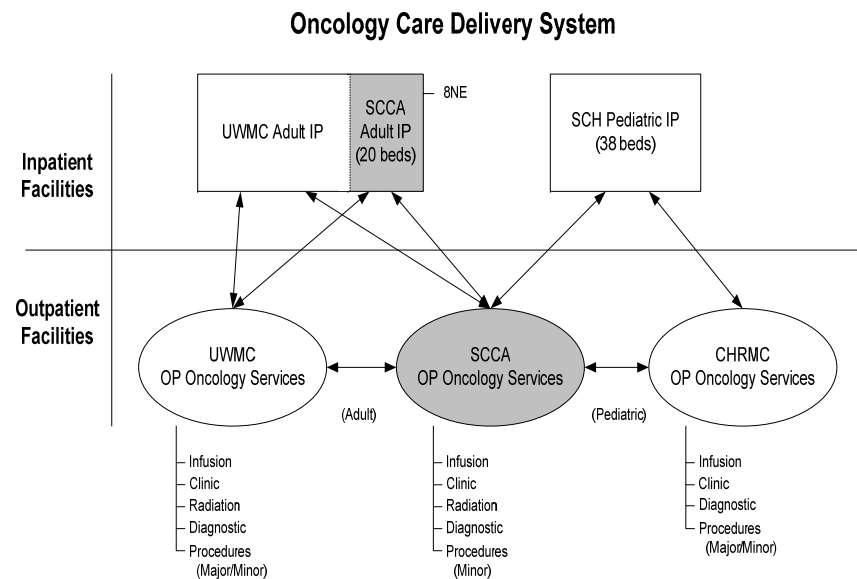
The Study Coordinator completes the research anticipated services sheet (billing form); routes the completed sheet to the coder; reviews the bill for expected and unexpected charges (if there are unexpected or disputed charges, study coordinator will contact the Research Billing Analyst to investigate disputed charges for resolution/correction); study coordinator authorizes payment of research services.

Role of Research Billing Analyst

The Research Billing Analyst receives the research activity bill, applies the research discount and sends the RRR account bill to the research study staff.

How to handle research billing complaints

All research billing complaints should be routed to the Research Billing Analyst.



Research Pricing and Budgeting

The Research Pricing process at SCCA

1. PI determines routine care vs. research activities.
2. PI or study staff complete and submit the SCCA Clinical Trial Planning and Implementation Form to the Research Implementation Office (RIO).
3. RIO reviews packet and distributes to appropriate managers/designated staff to complete pricing pages and return at or before the implementation meeting.
4. Completed pricing pages are forwarded the study contact indicated on the form.

Research Billing Process and Compliance

It is the policy of SCCA that research staff (PI, study coordinator, etc.) work collaboratively with the research implementation and research billing staff at the SCCA to ensure that billing for costs incurred in the conduct of clinical studies occur only as appropriate and in compliance with relevant laws and regulations. The PI is responsible for determining which services are research related and will be billed to a research study budget versus those services that are considered routine care, which can be billed to a patient or a third party payer. The research staff must establish mechanisms to check the accuracy of all clinical services that are being billed to their study budget and notify the research billing staff if errors are discovered.

Refer to the UW School of Medicine/SCCA policy “Billing Compliance in Clinical Research” for more information.

Services available at the SCCA

- Radiology
- Laboratory
- Pathology
- Pharmacy
- Psychiatry & Psychology
- Pastoral Care
- Patient Education
- Pain Management
- Oral Medicine
- Minor Procedures
- Social Services
- Physical Therapy
- Nutrition

Research Implementation Office (RIO)

The Research Implementation Office has two primary functions. First, the RIO manages our Human Subject Research Participant Protection Program, which is federally mandated for institutions involved in clinical research. Second, the RIO facilitates the implementation of new research studies into the clinic and inpatient environments to ensure that all operational issues are addressed prior to study participant accrual occurring.

Please feel free to contact the RIO staff if you have any questions about conducting research at the SCCA.

- Steve Johnson, Human Protection Administrator and Research Integration Program Manager
Phone: 206-288-1287 Email: sjohnson@seattlecca.org
- Gina Roper, Human Protection & Research Implementation Coordinator
Phone: 206-288-6607 Email: groper@seattlecca.org

Human Subject Research Roles & Responsibilities

SCCA's role and responsibility toward human subject research

- The SCCA is a site of practice for clinical research.
- SCCA staff support the conduct of clinical research.

SCCA's Human Research Participant Protection Program (HRPPP)

An HRPPP is a system that includes all structural units, policies and activities critical to protecting individuals studied in research and that is managed in accordance with these standards and with applicable federal, state and local laws. Some components of the HRPPP may be external to the organization, but the essential components of an HRPPP should be identifiable in all cases.

In summary; HRPP is the system that protects the rights and welfare of individuals who participate in research.

An HRPPP is federally mandated for any institution engaged in research. The Office for Human Research Protection (OHRP) oversees human research participant protection programs.

SCCA's HRPPP Goals:

- To protect participants involved in clinical trials and research;
- To facilitate clinical trial and research implementation;
- To assure compliance with federal regulations and other legal requirements.

Other committees that may be involved

Infection Control

Serves as a resource to the clinicians caring for patients that are treated in both inpatient and outpatient settings at the SCCA. The major directive of the committee is to focus on infection control in the oncology populations.

BMT Standard Practice (SPC)

The Standard Practice Review Committee serves as a resource to the Clinical Research Division by providing both structure and guidance for the establishment and maintenance of practice guidelines (monitoring for completeness, quality, and cost containment issues) and associated chart forms, including pre-printed physician's orders.

SCCA Committees Involved in Protocol/Clinical Trial Implementation and Operation Process

BMT Protocol Implementation (PIM)

An operationally focused multi-disciplinary group of people involved with patient care through out the clinic and inpatient areas which review transplant related clinical trials and address any implementation issues for the study to occur at the Seattle Cancer Care Alliance.

Clinical Trial Implementation (CTI)

An operationally focused multi-disciplinary group of people located in the Clinic, who review general oncology (non-transplant) clinical trials to provide research pricing and address implementation issues for the study to occur at the Seattle Cancer Care Alliance.

Institutional Biosafety (IBC)

A review body appointed by the SCCA to review and approve potentially biohazardous lines of research occurring at the SCCA clinic. IBCs were originally established under the NIH Guidelines for Research Involving Recombinant DNA Molecules to provide local, institutional oversight of nearly all forms of research utilizing recombinant DNA.

Radiation Safety

This committee evaluates all proposals for research, diagnosis, and therapeutic use of radioisotopes occurring at the SCCA clinic. The committee evaluates the adequacy of the radiation safety program for radiation safety for adherence to the policies and procedures for the radiopharmaceutical administration program, and adherence to the ALARA concept.

Federal-wide Assurance:

The Federal-wide Assurance (FWA) is a document filed with OHRP acknowledging that:

- Human subject research will be guided by ethical principles;
- The terms of the FWA apply whenever the institution engages in human subject research;
- The institution will comply with federal policy;
- Informed consent will be sought from each prospective subject and the process of consenting will be appropriately documented.

Above all, the FWA formalizes the institution's commitment to protect human subjects.

The SCCA has an FWA on file with OHRP.

Relationship between SCCA and IRB's:

The SCCA does not sponsor its own research, however, we support research as part of our relationship with our parent institutions. Since the SCCA does not sponsor its own research, we do not have our own institutional review board (IRB) or institutional ethics committee (IEC), which are responsible for reviewing research activities involving human subjects to ensure that ethical standards for the care and protection of human subjects have been established and research activities are in compliance with all pertinent regulations (federal, state and local) and with institutional policy.

The term "human subjects" may include patients, outpatients, donors of organs, tissues and services, informants and normal volunteers. However, the term "human subject"

is not limited to activities involving the intact human, but extends to activities involving the use of human embryos, fetuses, abortuses, organs, tissues, body fluids, or graphic written or recorded information.

The SCCA has agreements with several IRB's including SCH, FHCRC, UW, Swedish Medical Center and Western Institutional Review Board (WIRB) to review and approve human subject research on our behalf. If another IRB will be reviewing your research, please contact the Research Implementation Office (288-6607) to determine if we already have an agreement in place with the IRB or if one needs to be established.

In addition to IRB approval, your research project also needs to be logged and reviewed by the SCCA Research Implementation Office. Please allow sufficient time for this review and note that IRB approval alone does not authorize the research to begin occurring at the SCCA.

IRB's authorized to approve Human Subject Research on behalf of the SCCA:

1. Seattle Children's Hospital; Address: CHRMC, 4800 Sandpoint Way NE, P.O. Box 5371, Mailstop CH-36, Seattle, WA 98105-0371
2. Fred Hutchinson Cancer Research Center; Address: Institutional Review Office, Mailstop J6-110, 1100 Fairview Avenue North, PO Box 19024, Seattle, WA 98109-1024 (Attn: Karen Hansen)
3. Swedish Medical Center; Address: Swedish Medical Center, 747 Broadway, Mailstop 1120, Cherry, Suite 360,

Auditing & Monitoring Activities

The Integrity Officer will periodically and randomly select grants and contracts for audit. The review will include compliance with all applicable regulations including informed consent accuracy as well as compliance with research billing and records management rules. Audits may occur at any time at the discretion of the Integrity Officer.

Compliance Office and Program

Integrity Office & Compliance Program

The SCCA has a Corporate Integrity Officer who is in charge of the compliance program. The Integrity Program is a system that promotes compliance with applicable federal and state laws and regulations, develops individual and team character and virtue in the workplace, and creates and maintains a culture of integrity. Everyone associated with SCCA is responsible for acting in a manner consistent with our corporate integrity and compliance programs and SCCA supporting policies, as well as all applicable federal and state laws and regulations. Thus, you are obligated to comply with the standards contained in this handbook as well as the SCCA Statement of Ethics & Business Conduct, to report any alleged violations to your supervisor or the Integrity Officer, and to assist with investigations involving allegations of violations or other wrongdoing.

Reporting of Issues or Concerns

The SCCA has an Integrity Hotline (866-353-6098), which can be used to report issues or concerns anonymously. Calls to the Integrity hotline will not be traced. Callers do not have to identify themselves; however they may do so to assist in giving additional information about the situation. The Integrity Officer retrieves this information and will conduct an investigation based on the information provided. The Integrity Officer will investigate all reported concerns promptly and confidentially to the fullest extent possible and initiate corrective actions as appropriate. The Integrity Officer will follow-up with the individual reporting the situation and will provide information to the extent possible.

Seattle, WA 98122

4. University of Washington; Address: UW Human Subjects Division, 3945 15th Avenue NE, Seattle WA 98105-6607
5. Western Institutional Review Board; Address: WIRB, P.O. Box 12029, Olympia, WA 98508-2029

SCCA Human Protections Administration contact information

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Phone: 288-1287 Email: sjohnson@seattlecca.org
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Roles and Responsibilities of Principal Investigator (PI) and Study Staff conducting research at SCCA

PI's role and responsibility:

The PI has ultimate responsibility for the conduct of the research. The lead PI is responsible for all aspects of the protocol development, including the following aspects of clinical research:

- Coordinating the approval process, which includes protocol conference, scientific review, and IRB reviews;
- Incorporating changes into the protocol through a formal amendment process, including Scientific Review Committee (SRC) and IRB approval before such changes can be implemented;
- Informing fellows, nursing, pharmacy, and other staff about protocol requirements;
- Overseeing all study team members;
- Collaborating on forms of design;
- Reporting of serious adverse events (SAEs) as well as events that are unexpected
- Reporting trial results in a timely fashion;
- Providing information to the SCCA upon request in order to assist us in meeting compliance & other HRPPP requirements;
- Billing activities;
- Attending trainings;

- Reporting concerns or issues to the SCCA Integrity Officer at 288-6380 and;
- Reading this handbook and complying with all applicable policies & procedures.

Research Coordinator role and responsibility:

The Research Coordinator is an integral part of the study team. The Research Coordinator is usually responsible for reviewing research subject records, abstracting data, and completing the case report forms (CRFs). The Research Coordinator works closely with the PI, other research staff (if applicable), and the data analyst to perform protocol management for each trial. Research Study Coordinators are involved with several areas of the clinical trial process, including protocol review, forms design, data collection, eligibility confirmation and subject's protocol registration. Additional responsibilities may include scheduling subjects, submitting reports, and preparing IRB submissions, including amendments, continuing review reports, reporting protocol violation and deviations, investigational new drug (IND) safety reports, and SAE reports.