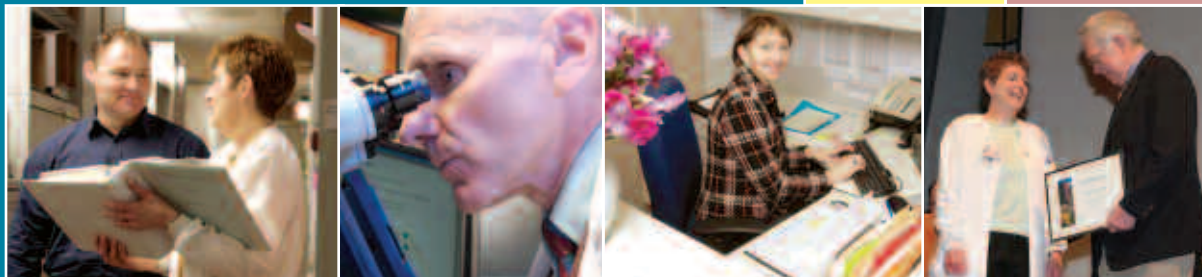


ROSWELL PARK CANCER INSTITUTE

Clinical Research Services



Committed to high quality clinical research that emphasizes
integrity, competence, communication and collaboration



Clinical Research Services

Clinical Research Services (CRS) is an NCI-supported shared resource critical to the submission, implementation and outcomes of research studies associated with Roswell Park Cancer Institute's clinical, translational and basic science research programs. CRS staff work in collaboration with Roswell Park Cancer Institute (RPCI) investigators to provide oversight of the research process and to facilitate the accrual of participants to research studies. CRS has collaborative relationships with RPCI departments involved in the clinical research process including Pharmacy, Radiology, Pathology, Laboratory Medicine, Nursing, Marketing, Information Technology (IT), Decision Support and Finance. Clinical Research Services is committed to performing high quality clinical research in an environment that emphasizes integrity, competence, communication and collaboration.

Mission



Clinical Research Services (CRS) is a diverse, interdisciplinary group of research professionals who strive to achieve excellence in all aspects of the research process. This collaboration facilitates the development of innovative and effective strategies for the prevention, detection and treatment of cancer. CRS promotes safe and ethical care for all who participate in clinical research at Roswell Park Cancer Institute.



Our Vision

1. To be recognized by our investigators, sponsors and external agencies as the “gold standard” for clinical research.
2. To ensure that clinical research study submission and implementation processes are efficient and concise.
3. To enhance participation and knowledge of clinical research at RPCI through the education of patients, families, staff and the community.
4. To inform all RPCI departments regarding clinical research and the significance of their collaboration to the research process.
5. To enhance clinical research collaborations within RPCI and with outside academic and medical facilities.

Services



CRS provides the following services in collaboration with RPCI investigators:

- Works with the investigator to resolve study implementation problems and concerns.
- Facilitates the documentation and reporting of adverse events.
- Develops and manages the centralized research database (eResearch).
- Manages study data acquisition and review.
- Prepares and submits periodic and continuing reviews to the IRB.
- Provides internal quality control audits for RPCI clinical research studies.
- Coordinates clinical research sponsor site visits and audits.
- Provides administrative support for the Concept Review and Feasibility Committee (CRFC), the Scientific Review Committee (SRC), the Phase I Committee, the Data and Safety Monitoring Board (DSMB) and the Response Review Committee.
- Facilitates the review of ongoing studies by the SRC via the Protocol Review and Monitoring System (PRMS).
- Develops and maintains the CRS internal and external websites.
- Facilitates both obtaining and renewing NCI investigator numbers for physician investigators.
- Monitors Human Subjects Protection Certification for investigators and research staff.
- Provides on-going educational programs for CRS staff and other RPCI departments.
- Manages the RPCI Clinical Research Center.
- Manages the Clinical Research Network.
- Prepares and submits new research studies and amendments for review by the Scientific Review Committee (SRC) and the Institutional Review Board (IRB).
- Facilitates the review and approval of all research studies by the Food and Drug Administration (FDA), National Cancer Institute (NCI), Cancer Therapy Evaluation Program (CTEP) and study sponsors.
- Prepares FDA Investigational New Drug (IND) submissions, amendments and annual reviews.
- Prepares research study budgets, negotiates the budget with study sponsors and provides study budget management.
- Facilitates accrual to clinical research studies.
- Implements intervention research studies and collects all related research data.

Sponsor Visits

CRS facilitates sponsor visits to RPCI for research study monitor visits or audits. All requests for sponsor site visits are scheduled through the Senior Secretary, Clinical Research Services, at **716-845-3870**.

Based on the information provided, CRS staff will facilitate the site visit/audit, including coordination of staff, records, documents and tours needed to fulfill the site visit/audit purpose. CRS staff will participate in an exit meeting to identify any follow-up needed prior to the next monitor visit/audit.



Clinical Research Network

Roswell Park Cancer Institute has a Clinical Research Network that includes contracted affiliations with cancer centers, hospitals, private practice physicians and investigators at other NCI-designated Comprehensive Cancer Centers. The Clinical Research Network allows “state-of-the-art” cancer prevention and treatment studies to be shared with investigators and participants in locations distant from RPCI and close to the homes of the study participants.

To learn more about the CRS Clinical Research Network or to become a Clinical Research Network location, call **716-845-1203**.





Alex Adjei, MD, PhD

Senior Vice President, Clinical Research; Chair, Department of Medicine; Katherine Anne Gioia Chair in Cancer Medicine

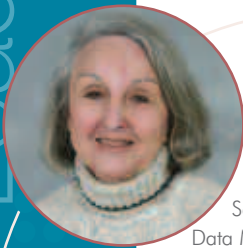
Alex Adjei, MD, PhD, joined the faculty of Roswell Park Cancer Institute (RPCI) in 2006 as Senior Vice President of Clinical Research and Chair of the Department of Medicine. Dr. Adjei has overall responsibility for RPCI's clinical research activities.

Dr. Adjei earned his medical degree from the University of Ghana Medical School in Legon. He obtained a doctorate degree in pharmacology at the University of Alberta in Edmonton, Canada.

Dr. Adjei completed residency training at Howard University, Washington, DC, and clinical and research fellowships in oncology at Johns Hopkins School of Medicine, Baltimore, MD. He is a Diplomate of the American Board of Internal Medicine.

Dr. Adjei is a distinguished national leader in translational research, drug development and thoracic oncology. He came to RPCI from the Mayo College of Medicine, Rochester, MN, where he served as Professor of Oncology and led highly successful thoracic oncology and Phase I clinical research programs.

Dr. Adjei's research is focused on assessing the toxicity, pharmacology and initial activity of novel agents for the therapy of solid tumors and developing biomarkers of drug effects. His laboratory studies focus on elucidating mechanisms of action and resistance of novel agents that inhibit cell signaling. He also conducts phase II studies of novel agents in lung cancer.



Joyce M. Yasko, PhD, RN

Vice President, Clinical Research Administration and Services

Joyce Yasko, PhD, RN has overall responsibility for Clinical Research Services, the Clinical Research Network, Data Management, and the Investigational Drug Service (IDS) in collaboration with RPCI's Pharmacy Department and Clinical Research Center.

Dr. Yasko joined the staff of RPCI in 2002 as Assistant Vice President, Clinical Research Services. She earned her Masters of Nursing Education degree with a specialization

in Oncology in 1976 and completed her doctoral degree in Academic Administration in 1981 at the University of Pittsburgh, PA.

Dr. Yasko is responsible for RPCI's Clinical and Research Administration and Services, including establishing policies and procedures to guide and facilitate clinical research, implementing education programs for clinical research staff and others and managing the financial aspects of research studies.



Leadership



● **Julie Honey, RN, BS, CCRC, Director, Study Submission and Regulatory Affairs**
Responsible for support of the Scientific Review Committee (SRC); submission of new clinical research studies, amendments and study documents to the SRC and Institutional Review Board; monitoring of compliance with human subject protections certification and management of the Regulatory Research Associates (RRA).

Regulatory Research Associates (RRAs) are assigned by the Clinical Research Program and assist investigators with the submission of clinical research documents and regulatory requirements. RRAs also maintain the study regulatory binder and assist the investigator and the clinical research coordinators in the preparation of periodic and continuing reviews.



● **Linda Schmieder, RN, BSN, MSN, Director, Study Implementation**
Responsible for oversight of research study implementation and accrual; coordination of all audits and monitor visits; management of the Implementation Research Associates and the Clinical Research Coordinators, acts as the liaison between RPCI, Principal Investigators and sponsors and assists in the development and clinical management of study budgets.

Clinical Research Coordinators (CRCs) collaborate with investigators to implement clinical research studies and to identify and accrue study participants. CRCs are assigned by the Clinical Research Program and are responsible for the education of the patient and family regarding the clinical research study; the consent process, assessment of study treatment; identification, documentation and reporting of adverse events; data oversight and communication with the principal investigator, research team, sponsors and oncology research Cooperative Groups.

Implementation Research Associates (IRAs) facilitate the implementation and data collection for clinical research studies. IRAs interface with other departments, study sponsors and oncology research Cooperative Groups to ensure a collaborative approach to clinical research.



● **Diane Bader, RN, BSN, CCRC, (top), Valencia Payne, RN, BSN, CCRC, (center) and Lise Hernandez, RN, BSN, CCRC, CHTC, (bottom)**
Study Implementation Administrators

Provides education, orientation clinical oversight and mentorship for the Clinical Research Coordinators and Transplant Coordinators.



● **Jan Pantano, RN, BSN, CCRC, Director, Clinical Research Compliance**

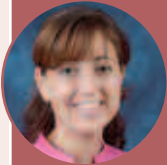
Responsible for the support of the Data Safety Monitoring Board (DSMB); facilitator of monthly CRS meetings and management of the Compliance Office Staff which includes Compliance Officers and Clinical Research Associates.

Compliance Officers/Clinical Research Associates (CRAs) are responsible for release and activation of studies, amendments and IRB approved documents; preparing and managing IND applications and annual reviews; submitting continuing/periodic reviews to the IRB; registering patient consents; conducting internal compliance audits; reporting serious adverse events; and managing internal/external clinical research websites.



● **Mary Eileen McPhee, RN, MSN, Director, CRS Clinical Research Network**

Responsible for the management of the Clinical Research Network which includes RPCI sponsored clinical research studies that are implemented at locations external to RPCI such as private physician offices, hospitals and cancer centers. This includes education and oversight of the research staff at these locations.



● **Laurie Musial, RN, BSN, CCRP, Clinical Research Center Administrator**

Responsible for the management of RPCI's Clinical Research Center, a new clinical research resource that opened in Spring 2008.

The Clinical Research Center has 17 treatment areas, a processing laboratory, state-of-the-art conference room and the Investigational Drug Service Pharmacy. The staff include Research Nurses who have both clinical research and clinical care knowledge and skills.



● **Barbara Todaro, PharmD, Investigational Drug Service (IDS) Administrator**

IDS is a shared clinical research resource in collaboration with Clinical Research Services and the Department of Pharmacy. IDS is responsible for all aspects of drug accountability and inventory maintenance including maintaining an accurate dispensing log; ordering, receiving, storing and returning investigational agents and the preparation of study specific pre-printed orders.

IDS Pharmacists Responsible for drug ordering and accountability and patient and staff education. Also, responsible for IDS coordination within the Clinical Research Center and the Clinical Research Network.

IDS Associates Assist in the day-to-day operations of IDS.

Leadership



● **Kathy Reitz, BS, *Data Management and Research Database (eResearch) Administrator***

Responsible for the development and maintenance of the centralized electronic research database, study specific data management, the generation of data related reports and the supervision of the Data Managers.

Data Managers: The Data Managers work with investigators and CRS staff to fulfill the clinical research data management needs of RPCI clinical research studies. They monitor the data contained within the Clinical Research Database and serve as data system administrators.



● **Cheri Parrish, MBA, *CRS Financial Administrator***

Coordinates the development of all clinical research budgets, negotiates the budget with commercial sponsors and manages the approved clinical research budgets. Prepares financial reports for all clinical research activities and manages the CRS Financial Team



● **Nancy Crenshaw, RN, MT, *CRS Laboratory Medicine Administrator***

Responsible for working with the investigators and clinical research coordinators to resolve laboratory related implementation issues. Ships all study specimens and prepares the laboratory components of study budgets.



● **Carol Sherer, RN, CCRC, *CRS Educator***

Responsible for CRS staff orientation and continuing education.



● **Ruth Wasmer, *Executive Assistant***

Provides support to the VP including scheduling all appointments and performing administrative departmental duties. She is the CRS "go to" person for information, supplies and resources.

Website Search Engine

Navigating our Website

The External RPCI Website, www.roswellpark.org, is a search tool for consumers/public to view the summary of RPCI clinical research studies. All study summaries are approved by the IRB. Prior approval of the research study summary from the sponsor is required for sponsored studies.

RPCI has clinical research studies in all of the categories noted.

Prevention

Blood and Marrow Transplant

Hematologic Blood Cancers:

- Leukemia
- Lymphoma
- Multiple Myeloma
- Myelodysplastic Syndrome

Phase 1 Studies

Melanoma/Sarcoma

Pediatric Oncology

Photodynamic Therapy

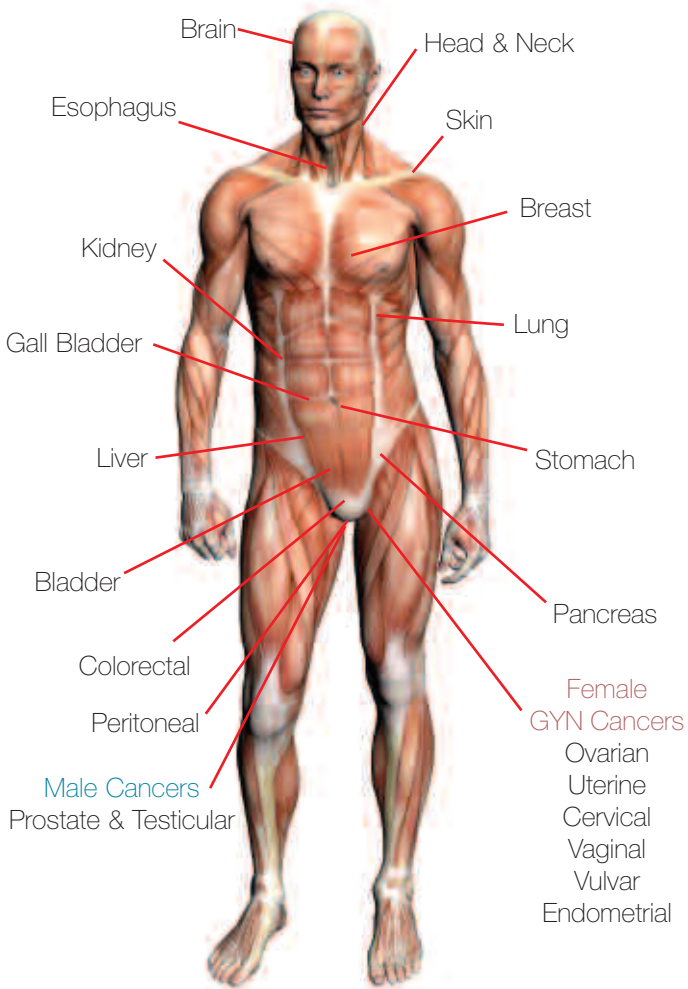
Infectious Disease

Radiation Medicine

Other

Clinical Trials Online Search

www.roswellpark.org/ClinicalTrials For additional information, call: 1-877-ASK-RPCI (1-877-275-7724).



CRS Information

Location

Administrative Services Building
(Rm 127, Administrative Offices)
and other locations throughout RPCI
Elm & Carlton Streets • Buffalo, NY 14263

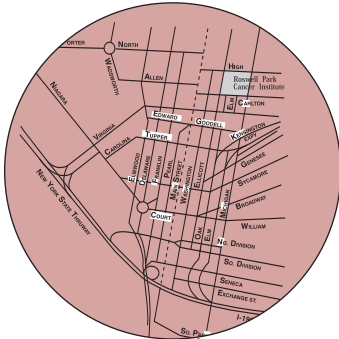
Hours of Operation

Weekdays, 8:00 am to 5:00 pm

Information Requests:

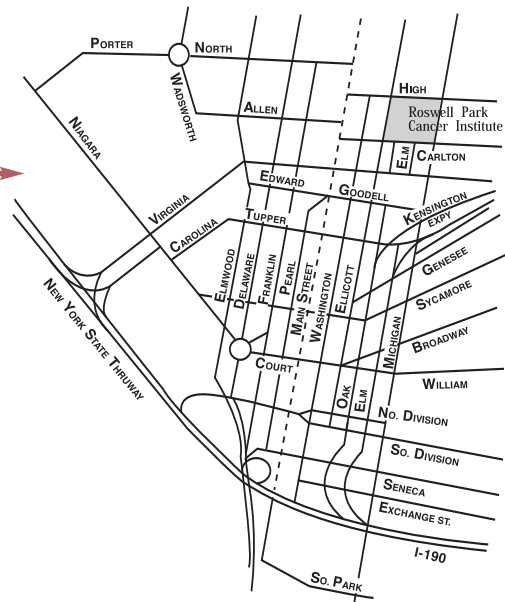
Ruth Wasmer, Executive Assistant
Phone: 716-845-8649 • Fax: 716-845-356

Directions to Roswell Park



From points east, west, north and south of Buffalo: Take the New York State Thruway (Interstate 90) to Exit 51W (Route 33 West, also called the Kensington Expressway). Exit from Route 33W at Locust St. Turn right at the first traffic light (Michigan Avenue). Continue on Michigan Avenue for two blocks to Carlton Street. Turn left at the traffic signal. Our intersection is Elm and Carlton Streets, Buffalo, NY 14263.

Buffalo, NY is available by air, train and bus. Further information for these travel options are available at www.roswellpark.org under the About Us tab.



Downtown Accommodations

Double Tree: (Attached to our Institute) 716-845-0112
Hyatt Regency: 1-800-233-1234
Hampton Inn & Suites: 716-855-2223
Adams Mark: Toll free # 1-877-905-6275
Other local accommodations available upon request.

Questions?

For more information about CRS, please call
716-845-8649 or e-mail joyce.yasko@roswellpark.org



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A Comprehensive Cancer
Center Designated by the
National Cancer Institute



National
Comprehensive
Cancer
Network