The Cooperative Group Concept

SWOG History and Objectives

SWOG was originally organized in 1956 as a pediatric cancer chemotherapy study group under the name Southwest Cancer Chemotherapy Study Group. The addition of seven Veterans Administration hospitals in 1958 started the subsequent evolution from a pediatric focus to one of adult clinical trials. In 1973, the name of the organization was formally changed to the Southwest Oncology Group. In 1976, the Group was augmented by the addition of Affiliates – formerly known as the Cooperative Group Outreach Program (CGOP), and by the Community Clinical Oncology Program (CCOP) in 1983. These and other programs further broadened the geographic scope of the group and increased both the number and type of patients entered on studies. The Group now includes institutions in all regions of the country and in Canada, Korea, Mexico, Saudi Arabia and Spain, and also researches cancer control, prevention and screening, and all modalities of cancer therapy such as surgery, radiation therapy and various types of systemic therapies.

SWOG was formed on the premise that significant advances would be made by a cooperative approach to the design and conduct of clinical trials on a large patient population. It is dedicated to the goal of improving the care of patients with malignant disease, to increasing their cure rate through multidisciplinary research and to developing cancer control and prevention programs. Each member of the Group actively supports the concept of entering into multi-institutional studies, of pooling patient and research resources with others, and of participating in study committees for the purpose of analyzing and evaluating the results of studies.

In 2014, the National Cancer Institute transformed the long-standing cancer clinical trial cooperative group program into a more tightly integrated National Clinical Trials Network (NCTN). SWOG is now a Network Group within the new NCTN.

SWOG is divided into three offices: the Group Chair’s Office, the Operations Office and the Statistical Center, each with different functions.
The Group Chair’s Office

The Group Chair’s Office is located in Portland, Oregon, where Charles D. Blanke, M.D., directs the Group’s business.

SWOG Chair’s Office
3181 SW Sam Jackson Park Road
MC:L586
Oregon Health & Science University
Portland, OR 97239
Phone (503) 494-5586 | Fax (503) 346-8038

Leadership:
Charles D. Blanke, M.D., Chair
Anne Schott, M.D., Deputy Chair
Lee M. Ellis, M.D., Vice-Chair for Translational Medicine
Dawn Hershman, M.D., M.S, Vice Chair for Cancer Control & Prevention/NCORP
Nathan Eriksen, Chief of Administration (Director of Operations)

Executive Officers oversee protocol development as follows:
Julie R. Gralow, M.D. for the breast and lung committees
Lisa A. Kachnic, M.D., oversees the integration of multiple treatment modalities into SWOG studies, including the work of the surgery, imaging, radiation therapy and bone marrow & stem cell transplant committees.
Craig R. Nichols, M.D., oversees digital engagement, adolescent and young adult oncology and patient advocacy.
Susan M. O’Brien, M.D. for the lymphoma, leukemia and myeloma committees
James M. Rae, PhD. oversees the development of the Group's protocols in translational medicine and contributes to activities that involve the Group's biospecimen repository.
Christopher W. Ryan, M.D. for the gastrointestinal, genitourinary, melanoma and early therapeutics & rare cancers committees
Gary Lyman, M.D. oversees the symptom control and quality of life committees
Katherine Crew, M.D., M.S. oversees the cancer survivorship and prevention committees
Manuel Valdivieso, M.D. is responsible for quality assurance and international initiatives for SWOG.

The major responsibilities of the Group Chair’s Office are to:
* Serve as the Group liaison with the National Cancer Institute (NCI)
* Set the scientific Agenda for the Group
* Oversee all administrative Group functions
* Oversee legal activities
* Manage all Group grants
* Handle all third-party consortium, contracts, payments and purchase service agreements per-case reimbursements for all studies
* Ensure compliance of all Group activities with regulatory agencies and NCI guidelines
* Publicize and promote studies
* Publish newsletters and press releases
* Manage peer-reviewed publications
* Coordinate SWOG Biorepository-related activities
The Operations Office

The Operations Office is responsible for most operational tasks within the Group. This office is located in San Antonio, Texas. Dana Sparks functions as the Chief of Operations and Protocols under the supervision of the Group Chair and the Chief of Administration.

SWOG Operations Office
4201 Medical Drive, Ste. 250
San Antonio, TX  78229-5631
Phone (210) 614-8808
Fax    (210) 614-0006

The major responsibilities of the Operations Office are to:

* Administer the Group’s website: swog.org
* Prepare electronic semi-monthly protocol postings to the web site
* Maintain and post all Group policies
* Monitor CCOP Credit assignments
* Develop and maintain protocols
* Coordinate investigational new drug (IND) applications
* Coordinate Radiation Therapy/BMT facility approval
* Coordinate Serious Adverse Event reporting
* Maintain regulatory records, to include Institutional Review Board (IRB) information and institution assurance approvals
* Maintain Group membership database
* Respond to questions regarding institutional and investigator membership
* Monitor and collect information regarding mandatory investigator training on protection of human subjects
* Coordinate semi-annual Group meetings and other meetings as needed to include site selection
* Coordinate quality assurance audit review program
* Coordinate the Young Investigator’s training course
* Participate/Present educational training
* Develop and maintain funding memos for all NCTN protocols
* Manage Conflict of Interest Database
* Assure ethics information is part of all Clinical Research Associate workshop and training sessions
* Monitor and collect signed Affirmations of Integrity forms for active members
* Review all documents to assure Health Insurance Portability and Accountability Act (HIPPA) compliance
The Statistical Center

The Statistical Center is responsible for all technical tasks within the Group. This office is located at the Fred Hutchinson Cancer Research Center in Seattle, Washington. The Statistical Center Director is Michael LeBlanc, Ph.D. This office is responsible for the coordination and performance of all statistical aspects of SWOG research.

**SWOG Statistical Center**
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North M3-C102
P.O. Box 19024
Seattle, WA 98109-1024
Phone (206) 667-4623
Fax (206) 667-4408

**Cancer Research and Biostatistics**
1730 Minor Avenue
Suite 1900
Seattle, WA 98101-1456
Phone (206) 652-2267
Fax (206) 342-1616

The major responsibilities of the Statistical Center are to:

* Participate in the review of new protocols.
* Register/randomize all patients.
* Process data including quality control review and interim evaluations.
* Develop forms, uniform toxicity, and response criteria.
* Analyze and publish results of studies with study chair.
* Publish the semi-annual Report of Studies.
* Conduct studies of prognostic factors and late effects.
* Perform statistical research.

Questions for the Statistical Center include those regarding:

* Open protocols (except medical or treatment questions which should be referred to the study chair).
* Patient eligibility/registration to a study.
* Forms completion, submission.
* Statistical analysis.
* Report of Studies.
* Clinical Trials Training Course.
* Pathology or radiation therapy materials submission.
* Institutional Performance Review.
SWOG SDMC Organizational Chart

Director/Group Statistician
SDMC Executive Committee

Group Chair
Director of Operations
Network Group
Operations Center Staff

BIOSTATISTICIANS
Deputy Director

Disease Committee and Cancer Control Faculty Biostatisticians

Staff Biostatisticians

Grants and Contracts Administrator

COMPUTING
Scientific Executive Officer

Applications Development Director

Systems Analyst/Programmer Supervisor

Technical Support Analyst

Systems Analyst/Programmers

Software Testing Manager

Software Tester

Case Report Form Programmer

SAS Programmer

Program Manager

Chief Technology Officer

Senior System Engineer

Network Administrator

Database Administrator

IT Director

Systems Administrator

Therapeutics

Data Operations Program Manager

Data Operations Supervisors

Data Operations Quality Assurance

Data Coordinators

Data Control Technician

Cancer Control And Prevention*

Program Director

Data Operations Manager

Data Operations Supervisor

Data Coordinators

Retention and Adherence Manager
COOPERATIVE GROUP CONCEPT

CHAPTER 3

REVISED: SEPTEMBER 2016

Mike LeBlanc, PhD, Director³
Catherine Tangen DrPH,., Deputy Director²
Garnet Anderson, PhD, Associate Director, Cancer Control & Prevention²
Cathryn Rankin, MS, Coordinating Biostatistician, Therapeutics²
Phyllis Goodman, MS, Coordinating Biostatistician, Therapeutics²
Joseph Unger, PhD, Coordinating Biostatistician, Cancer Control & Prevention²

Data Coordinators:¹
Diana Heaney, BS
Iris (Cat) Syquia
Jacqueline Scurlock, BS
Jennie Barrett, CCRP
Krystal Pagarigan, BS
Larry Kaye, BA
Louise Highleyman, BA
Sean O'Bryan, BS

Prevention
Karen Anderson, Retention Manager¹
Monica Yee, BA, CCRP, Program Manager¹

Data Coordinators:¹
Diane Liggett, BS, CCRP
Heidi Dong
Jennifer Patterson
Roxanne Topacio, CCRP, Data Operations Supervisor

Information Technology¹
Keith Goodman, DBA, Chief Technology Officer
Patrick Durham, BS, Program Director
Jane Xie, BA
Steve Dong-Lee, BA
Terry Lynch, BA

SWOG Centralized Monitors¹
Dona Marrah, CCRP, Project Manager, Clinical Monitor
Jennifer Stubbs, BS, Clinical Monitor

Data Management¹
Angela Smith, BA, Program Manager

Data Operations:¹
Rodney Sutter, CCRP, Data Operations Program Manager
Brian Zeller, Data Operations Supervisor
Christine McLeod, Data Operations Supervisor
Tracy Maher, BS, CCRP, Data Operations Supervisor
Laura Kingsbury, MRT, Quality Assurance Coordinator

Data Control Technicians:¹
Kimberly Carvalho
Caryn Munkers
Rachel Matthews, BFA

Location: ¹ CRAB, ² FHCRC, ³ Both
Membership in SWOG

Individual Membership
Individual members are scientists who participate in the scientific and/or administrative conduct of group studies at a member institution. These individuals are nominated by the principal investigator at a member institution.

Members have the following privileges:
* Participation in protocol design, coordination and publication.
* Registration and treatment of patients on appropriate group protocols (licensed physicians only).
* Receipt of drugs allocated to the Group to conduct group protocol studies (licensed physicians only).
* Election or appointment to any position and/or committee of the Group.
* Participation in SWOG education activities including Group Meetings
* May apply for SWOG/Hope Grants
They are reviewed and approved by SWOG’s designated Membership Reviewer with ratification by the Board of Governors.

Special Membership
Individuals may be proposed for special membership by the Group Chairman, or a discipline or disease committee, to be approved by the Board of Governors. Privileges of the special member are awarded by the same mechanism as individual membership.

Approval of Radiation Therapy and Bone Marrow Transplant Facilities
Protocol treatment that includes radiation therapy or bone marrow transplants must always be performed at a SWOG approved facility. Specific requirements and procedures for attaining facility approval are found in Policy Memorandums No. 26 and 27.

Institutional Membership
The Federal Policy (Common Rule) for the protection of human subjects requires that each institution “engaged” in Federally-supported human subject research file an "Assurance" of protection for human subjects with the Office for Human Research Protections (OHRP). This Assurance formalizes the institution’s commitment to protect human subjects and must remain current. The requirement to file an Assurance includes both “awardee” and collaborating “performance site” institutions.

Mandatory Probationary Membership
All institutions approved for membership by the Board of Governors will serve as probationary members for 18 months. After that time, they will either be moved to full membership by the Board of Governors or, at the Chairman’s discretion, the probationary membership may be terminated.
Membership Programs

Full Member Institutions (Member)

There are currently 55 full member institutions in SWOG. These include 14 Lead Academic Participating Sites (LAPS) funded on U10 agreements by the National Cancer Institute for this grant cycle, 41 Main Member institutions without U10 agreements, and two translational medicine institutions (non-accruing). There are currently 2,526 participating investigators at these full member institutions.

Member institutions must document a multidisciplinary program (e.g., participation of medical oncology, radiation oncology, surgery, urologic oncology, etc.) and their ability to accrue a minimum number of registrations to SWOG and SWOG-credited studies in all disease categories to remain in good standing. In addition, the institution must provide high quality and innovative scientific contributions to further the research aims of the group. Specific criteria for group membership include the following:

1) Projected minimal accrual of at least five evaluable SWOG-credited enrollments per year for a LAPS and >/= 10 SWOG-credited enrollments per year for a Main Member based over a three year period (not applicable for Translational Medicine Members). For Translational Medicine Members, projected minimal participation in five SWOG translational medicine research projects based over a three year period.

2) An acceptable Quality Assurance audit every three years.

3) Acceptable timeliness of data submission and quality of data.

4) Representation of the institution at a minimum of one semi-annual Group meeting every two years.

5) Every physician at the Member institution who is a Group member must be credentialed with SWOG in order to register patients to clinical trials. To meet the credentialing requirements, investigators must have: a) completed a medical fellowship program or the Young Investigators Workshop, b) completed NIH, or equivalent, required training on the protection of human research subjects, c) a signed affirmation of integrity, and d) no misconduct, disbarment or other administrative actions against them. In addition, investigators must submit on an annual basis an FDA 1572 (Statement of Investigator) to the Pharmaceutical Management Branch (PMB) with a copy of their curricula vitae.
Affiliate Program

The Affiliate Program was developed in 1976 by the National Cancer Institute. This program was developed with direct supervision by the Member institutions, ensuring a geographic relationship and close communication between the principal investigator at the Member institution and the affiliate. Currently, there are 750 investigators and 78 institutions participating in the Affiliate Program.

Most affiliates are directly funded through the Group Chair’s Office through a Purchase Service Agreement. The funding is awarded from the NCI as a fixed amount each year and is dispersed based on accrual at a maximum per case figure of no more than $2,250 for Phase II and Phase III registrations. These reimbursement figures are paid on a monthly basis. However, the amount paid may vary from month to month due to fluctuations in accrual. The affiliate investigators are reimbursed for each individual patient registration when it is determined that the patient registered is eligible and evaluable.

The Affiliate Program objectives include the following:

1) To make state-of-the-art cancer management available to cancer patients in the community.
2) To involve a wider segment of the community in clinical research.
3) To enhance the recruitment of patients from the community hospitals onto appropriate protocols.
4) To evaluate the transfer of new patient care technology to the community.

Affiliate investigators are required to meet a minimal accrual of five initial registrations per year based over a three year period, and are eligible to accrue to almost all Group-wide trials, including those with investigational and biological agents. SWOG allows registrations by Affiliate investigators to Phase II new agent clinical trials open either Group-wide or to a select group of member Institutions.

Affiliate institutions may be monitored by their parent member institution, as well as by the Statistical Center, to ensure adherence to Group standards for quality of data. Affiliate institutions are also audited in cycle with their Member institutions, by the Operations Office. Affiliate participation is reviewed annually to ensure compliance with minimal accrual requirements. Affiliates failing to meet the minimum accrual requirements receive a warning, and if increased activity is not demonstrated in subsequent months, registration privileges are revoked.

Every physician at the Affiliate institution who is a Group member must meet the same credentialing requirements as a Member institution physician in order to register patients to clinical trials.
NCI Community Oncology Research Program (NCORP) and the Minority-Underserved NCORP

The NCI Community Oncology Research Program was initiated on August 1, 2014. This is a community-based program that builds upon the scope and activities of the NCI's previously supported community networks: Community Clinical Oncology Programs (CCOP), Minority-Based Community Clinical Oncology Programs (MB-CCOP), CCOP Research Bases, and the NCI Community Cancer Centers Program (NCCCP).

Twenty-six SWOG institutions are funded by the Division of Cancer Prevention (DCP) of the NCI through UG1 agreements to participate in the NCORP, which includes six funded Minority/Underserved-NCORP institutions recruited specifically to allow access to large numbers of minority patients. Accrual goals for these Minority/underserved institutions require that greater than 30% of the new cancer patients seen by the participating physicians are from minority groups. Currently, 2,155 investigators participate at these NCORP institutions.

The objectives of the NCORP and MU-NCORP programs are as follows:

1) Design and conduct cancer prevention, control, and screening clinical trials.

2) Design and conduct cancer care delivery research.

3) Enhance patient and provider access to treatment and imaging clinical trials conducted under the reorganized National Clinical Trials Network (NCTN).

4) Integrate disparity research questions into clinical trials and cancer care delivery research.

NCORP institutions are primarily community hospitals. Criteria for membership includes continued funding by the DCP (requires annually 80 new patient/participant accruals evenly distributed over the available cancer prevention, control and screening/post-treatment surveillance clinical trials versus treatment and imaging clinical trials, respectively), an acceptable audit every three years, and acceptable quality of data and timeliness of data submission. Standards for quality of data and timeliness of data submission are the same as for the Group’s Member Institutions.

Every physician at the NCORP institution who is a Group member must be credentialed with SWOG in order to register patients to clinical trials. To meet the credentialing requirements, investigators must have: a) completed a medical fellowship program or the Young Investigators Workshop, b) completed NIH required training on the protection of human research subjects, c) a signed affirmation of integrity, and d) no misconduct, disbarment or other administrative actions against them. In addition, investigators must submit on an annual basis an FDA 1572 (Statement of Investigator) to the Pharmaceutical Management Branch (PMB).
International Participation

With a growing interest from international sites requesting participation in cooperative group clinical trials, SWOG agreed to consider collaboration with selected investigators and institutions outside the United States. As a result, in addition to efforts to increase international intergroup participation, the Group developed guidelines (Policy No. 40) for international sites to participate directly on Group trials in April 2003. International sites must hold an OHRP-approved Federal Wide Assurance (FWA) and must have official U.S. State Department approval for participation in NCTN trials. Every physician at the international institution must meet the same credentialing requirements as a Member institution physician in order to register patients to clinical trials. The Group will work with each international site on an individual basis to resolve any regulatory, contract, funding, or shipping requirements, although international sites must agree to assume responsibility for any drug shipment charges and the cost of quality assurance audits. Also, all Group data must be submitted in English and in units of measure as specified on the study forms.

Currently, two sites in Canada and one site in each of the following cities participates in clinical trials throughout all disease and research committees: Riyadh, Saudi Arabia; Mexico City, Mexico; Goyang, Korea; Bogota, Colombia; and, Lima Peru. Preliminary discussions for future participation in the Group are currently underway with several other South and Central American institutions.

Sustaining Membership with SWOG

Institutional Performance Review

The timeliness of submission of patient data, the percentage of patients overdue for follow-up and the eligibility rate of patients are monitored and reported by SWOG Statistical Center. The primary investigator of every institution is provided with the data pertinent to his or her institution’s performance monthly. The institutional performance data for all SWOG institutions is published semi-annually in the Report of Studies.

Each month the Group Chair reviews these reports of institutional performance. At the Chair’s discretion, an institution’s registration privileges may be suspended due to inadequate performance.

Inadequate performance can include any of the following:

* 10% or more of the initial forms sets for patients registered to all studies requiring patient follow-up are more than 30 days overdue.
* Greater than 15% for patients still known to be alive and on protocol treatment are overdue for follow-up.
* Greater than 20% for patients still known to be alive and off protocol treatment are overdue for follow-up.

Prior to placing an institution on suspension, a letter of warning will be sent to the institution’s principal investigator. The institution has 30 days to correct the problem or challenge the action before the suspension goes into effect.
Suspension and Revocation of Membership

Institutional membership will lapse automatically if the institution is without a principal investigator for more than six months. It can also be terminated for cause at any time by a simple majority vote of the Board of Governors.

Individual membership is terminated automatically if a member leaves the sponsoring institution or the institution withdraws from membership or the membership of the institution lapses or is revoked. If a member physician transfers to another member institution, a letter of confirmation must be submitted by the new principal investigator in order to sustain membership. Individual membership can be terminated by a letter of resignation from an individual member.

Individual membership may be revoked for cause upon the recommendation of the appropriate Principal Investigator or the Group Chair.

Lifting a Suspension

A suspension may be lifted if the institution meets the following criteria:
* All patient data must be submitted and any discrepancies must be resolved.
* The last reported contact date must be within the past four months for all patients on treatment.
* The last reported contact date must be within the past 14 months for at least 85% of patients last known to be alive on studies requiring follow-up.
* All pathology and radiation therapy materials must be submitted or reported as being lost or not collected.

Committees of SWOG

There are two types of committees within SWOG: disease and research committees and administrative committees.

Disease and Research Committees

Disease and Research committees form the basis for all the Group’s scientific efforts. These committees are responsible for defining scientific programs and priorities, as well as reviewing protocols in development and reviewing reports, and publications generated by the Group. Studies are developed through the Disease and Research Committee structure. An investigator with a treatment proposal submits it to the Disease and Research Committee Chair, who initiates the process of review and development into a SWOG research protocol. The disease and research committees are:

- Breast Cancer
- Cancer Care Delivery
- Cancer Survivorship
- Early Therapeutics and Rare Cancers
- Gastrointestinal Cancer
## Administrative Committees

Administrative committees provide scientific input to the Disease and Research Committees in the development of Group research protocols with respect to consistency of treatment description and current state-of-the-art treatment regimens, assure quality control of data respective to each discipline, develop and conduct educational programs for the Group, provide ongoing administrative support of specific scientific activities of the Group, and support the Group’s quality and standards goals. The Administrative Committees are:

- Adolescent and Young Adults
- Board of Governors
- Bone Marrow and Stem Cell Transplantation
- Conflict Management
- Data and Safety Monitoring
- Imaging
- Membership
- Oncology Research Professionals
- Patient Advocates
- Pharmaceutical Sciences
- Professional Review
- Quality Assurance
- Radiation Oncology
- Surgery

<table>
<thead>
<tr>
<th>COOPERATIVE GROUP CONCEPT</th>
<th>CHAPTER 3</th>
<th>REVISED: SEPTEMBER 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genitourinary Cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung Cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melanoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myeloma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevention and Epidemiology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom Control and Quality of Life</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Report of Studies

All open and most recently closed studies are described in the semi-annual Report of Studies. The Report of Studies can be accessed via the website “swog.org”. The Report of Studies forms the basis for much of the discussion in the disease committees at the group meeting.

The Report of Studies contains:
1. A report from the Director of the Statistical Center.
3. Location of future group meetings.
4. A list of SWOG related studies that were recently published, including authors and journal references.
5. Accrual data by institution, institution type, and the Group as a whole.
   The data presented include: Number of registrations by institution and type of study.
   Number of registrations lacking data.
   Timeliness of follow-up.
   Number of registrations lacking pathology or radiation therapy materials.
6. Information about studies listed by disease committee which includes accrual and toxicity information.

SWOG Meetings

The semi-annual Group Meetings occur every fall and spring in various locations around the country. These meetings are held to discuss Group business, review progress and determine future research directions; therefore all clinical research associates are encouraged to attend. General information relative to the Group meeting is provided on the Group website. The schedule of meeting events and hotel information will be posted to the website approximately nine weeks prior to each meeting. The on-line meeting registration program will also be available at that time to register for the group meeting and specific events that require a separate registration. All meeting materials will be available for pick-up at the Group Registration/Information Desk.

Committee Members Only meetings: Open only to those persons invited to attend.
Examples: Oncology Research Professionals Executive Board; disease committee working group sessions

Disease and Research committee meetings and Administrative committee meetings: Open to anyone unless stated on the agenda as Committee Members Only. The meetings include an update of committee activities, a report of current studies and a report of closed and proposed protocols. Many committees have a brief educational/plenary session as well.
Examples: Breast, GU.

Group Plenary sessions: All participants are invited to attend. Topics may include presentations of specific group studies, current scientific issues, and other items of interest. As
a general rule, Plenary I, held on Thursday, is devoted to Translational Medicine topics, while Plenary II, held on Friday, covers a broader scope of topics relevant to Group members.

**Other Areas of Interest to Clinical Research Associates:**
* Clinical Trials Training Course for Clinical Research Associates (no fee)
* Oncology Research Professionals Committee activities: plenary session, open forum
* Oncology Research Professionals subcommittee meetings.
* Poster session.
* Group reception.
* Continuing education workshop (contact the Oncology Research Professionals Committee chair for details).

**Clinical Research Associates in SWOG**

The following job description has been provided by SWOG Oncology Research Professionals committee. It is to be used only as a general guide for responsibilities. Educational, training and experience requirements are not mandatory.

**Coordinating Clinical Research Associate (CCRA):** SWOG coordinating clinical research associate is a professional person who possesses a working knowledge of data management activities, communication skills, leadership ability, a willingness to cooperate as a team member and who is responsible for the coordination of all activities relating to SWOG. In the comprehensive description below, job responsibilities most likely performed by the coordinating clinical research associate are indicated by *.

**Clinical Research Associate (CRA):** SWOG clinical research associate is responsible for the registration, compilation and submission of data, monitoring of study compliance and maintaining a system for perpetration of effective data flow.

**Major Duties and Responsibilities**

1. **Administration**
   
   a. *Design a system for organizing, planning and controlling work flow related to SWOG activities.*
   b. *Design means for coordination and submission of data compilation to the Statistical Center.*
   c. *Develop an institutional program to assure that quality control and quality assurance guidelines are met.*
   d. *Assist investigators in evaluating the quality of patient care and compliance to protocol requirements.*
   e. *Supervise SWOG related activities at affiliated hospitals including maintenance and submission of patient data, pathology, radiation therapy and surgery materials.*
   f. *Conduct continuous study, analysis and evaluation of SWOG activities and make recommendations to the principal investigator or designated person for improvements.*
g. Suggest improved methods for accomplishing research goals.

h. Review records with the SWOG site visit team, FDA, NCI or other agents designated by SWOG (especially as related to appropriate consent, proper record keeping, and quality assurance) when requested.

i. Develop appropriate consent forms consistent with legal, institutional review board and Department of Health and Human Services (HHS) requirements.

j. Prepare annual reports and statistical information on SWOG protocols as required by the institutional review board and DHHS.

k. *Consult with and advise the principal investigator on budget requirements, equipment needs, and supplies, as well as preparation of grant proposals.

l. *Prepare personnel budget for SWOG grants.

m. *Supervise selection and ordering of equipment and supplies as required for grant activities.

n. Order investigational drugs as needed for protocol purposes.

o. Alert investigators and appropriate personnel of communications regarding adverse drug reaction reports.

p. *Periodically review investigational drug logs and inventories with pharmacy staff to assure that appropriate documentation is maintained and that federal guidelines are being met.

2. Communications and Liaison

a. Act as a liaison between institutional investigators, and the Operations Office and Statistical Center.

b. *Maintain cooperative relationship with surgery, radiation therapy, and pathology departments as well as other SWOG disciplines and team members.

c. Coordinate the evaluation of SWOG studies managed by institutional investigators.

d. Cooperate with medical staff in conducting related research and assist in the planning of new group studies.

e. Assist pathology department with slide submission.

f. *Assist pathology, radiation therapy and surgery departments in the preparation of the discipline grant application.

g. Assist pathology, radiation therapy, and surgery departments with data submission.

h. *Advise and assist designated person(s) on the maintenance of investigational drug records.

3. Employee Relations

a. *Supervise personnel directly involved in SWOG activities.

b. *Participate in interviewing new personnel for SWOG positions.

c. *Prepare employee performance appraisals of personnel directly supervised, review evaluations, and plan for improvements.

d. *Conduct monthly meetings of SWOG personnel to discuss any problems or grievances and obtain suggestions for operational improvements.
4. Instruction and Training
   a. *Supervise training of all new SWOG personnel.
   b. *Instruct personnel in SWOG patient registration, form completion, data quality control and quality assurance procedures.
   c. *Review completed SWOG forms for technical accuracy and suggest improved methods.
   d. Orient fellows, residents, interns, and students on proper protocol participation and follow-up with supervision.
   e. Discuss protocol participation with cancer patients and keep them informed of procedures and changes in studies in which they are participating.
   f. Instruct participating Affiliate’s physicians, nurses and clinical research associates in SWOG procedures, assure data are submitted at appropriate intervals, and monitor their participation.
   g. Serve as a clinical instructor for health-related profession students rotating through or working with SWOG.
   h. Prepare and present lectures or written materials for health-related students or other professionals on oncology, SWOG, and medical research positions.
   i. Assist in continuing education of physicians, residents, interns, nurses and other health-related personnel in updating their knowledge of SWOG protocols and activities.
   j. *Plan conferences with SWOG physicians and other personnel to discuss new protocols, new cancer patients, and patient registrations.
   k. Participate in continuing education activities as related to cancer and other areas to improve knowledge for job performance.
   l. Participate in presentations or seminars related to field of data management.

5. Data Management Activities
   a. Patient Registration
      1) Ascertain that there is documented IRB approval, and submit annual reports to the IRB for protocols prior to registration.
      2) Check eligibility requirements to determine patient eligibility for SWOG protocols.
      3) Ascertain that pretreatment and eligibility requirements of the protocol have been met including informed consent prior to registration.
      4) Register all protocol patients using the OPEN registration program.
      5) Document record of institutional patient registration as well as data expected by the Statistical Center.

   b. Data Compilation
      1) Maintain logs or indices and statistics of protocol patients.
      2) Abstract data from necessary sources to complete on study forms, off study forms and any other special forms on protocol patients.
      3) Submit data to the Statistical Center to meet protocol requirements.
<table>
<thead>
<tr>
<th>COOPERATIVE GROUP CONCEPT</th>
<th>CHAPTER 3</th>
<th>REVISED: SEPTEMBER 2016</th>
</tr>
</thead>
</table>

4) Keep records of data submission.
5) Initiate forms/appropriate procedures to obtain pathology materials as required by protocol.
6) Submit pathology materials and appropriate forms to pathology review center.
7) Obtain and submit X-rays, operative reports, or other specialized reports as needed for protocol purposes.
8) Obtain data from outside physicians when needed for data collation and submission.
9) Submit appropriate radiation therapy forms and films to designated places in a timely manner.

c. Follow-up and Maintenance

1) Maintain updated records on protocol patients.
2) Review follow-up request logs to ascertain that information is current on all patients.
3) *Review patient evaluation forms to determine eligibility, evaluability and deficiencies for the institution, and follow-up on any problems.
4) Review the institutional pathology listing for deficiencies.
5) Obtain continuous follow-up on protocol patients.
6) Schedule appointments or tests, after consulting with physician, as needed for protocol compliance.
7) Monitor dosage modifications and treatment calculations.
8) Report serious adverse events within prescribed time limits, and according to group procedures and complete required forms.
9) Update protocol books and manuals with new studies, amendments, closure notices and priority lists.

d. Quality Control and Quality Assurance

1) Evaluate protocol study forms for completeness, accuracy and compliance to protocol.
2) *Review records and forms for compliance with quality assurance guidelines.
3) Perform consistency checks, edit for errors and monitor timeliness of data submission.
4) *Gather records, reports, radiographs, scans and other necessary materials required for institutional site visits.
5) Work with quality assurance teams and attend institution site visit review.
6. Other
   a. Participate in SWOG Oncology Research Professionals committee activities.
   b. Participate in SWOG disease and discipline committee activities.
   c. Participate in the review of proposed Group protocols with emphasis on areas concerning data management.
   d. Assist investigators with special requests for data retrieval on SWOG patients.

Education, Training and Experience
1. Education (not required)
   a. B.S. in medical record administration or health information systems (registered health information administrator).
   b. B.S. in nursing (registered nurse).
   c. B.S. degree in health-related field.
   d. Degree from an approved cancer program management school.
   e. Certified tumor registrar (CTR).
   f. A.A. degree in medical record information or health information systems (registered health information technician).
   g. Certified radiation therapy technologist (radiation therapy clinical research associate).

2. Special Training (recommended)
   a. Typing proficiency.
   b. Operation of office machines.
   c. Computer experience or exposure helpful.

3. Experience (recommended)
   a. B.S. in medical/health record administration or health information management (registered health information administrator).
   b. Supervisory experience for coordinating clinical research associate.
   c. Prior administrative responsibilities helpful for coordinating clinical research associate.
CONTACT REFERENCE SHEET

Data Operations Center: SWOG Data Operations Center
c/o Cancer Research And Biostatistics
1730 Minor Ave., STE 1900
Seattle, WA 98101-1468

Hours: 6:30-4:00 PT

Data Submission Fax Line: 800-892-4007

Study-Specific Questions:
- Breast: breastquestion@crab.org
- Cancer Control: cancercontrolquestion@crab.org
- Early Therapeutics: earlytx@crab.org
- GI: giquestion@crab.org
- GU: guquestion@crab.org
- Leukemia: leukemiquestion@crab.org
- Lung: lungquestion@crab.org
- Lymphoma: lymphomaquestion@crab.org
- Melanoma: melanomaquestion@crab.org
- Myeloma: myelomaquestion@crab.org
- General Questions: datamanagement@crab.org

Contact the SWOG Data Operations Center for assistance with:

CRA Clinical Trials Training Course (CTTC): Questions pertaining to the planning of or attendance at the training course should be directed to the Data Operations Center.

Forms Completion, Data Submission, Queries and Expectation Reports: All data are submitted electronically via Medidata Rave® or the CRA Workbench. Information regarding the proper forms to complete and when to submit them is outlined in the Data Submission section of the protocol. Questions about forms or outstanding queries for SWOG-coordinated studies should be directed to the committee-specific email address above. Questions regarding your Expectation Report should be directed to expectationreportquestion@crab.org.


Pathology and Radiotherapy Material Submission: The Discipline Review section of the protocol provides details on whether pathology and/or radiotherapy review are required, and, if so, which specific materials are to be submitted, and where to send them. Questions regarding these requirements should be directed to the study Data Coordinator.

Patient Registration/Patient Eligibility: Patient registrations to all SWOG studies are detailed in Section 13 of each protocol. Nearly all SWOG studies now use the OPEN application accessed at https://open.ctsu.org or from the OPEN Patient Registration link on the SWOG
CRA workbench. Eligibility criteria are always in Section 5 of the protocol. Questions pertaining to patient eligibility to Group protocols should be directed to the study Data Coordinator.

**Patient Registration/Patient Eligibility:** Patient registrations to all SWOG studies are detailed in Section 13 of each protocol. All SWOG studies now use the OPEN application accessed at [https://open.ctsu.org](https://open.ctsu.org) or from the OPEN Patient Registration link on the SWOG CRA workbench. Eligibility criteria are always in Section 5 of the protocol. Questions pertaining to patient eligibility to Group protocols should be directed to the study Data Coordinator.

**Specimen Tracking System (Spec Track):** General questions in how to access or use the Specimen Tracking System should be directed to the study Data Coordinator. Errors or technical issues resulting in a failed submission should be emailed to us at [technicalquestion@crab.org](mailto:technicalquestion@crab.org) and include a screen shot or copy of the error received.
CONTACT REFERENCE SHEET

Operations Office: SWOG Operations Office
                  4201 Medical Drive, Suite 250
                  San Antonio, Texas  78229-5631
                  Phone:  210/614-8808

Contact the SWOG Operations Office for assistance with:

**Serious Adverse Events:** When a patient experiences Serious Adverse Events you will document according to protocol specifications and via CTEP-AERS. Should you need assistance with this process or are unclear if the event needs to be reported, contact the Adverse Event Specialist.

**Audits:** Any items related to past, present or future audits should be referred to the Quality Assurance Manager or other available Auditors.

**Credits:** If you need to obtain information on Credit assignments for treatment and cancer control trials, contact the Operations Office.

**Membership/Institution Assurances:** Questions about membership or updates/changes to SWOG Roster information should be directed to the Programs Manager.(member@swog.org)

**Protocol Mailings/Updates:** Notifications for protocol mailings and updates are sent electronically the 1st and 15th of each month. Contact the disease site Protocol Coordinator for assistance.

**SWOG Group Meeting:** Questions pertaining to the conduction of or attendance at the spring or fall group-wide meetings should be directed to the Meetings Manager.
**CONTACT REFERENCE SHEET**

| Group Chair’s Office: | SWOG Group Chairs Office  
| Hours: 8:00-4:00 PT | 3181 SW Sam Jackson Park Road  
| | MC: L586  
| | Oregon Health & Science University  
| | Portland, OR 97239  
| Phone: 503/494-5586 |

**Contact the SWOG Group Chair’s Office for assistance with:**

**Funding/Payments/Reimbursement:** If you have questions about funding, payments you have received, status of reimbursements or need assistance in reconciling your records with these payments you should contact the group Financial Administrator.

**SWOG Newsletter:** Do you have an idea or suggestions for the SWOG Newsletter? Would like to provide feedback or inquiry on a current edition? Contact our Group Chair’s Office for assistance.

| Statistical Center: | SWOG Statistical Center  
| Hours: 8:00-5:00 PT | Fred Hutchinson Cancer Research Center  
| | 1100 Fairview Ave N, MC-C102  
| | PO Box 19024  
| | Seattle, Washington 98109-1024  
| Phone: 206/667-4623 |

**Contact the SWOG Statistical Center for assistance with:**

**Institutional Performance Review Reports:** These reports are distributed monthly to institutions. Questions concerning the Institutional Performance Review Report are handled by Phyllis Goodman, Coordinating Statistician at the Statistical Center.

**Meeting Report:** The Group Report of Studies is prepared by the Statistical Center. You may download a copy of the Report at the SWOG website: [www.swog.org](http://www.swog.org). Questions with regard to contents of the Report should be directed to the Statistical Center.

**Protocol Accrual and Statistical Analysis:** Questions regarding accrual and statistical analysis of Group protocols should be directed to the committee Statistician at the Statistical Center.
REFERENCE SHEET – OTHER CONTACTS

Medidata Rave®: All new studies require the use of Medidata Rave® as the common electronic data capture (EDC) software mandated for use by all groups within the NCTN. Questions regarding user access, passwords, study invitations or technical issues with the site should be directed to the CTSU Helpdesk by email (ctsucontact@westat.com) or phone (888-823-5923). Form or study-specific questions should always be sent by email using the committee-specific distribution lists on page 5.

Treatment Modification or Interpretation: Questions which require medical judgment should be directed to the physician assigned as the Study Chair for that protocol. Prior to contacting the Study Chair, the protocol should be reviewed and a physician within your institution should be consulted. Phone numbers for Study Chairs are provided on the title page of each protocol. Typically, a backup contact is also provided here and at the end of Section 8.0 if the primary Study Chair is not available. If neither is available, you can contact the disease site chair, then the Executive Officer at the Group Chair’s Office.

Trials Conducted by Another Group: Questions regarding protocols coordinated by a different LPO should be directed to that coordinating group or the CTSU.
REFERENCE SHEET – INTERGROUP STUDIES

Refer to the ORP Manual for complete information. The ORP Manual can be accessed or downloaded from the SWOG website; Go to www.swog.org, click on Policies & Manuals, ORP Manual.

Definitions:
- **Intergroup Studies**: studies involving more than one LPO (e.g., SWOG and ECOG-ACRIN). It is important to note that only one LPO coordinates the study.
- **Coordinating group**: the LPO conducting the study. This group writes the study, dictates eligibility, randomizes the patient to a specific treatment, collects and analyzes the data, and publishes the results of the study.

Purpose:
The purpose of an intergroup study is to hasten the accrual of patients so that the study results may be obtained in a timelier manner. This is achieved by having several LPO’s participate in the study. Generally, intergroup studies are large Phase III studies in which two or more treatments are being compared.

The NCI has implemented the Clinical Trials Support Unit (CTSU), through which most Phase III intergroup trials are conducted. Please see the CTSU website at www.ctsu.org for additional information.

Identifying intergroup studies:
Both the title page of the protocol and the priority list specify the participants of the study. For intergroup studies, these participants will include more than one LPO.

Determining the coordinating group:
The coordinating LPO of an intergroup study will be capitalized or boldfaced and is almost always at the top of the title page of the protocol.

Steps to follow when enrolling a patient to a non-SWOG coordinated study:
(All of these steps must be completed before the registration is considered final and treatment can begin).

1) **Determine Eligibility.** Use the eligibility criteria provided in the protocol. Some LPO’s do not provide a separate checklist so it is the institution's responsibility to work through the eligibility criteria stated in the body of the protocol before completing the registration.

2) **Fill out all required paper work** (e.g., eligibility checklists, randomization worksheets) and have them on hand when you initiate the enrollment in OPEN.
Data Flow and Expectation System for Intergroups:
SWOG Institutions are responsible for submission of all information required by the individual intergroup protocols. Required forms and follow-up information should be sent directly to the responsible LPO conducting the study.

SWOG does not post expectations for studies coordinated by other LPO’s. (Exceptions to this policy are for selected studies that require pathology submissions directly to SWOG. In these rare cases, expectations will continue to be posted). Institutional Performance Review (IPR) statistics only reflect data for SWOG coordinated trials.

Intergroup treatment start policies:
Depending on the LPO that is coordinating the study, there is a different time frame allowable between patient registration and the projected date of start of treatment. When doing a registration for a study not coordinated by SWOG, please make sure that the date on which treatment is planned to begin falls within the appropriate time frame stated in the protocol.

Questions related to an intergroup study:
Questions about an intergroup study must always be directed to the coordinating LPO. If the study is not coordinated by SWOG, the SWOG Data Operations Center is not authorized to answer protocol related questions, including those pertaining to eligibility, treatment plan, or dosage modification. Be sure to follow up directly with the other group’s data management department.