

# SouthWest Oncology Group



## Nursing Committee

NC Booklet revised April 2010

For changes, additions or corrections to this booklet, please contact the  
Puget Sound Oncology Consortium SWOG office at (206) 386-2441

# Nursing Committee Table of Contents

1	Table of Contents
2	NC Executive Nursing Committee
3	NC Strategic Plan
4	NC Nursing Subcommittees
5-6	NC Executive Committee Members
7-13	SWOG Research Terminology
14	NC Membership Application Form

For information about the Southwest Oncology Group Headquarters Staff, Operations Office Staff or Statistical Center Staff, please visit their website at: [www.swog.org](http://www.swog.org).

For more information about becoming a member of the Nursing Committee, please contact:

Patra Grevstad, RN, MN  
Membership Chair  
Swedish Cancer Institute

Telephone: 206-386-2442  
Fax: 206-385-2310  
E-mail: [patra.grevstad@swedish.org](mailto:patra.grevstad@swedish.org)

# EXECUTIVE NURSING COMMITTEE

## SouthWest Oncology Group

**SWOG CHAIR**  
Laurence H. Baker, DO

**NURSING COMMITTEE CHAIR**  
Marge Good, RN, BSN, MPH, OCN

**VICE CHAIR**  
Rose Ermete, RN, BSN, OCN, CCRP

- NCI Executive Contact
- Nurse Scientists
  - Behavioral Scientists
  - Women's Health
- Operations Office Contact
- Statistical Center Contact
- Headquarters Contact

### Sub-Committee Chairs

- Disease & Discipline
- Education
- Membership
- Program
- Research

### Executive Liaisons

- CCOP
- Affiliate
- Cancer Control

# SouthWest Oncology Group

## Nursing Committee

### Strategic Plan – 2009

#### The mission of the Nursing Committee is:

- 1) To systemically study individual patient responses to cancer and its treatment.
- 2) To develop interventions targeted toward patient education, supportive care, prevention, minority and special population issues, early detection and screening, and quality of life.
- 3) Design and conduct nursing-based research studies on diverse patient populations and report the results to SWOG committees and in publications.
- 4) Promote and conduct collaborative educational activities that are responsive to the membership.

#### The Strategic Plan of the Nursing Committee and Subcommittees will be accomplished through implementation of the following goals:

- To provide a framework for the development and conduct of quality nursing research activities within the cooperative oncology group setting.
  - 1) Provide orientation to clinical research for the membership.
  - 2) Develop and implement a nurse researcher mentor program.
  - 3) To coordinate and provide interdisciplinary research with significant nursing contributions.
  - 4) To promote and support local, regional and national SWOG nurse oncologists.
- To provide quality educational opportunities for SWOG nurse oncologists
  - 1) Implement and strengthen educational strategies that enhance nursing care and research.
  - 2) Promote and support local, state, regional and national SWOG education and research opportunities.
  - 3) Collaborate with Disease & Discipline and Standing Committees of SWOG.
  - 4) Develop SWOG Audit Manual.
- To strengthen membership and membership participation within the Nursing Committee
  - 1) Actively recruit new nurses to the SWOG membership.
  - 2) Actively recruit new nurses to the various subcommittees.
  - 3) Provide networking opportunities for nurses among the diversified SWOG membership.
  - 4) Promote communication between the Nursing Committee chair, subcommittee chairs, liaisons, and SWOG nurse membership.
  - 5) Promote communication among SWOG physicians, primary care providers, clinical research associates, pharmacists and other allied health members.
- To ensure that the SWOG Nursing Committee operates with effective and efficient leadership
  - 1) Address issues of concern, long-range planning, and goals/objectives of the committee.
  - 2) Maintain written policies and procedures.
  - 3) Monitor the financial status, develop budgets, and administer funds of the Nursing Committee.
  - 4) Monitor legislation and health policy as it affects SWOG activities.
  - 5) Promote leadership development and succession planning

# Nursing Subcommittees

## Disease & Discipline

**Purpose:** To provide a nurse liaison to each Disease/Discipline Committee within SWOG; maintain procedure for ongoing review and input for all new protocols, manuscripts and publications; and develop, identify, and activate nursing quality assurance activities.

**Disease Committees:** The committees are responsible for definition of scientific programs and priorities and the development and review of protocols.

**Discipline Committees:** These committees provide discipline-specific information to the Disease Committees, maintain quality control of data, and provide educational programs for SWOG.

**Quality of Life:** Provide studies with nurse quality of life coordinators.

## Education

**Purpose:** To collect, develop, evaluate and distribute educational materials, tools and other resources. Standing Ad Hoc Committees and temporary task forces are formed as needed for various committee tasks and projects.

## Membership

**Purpose:** To coordinate and recruit membership in the Nursing Committee and Subcommittees. This includes maintenance of membership rosters, coordination of membership applications with the Operations Office, enhancing awareness of subcommittees and their needs, and informing chairpersons of new members.

## Program

**Purpose:** To provide Nursing Committee members with relevant and timely information. Provide CEUs at the biannual Nursing Committee Primary Sessions. This includes all aspects of program planning (i.e., confirmation of speakers, submission of CEI applications, arrangement of rooms, etc.).

## Research

**Purpose:** To develop innovative clinical trials in the management of patients with neoplastic diseases and disseminate results within SWOG. This includes review and critique of research protocols, adhering to SWOG protocol guidelines and deadlines, and participation in the research protocols at member institutions and collaboration with other committees as necessary.

# SouthWest Oncology Group

## NURSING EXECUTIVE COMMITTEE

Rose Ermete, RN, BSN, OCN, CCRP  
Michigan Cancer Research Consortium  
St. Mary Mercy Hospital  
14555 Levan, Ste. 118  
Livonia, MI 48154

734-655-2792  
734-655-8820 fax  
[ermeter@trinity-health.org](mailto:ermeter@trinity-health.org)

Vice-Chair  
Co-Chair Program

Lisa Hansen, RN, MS, AOCN  
Good Samaritan Hospital  
1015 NW 22<sup>nd</sup> Avenue W003  
Portland, OR 97210

503-413-6285  
503-413-6920 fax  
503-299-5105 pager  
[lhansen@lhs.org](mailto:lhansen@lhs.org)

Executive Liaison Cancer Control,  
Historian

Maggie Clarkson  
Singing River Hospital Regional  
Cancer Center  
2809 Denny Avenue  
Pascagoula, MS 395581

228-809-5625  
228-809-5324/2056  
[m\\_clarkson@srhshealth.com](mailto:m_clarkson@srhshealth.com)

Chair, Research

Dorothy Coleman, RN, MSN  
Cancer Research Center of Hawaii  
1236 Lauhala Street, Suite 402  
Honolulu, HI 96813

808-586-2979  
808-586-3016 fax  
[Dorothy@crch.hawaii.edu](mailto:Dorothy@crch.hawaii.edu)

Co-Chair  
Education

Marjorie Godfrey  
Southwest Oncology Group  
Operations Office  
14980 Omicron Drive  
San Antonio, TX 78245-3217

210-677-8808  
210-677-0006 fax  
[mgodfrey@swog.org](mailto:mgodfrey@swog.org)

Executive Liaison  
Operations Office

Patra K. Grevstad, RN, MN  
Swedish Medical Center/Cancer Institute  
1221 Madison Street, Fourth Floor  
Seattle, WA 98104

206-386-2442  
206-386-2310 fax  
[patra.grevstad@swedish.org](mailto:patra.grevstad@swedish.org)

Chair  
Membership

Karen Mack, LRNP, BSN, OCN, CCRP, UAMS  
4301 West Markham, Slot 721  
Little Rock, AR 72205

501-296-1502 ext 1231  
501-296-1274 fax  
[mackkarenl@uams.edu](mailto:mackkarenl@uams.edu)

Co-Chair  
Program

Nancy Sprouse  
Upstate Carolina CCOP  
Spartanburg Regional Medical Center  
101 East Wood Street  
Spartanburg, SC 29303-2072

864-560-6812  
864-560-6016  
[nsprouse@srhs.com](mailto:nsprouse@srhs.com)

CCOP Liaison  
Co-Chair Education

Katie Stoermer, MSBA  
Grants and Contracts Manager  
Southwest Oncology Group  
PO Box 483  
Ann Arbor, MI 48106-0483

734-998-7130  
734-998-7118 fax

# SWOG Research Terminology

<b>ADDENDUM</b>	Includes information that affects patient management but does not change the treatment plan. Addenda usually address items such as newly-discovered toxicity data or drug administration information which investigators use in managing a patient. Addenda may require IRB review.
<b>ADR</b>	<b>Adverse Drug Reaction.</b> May be defined as 1) any unsuspected side effect of an anticancer agent; 2) any unsuspected interaction of an anticancer agent with other drug(s); or 3) a life-threatening Grade 4 or fatal toxicity, even if that type of toxicity has already been noted with a particular anticancer drug.
<b>ADJUVANT TREATMENT</b>	Secondary treatment that is given after all visible disease has been removed by a primary treatment.
<b>AFFILIATE</b>	A community-based oncology program that has a relationship with a Member Institution. May participate in SWOG studies after meeting requirements of the Affiliate Program (see SWOG policy No. 5).
<b>AMENDMENT</b>	Changes to the protocol which directly affect patient care or treatment; these changes usually constitute a change in the treatment plan, dosage modifications or study parameters. Examples of amendments include an increase or decrease in the dose of a drug and addition or deletion of a study parameter. Justification for the amendment is required; all amendments must be submitted. The amendment date appears in the right upper-hand corner of the amended pages. All amendments require IRB review.
<b>ANCILLARY STUDIES</b>	These studies typically address biologic questions, such as the predictability of human tumor stem cell assays for response. Subjects for these studies are patients participating in clinical trials.
<b>CANCER CONTROL STUDIES</b>	Cancer control research is aimed toward identifying interventions that will reduce cancer incidence and morbidity in defined populations. It includes studies on prevention, symptom control, quality of life, toxicity management, treatment compliance and rehabilitation.
<b>CCOP</b>	The Community Clinical Oncology Program was initiated in 1983 to bring the benefits of clinical research to cancer patients in their own communities by providing support for physicians to enter patients onto treatment research protocols. Through CCOP participation, physicians have access to the latest anticancer agents and protocol information regarding treatment, follow-up and overall cancer management.
<b>CLINICAL RESEARCH ASSOCIATE (CRA)</b>	An individual who functions as an administrator, coordinator, consultant, educator, or researcher in the management of clinical trials and functions in one or more of the following aspects of clinical trial research: data collection, analysis or monitoring, case management of protocol patients, recruitment, and enrollment of human subjects, protection of subjects and subject's rights through IRB relations, development of consent forms, preparation of adverse event experience reports, construction or monitoring of case report forms, maintenance of drug accountability records, grant and budget development, report preparation and education.
<b>CLINICAL TRIAL</b>	A clinical trial is a planned experiment designed to answer questions concerning the most appropriate treatment for patients with a specific medical condition.
<b>CLOSED MEETINGS</b>	Meetings on the Southwest Oncology Group Meeting agenda that are by invitation only.
<b>CONFIDENTIALITY</b>	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's family.
<b>CONTROL GROUP</b>	The group of subjects in a controlled study that receives no treatment, a standard treatment, or a placebo.

<b>CANCER RESEARCH &amp; BIOSTATISTICS (CRAB)</b>	Non-profit organization who works with SWOG for data management and statistical analyses.
<b>CROSSOVER TRIAL</b>	Each subject receives both treatments being compared or the treatment and control. Such trials are used for patients who have a stable, unusually chronic condition during both treatment periods.
<b>CURRICULUM VITAE</b>	Document that outlines a person's educational/professional history.
<b>DATA &amp; SAFETY MONITORING BOARD (DSMB)</b>	Researchers, ideally, dependent of the trials they monitor, who periodically review data from blinded, placebo-controlled trials. A DSMB can stop a trial if toxicities are found or if treatment is proven beneficial.- also see, independent data-monitoring committee.
<b>DATABASE</b>	Data stored in computer form for easy retrieval, processing and/or analysis.
<b>DATA MONITORING</b>	Process by which case report forms are examined for completeness, consistency, and accuracy.
<b>DECLARATION OF HELSINKI</b>	A set of recommendations or basic principles that guide medical doctors in the conduct of biomedical research involving human subjects. It was adopted by the 18 <sup>th</sup> World Medical Assembly (Helsinki, Finland, 1964) and revised by the 29 <sup>th</sup> (Tokyo, 1975) and 35 <sup>th</sup> (Venice, Italy, 1983) World Medical Assemblies. The full text is in 21 CFR 312.120, in an appendix to the Nordic Council on Medicine Guidelines for Good Clinical Practice, and in other reference materials.
<b>DEMOGRAPHIC DATA</b>	Characteristics of subjects or study populations, which include such information as age, sex, family history of the disease or condition for which they are being treated, and other characteristics relevant to the study in which they are participating.
<b>DIRECT ACCESS</b>	Permission to examine, analyze, verify and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirements to maintain the confidentiality of the subject's identities and sponsor's proprietary information.
<b>DOCUMENTATION</b>	All records, in any form (including, but not limited to, written, electronic, magnetic and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct and/or results of a trial, the factors affecting a trial and the actions taken.
<b>DOUBLE-BLIND STUDY</b>	A study in which neither the subjects nor the investigators know what treatment a subject is receiving.
<b>EFFECTIVENESS</b>	The desired measure of a drug's influence on a disease condition as proved by substantial evidence from adequate and well-controlled investigators
<b>EFFICACY</b>	A product's ability to produce beneficial effects on the course or duration of a disease.
<b>ENDPOINT</b>	An indicator measured in a subject or biological sample to assess the safety, efficacy or other objective of a trial. (see surrogate marker)
<b>EXCLUSION CRITERIA</b>	A list of criteria, any of which excludes a potential subject from participation in a study.
<b>FINAL REPORT</b>	Complete, comprehensive description of a completed trial that describes the experimental materials and statistical design. It also presents and evaluates the trial results and statistical analyses.
<b>FOOD &amp; DRUG ADMIN. (FDA)</b>	The United States regulatory authority charged with, among other responsibilities, granting IND and NDA approvals.
<b>GOOD CLINICAL PRACTICE (GCP)</b>	A standard for the design, conduct, performance, monitoring, auditing, recording analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of the trial subjects are protected.

<b>HEADQUARTERS OFFICE</b>	The Headquarters Office in the Group, located at the University of Michigan, is under the Director of the Group Chair. Main responsibilities are: 1) Director of general Group business 2) Serves as liaison with the NCI 3) Administer and oversees all group financial affairs.
<b>HUMAN SUBJECT</b>	An individual who is a participant in research, either as a recipient of the test article or as control. A subject may be either a healthy human or a patient (Synonym: Subject/trial subject).
<b>HIPAA</b>	<b>Health Insurance Portability and Accountability Act.</b> A policy defining the Designated Record Set that will be used to identify the Protected Health Information to which certain patient rights apply.
<b>INCLUSION CRITERIA</b>	The criteria which prospective subjects must meet to be eligible for participation in a study. See exclusion criteria
<b>IRB</b>	<b>Institutional Review Board.</b> Oncology studies which accrue and actively treat subjects must be reviewed by the entire IRB. Cancer control research protocols, such as those involving the use of questionnaires, may qualify for what is termed <i>expedited</i> review. <i>Pre-review:</i> One board member receives a protocol 2-3 weeks prior to the Board meeting. The protocol is carefully reviewed and questions or problems are presented to the investigator to be addressed prior to the Board meeting. <i>Full Board Review:</i> Following a pre-review, the protocol is reviewed by all Board members, resulting in the protocol and the informed consent form being approved, disapproved or approved with stipulations. <i>Risk Assessment:</i> After approval, the protocol is rated according to the degree of risk involved; this rating is used to determine whether IRB review should be done more frequently than the annual review that is normally required.
<b>INFORMED CONSENT</b>	A process by which a subject voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. No informed consent may include any language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, sponsor, institution, or its agents from liability for negligence.
<b>INTERIM REPORT</b>	A report of intermediate results and their evaluation based on analyses performed during the course of a trial.
<b>INVESTIGATIONAL NEW DRUG</b>	A drug allowed by the US Food and Drug Administration (FDA) to be used in clinical trials, but not approved by the FDA for commercial marketing.
<b>INVESTIGATOR</b>	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. An investigator is the individual "under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team".
<b>INVESTIGATOR BROCHURE</b>	A compilation of the clinical and non- clinical data on the investigational products which is relevant to the study of the investigational products in human subjects.
<b>MAINTENANCE</b>	Maintenance therapy is to maintain (status-quo) or disease-free state. Maintenance follows induction and/or consolidation (myeloma, leukemia)
<b>MEAN</b>	The sum of values of all observations or data points divided by the number of observations, an arithmetical average.

<b>MEDIAN</b>	The middle value in a data set, that is, just as many values are greater than the median and less than the median value.
<b>MEMBER INSTITUTION</b>	Member institutions are hospitals, medical centers, Community Clinical Oncology Programs (CCOP), or research institutes capable of entering at least 50 patients per year on SWOG protocol studies. A principal investigator, responsible for the scientific and technical conduct of SWOG activities, is appointed at each institution.
<b>MEMORANDUM</b>	Used to reiterate or clarify a section of the protocol which may be overlooked or be the source of confusion. Memoranda are not usually accompanied by any protocol.
<b>MODE</b>	The most frequently occurring value in a data set.
<b>MULTI-CENTER TRIAL</b>	A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
<b>MULTI-MODALITY THERAPY</b>	The combined use of more than one method of treatment, for example, surgery and chemotherapy.
<b>NATURAL HISTORY STUDIES</b>	A cancer control study. Natural history studies are designed to determine the normal course of disease for patients with specified characteristics, or to determine whether differences in specified non-treatment factors predict differences in the course of the disease.
<b>NCI</b>	National Cancer Institute
<b>NIH</b>	National Institutes of Health
<b>NEO-ADJUVANT TREATMENT</b>	Treatment for locally advanced diseases that attempts to reduce the size of a tumor so that it can be completely removed by other means.
<b>NEW DRUG APPLICATION</b>	An application to FDA for a license to market a new drug in the USA.
<b>NUREMBERG CODE</b>	Code of ethics for conducting medical research set forth in 1947.
<b>OBSERVATIONAL STUDIES</b>	A cancer control study. This includes studies, such as studies of tumor markers, which help determine "prognostic" factors. Also included are studies where patients are followed for the purpose of collecting information on sequelae or costs of the disease and its treatment. In one such study of testicular cancer, patients are followed over time for the purpose of studying their reproductive function.
<b>OHRP (OFFICE FOR HUMAN RESEARCH PROTECTION)</b>	The OHRP is an administrative subdivision within the US Dept. of Health and Human Services (DHHS) designed to protect human research subjects. OHRP functions include negotiating compliance assurance with regulations for the protection of human subjects and providing guidance on ethical issues concerning human subjects involved in biomedical or behavioral research.
<b>OPEN MEETINGS</b>	Scheduled meetings that anyone in attendance at the SWOG meeting may participate in.
<b>OPERATIONS OFFICE</b>	The Operations Office in the Group, located in San Antonio, Texas, is under the direction of the Group Chair. The main responsibilities of the operations office are to: 1) Function as the communications hub for Group member; 2) Serve as a liaison with NCI; 3) Administer some Group Cooperative Agreements and selected financial affairs.
<b>PATIENT</b>	Person under a physician's care for a particular disease or condition. See subject/trial subject and healthy volunteer.
<b>PHARMACO-ECONOMICS</b>	Branch of economics that applies cost-benefit, cost-effectiveness, cost minimization, and cost-utility analyses to compare drug therapy to other treatments. Sometimes referred to as outcome research.
<b>PHARMACO-KINETICS</b>	The study of the process of bodily absorption, distribution, metabolism, and excretion (ADME) of compounds and medicines.
<b>PHASES OF CLINICAL TRIALS</b>	Clinical trials are generally categorized into four or five phases. An Investigational medicine or product may be evaluated in two or more phases simultaneously in different trials and some trials may overlap the two different phases.

<b>PHASE I STUDIES</b>	The purpose of Phase I trials is to: <ul style="list-style-type: none"> <li>◆ Determine a safe maximum dose for a new drug (maximum tolerated dose = MTD)</li> <li>◆ Establish an optimum schedule for implementation in Phase II trials</li> <li>◆ Identify acute effects (toxicities) on normal tissues</li> </ul>
<b>PHASE II STUDIES</b>	In a Phase II study, a single agent is tested after a drug dose and schedule have been determined during Phase I testing. The drug is then subject to additional testing in selected populations. The purpose of Phase II testing is to: <ul style="list-style-type: none"> <li>◆ Evaluate the level of anti-tumor activity against a specific tumor type</li> <li>◆ Further define normal tissue toxicities</li> </ul>
<b>PHASE III STUDIES</b>	In a Phase III Study, multiple drugs may be used to determine the effectiveness of a treatment for a particular disease. The purpose of Phase III testing is to: <ul style="list-style-type: none"> <li>◆ Determine effectiveness of new treatments versus a standard treatment.</li> <li>◆ Determine if a new treatment is less toxic than a standard treatment.</li> <li>◆ Determine degree of tumor regression, disease-free interval and survival status.</li> </ul>
<b>PHASE IV TRIALS</b>	After medicine is marketed, Phase IV trials provide additional details about the product's safety and efficacy. They may be used to evaluate formulations, dosages, duration of treatment, medicine interactions, and other factors. Patients from various demographic areas.
<b>PHASE V TRIALS</b>	Post-marketing surveillance is sometimes referred to as Phase V areas.
<b>PLACEBO</b>	An inactive substance resembling medication, given for psychological effect or as a control in evaluating a medicine believed to be active. It is usually a tablet, capsule or injection that contains a harmless substance but appears to be the same as the medicine being tested. A placebo may be compared with a new drug when no one knows if any drug or treatment will be effective.
<b>PRECLINICAL STUDIES</b>	Animal studies that support Phase 1 safety and tolerance studies and must comply with good laboratory practice (GLP). Data about a drug's activities and effects in animals help establish boundaries for safe use of the drug in subsequent human testing (clinical studies or trials). Because many animals have much shorter life spans than humans, preclinical studies can provide valuable information about a drug's possible toxic effects over an animal's life cycle and on its offspring.
<b>PROSPECTIVE STUDY</b>	Investigation in which a group of subjects is recruited and monitored in accordance with criteria described in a protocol.
<b>PROTOCOL</b>	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial.
<b>PROTOCOL AMENDMENT</b>	A written description of a change(s) to or formal clarification of a protocol.
<b>QUALITY ASSURANCE</b>	All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with good clinical practice (GCP) and the applicable regulatory requirement(s).
<b>QUALITY CONTROL (QC)</b>	The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.
<b>RANDOMIZATION</b>	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
<b>RAW DATA</b>	Records of original observations, measurements, and activities (such as laboratory notes, evaluations, data recorded by automated instruments) without conclusions or interpretations.

<b>RANDOMIZATION CLINICAL TRIALS</b>	A study in which patients with similar traits, such as extent of disease, are chosen or selected by chance to be placed in separate groups that are comparing different treatments. Because irrelevant factors or preferences do not influence the distribution of patients, the treatment groups can be considered comparable and results of the different treatments used in different groups can be compared. There is no way at the time for the researchers to know which of the treatments is best. It is the patient's choice to be in a randomized trial or not.
<b>RECURRENCE</b>	When the disease has been in remission and the patient has definite objective and subjective symptoms of disease.
<b>RELAPSE</b>	Relapse is when there is evidence that the disease has returned (i.e., as in leukemia).
<b>RECRUITMENT</b>	Process that employs inclusion and exclusion criteria and is used by investigators to enroll appropriate subjects into a clinical study
<b>REVISIONS</b>	Administrative changes to a protocol, which do not affect patient care or patient treatment. Examples of revisions include change in study coordinator, addition or deletion of a participating institution, or correction of an error. The revision date appears in the upper right-hand corner of revised protocol pages.
<b>RISK/BENEFIT RATIO</b>	The relationship between the risks and benefits of a given treatment or procedure. Institutional Review Boards, (located where the study is to take place,) determine that the risks in a study are reasonable with respect to the potential benefits. It is also up to the patient to decide if it is reasonable for him or her to take part in a study.
<b>RISK</b>	In clinical trials, the probability of harm or discomfort for subjects. Acceptable risk differs depending on the condition for which a product is being tested. A product for sore throat, for example, will be expected to have a low incidence of side effects. However, unpleasant side effects may be an acceptable risk when testing a promising treatment for a life-threatening illness.
<b>SAFETY</b>	Relative freedom from harm; in clinical trials, this refers to an absence of harmful side effects resulting from use of the product and may be assessed by laboratory testing of biological samples, special tests and procedures, psychiatric evaluation, and/or physical examination of subjects.
<b>SCHEMA</b>	The schema is a diagrammatic overview of a protocol from registration to off-treatment.
<b>SERIOUS ADVERSE EVENT (SAE)</b>	Any untoward medical occurrence that at any dose: results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.
<b>SIDE EFFECT</b>	A secondary and usually adverse effect, as from a drug or other treatment. For example, nausea is a side effect of some anticancer drugs.
<b>SOURCE DOCUMENTS</b>	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
<b>STAGING</b>	Methods used to establish the extent of a patient's disease.
<b>STANDARD TREATMENT</b>	A treatment or other intervention currently being used and considered to be of proven effectiveness on the basis of past studies.

	<ul style="list-style-type: none"> <li>◆ Publish the twice-yearly Report of Studies</li> <li>◆ Conduct studies of prognostic factors and late effects</li> <li>◆ Perform statistical research</li> </ul>
<b>STATISTICAL SIGNIFICANCE</b>	Level at which an investigator can conclude that observed differences are not due to chance alone; for example, a p value of .05 (also called significance at the .05 level) indicates that there is about 1 chance in 20 that the differences observed occurred by chance alone.
<b>STUDY ARM</b>	Patients in clinical trials are assigned to one part or segment of a study, a study "arm"; one arm receives a different treatment from another.
<b>SUBINVESTIGATOR</b>	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
<b>STUDY REPORT</b>	A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report.
<b>SUBJECT</b>	An individual who participates in a clinical trial, either as recipient of the investigational product(s) or as a control.
<b>SUBJECTIVE RESPONSE</b>	Subjective response is based on the investigator's judgment of disease symptom improvement.
<b>SURROGATE MARKER</b>	A measurement of a drug's biological activity that substitutes for a clinical endpoint such as death or pain relief.
<b>SYMPTOM CONTROL TOXICITY MANAGEMENT</b>	A cancer control study. Symptoms related to the disease itself, or to treatment of the disease, may possibly be alleviated through intervention. The intervention might be systemic or behavioral. An example of this type of study would be to attempt control of menopausal-like symptoms associated with breast cancer treatments.
<b>SWOG</b>	Southwest Oncology Group. Cooperative effort by radiotherapists, data managers, medical oncologists, surgeons, pathologists, nurses and dentists to conduct clinical trials on patients with neoplastic diseases.
<b>THERAPEUTIC</b>	Pertaining to treatment.
<b>TOP</b>	The Thoracic Oncology Program is a new initiative in SWOG designed to encourage the participation of thoracic surgeons in SWOG trials for early lung cancer, mesothelioma and esophageal cancer.
<b>TOXICITIES</b>	Toxicities are adverse reactions attributed to the treatment, not due to disease. Most chemotherapy toxicities are a consequence of the drug's action on rapidly reproducing tissue (bone marrow, mucous membranes, hair follicles). Toxicity evaluation is important during all phases of clinical trials.
<b>UCOP</b>	The Urologic Cancer Outreach Program is a SWOG project funded by the NCI in order to provide urologists with resources to facilitate their participation in cancer clinical trials.
<b>UNEXPECTED ADVERSE DRUG REACTION</b>	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., investigator's brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product).
<b>VALIDITY</b>	The accuracy of the relationship between two or more variables.
<b>VULNERABLE SUBJECTS</b>	Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

SOUTHWEST ONCOLOGY GROUP  
Nursing Committee  
MEMBERSHIP APPLICATION FORM

Date Submitted: \_\_\_\_\_

Date Received: \_\_\_\_\_

*Please note that it is highly recommended that you attend at least one out of every four meetings to become a member and maintain membership status. If you have questions regarding this application, please call Patra K. Grevstad, RN, MN, at (206) 386-2442 or email her at: [patra.grevstad@swedish.org](mailto:patra.grevstad@swedish.org)*

Name & Credentials: \_\_\_\_\_

Current Position: \_\_\_\_\_

Specialty: \_\_\_\_\_

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

\_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-Mail address: \_\_\_\_\_

Principal Investigator \_\_\_\_\_

Group Status:       Member     CCOP     Affiliate     UCOP     Hi-Priority     Other: \_\_\_\_\_

**WOULD YOU BE INTERESTED IN HAVING A MENTOR?**       YES     NO

If you are interested in becoming a member of a specific Subcommittee, please check the appropriate box(es) below; information will be sent to you.

Disease and Discipline     Education     Research     Program     Membership

**REQUIRED INFORMATION - must accompany the application: CV (Resume or Biosketch)**

I have reviewed the above application for membership in the Nursing Committee and recommend approval for the above applicant. My signature below affirms this recommendation plus my commitment to providing opportunities for attendance to SWOG meetings in order to maintain membership status.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

**PLEASE MAIL COMPLETED FORM AND REQUIRED INFORMATION TO:**

Patra K. Grevstad, RN, MN  
Membership Chair, SWOG Nursing Committee  
Swedish Cancer Institute  
1221 Madison, Suite #400  
Seattle, WA 98104