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QUARTERLY NEWSLETTER OF THE CANCER AND LEUKEMIA GROUP B

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CALGB heads north for summer Group meeting in Toronto.



Toronto, Canada is the site for the CALGB Summer Group Meeting, June 25-27, 1999.

- Advance Registration Deadline:** **June 2, 1999**
- Hotel Reservation Deadline:** **June 2, 1999**
- Meeting Registration Cancellation/ Substitution Deadline:** **June 9, 1999**
- Agenda Book Order Deadline (if not attending meeting):** **June 2, 1999**

NOTE: All Summer Meeting registration forms appear in this issue. There will NOT be a separate mailing. For extra forms, visit our Web site at www-calgb.uchicago.edu.

SUMMER GROUP MEETING SECTION
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Cancer and Leukemia Group B

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While we make every effort to provide accurate dosing information in the *CAL·GAB*, you should always check the appropriate drug dosages before prescribing and/or administering any medication.

MESSAGE FROM THE CHAIR

At ASCO this year, CALGB will present the preliminary results of protocol 9082, a study comparing high-dose chemotherapy with bone marrow and stem cell transplant to intermediate-dose chemotherapy in women with breast cancer involving 10 or more axillary nodes. A



Richard L. Schilsky, M.D.

laypersons abstract summarizing the results of the study is included in this issue of the *CAL•GAB* and is also available at the ASCO web site www.asco.org. With median duration of follow-up of three years, the results are not yet conclusive largely because women in both arms of the study are doing better than was anticipated when the protocol was designed. The overall favorable outcome is likely due, in part, to the rigorous staging

required prior to protocol entry as well as to the aggressive treatment administered in both arms of the study.

At this point in time, there are no significant differences in event-free or overall survival between the intermediate- and high-dose chemotherapy groups. Interestingly, there appear to be fewer breast cancer relapses among women receiving the high-dose chemotherapy.

Unfortunately, however, there are more treatment-related deaths in this group as well leading to no overall benefit for the high-dose treatment at the present time. It is certainly possible, however, that results may change with continued follow-up of the patients. Of note is that centers enrolling the largest numbers of patients have the lowest transplant-related mortality rates.

Since the results of the study are still very preliminary, some have wondered why CALGB has released the data at this time. To answer that question, I thought it would be useful to review briefly the process that led to the decision to release the study results. As with all CALGB phase III treatment trials, 9082 was monitored by an independent Data and Safety Monitoring Board. At the time of our Group meeting in November, 1998, I received a recommendation from the 9082 Data Monitoring Committee that the results of the study be released to the CALGB Breast Committee. The recommendation, which was unanimous, came after careful deliberation by the monitoring committee, a group that included clinical investigators, statisticians, a patient advocate and representatives of the National Cancer Institute. Recognizing that release of these data would likely touch off intense interest and debate among the investigator community, patients and insurers,

I consulted with Dr. Michael Christian, Associate Director, Cancer Therapy Evaluation Program, NCI. We decided to convene a meeting to discuss the ramifications of release of the data and, in mid-December, brought together the 9082 study chair, Dr. William Peters, the

study statistician, Dr. Gary Rosner, the Breast Committee chair, Dr. Larry Norton, members of the data monitoring committee, representatives of the NCI and a patient advocate to discuss the study results. An intense afternoon of discussion culminated in a unanimous decision to release the study results and to request permission from ASCO to submit an abstract for presentation at the 1999 annual meeting. The decision to release the information was based largely on the philosophy that no patient enrolled in the study would be harmed by release of the information; that, since all patients had completed chemotherapy, the integrity of the study would be maintained even with release of the data, and that even preliminary results might be useful to patients contemplating the difficult decision of whether to undergo high-dose chemotherapy as part of their breast cancer treatment.

ASCO agreed to allow CALGB to submit an abstract for review by the ASCO Program Committee and the abstract was accepted for presentation on the Plenary Session.

Unknown to CALGB was the fact that four other abstracts had been submitted to ASCO reporting results of randomized trials of high-dose chemotherapy for treatment of breast cancer. In an attempt to determine how best to present all the data to the patient community, Dr. Richard Klausner, Director of the National Cancer Institute, convened a meeting at NCI in February 1999 that included CALGB and ECOG investigators, ASCO leaders, NCI staff and representatives of several breast cancer advocacy organizations. Discussions were held concerning the optimal timing for release of the results of these studies and strategies to disseminate the information as effectively as possible. Decisions were reached to follow the usual ASCO timelines for release of the abstracts but to prepare for the many questions that would be raised when the abstracts were posted at the ASCO web site on April 15. To that end, CALGB worked closely with ASCO, NCI and the patient community to prepare supplementary information that is available at the ASCO web site and Dr. Peters participated in two teleconference briefings with the press and with the patient advocate organizations interested in breast cancer.

CALGB 9082 is an important study that will continue to be discussed and analyzed for years to come. We could not have completed this landmark trial without the enormous support of our investigators, our colleagues in SWOG and NCIC and the many courageous women who agreed to participate in the trial. We are deeply grateful to you all. We believe that we have handled this process responsibly and have always tried to put the interests of current and future patients first. For those who will not be able to hear Dr. Peters' presentation at ASCO, I am pleased to say that he will present the results of 9082 at our Group meeting in June. I invite you all to attend.

CALGB GROUP NEWS

NEWS IN BRIEF

CALGB Pathology Coordinating Office Leaves Roswell Park

Effective April 1, 1999, the CALGB Pathology Coordinating Office (PCO) has officially relocated to Ohio State University from Roswell Park Cancer Institute. In 1997, after many years of enormous contributions to pathology correlative sciences in CALGB, Maurice Barcos stepped down as Chair of the Pathology Committee. Dr. Barcos was replaced as Committee Chair by Carolyn Compton, Massachusetts General Hospital. CALGB has elected to transfer the PCO and associated CALGB tissue bank from RPCI to OSU. The directors of the newly relocated PCO are Drs. Saul Suster and Scott Jewell. Coupled with the new Informatics initiative LabTrak (scheduled to go online in May of this year), this further strengthens CALGB as one of the leaders in correlative sciences among cooperative groups.

The Lab Coordinator at the new PCO is Cindy Coleman. She can be reached at 614-688-3495; e-mail: coleman.15@osu.edu.

Audit Committee Leadership Changes

Janice Grimes of the Mount Sinai Medical Center, Miami CCOP, and Vice Chair of the CALGB Data Audit committee, is stepping down after 10 years on the Audit Committee. CALGB extends its heartfelt appreciation to her for valuable service. Susan Tuttle of Wake Forest University School of Medicine has been named new vice chair.

Radiation Oncology Committee Changes

Committee Chair Andrew Turrisi, M.D. announced the departure of Vice Chair Srinivasan "V-J" Vijayakumar, M.D., University of Illinois-Chicago, from the committee. The new vice chair will be Steven Westgate, M.D., University of Missouri/Ellis Fischel Cancer Center.

CALGB Physicians Lead *Good Housekeeping* List of Best Cancer Doctors for Women.

CALGB-affiliated physicians accounted for nearly one-third of the 300 cancer doctors cited for their expertise in a survey published in the March, 1999 issue of *Good Housekeeping*. The survey asked department chairs and

section chiefs in surgical, medical and radiation oncology at major medical centers across the country to name the best physicians at treating lung, breast and colon cancer in women.

By disease category: 36 of 106 lung cancer specialists, 28 of 92 colon cancer specialists, and 33 of 102 breast cancer specialists cited had CALGB affiliation.

By specialty: 48 of 156 surgical oncologists, 29 of 92 medical oncologists, and 17 of 54 radiation oncologists had CALGB affiliation.

1st Milan Breast Cancer Conference

The European School of Oncology in Milan, Italy will host its inaugural conference on advances in breast cancer research June 17-19, 1999 in Milan.

CALGB breast cancer specialists and oncologists are invited to attend to share information and learn about research efforts underway at the ESO and the Instituto Tumori.

The conference will be a short, intensive scientific meeting with sessions on genetics, chemoprevention, DCIS, surgery, radiation and adjuvant therapy, predictors of response, and breast cancer advocacy in the U.S. and Europe.

For more information contact the European School of Oncology in Milan, Italy. E-mail: esomi@tin.it; phone: +39/0258317850.

NEW STAFF

CENTRAL OFFICE

Barbara Smith and **Kim Haddon** have recently joined the Central Office Fiscal Affairs staff.

Barbara has a B.A. degree in Political Science from Purdue University, and comes to us from the Department of Physiology at Northwestern University Medical School.

Kim is a candidate for a B.A. degree in Education, May 1999, Loyola University, and comes to us from the University of Chicago Graduate School of Business.

Barbara and Kim will support pre- and post-award grant activities of the CO, such as the grant application process, various per-case payment programs, travel direct-bill and travel reimbursement programs. Barbara can be reached at 773-834-3494 or basmith1@midway.uchicago.edu; Kim can be reached at 773-702-9904 or jhaddon@midway.uchicago.edu.

NEW STAFF continued on page 4

The CALGB is published quarterly by the Cancer and Leukemia Group B and is distributed free to the CALGB active membership. Suggestions for articles are encouraged. The next copy deadline is July 15, for the Summer 1999 edition.

Articles and correspondence should be sent to: Robert Blount-Lyon, CALGB Publications Coordinator 208 S. LaSalle St., Suite 2000, Chicago, IL 60604-1104 Voice: (773) 702-9479 Fax: (312) 345-0117

NEW STAFF *continued on page 4*

Avis C. Rodgers is the new CALGB Central Office secretary—the voice of CALGB for outside callers. She attended Chicago State University and Taylor Business Institute, and comes to CALGB from the University of Chicago. Avis has two school-age boys at home; her favorite activities are chess and bowling.

CALGB Information Systems

Charles Keen recently joined the CALGB Information Systems group as a Senior Programmer Analyst. Charles has a B.S. in Applied Math from N.C. State University and has 30 years experience in industrial control and laboratory data acquisition system development. He came to us from Technology Planning and Management in RTP. He enjoys bowling and salt water fishing. His e-mail address is cakeen@elephant.mc.duke.edu.

Benjamin Adair, formerly User Support Specialist at the Central Office, has been promoted to Programmer Analyst, assigned to Central Office reporting needs.

CALGB Data Management Center

The Data Management Center would like to welcome CALGB's new Protocol Registrar, **September Mihaly**. Tember has a B.A. in Biology and over a year's experience in medical research. She came to CALGB from the Duke Clinical Research Institute. Her e-mail address is srmi-haly@elephant.mc.duke.edu.

Penny Wade, CALGB's former Protocol Registrar, has been promoted to the position of Data Coordinator I. She will coordinate studies for the Cancer Control and Respiratory Committees.

Joyce Chilongo recently joined the Data Management Center as a Data Technician. She is currently working on a variety of tasks for the Breast Committee and also serves as back-up registrar. Joyce has bachelor's and master's degrees in education from the University of Malawi at Malawi, Africa. She enjoys her hobbies of reading, knitting, and also loves meeting new people. Her e-mail address is jpchilongo@elephant.mc.duke.edu.

Audrey Bennett began working as a Data Technician at the CALGB Data Management Center on November 9, 1998. Audrey came to CALGB from Bayer Corporation Quality Assurance Division. She received a B.S. degree in Biology from the University of North Carolina at Chapel Hill and is an avid basketball fan. Her e-mail address is albennett@elephant.mc.duke.edu.

CALGB Studies Presented at ASCO 1999

Eighteen abstracts on CALGB studies will be presented at this year's annual meeting of the American Society of Clinical Oncology May 17 in Atlanta, GA.

Besides CALGB 9082, the study on high-dose chemotherapy for high-risk breast cancer (see story page 6), three other abstracts from Breast Committee studies will be presented, including an abstract by Donald Berry, Ph.D., comparing CALGB and ABMTR databases on conventional versus high-dose therapy for metastatic breast cancer.

There will be four abstracts from the Respiratory Committee, two each from Leukemia, Prostate, Psycho-Oncology and P.E.T. Committees, and one study apiece from the GI and Solid Tumor Correlative Sciences Committees.

“Thank You” To Organizations Supporting CALGB in 1999

The following organizations have generously supported CALGB research, educational programs, publications, and data resources in 1999:

Amgen, Inc.
 Bristol-Myers Squibb Oncology
 Cytogen
 Genentech BioOncology / IDEC Pharmaceuticals
 Glaxo Wellcome Oncology
 Lilly Oncology
 Novartis Oncology
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 Schering Corporation
 SmithKline Beecham
 T.J. Martell Foundation for Leukemia, Cancer and AIDS Research

CALGB SCIENTIFIC REPORT

Hereditary Colon Cancer: The Importance of Recognizing Familial Risk

Monica M. Bertagnoli, MD

Strang-Cornell Hereditary Colon Cancer Program

A familial predisposition to certain cancers has been recognized for over 200 years, but only recently have clinicians understood cancer family syndromes in sufficient detail to impact treatment. For colorectal cancer, identification of a cancer patient as a susceptibility gene carrier indicates that they may be at risk for multiple primary colon tumors, as well as for extracolonic cancers such as endometrial, ovarian, or urologic malignancies.¹ Patients from colon cancer-prone families develop their tumors at an earlier age than individuals with sporadic disease, and their cancers are generally poorly differentiated and of mucinous histologic type. Surprisingly, patients with hereditary colon cancers have a significant survival advantage at every stage when compared to individuals with sporadic tumors.² These observations suggest that patients with familial colorectal cancer may require more intensive screening and surgical treatment than individuals with sporadic tumors, but they may have a more successful treatment outcome.

Colorectal cancer is common, striking 131,600 new patients in 1998.³ Twenty percent of these individuals have a parent, sibling, or child with colorectal cancer. A very small fraction of colon cancer patients (1%) have cancer arising in the setting of multiple intestinal polyps, a condition known as Familial Adenomatous Polyposis (FAP). FAP is caused by germline transmission of a mutation in the *APC* (Adenomatous Polyposis Coli) gene, and individuals with FAP have a 100% lifetime risk of colorectal cancer. An additional 8-10% of patients with colorectal cancer have a family history suggesting high penetrance of an inherited cancer predisposition gene, but lack the multiple intestinal adenomas seen in FAP. This syndrome is termed Hereditary Nonpolyposis Colon Cancer (HNPCC), and is clinically defined by the following requirements, known as the Amsterdam Criteria: *a*) at least three relatives with histologically verified colorectal cancer, with one of them a first degree relative to the other two; *b*) at least two successive generations affected by colorectal cancer; and *c*) colorectal cancer under the age of 50 in at least one family member.

Patients with HNPCC have an abnormal DNA repair capacity resulting from germline mutation of one of several mismatch repair (MMR) genes. Tumors from these individuals exhibit microsatellite instability, a measure of DNA repair failure that is detected by comparing DNA segments from tumor and normal tissue. At the present time, the diagnosis of HNPCC is made clinically, through identification of the patient as a member of a family meeting the Amsterdam Criteria. The presence of endometrial, ovarian,

renal pelvis, ureter, small bowel or stomach cancer in an HNPCC family is also significant. Many families with increased colorectal cancer risk, however, do not meet the full Amsterdam Criteria for HNPCC. Discovery of microsatellite instability in a tumor from one of these lower penetrance families suggests an inherited MMR gene defect. Further testing for germline loss of one of the two most common MMR genes, hMSH2 and hMLH1, can be offered to patients suspected of having HNPCC. Because there are multiple other genes associated with HNPCC, however, this test will fail to identify the causative MMR mutation in at least 25 percent of HNPCC patients.

There are several important reasons to identify carriers of colon cancer predisposition genes. These individuals clearly benefit from intensive colonoscopic surveillance for early detection of malignancy. For patients with FAP, total proctocolectomy performed in early adulthood is a lifesaving procedure. Prophylactic surgery for asymptomatic MMR gene mutation carriers is a controversial issue. Such management may be appropriate for patients with hMSH2 mutations, where lifetime risk of colorectal cancer approaches 85%,⁴ and in women at risk of endometrial cancer who have completed child-bearing. Total colectomy should be strongly considered for MMR gene carriers who develop a colon cancer or multiple recurrent adenomas. Finally, the presence of microsatellite instability in a colon cancer from a patient without a significant cancer family history may indicate a better prognosis or response to adjuvant therapy. Understanding the prognostic implications of tumor DNA repair capability is the focus of CALGB 9865: Tumor Replication Error Status Versus Outcome in a Colon Cancer Adjuvant Chemotherapy Trial.

References:

1. Thorson AG, Knezetic JA, Lynch HT. A century of progress in hereditary nonpolyposis colorectal cancer (Lynch syndrome). *Dis Colon Rectum* 1999;42:1-9.
2. Watson P, Lin KM, Rodriguez-Bigas MA, et al. Colorectal carcinoma survival among hereditary nonpolyposis colorectal cancer family members. *Cancer* 1998;83:255-266.
3. Landis SH, Murray T, Bolden F, Wingo PA. Cancer Statistics, 1998; *CA Cancer J Clin* 1998;48:6-30.
4. Lin KM, Shashidharan M, Thorson AG, et al. Cumulative incidence of colorectal and extracolonic cancers in MLH1 and MSH2 mutation carriers of hereditary non-polyposis colorectal cancer. *J. Gastrointest Surg* 1998; 2:67-71.

CALGB PROTOCOL AND CLINICAL TRIAL NEWS

BREAST COMMITTEE

ASCO Plenary Session to Focus on High-Dose Therapy in Breast Cancer

CALGB 9082 FEATURED WITH THREE OTHER TRIALS.

Results from four clinical trials of high-dose chemotherapy supported by bone marrow transplant for breast cancer patients will be presented at the plenary session of the American Society of Clinical Oncology's 35th annual meeting May 17 in Atlanta.

Dr. William P. Peters, M.D., Ph.D., Barbara Ann Karmanos Cancer Institute, will report preliminary findings from CALGB 9082.

National media controversy arose in early March when NBC News reported that researchers on these studies had found high-dose treatments gave no better results while posing significant risks to patients; NBC alleged that the NCI was withholding release of these findings for political purposes. The report suggested that women and their doctors considering this intensive, high-risk treatment for advanced breast cancer should immediately be made aware of study results showing no advantage to the high-dose chemotherapy. To address the public and media questions about the treatment results, ASCO posted abstracts of the four studies on its web site April 15, along with news releases to the media interpreting the results.

In CALGB 9082, a multi-center Phase III trial, 783 women with high-risk primary breast cancer (cancer that has spread to 10 or more under-arm lymph nodes) were randomized to receive either high-dose chemotherapy supported by bone marrow transplant or intermediate-dose chemotherapy using the same drugs at doses that could be safely administered without bone marrow and peripheral blood stem cell support.

Preliminary data on patients three years after treatment offer insufficient evidence to conclude that there is any difference in survival between the two therapies. Patients who received the high-dose therapy have an estimated 68% chance of being alive and cancer-free at three years, compared to a 64% chance for patients who received the intermediate-dose therapy. While fewer breast cancer relapses have occurred among high-dose treatment patients, there were 29 (7.4%) treatment-related deaths among high-dose patients versus none among intermediate-dose patients. Overall, a patient's chances of being alive at three years are 78% for the high-dose therapy and 80% for the intermediate-dose therapy. Further follow-up should clarify the impact of high-dose therapy on the long-term chances of

patients surviving cancer-free.

CALGB plans to carry out another analysis beginning about mid 2001, three years after the last patient was randomized, when information from patients with longer follow-up can be incorporated.

All patients received an initial chemotherapy treatment consisting of 4 cycles of cyclophosphamide/adriamycin/5-fluorouracil (CAF); followed by a high- or intermediate-doses of cyclophosphamide, cisplatin and BCNU. All patients were to receive radiation therapy to the chest area and tamoxifen was prescribed for women whose tumors were hormone receptor positive or unknown.

An assessment of the quality of life for patients in this study found no differences between treatment groups one year after completion of therapy.

GI COMMITTEE

ICE-T Study: Trimodality treatment (chemo- & radiotherapy followed by surgery) for esophageal cancer

UPDATE ON CALGB 9781

CALGB is increasing marketing efforts to generate accrual for an important GI Committee study of trimodality treatment for esophageal cancer. The Intergroup Cancer of the Esophagus Trial (ICE-T) tests whether trimodality treatment—chemotherapy and radiotherapy before surgery—offers any benefit over surgery alone for patients with local/regional esophageal cancer.

A new patient education brochure for CALGB 9781 has been printed and distributed to participating institutions as well as to thoracic surgeons, GI surgeons, gastroenterologists, and oncologists.

Esophageal cancer, while uncommon, is highly lethal, according to study chair Mark Krasna, M.D., primarily because the cancer has usually spread by the time it is discovered. Five-year survival rates for patients treated with surgery alone or chemoradiation without surgery range from 10 - 25%, with median survival of approximately 12 months.

CALGB 9781 builds on the experience of CALGB 9091—a Phase III study testing chemotherapy plus surgery versus surgery alone for esophageal cancer patients. Preliminary results showed acceptable tolerance for the adjuvant therapy, but no significant improvement in overall survival.

Two recent European studies of trimodality treatment showed conflicting results regarding overall survival. At the same time, several small single-institution prospective ran-

domized trials indicate a potential benefit for trimodality treatment.

CALGB 9781 was opened in October 1997, with an accrual goal of 500 patients. To date 26 patients have been enrolled.

"We are finding that many oncologists and surgeons worry that patients will not be able to tolerate all three therapies," said Dr. Krasna. "As a result patients are often treated according to local preferences: surgery alone or chemoradiation without surgery.

"This study targets patients with no distant metastases whose tumors are still surgically resectable and who are capable of tolerating chemoradiation. We are now seeing many major educational institutions choose trimodality therapy off-study to treat some of these patients. Definitive study results will be especially valuable at this juncture, which is why we are strongly encouraging surgeons and oncologists to consider the ICE-T study for their esophageal cancer patients."

The patient education brochures, produced by the CALGB Central Office with assistance from Julie Schuetz, nurse coordinator on CALGB 9781, explain the study and treatment options to patients in plain language at reading levels typical of esophageal cancer patients. Additional brochures and information are available from Dr. Krasna's office at the University of Maryland Cancer Center in Baltimore.

"It is only through the cooperative efforts of trials like this," said Dr. Krasna, "that we will have the scientific basis to make progress in the treatment of esophageal cancer."

**FOR MORE INFORMATION ON ICE-T STUDY—
CALGB 9781**

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email: mkrasna@surgery1.umaryland.edu

website: www.umm.edu/thoracic

CANCER CONTROL

CAPS Study promoted nationwide

UPDATE ON CALGB 9270: COLORECTAL ADENOMA PREVENTION STUDY

Over 10 million Americans watched news reports recently about a clinical trial to test aspirin's effectiveness in reducing the risk of colon cancer—CALGB's CAPS study (9270). The reports aired on local news broadcasts in 53 U.S. cities in November and December, 1998.

An aspirin manufacturer distributed a video news release (VNR) about the CAPS study to television news sta-

tions in every major city in the country in November. Over a six-week period, 60 different stations aired a report on the study in local news broadcasts. In some cities the report aired more than once—on morning and evening news programs, for example. In all, the segment was shown a total of 134 times.

The video features study chair Robert Sandler, M.D. of the University of North Carolina discussing the rationale and objectives of the clinical trial and how it works. A patient who enrolled in the trial is also interviewed. Viewers were advised to call an 800 number for more information about the CAPS trial.

The report calls attention to the clinical trial by noting that a common drug in every home—aspirin—may prove to be an effective medication to prevent some forms of cancer. The VNR is strictly a news report and includes no advertising, although aspirin bottles with the manufacturer's labels are shown moving across a conveyor belt several times in the news report.

The report was aired in large and small markets from coast-to-coast: 1.5 million people watched it in 3 broadcasts on WNBC in New York City; 37,000 people saw it in 2 broadcasts in Bakersfield, California on the local NBC affiliate KGET.

The video is available to be duplicated for institutional internal use or for institutions to distribute to their local news stations for broadcast. Institutions that arrange for a local news station to broadcast the video should ask the news stations to give out the local institution's contact phone number for further information. The original 800 phone number given in the broadcast connected callers to the University of North Carolina at Chapel Hill Medical Center and the offices of study chair Dr. Sandler.

"We received hundreds of calls and inquiries about the CAPS study after the video was aired," said Sandler. "The level of interest was encouraging, but unfortunately we can't enroll patients over a toll-free phone number. We ended up referring them to their closest local institution that could participate in the study."

Institutions interested in obtaining copies of the video or a list of news stations that have aired the report can contact Avis Rodgers, CALGB Secretary, 773-702-9163.

CALGB 9270 is a randomized, placebo-controlled, double-blind Phase III study testing whether 325 mg daily aspirin use can prevent large bowel polyps (adenomas), which are precursors to most colorectal cancers. The Cancer Control Committee intergroup study was opened in 1993 and is also open at M.D. Anderson Cancer Center, ECOG, and NCCTG. NCI DCP supplemental funding of \$500 per patient accrued to 9270 is also available for non-CCOP institutions. Target accrual for the study is 890 patients. To date (as of April 1), 663 patients have been enrolled. For more information about CALGB 9270, contact Penny Wade at the CALGB Data Management Center, 919-286-0045 ext. 286.

CANCER CONTROL *(continued)*

Treating Cancer Cachexia with Fish Oil

UPDATE ON CALGB 9473: Phase I/II Trial of Omega-3 Fatty Acids for Cancer Cachexia

CALGB 9473 is a phase I/II trial to determine if certain fatty acids found in fish oil can reverse weight loss or impact tumor growth in patients suffering from cancer-related cachexia. The phase II portion of 9473 has been open since December 1997.

Cancer cachexia weakens patients' natural disease resistance and their ability to tolerate cancer-fighting therapies; progressive cachexia is one of the major causes of mortality in patients with advanced cancer.

According to study chair C. Patrick Burns, M.D., University of Iowa, "The double tragedy of terminal cancer is that life is not only shortened, but also that the quality of that remaining time is eroded by cancer cachexia." The devastating malnutrition and associated loss of muscle mass and fat stores has a number of causes: functional blockages, poor intake, malabsorption, diarrhea, vomiting, anorexia and protein loss, as well as the after-effects of surgery, radiotherapy and chemotherapy. There is also evidence that tumor activity affects the body's metabolism of fat and protein, inducing or mediating lipolysis and depletion of fat stores.

"This protocol addresses the question of whether fish oil fatty acids can ameliorate the syndrome, as it does the weight loss of experimental cancer in animals," said Dr. Burns.

Tumor activity could affect body metabolism: inducing or mediating lipolysis and depletion of fat stores.

Eicosapentaenoic acid (EPA), one of the key omega-3 fatty acids in fish oil, has been shown in animal studies to reverse tumor-associated weight loss and also inhibit the growth of experimental tumors. Other animal studies demonstrate that dietary supplements can change the fatty acid composition of cancer tumor cells. EPA-enriched malignant cells have increased susceptibility to oxidation, physical properties, membrane transport and eicosanoid production.

A patient with lymphocytic leukemia participating in phase I of CALGB 9473 had a four-fold increase in the EPA composition of his leukemic cells after one month of treatment. A sufficient daily dosage of EPA may therefore have a direct effect on tumor growth kinetics.

Fish oil fatty acids may not only ameliorate cachexia, but also have a direct effect on tumor growth kinetics.

The phase I portion of 9473 established the maximum tolerated dose for omega-3 fatty acids of 0.3 gram per kilogram of body weight. Diarrhea was the dose-limiting toxicity encountered in Phase I. Dr. Burns stated that early accrual to the phase II trial has been limited by the large number of capsules to be taken. "We have an amendment now before the NCI DCP to decrease the dose so that more patients will be able to take the number of capsules required," he said. The dosage for Phase II will be lowered to 0.15 g/kg/day. At this dosage, a 70 kg patient would take 11 capsules a day in two doses. This dose will deliver 4.8 g of EPA and 2.5 g of docosahexaenoic acid (DHA), another major omega-3 fatty acid in fish oil.

The amendment will also allow patients who do not have a response of either cachexia or tumor after two months of treatment to then receive chemotherapy or radiation therapy.

Patients with any solid tumors or hematologic malignancies (except brain tumors) are eligible, and can receive chemo- or radiation therapy post-study.

The ongoing phase II study seeks patients with advanced cancer and cachexia who have had weight loss of at least 2% within a one-month period and who are not currently undergoing radiation therapy or chemotherapy. Patients with any solid tumors and hematologic malignancies except brain tumors are eligible. Patients with other medical conditions and treatments that could affect digestion and metabolism or contribute to malnutrition are ineligible.

Accrual has been slow: 12 patients have been enrolled during the first 15 months of the phase II portion; only two patients in the last 6 months. The accrual goal for phase II is 43 patients.

NCI DCP supplemental funding of \$250 per patient accrued to CALGB 9473 is available for non-CCOP institutions.

For more information about CALGB 9473, please contact the study chair, C. Patrick Burns, M.D. at the University of Iowa College of Medicine. Voice-mail 319-356-2038, e-mail c-burns@uiowa.edu.

CRA NEWS

CALGB 309801: Determination of utilities for control of chemotherapy-induced nausea and vomiting

*Study Chair: Steven Grunberg, M.D.,
Vermont Cancer Center*

This exciting new protocol being developed by the Clinical Economics Committee is part of a growing effort to apply objective measurements using decision analysis techniques to the study of supportive care and symptom control. CALGB 309801 will attempt to measure the degree to which patients' quality of life would be affected by various levels of nausea and/or vomiting that could be experienced with chemotherapy. This is a free-standing protocol which is not directly linked to any treatment study and therefore represents a new direction for CALGB and the Clinical Economics Committee. The principles being developed in this study will permit the committee to develop similar studies in other areas of supportive care, as well as new techniques to complement quality of life measures in selected treatment protocols.

The primary objective of this study is to explore the feasibility of using the Standard Gamble technique to determine the effect of various levels of nausea and/or vomiting on global quality of life in a population of patients undergoing chemotherapy. By using the Standard Gamble, CALGB 309801 will assess quality of life by determining the amount of risk a subject would accept to resolve a present health problem, i.e., nausea and vomiting. The results of the Standard Gamble are shaped by the varying levels of risk that different participants are willing to accept. The Standard Gamble exercise will be administered via structured interview by a trained CRA or other research personnel. Since accurate administration of this exercise requires uniform presentation of the scenarios and questions, participating CRAs will be provided with an interview script and visual aids for the Standard Gamble and for a Feeling Thermometer exercise that allows the patient to rate his/her current state of health as compared to other differing health states.

Eligible patients will be receiving chemotherapy currently for breast or lung cancer, but they will not have to be registered to a treatment protocol. The interview will be conducted after one or more cycles of chemotherapy have been completed but before a new cycle has started. The interview will be administered on only one occasion to each patient. All patients will need sufficient written and/or spoken English skills to complete the interview and questionnaires.

After informed consent has been obtained the patient will fill out two brief questionnaires — the Morrow Assessment of Nausea & Emesis (MANE), and the Functional Assessment of Cancer Therapy-General (FACT-G). The CRA or research nurse will then conduct the Feeling Thermometer and Standard Gamble exercises. Upon completion of the interview, the patient's participa-

tion in the study is concluded.

Participation of the CRAs and research nurses is vital to the successful completion of this study. For this reason, a training workshop for CRAs from participating sites will be conducted at CALGB's June 1999 Group Meeting in Toronto. CRAs will receive introductory information about the goals of the Clinical Economics Committee and the relevance of this study to supportive care. They will be instructed in the minimal forms completion required for this study. The primary focus of the workshop will be to provide CRAs with instruction in the administration of the Standard Gamble technique and to provide an opportunity for the CRAs to practice the interview with the script and visual aids. Representatives from the Clinical Economics Committee who have experience with the Standard Gamble will serve as instructors for the workshop.

This protocol presents an excellent opportunity for both CRAs and patients to participate in an innovative area of research. Since CALGB 309801 is a limited-access study, all interested institutions should contact Dr. Steven Grunberg at Vermont Cancer Center at (802) 656-3827 as soon as possible.

ATTENTION: Beginning CRAs— Mark Your Calendars

The next Beginner's Workshop for Clinical Research Associates will be held August 13-15, 1999 at the Washington Duke Inn in Durham, North Carolina. A special mailing scheduled for early May, will be circulated to lead CRAs at CALGB institutions asking them to identify those who should attend this workshop. Travel support will be offered. Please watch for this announcement.

SUMMER GROUP MEETING WORKSHOPS OF INTEREST TO CRAs:

- CALGB Database: On-line Patient Registration software training
- Entering Common Toxicity Criteria on Palm PCs: NCI-sponsored software demonstrations
- Educating Patients about Clinical Trials: NCI-Oncology Nursing Workshop
- Training Session on CALGB 309801
- SoCRA-CCRA Certification Exam
- CRA Continuing Education Workshop

Advance registration is required for some of these workshops. See the meeting schedule and articles beginning on page 13 for more information.

ONCOLOGY NURSING

Diarrhea in the Cancer Patient

Deborah Berg, R.N., B.S.N., Dana-Farber Cancer Institute, Center for Gastrointestinal Oncology

Diarrhea is a common side effect of anticancer therapy, but it has been overshadowed by other side effects such as nausea, vomiting, pain, and fatigue in health care literature and in research. Multiple and overly broad definitions of diarrhea, as well as patients' hesitation to raise this issue, contribute to the lack of research and focus. For a variety of reasons, diarrhea is a bodily function that many patients do not discuss with their health care provider.¹ Diarrhea is described as "abnormal looseness of the bowels" in a standard dictionary.² In a medical dictionary, it is defined as "frequent passage of watery bowel movements, often a symptom of GI disturbances and primarily the result of increased peristalsis; etiologic factors are: diet, inflammation or irritation of the intestinal mucosa, GI infections, certain drugs, and psychogenic factors."³ These definitions leave much to interpretation, and portray many causes for this symptom.

Diarrhea occurs in approximately 12–87% of cancer patients.⁴ It is often related to osmotic, secretory, hypermotility, malabsorptive, dysmotility, and exudative changes in the intestine which are caused by the cancer itself, pre-existing medical conditions, cancer treatment, and/or the pharmacologic treatment of cancer related symptoms.^{4,5} The anticancer treatments that most commonly cause diarrhea are radiation therapy to the abdominal-pelvic area, and the chemotherapeutic agents: 5-fluorouracil, irinotecan, cytarabine, dactinomycin, methotrexate, Tomudex, topotecan, capecitabine, UFT, and Hydrexa.

The Value of Complete Information

Assessment of the bowel function of patients receiving these anticancer treatments is invaluable and must be comprehensive. One way to obtain very factual information is with a symptom diary in which the patient records all bowel movements for several days. This assessment must start prior to therapy and continue during therapy. The National Cancer Institute (NCI) Common Toxicity Criteria (CTC) Scale grades the severity of diarrhea based on an increase in the number of stools from the patient's pretreatment level. The NCI CTC grading scale is often used by the manufacturers of chemotherapeutic agents to recommend dose modifications. If the healthcare provider does not know the "normal" bowel function of a given patient, they cannot adequately assess the impact of the treatment on the patient's bowel movements. Doctors are thus not able to prescribe appropriate antidiarrheal therapy or modify the anticancer treatment dosage. This lack of information could have a detrimental effect on the patient's outcome, both in terms of successful treatment of their disease and their quality of life. Though not well documented in health care literature on quality of life, every health care provider

knows of many patients who refuse to go to work, socialize, travel to the hospital, or leave home for fear of experiencing diarrhea while they are away.

The first challenge is gathering quality information about patients' diarrhea. Three-fourths (74%) of nurses in a recent study by Rutledge and Engelking⁵ simply ask the patient if they experienced diarrhea or not. Another 14% reported they did not use any consistent measurement tool. Symptom diaries were used by 25% of the respondents; but only 17% used the NCI Common Toxicity Criteria—probably because they had patients on clinical trials which required use of NCI CTC. These are disturbing results. Asking patients only if they have had diarrhea, or not using a consistent measurement tool, does not allow for a complete assessment of the incidence, character, or severity of diarrhea. It fails to provide the health care provider with appropriate information about the effectiveness of antidiarrheal treatment.⁵

Every health care provider knows of many patients who refuse to go to work, socialize, travel to the hospital, or leave home for fear of experiencing diarrhea.

Many nurses may not have comprehensively assessed their patients' diarrhea because of patients' hesitation to talk about a somewhat unpleasant symptom. The poor usage of measurement tools may be partially due to the fact that, until recently, there were several toxicity-grading tools with different definitions for grading the same toxicity. The NCI CTC scale had an inadequate definition of diarrhea with no definitions for patients with special issues, such as those with a colostomy, ileostomy, or undergoing bone marrow transplant. Version 2.0 of the NCI Common Toxicity Criteria Scale is meant to be a universally accepted tool and provides separate definitions for diarrhea in patients with a colostomy, for patients undergoing a bone marrow transplant, for pediatric patients, and for patients experiencing late morbidity from radiation therapy. This new version of the CTC and recent research, such as Rutledge and Engelking's, will improve our knowledge base, provide us with a common language to discuss diarrhea, and thus improve the care of patients experiencing diarrhea.

Treatment Dictated by Cause

Once diarrhea has been diagnosed and comprehensively assessed, treatment is dictated by its cause. Diarrhea caused by chemotherapy is often treated with dietary alterations and antidiarrheal medications. Patients are often taught to eat mild (BRAT) or bland low-fiber foods, though there is no scientific evidence to prove their effectiveness.

The BRAT diet consists of Bananas, Rice, Applesauce, and Toast. Examples of bland low fat foods are skinless white chicken meat, scrambled eggs, crackers, plain pasta, and canned or cooked fruits. The rationale is that these foods do not irritate the GI tract.⁶ Patients must increase their fluid intake to replace fluid lost with diarrhea. Their fluid intake should be approximately 2 quarts per day and include water, juices, soups, sports drinks (e.g. Gatorade®) or electrolyte replacement fluids (e.g. Pedialyte®—available as a drink and as popsicles). If the patient develops symptoms of dehydration, admission to the hospital and intravenous hydration are warranted.

Antidiarrheal medications often include opiates (deodorized tincture of opium, lomotil, loperamide), anticholinergics (atropine), antisecretory agents (octreotide acetate), adsorbent agents (kaolin), or absorbent agents (hydrophylic agents).⁵ Mild diarrhea is often treated symptomatically, while moderate to severe diarrhea also warrants a decrease in the therapy dosage.⁶ For life-threatening diarrhea, the recommendation is to suspend the therapy until the diarrhea has resolved.⁷ The hormone antagonist octreotide acetate is under investigation in a clinical trial led by the Eastern Cancer Oncology Group to assess its effectiveness in the treatment of severe diarrhea caused by 5-FU (CALGB 9770). This is a randomized clinical trial comparing the effectiveness of conventional dose Octreotide (150 ug TID subcutaneously for 5 days) versus high dose Octreotide (1500 ug TID subcutaneously for 5 days) versus standard dose loperamide (maximum 16mg/d) given orally for 5 days. The results of this trial could impact our care of patients experiencing diarrhea caused by 5-FU.

Since diarrhea is often a dose-limiting toxicity, patients have a greater chance of tumor response if it could be managed well enough to allow the full dose of chemotherapy.

There are two different types of diarrhea associated with irinotecan. The first is associated with a cholinergic syndrome that occurs during or within 24 hours of the irinotecan infusion. It is treated with IV or SQ atropine. The second occurs more than 24 hours after treatment (median time to onset: 11 days with the weekly schedule or 5 days with the once q3-week schedule) and is felt to be due to a direct cytotoxic effect on the intestinal mucosa which causes a secretory-like diarrhea. This diarrhea is treated with intensive loperamide (4mg loading dose followed by 2mg q2 hours until diarrhea resolution).⁸

Patient Benefits of Effective Treatment

Diarrhea is a neglected cause of cancer-related symptom distress. Since diarrhea is often a dose-limiting toxicity, patients have a greater chance of tumor response if it

could be controlled or managed safely to allow the full dose of chemotherapy. Control or adequate management of diarrhea could also improve the quality of life for patients and their caregivers. Self-care measures can be a burden for the patient and their untrained caregivers. Caring for a loved one who is experiencing uncontrolled diarrhea can be distressing. Diarrhea management can improve patients' social support and reduce lost income due to missed days of work.

All this is possible if healthcare providers adequately evaluate patients for diarrhea toxicity, and make a comprehensive assessment with a consistent measurement tool to determine the severity of the diarrhea. In this way effective anticancer treatment can be prescribed according to a predetermined dose-modification plan.

References

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2. *The Merriam-Webster Dictionary*. (1975) New York: Pocket Book Publishers. 1975; 204.
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7. Marsh JC. Carcinomas of the Gastrointestinal Tract. In R.T. Skeel & N.A. Lachant (Eds) *Handbook of Cancer Chemotherapy* 4th edition. Boston: Little, Brown, and Company; 1995.
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PROTOCOL NEWS

NEW STUDIES

February 15, 1999

- 9767** – Assessment of fusion transcripts in longterm survivors of acute myeloid leukemia. *Study Chair: Clara D. Bloomfield, M.D.*
- 9769** – Assessment of the partial tandem duplication of ALL1 (MLL) in patients with acute myeloid leukemia (a leukemia tissue bank project). *Study Chair: Michael A. Caligiuri, M.D.*
- 39804** – Phase III randomized prospective trial of open versus minimally invasive, video-assisted resection of pulmonary metastases. *Study Chair: Joshua R. Sonett, M.D.*
- 509801** – Phase III study of adjuvant ganglioside vaccination GM2-KLH/QS-21 therapy vs high dose interferon Alfa-2b (IntronA) for high risk melanoma (T4>4 mm primary or regional lymph node metastasis). *Study Chair: Marc S. Ernstoff, M.D.*

March 15, 1999

- 9768** – Assessment of the AML1/ETO and CBFb/MYH11 fusion transcripts in patients with acute myeloid leukemia. *Study Chair: Michael A Caligiuri, M.D.*
- 19803** – A randomized phase II trial of oral topotecan given twice a day for 5 days vs. once a day for 10 days to patients with myelodysplastic syndromes. *Study Chair: David L. Grinblatt, M.D.*
- 39808** – Limited stage small cell lung cancer—a phase II study. *Study Chair: Alan P. Lyss, M.D.*

March 24, 1999

- 49802** – Phase III study of adriamycin/taxotere vs. adriamycin/cytoxan for the adjuvant treatment of node positive or high risk node negative breast cancer. *Study Chair: Lawrence N. Shulman, M.D.*

April 15, 1999

- 9862** – Molecular genetic features of acute myeloid leukemia. *Study Chair: Wendy Stock, M.D.*
- 89803** – Phase III intergroup prospectively randomized trial of irinotecan (CPT-11) plus fluorouracil/leucovorin (5-FU/Lv) versus 5-FU/Lv alone after curative resection for patients with stage III or high-risk stage II colon cancer. *Study Chair: Leonard B. Saltz, M.D.*

CLOSED STUDIES

February 26, 1999

- 9343** – Evaluation of lumpectomy, tamoxifen, and irradiation of the breast compared with lumpectomy plus tamoxifen in women 70 years of age or older who have carcinoma of the breast that is less than or equal to 2 cm and clinically negative axillary nodes: a phase III study. *Study Chair: Kevin S. Hughes, M.D.*
- 9534** – Phase II study of paclitaxel, carboplatin and radiation therapy for inoperable stage IIIA/IIIB non-small cell lung cancer. *Study Chair: Wallace L. Akerley, M.D.*

March 31, 1999

- 9741** – Randomized phase III trial of sequential chemotherapy using doxorubicin, paclitaxel, and cyclophosphamide or concurrent doxorubicin and cyclophosphamide followed by paclitaxel at 14 or 21 day intervals in women with node positive stage II/IIIA breast cancer. *Study Chair: Marc Citron, M.D.*

April 15, 1999

- 8364** – Immunological diagnostic studies in adult acute lymphoblastic leukemia. *Study Chair: Carleton C. Stewart, Ph.D.*
- 8762** – Molecular genetic features of acute lymphoblastic leukemia. *Study Chair: Wendy Stock, M.D.*

CALGB STUDY FUNDING

Support is available to qualifying institutions for participation in these studies. Payments are made through the main member institution. For more information, visit the CALGB website or contact Mary A. Sherrell, Financial Officer at (773) 702-9856.

- 9270** – Colorectal Adenoma Prevention Trial Using Aspirin. Phase III Study.
- 9334** – Sclerosis of Pleural Effusion by Talc Thoracoscopy vs. Talc Slurry. Phase III Study.
- 9335** – Video-assisted Wedge Resection + Radiotherapy for High Risk T1 NSCLC. Phase II Study.
- 9380** – Thorascopic Staging for Esophageal Cancer. Phase II Study.
- 9473** – Omega-3 Fatty Acids for Cancer Cachexia. Phase I/II Trial.
- 9481** – Hepatic Artery Floxuridine, Leucovorin, and Dexamethasone vs Systemic 5-FU and Leucovorin as Treatment for Hepatic Metastases from Colorectal Cancer. Phase III Study.
- 9484** – Linkage of Molecular and Epidemiological Breast Cancer Investigations with Treatment Data. Specialized Registry.
- 9490** – Does an Oral Analgesic Protocol Improve Pain Control for Patients with Cancer? (ECOG E4293)
- 9499** – Chemoprevention Trial to Prevent Second Primary Tumors with Low-Dose 13-CIS Retinoic Acid in Head and Neck Cancer. (MDACC DM90-094)
- 9581** – Adjuvant Immunotherapy with Monoclonal Antibody 17-1A after Resection for Stage B2 Colon Cancer. Phase III Randomized Study.
- 9594** – Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer. Phase III Study. (SWOG 9346)
- 9596** – Vincristine, Doxorubicin, and Dexamethasone with or w/o PSC-833 in Patients with Relapsing or Refractory Multiple Myeloma. Phase III Study. (ECOG E1A95)
- 9670** – Barriers to Participation of Older Women with Breast Cancer in Clinical Trials. Pilot Study.
- 9682** – Prognostic Significance of Endorectal MRI in Predicting Outcome After Combined Radiation and Androgen Suppression for Prostate Cancer. Prospective Phase II Study.
- 9730** – Taxol vs. Taxol + carboplatin for advanced NSCLC. Randomized Phase III Study.
- 9770** – High-Dose vs Conventional Dose Octreotide Acetate vs Loperamide in the Treatment of Chemotherapy-related Diarrhea in Patients with Colorectal Cancer. Randomized Trial. (ECOG E1295)
- 9782** – Phase II trial of potency-sparing hormonal therapy in patients with elevated serum PSA after radiation therapy or radical prostatectomy for prostate cancer.
- 9791** – Salvage therapy with paclitaxel and carboplatin vs salvage therapy with stem cell supported carboplatin, mitoxantrone and cyclophosphamide in patients with persistent low volume ovarian cancer. (GOG 164)
- 9870** – Quality of life and cost analysis of a prospective randomized phase III trial comparing trimodality therapy to surgery alone for esophageal cancer.
- 19801** – A Phase II Study of 506U78 in Patients with Refractory or Relapsed T-Lineage Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL)
- 19803** – Randomized phase II trial of oral topotecan given twice a day for 5 days vs. 1x/day for 10 days to patients with myelodysplastic syndromes
- 509801** – Phase III Study of Adjuvant Ganglioside Vaccination GM2-KLH/QS-21 Therapy vs High-Dose Interferon Alfa-2b (IntronA) for High Risk Melanoma (T4 > 4 mm Primary or Regional Lymph Node Metastasis).
- 89804** – Randomized phase III trial of 3 different regimens of CPT-11 plus 5-FU and leucovorin compared to 5-FU and leucovorin in patients with measureable advanced adenocarcinoma of the colon and rectum.

CALGB SUMMER MEETING SPECIAL SECTION



Toronto, Ontario's most cosmopolitan city, sets the stage for CALGB's Summer Group Meeting. The Sheraton Centre, Toronto's premiere, award-winning hotel, will host CALGB's conference delegates. Located in the heart of the city, its central location to shopping, dining and entertainment options makes the Sheraton Centre Toronto's preferred convention hotel. The hotel's concourse level connects to a massive shopping complex which includes Hudson's Bay Department Store and Eaton Shopping Center along with a variety of restaurant and food court options.

Die-hard shoppers will not only appreciate Toronto's reputation as a true shopping mecca, but will certainly appreciate the fact that the U.S. dollar, with its current exchange rate of about 1.50, really gives a shopper a lot for their money.

NO Study Chair Workshop at Summer Group Meeting

There will NOT be a Study Chair Workshop at the Toronto meeting. The next Study Chair Workshop will be during the Fall Combined Core/Group Meeting November 11-14, 1999 in Miami. CALGB requires that all first-time study chairs attend the Study Chair Workshop. The workshop is designed to provide new study chairs with the necessary skills and information to be an effective study chair during protocol development and after study activation. If the first-time study chair does not attend this Workshop, he/she will not be permitted to continue with the study. In addition, study chairs are required to attend the Study Chair Workshop every four years. Therefore, current study chairs who last attended a workshop in 1995 will be required to attend this November.

GROUP MEETING HIGHLIGHTS:

Plenary Session

Saturday, June 26, 1:30 – 4 p.m.

- **Group Chair Remarks**
- **Announcement of the CALGB-Janssen and CALGB-Amgen Award Recipients**
- **“The Patient’s View of Cancer”**
Deborah Collyar
President, PAIR: Patient Advocates In Research
Director, Advocacy Core at UCSF
Director, CTIP: Clinical Trials Information Project
- **Drug development of non-cytotoxics: do we need a new approach?**
Elizabeth Eisenhauer, M.D., NCIC Clinical Trials Group
- **Presentation of initial results of CALGB 9082**
William P. Peters, M.D., Ph.D.
Barbara Ann Karmanos Cancer Institute

Solid Tumors Correlative Sciences Committee Symposium

Daniel F. Hayes, M.D., Georgetown University

Friday, June 25, 1 – 4 p.m.

Over the last few years, the STCSC has made a major effort to provide educational symposia to CALGB members regarding late-breaking areas of technology and science related to the biology of solid tumors. These symposia are geared towards all participants who contribute to CALGB trials and science: clinicians, clinical investigators, laboratory investigators, social scientists, and patient advocates. They have included reports of DNA and RNA array technology, tissue micro-dissection, and an overview of p53 as a tumor marker in solid tumors.

In June, we are planning two components:

1. Tissue Arrays.

Recently, investigators have reported that small samples of up to 1000 or more separate tissues can be harvested and placed on a single glass slide. Why would we do this? First, this might save our valuable blocks by using the tissue more sparingly. Perhaps more importantly, it might permit us to perform our studies faster and more efficiently. For example, it would be possible to study all tissues from one study by staining just one or two slides! Obviously there are downsides, too, including sampling issues and tissue manipulation.

Drs. Saul Suster and Scott Jewell of CALGB's Pathology Coordinating Office have already incorporated this technology into their work at Ohio State University. Come hear and discuss whether we should consider using this strategy for CALGB tissue samples.

Continued on page 14

2. Detection of Minimal Residual Disease.

We all know that for most newly diagnosed solid tumors, routine, H&E light microscopic detection of regional nodal metastases is profoundly prognostic. However, for several years, investigators have reported that “minimal residual disease” (MRD) after therapy (surgery and or systemic therapy) can be detected in lymph nodes, bone marrow, and even blood samples by using special techniques: immunohistochemistry, flow cytometry, PCR, etc.

Are you confused over the “state-of-the-art?” You should be! Papers addressing MRD are being published monthly in every disease, and CALGB already has several investigations actively studying this issue.

It is difficult to balance the tension between the advancing edge of technology vs. what is clinically useful. How is MRD detected? What are the reasons, and for whom should MRD be evaluated? What are the CALGB studies addressing MRD?

These and other questions will be addressed in a two-hour symposium following Drs. Suster and Jewell’s presentation.

Please plan to come to Toronto on Friday so that you can keep up with what the STCSC is doing. We hope these efforts will enhance your participation in CALGB therapeutic and correlative protocols!

Oncology Nursing Workshop: “Cancer Clinical Trial Education”

Friday, June 25, 8 a.m.–1 p.m.

The National Cancer Institute (NCI) and the ONS Clinical Trial Nurses Special Group are collaborating to offer a workshop session on clinical trials. This workshop, first presented at the Oncology Nursing Congress in Atlanta, Georgia in April, will be repeated at the CALGB Group Meeting in Toronto.

Please attend this session with the objective of learning about basic and specific information on cancer clinical trials. The ONS position paper on Cancer Clinical Trials supports the role of all oncology nurses in helping to promote, educate, recruit and facilitate cancer clinical trials as a treatment option for all cancer patients. Presentations by the core trainees of the NCI/ONS Cancer Clinical Trials Education Program will provide you with information that you can use to educate colleagues, patients and the public.

Increasing patient accrual to clinical trials is crucial to advancing cancer care. Educational materials and resources will be provided so that you can disseminate information in your workplace and communities.

This workshop will be open to all interested CALGB members. Pre-registration is required—see the workshop registration form on page 18. For more details contact Debbie Berg, RN at (617) 632-3898 or deborah_berg@macmailgw.dfci.harvard.edu. For more information about the program please contact Rita Zamek, RN, MSN, CS, OCN, at 732-235-6786 or zamekrm@umdnj.edu.

CRA Training Workshop on CALGB 309801: Utilities for Control of Chemotherapy- Induced Nausea and Vomiting

Saturday, June 26, 9 a.m.–noon

CRAs will receive introductory information about the goals of the Clinical Economics Committee and the relevance of this study to supportive care (see article about CALGB 309801 on page 9 of this *CAL•GAB*). CRAs will be instructed in the minimal forms completion required for this study. The primary focus of the workshop will be to provide CRAs with instruction in the administration of the Standard Gamble technique and to provide an opportunity for the CRAs to practice the interview with the script and visual aids. Representatives from the Clinical Economics Committee who have experience with the Standard Gamble will serve as instructors for the workshop.

CALGB Database Hands-On Training: On-Line Patient Registration

Friday, June 25: 2–3 p.m., 5–6 p.m.

*Saturday, June 26: 9–10 a.m., 11:30 a.m.–12:30 p.m.,
5–6 p.m.*

Sunday, June 27: 11 a.m.–noon

On-line patient registration hands-on training sessions will be conducted at the June, 1999 group meeting. These sessions will allow you to become familiar with the software that you will be using to register patients. Any institution that has registration privileges and that has been given an account on the Statistical Center computer system and has downloaded the CALGB IS software should plan on having at least two representatives attend a session.

It is anticipated that by June the on-line system will be in use for some trials.

Space is limited—you must register in advance. Please take a moment to register for one of the six available sessions.

CALGB Web Site Demonstrations

Friday, June 25: 1–2 p.m., 4–5 p.m.

*Saturday, June 26: 8–9 a.m., 10:30–11:30 a.m.,
4–5 p.m.*

Sunday, June 27: 10–11 a.m.

CALGB IS staff will present live demonstrations of new features and capabilities of the CALGB Web site. Computers will be available for optional use. Space is limited—please register in advance for one of the six available sessions.

NCI Common Toxicity Criteria (CTC) Interactive Application on Palm PCs

Friday, June 25: 11–11:30 a.m., 4–4:30 p.m.

*Saturday, June 26: 10–10:30 a.m., 10:45–11:15 a.m.,
4–4:30 p.m., 4:45–5:15 p.m.*

The National Cancer Institute will host several hands-on demonstrations of CTC entry on Palm PCs at the summer Group Meeting. Twenty Palm PCs will be available for par-

ticipants to use during the interactive presentation of the software. This new application is designed to use the Palm PC as a multi-user data management tool for entry of toxicity data and transfer to desktop computers. Pre-registration is required because space is limited in the six scheduled sessions. See the meeting schedule or workshop registration forms for times, and be sure to register early if you are interested.

Institutions interested in implementing this new technology will need to purchase their own Palm PCs. Information about compatible models and retail pricing will be available at the workshop.

SOCRA – CCRA Certification Exam

Friday, June 25, 9 a.m. – 1 p.m.

The Society of Clinical Research Associates will conduct a CCRA Certification Examination at the CALGB Summer Group Meeting. Please contact Lynn Dyke, CCRA, if you plan to take this exam at the CALGB meeting, or if you have any questions. Phone: 315-472-7504, Fax: 315-479-8639, e-mail: ldyke@hoacny.com. APPLICATIONS MUST BE RECEIVED BY MAY 14, 1999.

Application forms may be requested directly from SOCRA's web site: www.willowhill.com/socra; or call 800-SoCRA-92 or 215-345-7749

Reception Cruise on Lake Ontario

Saturday, June 26, 7 – 10:30 p.m.

CALGB attendees are invited to experience a magical evening of dining and entertainment aboard the Northern Spirit. Cruise Lake Ontario and thrill to Toronto's breathtaking skyline while you feast on a delectable array of foods and enjoy entertainment. At the conclusion of the evening, a magnificent fireworks display will light up the sky.

Shuttles will transport attendees from the Sheraton's side entrance. Continuous shuttle service begins at 6:30 pm through 7 p.m. to the harbor (about a 5 – 7 minute ride). Ship boarding is scheduled for 7 – 7:30 p.m.; cruising will begin at 7:30 p.m., returning to the dock approximately 10:30 pm. Shuttles will transport attendees back to the Sheraton.

MEETING REGISTRATION

Group Meetings are open to the membership of the CALGB, as well as to invited guests.

Funding: The purpose of the committee budgets in the Central Office grant is to support Core Meetings, not Group Meetings. Committee Chairs may, however, request that these budgets be used to support the travel and lecture fees of non-CALGB speakers at their Group Meeting Committee meetings.

Deadline and Fees: \$40 (for registrations received by June 2); \$65 for registrations postmarked after June 2 or on-site. Registration fees are nonrefundable.

Substitutions: If you are unable to attend the meeting, substitutions are permissible, providing, however, you must inform the Central Office in writing by June 9. After this date, we will be unable to accept substitutions.

Continuing Medical Education Credits

M.D., Ph.D., D.O., and P.A.s

The University of Chicago has approved co-sponsorship of CALGB's Summer Group Meeting Program. The University of Chicago is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. Approval of approximately 21.0 credit hours in Category I of the Physician's Recognition Award of the American Medical Association has been granted.

R.N., O.C.N., and A.R.N.P.s

The Illinois Nurses Association has approved Continuing Education Credit (approximately 24.0 contact hours) for nurses.

C.C.R.A.s

An application for approval of approximately 13.0 CEUs has been submitted to the Society of Clinical Research Associates.

CME and CEU forms and instructions will be available at the Information Table at the Group meeting located at CALGB Registration.

TRAVELING TO CANADA

Citizens and legal residents of the U.S. do not need passports, although they are preferred. Native-born U.S. citizens should have birth certificate, plus a picture I.D.; naturalized citizens need naturalization certificates with picture I.D.; permanent residents (who are not citizens) need the alien-registration card.

Shipping Meeting Materials to Canada?

If you are planning to ship materials to the meeting site, please first notify Helen Pollard, CALGB Meetings Manager via e-mail hpollard@midway.uchicago.edu, or phone (773) 702-4129 in order to obtain proper shipping instructions and customs clearance documents.

AIR TRANSPORTATION

CALGB has appointed Arrington Travel as the official air travel coordinator for its 1999 Summer Group Meeting. Arrington Travel provides attendees with personalized, unbiased airline reservations and ticketing at the lowest available fare with one easy toll-free call. Arrington will provide:

Meeting discounts on American Airlines: 5-10% off unrestricted coach fares (valid dates: June 17-July 4, 1999)

Zone fares (fares that do not require a Saturday night stayover, but must include a two-night stay.)

Guaranteed lowest available air fare.

Full mileage credit for all frequent flyer club members.

Easy payment by all major credit cards.

To secure airline reservations, telephone Arrington at 1-800-200-6338 (Monday-Friday, 8:00 am - 5:00 pm (Central Time) or e-mail: groups@arringtonusa.com.

TRAVEL REIMBURSEMENT

Per NCI grant guidelines, your airline tickets MUST be TICKETED on a US-flag airline in order to qualify for reim-

continued on page 18

CALGB Summer Group Meeting Schedule

June 25-27, 1999 • Sheraton Centre, Toronto, Ontario, Canada

FRIDAY, JUNE 25

7am – 5 pm	Registration
8 am – 1 pm	Clinical Trials Education Session
8 am – 1 pm	Extended Executive Committee*
9 am – 1 pm	SoCRA Certification Examination*
11 – 11:30 am	CTC Palm PC Demonstrations**
1 – 2 pm	CALGB Web Site Demonstrations**
1 – 4 pm	Psycho-Oncology Committee
1 – 4 pm	Solid Tumor Correlative Sciences Committee
1 – 4 pm	CRA Committee Meeting
1:30 – 3 pm	Conflict of Interest Committee*
2 – 3 pm	CALGB Database Hands-on Training**
3 – 6 pm	Respiratory Committee
3 – 7 pm	Lymphoma Committee & Lymphoma Correlative Sciences
3 – 7 pm	Patient Advocate Training
4 – 4:30 pm	CTC Palm PC Demonstrations **
4 – 5 pm	CALGB Web Site Demonstrations**
4 – 6 pm	Institution Performance Evaluation Committee*
4 – 7 pm	Oncology Nursing Core*
5 – 6 pm	CALGB Database Hands-on Training**
6 – 9:30 pm	Data & Safety Monitoring Board*
7 – 9 pm	Transplant Core Committee*
7:30 – 9:30 pm	Data Audit Committee*

SATURDAY, JUNE 26

6:30 am – 5 pm	Registration
7 – 9 am	Foundation Board of Trustees*
7:30 – 9 am	Surgical CRA Workshop
8 – 9 am	CALGB Web Site Demonstrations**
8 am – Noon	Leukemia Committee & Leukemia Correlative Sciences
9 – 10 am	CALGB Database Hands-on Training**
9 – 10:30 am	Surgery Committee
9 – 11 am	Membership Committee*
9 am – Noon	Cancer Control Committee
9 am – Noon	CRA Training Workshop for CALGB 309801
9 am – Noon	GI Committee
10 – 10:30 am	CTC Palm PC Demonstrations **
10:45 – 11:15 am	CTC Palm PC Demonstrations **

10 am – Noon	Pharmacy Core Committee*
10:30 – 11:30 am	CALGB Web Site Demonstrations**
10:30 am – 12:30 pm	Breast Surgery Sub-Committee
10:30 am – 12:30 pm	Prostate Surgery Sub-Committee
10:30 am – 12:30 pm	Thoracic Surgery Sub-Committee
11:30 am – 12:30 pm	CALGB Database Hands-on Training**
Noon - 1 pm	Constitution Committee*
Noon - 1 pm	Health Outcomes Research Council*
1:30 – 4 pm	Plenary Session
4 – 4:30 pm	CTC Palm PC Demonstrations **
4 – 5 pm	CALGB Web Site Demonstrations**
4:45 – 5:15 pm	CTC Palm PC Demonstrations **
4 - 6 pm	Melanoma Working Group
4 - 6 pm	GI Surgery Sub-Committee
4 - 6 pm	Membership Committee*
4 – 6 pm	CCOP Committee*
4 – 7 pm	Oncology Nursing/Pharmacy Committees Joint Session
4 – 7 pm	Breast Committee
5 – 6 pm	CALGB Database Hands-on Training**
7 - 10:30 pm	Reception – Aboard the Northern Spirit Cruising Lake Ontario

SUNDAY, JUNE 27

7 – 11 am	Registration
7 – 10 am	Board of Directors*
8 – 10 am	Patient Issues Committee
8 – 10 am	Prostate-Correlative Sciences Working Group*
8:30 – 11:30 am	CRA Continuing Education Workshop
10 – 11 am	CALGB Web Site Demonstrations**
10 am – Noon	Patient Issues Committee*
10 am - Noon	Cancer in the Elderly Working Group
10 am - 1 pm	Radiation Oncology Committee
10 am - 1 pm	Pathology Committee
10 am - 1 pm	PET Committee
10 am - 1 pm	Prostate Committee
11 am – Noon	CALGB Database Hands-on Training**

* Closed meeting

** Workshops/Training advance registration required

ATTENDEE INFORMATION

NAME & TITLE _____ SOCIAL SECURITY # _____
 INSTITUTION _____ PHONE # _____
 ADDRESS _____ FAX # _____
 _____ E-MAIL _____
 CITY _____ STATE _____ ZIP _____

REGISTRATION

ADVANCE REGISTRATION DEADLINE IS JUNE 2, 1999 - *Forms must be postmarked by deadline to receive discount.*
 Please check off your selections, enter the appropriate fees, and fill in your total below.

- | | <u>COST</u> |
|---|---|
| <input type="checkbox"/> GROUP MEETING
<i>(Fee includes Agenda Book)</i> | \$40 advance/
\$65 after June 2 |
| <input type="checkbox"/> AGENDA BOOK ONLY
<i>(Order by June 2 to guarantee availability)</i> | \$30 |
| <input type="checkbox"/> DONATION TO CALGB FOUNDATION <i>(Optional)</i>
I wish to make a tax-deductible donation in the following amount:
<i>You will receive an acknowledgment from the Foundation by mail.</i> | |

REGISTRATION DATE:	
<u>PAYMENT AMOUNT</u>	<u>CHECK #</u>
\$ _____	# _____
\$ _____	# _____
\$ _____	# _____
TOTAL DUE	
\$ _____	# _____

CENTRAL OFFICE USE ONLY

WORKSHOP REGISTRATION

Advance registration is required for the following workshops. Check your selections and **circle your preferred dates and times*** where applicable. There are no extra fees for workshop attendance. If you are submitting your registration via mail, you may fax this form separately to the CALGB Meetings Manager, 312-345-0117, to reserve your spot(s).

- | | |
|---|---|
| <input type="checkbox"/> Clinical Trials Education for Nurses & CRAs
<i>Fri. June 25</i> 8 am - 1 pm | <input type="checkbox"/> CALGB Web Site Demonstration
<i>Fri. June 25</i> 1 - 2 pm 4 - 5 pm
<i>Sat. June 26</i> 8 - 9 am 10:30 - 11:30 am 4 - 5 pm
<i>Sun. June 27</i> 10 - 11 am |
| <input type="checkbox"/> NCI Common Toxicity Criteria on Palm-PCs
<i>Fri. June 25</i> 11 - 11:30 am 4 - 4:30 pm
<i>Sat. June 26</i> 10 - 10:30 am 4 - 4:30 pm
10:45 - 11:15 am 4:45 - 5:15 pm | <input type="checkbox"/> CALGB Database Hands-on Training
<i>Fri. June 25</i> 2 - 3 pm 5 - 6 pm
<i>Sat. June 26</i> 9 - 10 am 11:30 am - 12:30 pm 5 - 6 pm
<i>Sun. June 27</i> 11 am - noon |
| <input type="checkbox"/> CRA Training Workshop on CALGB 309801
<i>NOTE: Limited access study. PI approval required.</i>
<i>Sat. June 26</i> 9 am - noon | |

*Space will be assigned on a first-come basis. CALGB will assign you to one of your preferred selections. We will send you your schedule via mail.

PAYMENT

- PAYING BY CHECK:** You may pay for all items with one check. Make check(s) payable to University of Chicago/CALGB
- PAYING BY CREDIT CARD:** You may use Visa or MasterCard

CARDHOLDER'S NAME _____ Visa MasterCard
 CARD NUMBER _____ EXP. DATE _____
 CARDHOLDER'S SIGNATURE _____

IMPORTANT

CANCELLATIONS AND SUBSTITUTIONS

Regretfully, we are unable to issue refunds for meeting cancellations. If your registration has been processed and you cannot attend the meeting, you may send a substitute provided we receive your request in writing by June 9, 1999.

AGENDA BOOKS

The registration fee includes the Agenda Book. However, Agenda Books may not be available if you register after June 2.

REGISTER BY FAX OR MAIL

For credit card payment, you may fax this form to CALGB Central Office, fax # 312-345-0117. You may also mail this form with your payment to: CALGB Registration, 208 S. LaSalle, Suite 2000, Chicago, IL 60604-1104.

MEETING INFORMATION *continued from page 15*

bursement from federal funds held by CALGB or your institution. Although Arrington travel agents are aware of this rule, please be certain that when you book your travel, the agent TICKETS on the US-flag airline, i.e., American Airlines or United Airlines. Code-shares are permitted, i.e., American Airlines code-shares with Canadian Air and United code-shares with Air Canada. This means that the actual ticket notes American Airlines or United Airlines, but the carrier may be Canadian Air or Air Canada. And, each airline will have its own flight number noted. There are also true American or United Airlines flights where the carrier is an American or United Airlines plane.

GROUND TRANSPORTATION

The Sheraton Centre is approximately 25-30 minutes from Toronto's Pearson International Airport. Most convenient method of transportation to the hotel is aboard the Airport Express shuttles. Shuttles are located outside of the baggage claim area and run approximately every half-hour. One-way rate to the Sheraton is \$12.50 CAN (\$8.40 US*) or \$19.50 CAN (\$13.08 US*) round-trip. One-way cab fares are approximately \$45.00 CAN (\$30.25 US*). Due to customs and immigration regulations, airline passengers returning to the U.S. must check in two hours before flight departure. Be sure to allow sufficient time when booking your return flight.

CURRENCY EXCHANGE

Booths are located throughout the airport. Currency can also be exchanged at the hotel. Current exchange rate is approximately 1.50 Canadian dollars per U.S. dollar.*

Traveling with children:

Canada has laws and regulations to protect children and to reduce abduction by parents or others. If you will be traveling with a child, you should carry identification (similar to that mentioned above) for children of all ages; a letter of permission from the child's parent or legal guardian when traveling with a child who is not legally your own; and copies of legal documents regarding custody rights if you share custody.

Shopping:

The Goods and Services Tax (GST) is a 7% tax that is charged on most goods and services sold or provided in Canada. Foreign visitors to Canada can apply for a rebate on GST paid on accommodations (up to 30 nights per visit) and on goods purchased in Canada and subsequently exported within 60 days of the purchase. You qualify for a tax refund if you are not a resident of Canada; you have original receipt; your total refund claim is for a minimum of CAN\$14 for each tax you are claiming and for eligible goods, each individual receipt has to show a minimum of CAN\$3.50 for each tax you are claiming. You may apply for a tax refund using application forms that are available at the airport, hotel or shops. You may obtain your tax refund at any participating Canadian duty free shop (for a cash refund up to a maximum of CAN\$500) or by completing and mailing an application to Revenue Canada.

Purchases not eligible for a tax rebate include food and

beverages, entertainment, local tours and admissions to outside events, and gratuities and service charges.

Visitors from the United States: Every 30 days, returning U.S. citizens are allowed to bring back duty free \$400 (retail value) worth of merchandise, provided they have been out of the U.S. for 48 hours. If the length of the stay is less than 48 hours, \$200 worth of merchandise may be taken back to the U.S. duty free.

HOTEL RESERVATIONS**RATES:**Standard Category

Single Occupancy: \$163 CAN (\$108 USD*)

Double Occupancy: \$183 CAN (\$122 USD*)

Club Level Category

Single Occupancy: \$193 CAN (\$128 USD*)

Double Occupancy: \$213 CAN (\$142 USD*)

Room rates are subject to 7% Goods & Services Tax (GST) and 5% Provincial Sales Tax (PST). Non-residents of Canada are eligible for rebate on the GST.

Hotel Check-in/Check-out Times: Check-in is 3 p.m.; check-out is noon.

Reservations Deadline: June 2, 1999. After June 2, the hotel will release unsold rooms in the CALGB block for general sale. Reservations received after the cut-off date will be accepted on a space-available basis only and at group rates for rooms remaining in the CALGB block.

Deposits: A NON-REFUNDABLE \$100.00 US deposit will be required when reserving your guest room. This deposit will be applied toward your first night's stay.

Phone Reservations: Call the Sheraton Centre Hotel at (416) 361-1000 requesting the Reservations Department. Be sure to identify yourself as a Cancer and Leukemia Group B (CALGB) meeting attendee in order to receive the special conference rate and have credit card information available at the time of your call.

Fax Reservations: (416) 947-4801. Fax the completed copy of the Hotel Reservation Form directly to the hotel. Be sure to include your credit card information on the form along with expiration date for a NON-REFUNDABLE deposit.

Reservations by Mail: Send the completed Hotel Registration Form from this Newsletter directly to the hotel at Sheraton Centre Toronto – ATTN Reservations; 123 Queen Street West, Toronto, Ontario M5H 2M9. If using the mail-in method, be aware of your mailing date. Reservations should be received at the hotel by June 2nd to ensure availability.

HOTEL SERVICES

Business Center Services: The hotel operates a full-service business center.

*** All prices approximate based on current exchange rates. Currently \$1.00 U.S. = \$1.49 Canadian**

CALGB 1999 Summer Group Meeting
June 25-27, 1999

Hotel Reservation Form

Toronto, Ontario
Sheraton Centre Toronto Hotel

ROOM RESERVATION DEADLINE: June 2, 1999. Please print or type.

NAME _____ PHONE # _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

NO. OF PERSONS IN ROOM: _____ ARRIVAL: _____ DEPARTURE: _____
(Date/Time-check-in time is 3:00 p.m.) (Date/Time-check-out time is noon)

Non-Smoking Room Handicapped-accessible room. (Please describe handicap: _____)

RATES:

	<input type="checkbox"/> Standard	<input type="checkbox"/> Club Level	Room rates are subject to 7% Goods & Services Tax (GST) and 5% Provincial Sales Tax (PST). Non-residents of Canada are eligible for rebate on guestroom taxes.
Single	\$163 Can (\$108 US*)	\$193 Can (\$128 US*)	
Double	\$183 Can (\$122 US*)	\$213 Can (\$142 US*)	

* Approximate based on current exchange rates. Room rates are in effect June 22-30, based on availability.

ALL RESERVATIONS MUST BE ACCOMPANIED BY \$100 U.S. NON-REFUNDABLE DEPOSIT.

Deposit will be applied to your first night's stay. Deadline for receipt of reservations is June 2, 1999. Reservations received after deadline will be accommodated on space-available basis; group rates apply if rooms are available in the CALGB block.

PAYING BY CHECK: Make your check for \$100 non-refundable deposit payable to Sheraton Centre Toronto Hotel.

PAYING BY CREDIT CARD:

Please provide credit card information below to guarantee your reservation. I understand my credit card will be immediately charged for my first night's deposit. **Room deposits are non-refundable.**

VISA MASTERCARD AMERICAN EXPRESS DISCOVER

CARDHOLDER'S NAME (Please print): _____

CARD NUMBER _____ EXP. DATE _____

CARDHOLDER'S SIGNATURE _____

MAIL OR FAX RESERVATION FORM TO: ATTN: Reservations, Sheraton Centre Toronto Hotel, 123 Queen Street West, Toronto, Ontario, Canada M5H 2M9. Fax: 416-947-4801; Tel.: 416-361-1000



The **CAL•GAB** is CALGB's quarterly newsletter. Copies are mailed free of charge to CALGB members. Interested non-members may also request complimentary subscriptions.

The **CALGB 40th Anniversary Book** is now shipping! Limited copies are still available. This two-volume commemorative edition features selected published studies from the Breast, Lymphoma, Respiratory, GI, Prostate and Leukemia Committees. The compiled articles offer a retrospective view of the Group's accomplishments and invaluable contributions to cancer research since 1956.

Cancel

Please **Start/Update my Cal•Gab Subscription.**

Please send me:

____ **40th Anniversary Book(s) (\$45 each)**

NAME _____ PHONE # _____

INSTITUTION _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

My check enclosed, payable to **CALGB Foundation**, in the amount of \$_____.

Mail to: CALGB Foundation
Mary A. Sherrell, M.A., Treasurer
208 S. LaSalle St., Suite 2080
Chicago, IL 60604-1104

FAX to: (312) 345-0117

CALGB CALENDAR

Summer '99 Group Meeting

June 25–27, 1999

Toronto, Ontario, Canada—*Sheraton Centre*

REGISTRATION DEADLINE

June 2, 1999

(Meeting Registration and Hotel Reservations)

Fall '99 Group Meeting

Nov. 12–14, 1999

Miami Beach, Florida—*Fontainebleu Hilton
Resort & Towers*

ABSTRACT DEADLINES

Abstracts reporting on CALGB studies must be submitted to the Central Office for review at least two weeks prior to the submission deadline.

	ABSTRACTS DUE AT CENTRAL OFFICE	SUBMISSION DEADLINE	MEETING DATE	LOCATION
ASH American Society of Hematology	August 16, 1999	Sept. 1, 1999	Dec. 3–7, 1999	New Orleans
AACR American Association for Cancer Research	October 16, 1999	Nov. 1, 1999	April 1–5, 2000	San Francisco



Cancer and Leukemia Group B
Central Office of the Chair
208 S. LaSalle St., Suite 2000
Chicago, IL 60604-1104