

Fall Group Meeting to Take Place November 21-23 in Orlando at Hilton at Walt Disney World Village



This overhead view of the hotel and its surroundings showcases the beauty of the area and all the amenities available to CALGB Fall Group Meeting attendees.

Inside:	Page
Fall Meeting Information	13-24
Message from the Group Statistician	2
Protocol Updates	4
Oncology Nursing Articles	6-7
New Patient Follow-up Requirements	8-9
Building Patient Advocate and Research Partnerships	11

The Cal Gab is published quarterly by the Cancer and Leukemia Group B and distributed to the active membership.

Suggestions for articles are encouraged.

Copy deadlines are:

February 15, June 15, August 15, November 15

Articles should be sent to:

Christina Hoffman, Newsletter Editor
Cancer and Leukemia Group B
208 South LaSalle Street, Suite 2000
Chicago, IL 60604-1104

(773) 702-9479 FAX (312) 345-0117

e-mail: choffman@midway.uchicago.edu

<http://www.calgb.uchicago.edu>

*Please Note: 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.

Reminder

Deadline for *AACR abstracts* is October 28. Please submit them to the CALGB Central Office by October 14.

Deadline for *ASCO abstracts* is December 4. Please submit them to the CALGB Central Office by November 20.

Message from the Group Statistician

New CALGB Information System Begins Operation

During the last few years, the CALGB Information Systems Group has been developing a new information system. The major change from the past lies in the concept of a single, official CALGB database combining administrative, regulatory, and scientific data. This integration allows for automated activities not previously feasible. Also, access to the system will be via graphical user interfaces already familiar to those using modern personal computer systems. This in turn will permit easy on-line access from the field for appropriate uses by members with proper authorization. One example of this is the new on-line registration system which will be implemented in several stages over the coming months.

Much of the effort to date has been devoted to the behind-the-scenes work of laying a solid foundation for the new structure through development of requirements and specifications for the new system. The first tangible evidence of this development activity has taken place recently with the activation of the administrative part of the system and the establishment of network connections between the Central Office at the University of Chicago and the Statistical Center at Duke University. The details given below were prepared by Don Kasprzak, Michael Moloney, and Rick Preston.

The new on-line CALGB system began operation July 14 when the Central Office and the Statistical Center established the necessary high-speed dedicated network connections between the University of Chicago and Duke University. The established connection is a private, secure data line. This system provides realtime updates to the Group's administrative, statistical, and data management teams located at both sites. It also permits both

offices to exchange information dynamically without delay.

Previously, data uploads occurred at the end of each business day. Data was uploaded from the Central Office to the Statistical Center. The updates would not be ready for use until the following business day.

The new system has permitted appropriate personnel (e.g., the Regulatory Affairs Coordinator at the Central Office; data coordinators at the Statistical Center) to add, update, or modify data in realtime. Then, authorized users can view the updated information immediately.

The system is built to support the multiple data needs of the Group, including administrative, patient registration, statistical, and scientific, including the research laboratories. It has been distributed to multiple computer platforms including Windows 95 and NT, and PowerMacintosh. There have been and will continue to be incremental updates released as the development team continues to add enhancements. Access will require an account and a unique email address, which will be determined by privileges granted to the role individuals have within the group. You will hear more about the security and authorizations in a later newsletter.

The new system also provides levels of automation to better serve the user community. Following a conversion of data from the Central Office to the Statistical Center, the new system now automatically generates new ID numbers for participants and institutions. Unique, automated ID numbers were necessary for the on-line patient registration currently in the early stages of implementation at main member institutions.

LabTrak, the laboratory sample tracking system, provides for the collection, storage, distribution, and tracking of samples submitted by treating institutions for research and

analysis. The LabTrak system has been developed as part of the new information system. It can be utilized for any CALGB protocol and will be used to track all CALGB samples obtained on those protocols. Many of these samples will be stored and processed at CALGB sample banks or repositories, such as the Leukemia Tissue Bank. These banks and repositories follow procedures defined in an approved banking protocol. Samples that are stored at a repository are then made available, after appropriate review of the request, to other CALGB researchers. Watch for new developments in the near future.

Stephen George, PhD

Important Fall Meeting Information.....

CALGB Fall Meeting Reception

Saturday, November 22
7pm to 10pm



Once again, the CALGB will host a reception on the Saturday evening of the Fall Group Meeting. All attendees and their guests are invited.

We invite you to partake in an Epcot World Showcase Reception to be held poolside at the Hilton at Walt Disney World Village. The reception will begin at 7:00 pm and end at 10:00 pm. In the event of inclement weather, the reception will be held in the pavilion adjacent to the pool. Enjoy this unique culinary tour of exotic ports of call. Be sure not to miss this opportunity to network with your colleagues. Suggested dress attire for the evening is "dressy casual". Following the reception, attendees may take advantage of the entertainment options across the street at Pleasure Island.

Introducing, New CALGB Staff.....

Kristi Cooke, the new Data Coordinator on the Leukemia Committee, has been employed by the CALGB since April. Before that, she worked as an administrative assistant for a real estate firm in Chapel Hill, NC. Ms. Cooke has a B.A. in biology from the University of North Carolina at Chapel Hill.

Edward Elliott is employed by the CALGB Statistical Center as an Analyst/Programmer II. Most of his career has been spent as a member of the Air Force. However, most recently, Mr. Elliott worked for Century Data Systems in Raleigh, NC.

Christina Hoffman is the new Publications Coordinator in the Central Office. Ms. Hoffman previously worked as a managing editor in the publications department of the Radiological Society of North America. She has a B.S. in communications from Illinois State University and an M.A. in journalism from Indiana University.

Alaina Johnson is a new Computer Programmer II at the CALGB's Statistical Center. A Duke University employee since 1982, Ms. Johnson's previous position was Analyst/Programmer with the Division of Medical Informatics, a division of the Department of Community and Family Medicine.

Poonam McFarland came to Durham, NC, from her native India in September 1995. She is employed as a Data Technician at the CALGB Statistical Center. Ms. McFarland has a bachelor's degree in Commerce from the University of Madras.

Janice Stewart, an employee of the University of Chicago for the past seven years, has recently taken the position of Accounting Assistant for the CALGB Central Office. Ms. Stewart has an associate's degree from Sawyer Business College, Hammond, IN, in accounting.

Elizabeth Stoepler is a new Data Coordinator at the CALGB Statistical Center. She has a B.S. in environmental sociobiology from Juniata College in Huntingdon, PA. She was most recently employed as a Data Technician at Pharmaceutical Product Development.

John Taylor has recently joined the Central Office as a Protocol Editor. Mr. Taylor has a B.A. from the University of Utah in biology and history and an M.A. in history from the University of Iowa. Prior to his employment at the CALGB, he was involved in teaching and research at the University of Iowa.

Penny Wade began her employment at the Statistical Center in August as a Data Coordinator on the Leukemia Committee. Prior to August, she worked for Glaxo Wellcome as an administrative assistant. Ms. Wade has a B.A. in psychology from Elon College.

Protocol Updates

Protocol Activations

3/15/97

CALGB 9760: Multidrug Resistance Studies in Acute Myeloid Leukemia. Study Chair: Maria Baer, M.D.

CALGB 9683: A Phase II Study of Oral GW776 (NSC #687296), 5-Fluorouracil (5-FU) (NSC #19893), and Leucovorin (LV) in Patients with Advanced Colorectal Carcinoma. Study Chair: Neal J. Meropol, M.D.

4/15/97

CALGB 9761: Detection of Occult Micrometastases in Patients with Clinical Stage I NSCLC: A Prospective Analysis. Study Chair: Michael Maddaus, M.D.

CALGB 9661: A Pilot Study of Low-Dose Interleukin-2 Plus Recombinant Human Anti-Her2 Monoclonal Antibody in Solid Tumors. Study Chair: Neal J. Meropol, M.D.

CALGB 9596: Phase II Study of PSC-833 in Combination with Vincristine, Doxorubicin, and Dexamethasone (PSC-833/VAD) Versus VAD Alone in Patients with Relapsing or Refractory Multiple Myeloma. Study Chair: Charles Schiffer, M.D.

5/31/97

CALGB 9581: Phase III Randomized Study of Adjuvant Immunotherapy with Monoclonal Antibody 17-1A Versus No Adjuvant Therapy Following Resection for Stage II (Modified Astler-Coller B2) Adenocarcinoma of the Colon. Study Chair: Thomas A. Colacchio, M.D.

CALGB 9687: The Role of Salvage Prostatectomy for Radiation Failure in Prostate Carcinoma: A Phase II Trial. Study Chair: Gary Steinberg, M.D.

CALGB 9682: Prognostic Significance of Endorectal MRI in Predicting Outcome After Combined Radiation and Androgen Suppression for Prostate Cancer: A Prospective Phase II Study. Study Chair: Anthony D'Amico, M.D., Ph.D.

7/15/97

CALGB 9731: Weekly Paclitaxel for Advanced Non-Small Cell Lung Cancer: A Phase II Limited Access Trial. Study Chair: Wallace Akerley, M.D.

Protocol Closures

CALGB 9254: Anti-B4-Blocked-Ricin (NSC# 639185) Adjuvant Therapy Post-Autologous Bone Marrow Transplant: A Phase III Study. Study Chair: Michael L. Grossbard, M.D. (3/18/97)

CALGB 9293: Phase III Double-Blind Randomized Trial of 13-Cis Retinoic Acid (13-CRA) to Prevent Second Primary Tumors (SPTS) in Stage I Non-small Cell Lung Cancer. Study Chair: Everett E. Vokes, M.D. (3/19/97)

CALGB 9331: A Phase II Feasibility Study of High Dose Cyclophosphamide, Cisplatin and Carmustine (CBP) Therapy as Consolidation for Patients with Limited Small Cell Lung Cancer (SCLC) in or Near Complete Response to Chemoradiotherapy. Study Chair: Anthony Elias, M.D. (3/31/97)

CALGB 9344: Doxorubicin Dose Escalation, With or Without Taxol, as Part of the CA Adjuvant Chemotherapy Regimen for Node Positive Breast Cancer: A Phase III Intergroup Study. Study Chair: I. Craig Henderson, M.D. (4/15/97)

CALGB 9631: High Dose Doxorubicin with Recombinant Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) plus Dexrazoxane for Malignant Mesothelioma: A Phase II Study. Study Chair: Michael P. Kosty, M.D. (7/15/97)

CALGB 9530: Gemcitabine (NSC #613327) for Malignant Mesothelioma: A Phase II Study. Study Chair: Frederick Millard, M.D. (3/15/97)

CALGB 9593: Phase III Randomized Trial Comparing Total Androgen Blockade versus Total Androgen

Blockade plus Pelvic Irradiation in Clinical Stage T3-4, NO,MO Adenocarcinoma of the Prostate. Study Co-Chair: Srinivasan Vijayakumar, M.D. (3/31/97)

CALGB 8361: Immunological Diagnostic Studies in AML. Study Chairs: Carlton Stewart, M.D. and Maria Baer, M.D. (5/30/97)

CALGB 9255: Phase II Study of Cyclophosphamide, Prednisone, and Infusional Doxorubicin Vincristine, and Etoposide (I-CHOPE) in Diffuse Lymphomas Relapse/Refractory to Bolus Therapy. Study Chair: Stuart Lichtman, M.D. (5/15/97)

CALGB 9394: Phase III Comparison of Adjuvant Chemotherapy with High-Dose Cyclophosphamide Plus Doxorubicin (AC) Versus Sequential Doxorubicin Followed by Cyclophosphamide (A->C) in High-Risk Breast Cancer Patients With 0-3 Positive Nodes (Intergroup). Study Chair: Charles Shapiro, M.D. (5/1/97)

CALGB 9450: Phase II Trial of Sequential Chemotherapy and Radiotherapy for AIDS-Related Primary Central Nervous System Lymphoma and Laboratory Correlate: Epstein-Barr Virus in Cerebrospinal Fluid in AIDS-Related Primary Central Nervous System Lymphoma. Study Chair: Richard F. Ambinder, M.D., Ph.D. (4/15/97)

CALGB 9342: A Phase III Study of Taxol at Three Dose Levels in the Treatment of Patients with Metastatic Breast Cancer. Study Chair: Eric Winer, M.D. (7/31/97)

CALGB 9420: Phase I Evaluation of Modulation of MDR with PSC-833 (NSC#648265) in patients with AML >or= 60 years, followed by rIL-2 (NSC#373364), Post-Completion of Chemotherapy. Study Chairs: Edward J. Lee, M.D., Michael Caligiuri, M.D.. (7/29/97)

Clinical Research Associate Liaisons

Due to the recent re-structuring of the CRA Liaison Program, six CRA liaisons to the disease committees (Breast, GI, Prostate, Leukemia, Lymphoma, and Respiratory) became members of the CRA Committee. Each disease liaison will also cover the modality committees that are relevant to individual disease committee protocols. As one can imagine, dividing the responsibility for draft protocol reviews and new/revised form reviews among six liaisons

who will still be performing their institutional responsibilities, constitutes an enormous duty.

Therefore, so that CRAs can continue to participate in the protocol and forms review process, we are asking for CRAs to volunteer their expertise if they have at least two years experience, either in CALGB or in another clinical research setting. This is an opportunity to contribute to the content of new protocols as well as the data collected, and also to determine

the appropriateness and usefulness of the data collection forms we all use. Draft review checklists and form review guidelines are available to help you through the processes. Please take this opportunity to make a difference.

If you are interested in participating, please complete the form below and fax or mail to: Terry Moore, North Shore University Hospital, 300 Community Drive, Manhasset, NY 11030; Fax (516)562-8950.

Call for CRA Volunteers

Name _____

Institution _____

Address _____

Phone _____

FAX _____

Email address _____

Please check one or both:

Draft Protocol Reviews Form Reviews

Please list specific diseases and/or modalities that interest you:

Testing for the BRCA1 Gene and Genetic Counseling

by Gail McCue Donnery, R.N., M.S.N., A.N.P., O.C.N., University Hospital, Syracuse, NY

Question: What is the BRCA1 gene? What is the clinical significance of gene mutation and who should be considered for genetic testing and counseling?

Answer: The BRCA1 (Breast Cancer) gene has been identified as both a breast cancer and an ovarian cancer susceptibility gene. The gene has now been cloned and more than 80 mutations have been detected.¹ Susceptibility to breast cancer can be inherited from either a mother or father. The offspring of a carrier has a 50% chance of inheriting the mutation.^{1,2} The BRCA1 gene is believed to act as a tumor suppressor gene. Individuals become susceptible to breast cancer when they inherit a mutated copy of the BRCA1 gene, which causes inactivation of that one copy. In order for tumorigenesis to occur, both copies of the gene must be inactivated.³ Women with a BRCA1 mutation on one copy of the genes are more susceptible to developing breast cancer due to the fact that one cancer causing mutation is present in all cells at birth. Therefore, fewer non-inherited mutations specific for breast cancer are needed for tumorigenesis.² The BRCA1 mutation appears to be responsible for 5% of all breast cancers. Women with the mutation have an 85-90% chance of developing breast cancer by the age of seventy.^{1,3}

Until very recently genetic testing for breast cancer susceptibility was being done in controlled clinical trials. In the fall of 1996, genetic sequence analysis for susceptibility to breast and ovarian cancer was made available to health care providers by a commercial laboratory. The general public is becoming more aware of genetic testing. Recently *Parade*, a Sunday newspaper magazine, ran an article about gene testing and breast cancer. With this new awareness of genetic testing it is anticipated that many women will request testing.

The literature is very specific as to who should be considered for genetic testing for breast cancer:^{1,4} 1) Women with multiple family members with breast or ovarian cancer. First degree relatives with breast cancer increase a women's risk of developing breast cancer threefold. The risk increases as the age of the first degree relative with breast cancer decreases. 2) Women who are known to have a blood relative with a BRCA1 or BRCA2 mutation. 3) Women who have been diagnosed with breast cancer. Women with breast cancer linked to the BRCA1 gene have been shown to be at a significantly higher risk of contralateral disease

Not all women who fall into the high risk category for the BRCA 1 mutation will want to be tested. These women must be supported in their decision not to be tested. They must be encouraged to participate in an

increased surveillance program with their health care providers to detect any breast cancer at an early stage. There are also psychological factors to be considered. Women who test positive live with the fear of knowing there is a 90% chance they will develop breast cancer in their lifetime. Testing positive may also factor into a young woman's decision to marry and start a family.⁵ Then there are the women who test negative but have siblings who test positive. These women have a tendency to feel guilty for testing negative and may live with the "why not me" syndrome. Testing negative for the BRCA1 mutation does not mean a woman is not at risk for developing breast cancer some time in her lifetime. A 10% lifetime risk of breast cancer applies to these women just as to women in the general population of the United States. These women should be encouraged to follow the American Cancer Society recommendations for breast self-examination and mammograms. There are also ethical and legal issues when considering genetic testing. People who have admitted to having a hereditary predisposition to an illness on employment or insurance forms have been denied services due to this preexisting condition. Though the practice of denying service or employment is illegal in most states, there are ways for businesses to circumvent this.^{5,6} It is because of the above concerns that pre- and post-test counseling is encouraged for all women undergoing genetic testing.

References

1. Cole, DEC, Gallinger, S, McCreedy, DR, Rosen, B, Engel, J, & Malkin, D. (1996). Genetic counseling and testing for susceptibility to breast, ovarian and colon cancer: Where are we today? *Canadian Medical Association Journal*, 154 (2), 149-155.
2. King, MC, Rowell, S, & Love, SM. (1993). Inherited breast and ovarian cancer: What are the risks? What are the choices? *JAMA*, 269 (15), 1975-1980.
3. Lancaster, JM, & Wiseman, RW, Berchuck, A. (1996). An inevitable dilemma: Prenatal testing for mutations in the BRCA 1 breast-ovarian cancer susceptibility gene. *Obstetrics & Gynecology*, 87 (2), 306-309.
4. Lerman, C, & Croyle, R. (1994). Psychological issues in genetic testing for breast cancer susceptibility. *Archives of Internal Medicine*, 154 (6), 609-616.
5. Dickens, BM, Pei, N, & Taylor, KM. (1996). Legal and ethical issues in genetic testing and counseling for susceptibility to breast, ovarian and colon cancer. *Canadian Medical Association Journal*, 154 (6), 813-818.
6. Billings, PR, Kohn, MA, de Cuevas, M, Beckwith, J, Alper, JS, & Matowicz, MR. (1991). Discrimination as a consequence of genetic testing. *American Journal of Human Genetics*, 50, 476-482.

Suramin for Hormone Refractory Prostate Cancer

By Mary Elshamy, M.S.N., R.N., Dartmouth-Hitchcock Medical Center

Suramin was first synthesized in 1916 for the treatment of African trypanosomiasis and onchocerciasis and used extensively for about 20 years. Interest in suramin was renewed in the 1980s when the observation was made that suramin is a potent reverse transcriptase inhibitor. Its effect on human immunodeficiency virus (HIV) was explored in clinical trials with responses noted in patients with HIV related malignancies. Further research revealed that suramin blocks the binding of a number of tumor growth factors to their cell surface receptors and antagonizes the ability of the factors to stimulate tumor cell growth in tissue culture. This led to testing in patients with a variety of metastatic cancers. Early results showed evidence of minimal or partial responses, particularly in prostate cancer, suggesting that suramin is an active agent in metastatic disease (Eisenberger et al, 1993; Stein, LaRocca, Thomas, McAtee & Myers, 1989).

The use of suramin in metastatic hormone refractory prostate cancer has been studied with interest based on several observations. Peptide growth factors blocked by suramin include platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF- β), epidermal growth factor (EGF), and basic fibroblast growth factor (FGF). The interruption of the growth factor pathway blocks the autocrine loop which is believed to be responsible for malignant transformation of cells. Suramin is an adrenocorticolytic drug that may slow prostate cell proliferation by lowering circulating adrenal androgen levels. Additionally, the growth of human prostate cancer cell lines in cell culture medium is inhibited in the presence of suramin at concentrations achievable clinically (Upadhyaya & Vogelzang, 1997).

The concentration of suramin in plasma is critical for both efficacy as well as minimizing toxicity. Adaptive control feedback dosing, using individual patient doses based on pharmacokinetic (PK) measurements and algorithms of individual PK parameters, is the most extensively tested approach but is costly and prohibitively inconvenient for patients and providers. CALGB 9480 is a study of three suramin dose levels, low, intermediate, and high, given according to the regimen studied at the University of Chicago (Kobayashi et al, 1994). The objectives of this include tumor response, toxicity, survival, and failure-free survival among the three dose levels. Additionally, pharmacokinetic studies, monitoring of FGF and PSA levels, as well as studying the quality of life among the population are included. As an available companion, CALGB 9663 is a study of bone marrow specimens collected in patients with

hormone refractory prostate cancer prior to starting on suramin. Objectives of the bone marrow study include determining the frequency of bone marrow invasion by prostate cancer cells along with the frequency of androgen receptor mutations. Secondary objectives will evaluate correlation of androgen receptor mutations with clinical outcomes, including survival and response, as well as the impact of pelvic irradiation on the ability to obtain informative bone marrow tissue.

Suramin is known to cause adrenal insufficiency. Patients enrolled on the suramin trial are given hydrocortisone replacement therapy to correct the glucocorticoid deficit. Patients enrolled into the high dose arm of the study are also supplemented with fludrocortisone due to potential mineral corticoid deficiency. It is recommended that patients receiving suramin and replacement cortisols wear a medic alert bracelet stating "adrenal insufficiency" to alert emergency medical personnel. The need for replacement cortisols may be lifelong and is determined by periodic ACTH stimulation testing.

Suramin is known to lower fibrinogen levels; therefore, patients are prohibited from study entry if they have evidence of decreased fibrinogen, increased PT, or PTT values. Additionally, patients receiving suramin must not use aspirin, warfarin, or heparin during treatment.

Over 140 patients have received suramin on the CALGB 9480 trial since the end of 1995. Analysis of toxicity data to date has demonstrated that cardiac arrhythmia, primarily atrial fibrillation, has been the most common grade 4 adverse event occurring in six of 62 patients analyzed. Other grade 4 toxicities to date have included edema, dyspnea, neutropenia, infections, and myalgias each occurring in three of 62 patients. Two patients experienced a grade 4 decline in platelet count and pO₂ levels. Less frequently seen were neuropathies and alterations in fibrinogen and prothrombin measurements. These toxicities only occurred at the intermediate and high dose levels.

Quality of life during suramin therapy will also be explored in this clinical trial using a global measure as well as measurement of pain and depression. These symptoms are often observed in patients with advanced cancer and it is hypothesized that increasing doses of suramin will not significantly decrease quality of life measurements.

References for this article can be found on page 10.

New Follow-up Terminology and Data Submission Requirements

By Sherry Breaux and Judith Wheeler, CALGB Statistical Center

In April 1997, the CALGB revised its Policies and Procedures Manual to include an updated section describing follow-up requirements. As part of the revisions, a table was included in an attempt to simplify what can be a complex and confusing issue: the extent of follow-up that is required according to a patient's status with respect to endpoints. The section also provides definition and clarification of the new long-term follow-up procedures implemented in many protocols activated since January 1996, and explains the linkage between these procedures and those used on studies which used the old "on-study/off-study" definitions. The on/off study terminology is not being used in new CALGB protocols to define follow-up or data submission requirements.

As indicated in section 8.1.2.1 of the Policies and Procedures Manual, the difference between studies using on/off study procedures and those using long-term follow-up procedures is not the amount of follow-up required by the institution (i.e., the frequency of contact with the patient or the examinations required as defined in the protocol). The primary distinction is the decrease in data submission to the DMC after 1 year post-completion of treatment for those studies using the new procedures.

New Follow-up Terminology

The follow-up requirements table therefore applies to all CALGB studies, those using long-term data submission procedures and those using the old on/off study definitions. A column is included in the table to show which on/off study category applies to the examples provided. In the table, follow-up

data are categorized as toxicity, relapse/progression, secondary malignancy, and survival. Based on the amount of follow-up required, the table defines the extent of follow-up using new terms: complete, limited, or none.

For patients who have not reached the endpoints of the study, the institution must continue to follow the patient for all categories (complete follow-up). The same applies to patients who start treatment but did not continue to receive it. This includes patients who withdrew consent to treat with permission to follow, those with excessive toxicity or extraordinary medical circumstances, MD decision to stop treatment, or patients who are declared ineligible after start of treatment. Once a patient has reached all appropriate endpoints, limited follow-up is required, namely secondary malignancy and survival data. If a patient withdraws consent for clinical evaluation, but agrees to be followed for survival, then survival data alone are collected. If a patient refuses all follow-up, including survival, then no further follow-up is expected. For both examples involving patient refusal, a letter signed by the patient indicating withdrawal of consent must be sent to the DMC. A patient who was registered to a study but never received treatment (cancelled) must only be followed for survival.

A change in policy can be found in example 3 of the table. Patients who begin non-protocol treatment need not be followed for toxicity because it is difficult to determine which treatment is causing toxicity. However, follow-up for these patients must continue in the three other categories.

Reduced Data Submission Requirements

In 1996, CALGB introduced in most new protocols the policy of reduced data submission requirements during long-term follow-up. As summarized in the update in Section 8.1.2.1 of the Policies and Procedures Manual, "after 1 year post-completion of protocol treatment, data submission for event-free patients is limited to the Long-Term Follow-Up Form which is sent every 6 months. More extensive data is required only if an event occurs, as defined in the protocol." A major victory for the dream of data reduction! No more flow sheets, no lab or test results, only one follow-up form required twice a year.

Note, however, that reduced data submission procedures have not yet been applied retroactively to pre-1996 studies. Also, some studies activated since January 1996 do not use the new procedures, since it was determined that they would not capture sufficient follow-up information to meet the study objectives. The new Long-term Follow-up Form and procedures should be used ONLY on those new studies in which they are required per the protocol data submission section.

As terms and requirements change, the main factors to remember are: consult the new table and the protocol to determine whether protocol specifications override the general policy and if you still have questions, consult with the Data Coordinator for the study. Communication and clarification will result in a much-desired work load reduction and more focused research.

CALGB FOLLOW-UP REQUIREMENTS*

EXAMPLE	FOLLOW-UP REQUIRED	FOLLOW PATIENT FOR :				ON-STUDY OR OFF-STUDY STATUS
		TOXICITY	RELAPSE OR PROGRESSION	SECONDARY MALIGNANCY	SURVIVAL	
Patient completed Rx, but has not reached endpoint defined in the protocol†	Complete	X	X	X	X	On
Patient started Rx but did not continue to receive it‡	Complete	X	X	X	X	On
Patient started a therapy (chemo, surgery, radiation, etc.) not defined in the protocol	Limited		X	X	X	On
Patient reached all appropriate endpoints defined in the protocol	Limited			X	X	OFF
Patient was cancelled (was registered but was withdrawn before treatment started)	Limited				X	OFF
Patient started Rx but withdrew consent for clinical status follow-up¶	Limited				X	OFF
Patient started Rx but withdrew consent for clinical and survival status follow-up¶	None					OFF

*Follow-up requirements specified in the protocol take precedence over those indicated in this table.

†This usually means that the patient has not progressed or relapsed.

‡Includes withdrawn patient consent to treat with permission to follow, excessive toxicity, extraordinary medical circumstances, M.D. decision, and ineligibility declared after the start of treatment.

¶Institution must provide the Data Management Center with documentation signed by the patient indicating the withdrawal of consent for follow-up.

References from Suramin article on page 7

Eisenberger MA, Reyno LM, Jodrell DI, Sinibaldi VJ, Tkaczuk KH, Sridhara R, Zuhowski EG, Lowitt MH, Jacobs SC & Egorin MJ (1993) Suramin, an active drug for prostate cancer: interim observations in a phase I trial. *Journal of the National Cancer Institute*, 85, 611-621.

Kobayashi K, Vokes EE, Janusch L, Vogelzang NJ, & Ratain MJ. (1994) Suramin is safe and active in prostate cancer without adaptive control: evidence for dose-response. *Proc ASCO*, 13, 140.

Stein CA, LaRocca RV, Thomas R, McAtee N & Meyers CE. (1989) Suramin: An anticancer drug with a unique mechanism of action. *Journal of Clinical Oncology*, 7, 499-508.

Upadhyaya H & Vogelzang NJ. (1997) Chemotherapy for prostate cancer. In MS Ernstoff, JA Heaney & RE Peschel (Eds.), *Urologic Cancer* (pp. 181-198). Cambridge, MA: Blackwell Science.

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, contact: Mary Sherrell, CALGB Financial Officer, (773) 702-9856.

- 8892 Orch/LHRH Analog + Flut +/- Suramin/HC (ECOG)
- 9170 Febrile Episodes in Neutropenia
- 9270 Asprn: Early Stage Colorect. in Hi Risk Pats
- 9334 Sclerosis: Pleural Effusions-Talc Thoracos. vs Slurry
- 9335 NSC: Video Asstd Wedge Resctn + RT in High risk T1
- 9371 Weight Loss Prgrm of Women w. BR Cancer
- 9380 Thoracoscopic Staging for Esophageal Cancer
- 9411 Econ Analysis/Modeling of Costs of Care for CALGB 9111
- 9431 NSC: Cisplat "Doublets" in Unresctble St III
- 9473 Trial of Omega 3 Fatty Acids for Cancer Cachexia
- 9480 Suramin Dose Comparison in Adv Prostate Cancer
- 9481 FUDR, LV + Dex vs. 5-FU, LV Colorectal Ca Hep Met
- 9484 Linkage Mol & Epidem Br Ca Invest Spec Registry Comp
- 9490 Oral Analgesic Protocol Improve Pain Control?
- 9499 13-cRetin: 2nd Prim Tmrs H&N (RTOG 9115/MDACC)
- 9511 PEG-Asparaginase During Chemo for Acute ALL
- 9594 Intermittent Androgen Depriv St D2 (SWOG 9346)
- 9670 Barriers to Part of Older Women in Breast Ca Trials
- 9680 High-Dose Mitoxantrone + HC in Men w Prostate Ca

THANKS....

The following organizations have generously supported CALGB research, educational programs, publications, and data resources during 1997.

Alza Pharmaceuticals
Amgen Inc.
Berlex Laboratories
Breast Cancer Research Foundation
Bristol-Myers Squibb Oncology
Glaxo Wellcome Oncology
Immunix Corporation
Janssen Pharmaceutica Research Foundation
Leukemia Clinical Research Foundation
Lilly Oncology
Nexstar Pharmaceuticals
Novartis Oncology
Ortho Biotech Inc.
Pfizer Inc.
Pharmacia & Upjohn
Rhône-Poulenc Rorer Pharmaceuticals Inc.
Schering Corporation
SmithKline Beecham
Strato/Infusaid, Inc.
T.J. Martell Foundation for Leukemia, Cancer and AIDS Research
Vysis/ATC Diagnostics, Inc.
Zeneca Pharmaceuticals

Building Patient Advocate and Research Partnerships

By Deborah Collyar, President, Patient Advocates in Research (PAIR)

Patient advocates and cancer researchers have many common goals, such as:

- 1) Making progress against cancer with new therapies, support, and prevention;
- 2) Eliminating barriers to progress;
- 3) Increasing creativity and innovation; and
- 4) Protecting people from harm (physical, emotional, social, and economic).

Advocates and researchers have very different approaches, however. So the question has always been, how do we work together toward these common goals?

CALGB has included patient advocates in the Breast Committee for the past 3 years. The partnership has been very successful, and the Executive Committee has now decided to include patient advocates in all disease committees. In order to help this partnership work as effectively as possible, this article discusses how advocates think, how to become partners, and how to find advocates.

How Advocates Think

Advocates concentrate on the patient's point of view, although science also interests them. They don't need to become excellent scientists---CALGB already has that covered. Because advocates automatically focus on the end result and its impact on cancer survivors (a broader endpoint than most trials include), they consider people long before a trial is ready to accrue. Bringing that patient perspective into the clinical trial process will help the CALGB:

- 1) Design trials that are more appealing to patients while answering scientific questions, and
- 2) Possibly increase accrual rates so we can answer more questions sooner.

Advocates want the most value possible out of each clinical trial, and they want the results as soon as possible. These are two considerations that should always be major motivators to scientists as well, and many of you try. The difference between our approaches, however, is that you have accepted the limitations of the clinical trial system. We don't, and we're changing them so that the system works for you, not against you.

People who enter trials should be thought of as participants, never "subjects." Advocates are working with the Office for Protection from Research Risks (OPRR) and Institutional Review Boards (IRBs) across the country to help balance the efforts to protect people and still accomplish research that can improve people's lives. The sooner the scientific community readjusts its image to participants, the sooner the system will change. IRBs may even be more receptive if they see that researchers treat clinical trials more as a partnership than a sterile experiment.

Finding ways to maximize the knowledge that can be gained from their participation is critical to the patient community. Correlative science and new approaches that lead to more effective treatment and care are enthusiastically supported. P.I.s and institutions that don't develop and promote *real* partnership with multiple scientific disciplines will fall behind those that do.

Better approaches with less toxicity are also fundamental factors that concern patient advocates. Having someone personally focused on how each study impacts cancer patients in their daily lives can help make clinical trials more practical. This may also help the trial results translate more quickly into oncology practices across the country (another thing that is rarely addressed). That is, after all, why the public thinks clinical trials are done in the first place.

How to Become Partners

Remember that our goals are the same, even if our focus is different. Obviously, patient advocates need to learn about CALGB and how the clinical trial process works.

Expect a learning curve when advocates first get involved with your committees, and try to discuss your concepts in "plain English". This does not mean talking down to them, or speaking "lay language" (a term that should be eliminated because it sets up an artificial barrier that doesn't need to be there).

I can tell you from numerous experiences that many of your own colleagues remain confused about what you're doing until you state the concepts simply and clearly! There is also little reason for other people to support your efforts unless you connect those efforts to people's everyday lives. CALGB is currently assembling advocate orientation materials, and welcomes your ideas and input. You can send them to Deborah Berg, Dana Farber Cancer Institute, Dept. of Medical Oncology, 44 Binney St, Boston, MA 02115. Or you can send them to me, Deborah Collyar, at the address that appears at the very end of this article.

(Continued on next page)

(Continued from previous page)

The advocates that get involved in research are interrupting their own careers to contribute. There is no hierarchy for them to aspire to (in other words, this is not a job to them). It is important to realize this, and respect the commitment and sacrifices required of them. They are here because they truly believe that partnering with excellent scientists will create the kind of synergy that can help us find better and faster ways to help cancer patients. They can be passionate and frustrated at times, but don't confuse this with not being objective. Their eye is always on the prize, and they will do what it takes to make clinical trials better for current participants and for future cancer patients.

Believe it or not, clinicians also learn new ways to approach problems. Advocate involvement helps spur more brainstorming on ways to accomplish goals with a "can do" attitude. One of the real assets that advocates bring is the fact that we are not a part of "the system", so we continually question why things are done in the current ways. If it doesn't make sense, advocates can help make changes in the system that help science rather than hinder it. The faster you can help them learn how the system works, the faster they can help improve it.

How to Find Advocates for CALGB
Not all patients, or patient advocates, will be effective in CALGB. That's okay, because we only need a few people who really want to help make research better. They can provide valuable input while learning about the clinical trial process. Here are a few things to keep in mind while you scout for potential advocate members:

- 1) Advocates must be able to represent the broader patient community, not solely their own situation or experience.
- 2) They must be able to voice their opinions, even in intimidating situations.
- 4) Persistence and not taking things personally are valuable assets; in this context, it is better not to have scientists or medical professionals.
- 5) They must be willing to learn, and to become involved partners.
- 6) It is preferable to have survivors, but in some cases, family members may also be effective, especially in germline issues and prevention. (Remember that prevention from recurrence as well as from cancer are both important.)

CALGB needs your help in finding advocates that can be effective members. Each committee can have up to 3 advocates. If you have someone in mind, give his or her name and personal information to your committee chair, and to Dr. Schilsky. The advocate candidates will then talk to several people, including CALGB advocates, who can explain the process and measure each candidate's experiences to the important work that lies ahead.

Comments or future topics you would like to see covered may be directed to :

Deborah Collyar
PAIR
P.O. Box 1551
Danville, CA 94526-1551
510/736-8155
510/736-2836 fax
collyar@worldnet.att.net

Central Office Holiday Closings

The CALGB Central Office will be closed or will close early on the following days. Please schedule your calls accordingly so that we don't miss them. Thank you.

November 27, Thanksgiving Day

November 28

December 19, at 3:00 pm

December 24, Christmas Eve, at 2:00 pm

December 25, Christmas Day

December 31, New Year's Eve, at 2:00 pm

January 1, New Year's Day

CALGB Fall Meeting Information

Location

Hilton at Walt Disney World Village
1751 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830
Telephone: (407) 827-4000

The Hilton at Walt Disney World Village will host CALGB's Fall Group Meeting. Located in Lake Buena Vista, the Hilton stands directly across the street from Disney's Pleasure Island, where a variety of shops, restaurants, and entertainment complexes await visitors.

Orlando, home to Disney World, MGM Studios, Universal Studios, Sea World, and many other attractions offers a multitude of activities for adults and children alike. What's more, CALGB attendees are eligible for discounts on a number of amusements (see page 18 of this newsletter for order forms).

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 their budgets be used to support the travel and lecture fees of non-CALGB speakers at their Group Meeting Committee meetings provided that the constraints of their budgets will permit the expense.

NOTE: If you are a member of a disease or modality core committee, you should have received a separate mailing relative to travel to Orlando. If you have not received this mailing, please contact Helen Pollard at (773) 702-4129 or e-mail hpollard@midway.uchicago.edu.



Deadline and Fees

\$40 for registration received on or before October 23; \$65 on site. Registration fees are nonrefundable.

Substitutions

If you find that you are unable to attend the meeting after you have registered, you may find a substitute. You must inform the Central Office in writing by October 23 of any substitutions. After this date, we will be unable to accept substitutions.

Transportation

Airline: CALGB has selected Delta Air Lines as the official air carrier and International Travel Service as the official travel agency. There are special guaranteed fares with no Saturday night stay required. Also, 10% discounts are available off unrestricted coach fares and 5% discounts off lowest applicable fares, including first class. To receive the exclusive CALGB air fares, call I.T.S.

toll-free, 1-800-621-1083 available nationwide and Canada (Monday through Friday, 8:00 am to 5:00 pm Central time). Or, call Delta Air Lines direct at 1-800-241-6760, Reference: 104800A (Monday thru Sunday, 7:00am to midnight).

Ground Transportation: The least expensive fares and most convenient and reliable service to and from the hotel and airport can be found with Mears Transportation. A \$4.00 discount coupon for CALGB attendees can be found at the back of this newsletter. With this coupon, round-trip transportation from the Orlando International Airport to the Hilton at Walt Disney World Village will be \$21.00. Approximate travel time one-way is 35-45 minutes. Shuttle service runs approximately every 15 to 20 minutes. Mears Motor Shuttle Booth locations are located on the baggage claim level directly

Fall Meeting

outside from the following baggage carousels: A Side #5, B Side #8, and Delta #14. For return reservations, call 24 hours in advance (407) 423-5566.

Attraction Tickets

CALGB has appointed Mears Guest Services to coordinate the sale of amusement park tickets. (See page 19 for pricing information to various Orlando attractions.) These discounts are only available to group attendees/families. With the exception of Disney's one-day pass, all other attractions are discounted for CALGB attendees. Note: Two-day passes are NOT available at the Disney gate; these passes are only available via this group discount program.

By pre-ordering your tickets (see order form on page 18), you will be able to take advantage of an additional discount. If you prefer to order tickets on site, Mears will have a booth at the hotel near CALGB's registration desk, but tickets will be slightly higher if purchased on site.

Hotel Reservations

Rates

Standard Category

\$109 single occupancy

\$129 double occupancy

Alcoves Category

\$159 single/double occupancy

Towers Category

\$179 single/double occupancy

Room rates are exclusive of appropriate state and local taxes, currently 11%.

Hotel Check-in/Check-out Times

Check-in is 3:00 pm; check-out is 11:00 am.

Reservations Deadline

All room reservations must be received by the hotel no later than October 23, 1997. Room reservations will be available on a first-come, first-served basis until the CALGB hotel block is filled. The hotel will continue to take reservations after the deadline of October 23, 1997, on a space-available basis.

Deposits

A first-night deposit will be required when securing your hotel reservation. Reservations not cancelled five (5) days prior to arrival will forfeit deposit. Note: Your room will be guaranteed for late arrival when reservation is accompanied by a deposit payable by either check or credit card.

Phone Reservations

Reservations can be made by calling the Hilton at Walt Disney World Village at (407) 560-2125 or Hilton Reservations at (800) 782-4414. Be sure to identify yourself as a Cancer and Leukemia Group B attendee in order to receive the special convention rate, and please have credit card information available at the time of your call.

FAX Reservations

(407) 827-3888. FAX the completed copy of the Hotel Reservation Form at the back of this newsletter directly to the hotel. Be sure to include your credit card information on the form along with expiration date for first night's deposit.

Reservations by Mail

Send the completed Hotel Registration Form from this newsletter directly to the hotel. If using the mail-in method, be aware of your mailing date.

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 Fall 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 15.0 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 21.6 contact hours) for nurses.

C.C.R.A.s

An application for approval of approximately 9.0 CEU's 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.

AV Preparation

All slides and transparencies should be clear, crisp, and legible from a long distance.

Slides

To project well, a 35mm slide should be easy to read with the naked eye. A good rule of thumb is that a slide, when held at arm's length, should be easy to read with the naked eye. All slides should be horizontal.

Overhead Transparencies

Use large type and be aware that the image narrows from top to bottom.

CALGB Fall Group Meeting Schedule

THURSDAY, NOVEMBER 20

8:00 am - 9:00 am	Foundation Executive Committee*
9:00 am - 1:00 pm	Extended Executive Committee*
Noon - 5:00 pm	Data & Safety Monitoring Board*

FRIDAY, NOVEMBER 21

8:00 am - 3:30 pm	Genetics Education Workshop**
1:00 pm - 6:00 pm	Registration
3:00 pm - 6:00 pm	CRA Continuing Education Workshop
8:00 pm - 10:00 pm	Data Audit Committee*

SATURDAY, NOVEMBER 22

7:00 am - 5:00 pm	Registration
8:00 am - 9:00 am	Institution Performance Evaluation Committee*
8:00 am - 10:00 am	AIDS/Malignancies Working Group
8:00 am - 10:00 am	Surgery Committee
8:30 am - 10:00 am	PET Committee
9:00 am - Noon	Radiation Oncology Workshop & Committee Meeting
9:00 am - Noon	Lymphoma Committee
9:00 am - Noon	CRA Committee
9:30 am - 11:30 am	Cancer in the Elderly Working Group
9:30 am - Noon	Solid Tumor Correlative Sciences Committee
10:00 am - Noon	Pharmacy Committee
10:00 am - Noon	Thoracic Surgery Sub-Committee
10:00 am - Noon	Breast Surgery Sub-Committee
10:00 am - Noon	GI Surgery Sub-Committee
Noon - 1:00 pm	Membership Committee*
1:00 pm - 3:00 pm	Plenary Session
3:00 pm - 6:00 pm	Psycho-Oncology Committee
3:00 pm - 7:00 pm	Breast Committee
3:00 pm - 7:00 pm	Respiratory Committee
3:00 pm - 7:00 pm	Corr Sciences Leukemia/Lymphoma Committee
4:00 pm - 7:00 pm	Oncology Nursing Committee
4:00 pm - 7:00 pm	GI Committee
5:00 pm - 7:00 pm	Minority Issues Committee
5:00 pm - 7:00 pm	Epidemiology Working Group
5:00 pm - 7:00 pm	CCOP/CGOP Committee
7:00 pm - 10:00 pm	Reception

SUNDAY, NOVEMBER 23

7:00 am - Noon	Registration
7:00 am - 8:30 am	Surgical Pathology Sub-Committee
7:00 am - 8:30 am	Hematopathology Sub-Committee
8:30 am - 9:30 am	Combined Pathology Committee Meeting
8:00 am - 9:00 am	9082 Monitoring Committee*
9:00 am - Noon	Cancer Control Committee
9:00 am - Noon	Prostate Committee & Prostate Surgery Sub-Committee
9:00 am - Noon	Surgical CRA Workshop
9:00 am - Noon	Leukemia Committee
Noon - 1:00 pm	Conflict of Interest Committee*
1:00 pm - 4:00 pm	Board of Directors*

*closed meeting

** separate registration fee required

Fall Meeting

Special Program for Fall 1997 Meeting!!! An ASCO/CALGB collaborative program....

Cancer Genetics for Oncology Health Professionals

Friday, November 21, 1997

8:00 am	Registration and Pretest
8:45 am	Overview of Cancer Predisposition
9:30 am	Laboratory Methods
10:00 am	Refreshment Break
10:15 am	Cancer Genetic Counseling
11:00 am	Inherited Colorectal Cancer Syndromes
11:45 am	Multiple Endocrine Neoplasia
12:15 pm	Lunch and Patient Panel Video Tape
1:30 pm	Familial Breast and Ovarian Cancer
2:15 pm	Breakout Sessions: Integrative Case
3:30 pm	Post-Test and Adjournment

Course Coordinators

Judy Garber, MD, MPH

Kenneth Offit, MD, MPH

Olufunmilayo Olopade, MBBS

Workshop Description

The "Cancer Genetics for Oncology Health Professionals" workshop will be directed at clinical oncologists, nurses, and other professionals involved in delivering care to cancer patients. Lectures and workshops on specific topics will be presented by experts in the field of cancer genetics and predisposition testing to provide participants with an overview of ASCO's cancer genetics curriculum.

Workshop Objectives

- 1) To educate clinical cancer specialists in the role of genetics in the etiology, diagnosis, and management of various malignancies.
- 2) To become familiar with hereditary cancer syndromes and to gain insight into management and surveillance strategies for at-risk families.
- 3) Participants will gain an understanding of how to analyze and disclose results of genetic tests and will learn about available resources for patient support.

CME Credits

CME Credits will be available to program participants: 5.5 credit hours will be awarded to physicians and 6.6 contact hours will be awarded to nurses.

Pre-Registration Fees*

Physicians: \$75

Oncology Nurses: \$50

Clinical Research Associates: \$50

*These fees will be \$20 higher if participants register on site rather than pre-registering. The fee includes meals served during the workshop.

Genetics Workshop Registration Form

Friday, November 21, 1997

Please fill out this form and send it, along with your payment by check or money order, to Elmetricia Holman, CALGB Central Office, 208 S. LaSalle St., Suite 2000, Chicago, IL 60604-1104. Payments may be made out to the CALGB. The deadline for pre-registration is **October 23, 1997**.

Name: _____

Degree: _____

Institution: _____

Mailing Address: _____

City, State, and Zip Code _____

Telephone: _____

FAX Number: _____

Please circle the category to which you belong and the corresponding payment enclosed:

Physician: \$75

Oncology Nurse: \$50

Clinical Research Associate: \$50

Note: On-site registration fees will be \$20 higher. Regretfully, we will be unable to accept cancellations. However, we will be pleased to consider substitutions.

MEARS Guest Services Direct Mail Order Form

CALG B • Hilton at Walt Disney World Village

(All advance order forms and payments must be received no later than 10-27-97.)

Description	Adult/Child	Unit Price	Quantity	Total

All prices include sales tax. Subtotal:

Tickets requested to be mailed (U.S. Orders only-*Recipient Signature Required.*)
- Shipping, Handling & Insurance (per order):

\$7.00

(All orders must be in U.S. funds only) Total Enclosed:

* Charge customers **only**: Orders can be faxed to: (407) 425-1859

**For questions regarding attraction tickets or transportation, please call between the hours of 10:00 AM - 4:00 PM (EST)
(407) 843-0900**

Please complete the following information block in it's entirety! Omission will cause delays in processing.

Please charge the above fees to: AMEX MC Visa Discover Check

Check or Card # _____ Card Expiration _____

Check/Cardholder Name _____ Signature _____

Address _____ City/State/Zip _____
We cannot deliver to P.O. Boxes or P.O. Zip Codes. Recipient Signature Required

Daytime Phone _____ Daytime Fax _____

- Please mail my tickets (U.S. Addresses Only).
- Will pick up tickets at the Hospitality Desk located at the Hilton near the Registration area. Tickets will be available on 11-18-97.
- Will pick up tickets at the Concierge Desk at the Hilton. Tickets can be picked up at the desk anytime after 11-13-97.

All advance order forms and payments **must** be received no later than **October 27, 1997**. Please allow 10 (ten) days from cut-off date to receive your tickets. If you would like to pay by check or money order, please mail this **completed form**, along with the **check or money order** made payable to:

Mears Guest Services • Attn: Mail Order
324 W. Gore Street
Orlando, FL 32806

For Office Use Only

Date Rec'd _____ Ck# _____ Dated _____ Credit Approval _____ Batch# _____ Initials _____

MEARS Direct Mail Convention Ticket Prices for **CALG B**

November 18 - 28, 1997 • Hilton at Walt Disney World Village

Arriving Early? Staying Late? Take advantage of your special discounts!

(All advance order forms and payments must be received no later than 10-27-97.)

WALT DISNEY WORLD TICKETS

FOUR-DAY MEETING/CONVENTION TICKET:

Includes four (4) days unlimited admission to:
the MAGIC KINGDOM Park, EPCOT Center,
Disney-MGM Studios Theme Park.

	<u>On Site Hospitality Desk</u>	<u>Direct Mail</u>
ADULT PRICE:	\$159.00	\$149.45
CHILD PRICE (3-9):	\$127.20	\$117.55

Tickets are valid for 10 DAYS from the first day of use.

PLUS one (1) night admission to Pleasure Island.

THREE-DAY MEETING/CONVENTION TICKET:

Includes three (3) days unlimited admission to:
the MAGIC KINGDOM Park, EPCOT Center,
Disney-MGM Studios Theme Park.

	<u>On Site Hospitality Desk</u>	<u>Direct Mail</u>
ADULT PRICE:	\$126.40	\$118.80
CHILD PRICE (3-9):	\$101.75	\$95.65

Tickets are valid for 10 DAYS from the first day of use.

PLUS one (1) night admission to Pleasure Island.

TWO-DAY MEETING/CONVENTION TICKET:

Includes two (2) days unlimited admission to:
the MAGIC KINGDOM Park, EPCOT Center,
Disney-MGM Studios Theme Park.

	<u>On Site Hospitality Desk</u>	<u>Direct Mail</u>
ADULT PRICE:	\$84.25	\$81.75
CHILD PRICE (3-9):	\$67.80	\$65.80

Tickets are valid for 10 DAYS from the first day of use.

NOTE: Transportation between the Walt Disney World Parks is provided free of charge for all two, three, & four-day ticket holders via the Walt Disney World Monorail System, Shuttle Buses, and/or Watertaxis.

PLEASURE ISLAND TICKET:

Includes one (1) visit to Pleasure Island
during regular operating hours.

ADULT/CHILD PRICE:	\$16.00
---------------------------------	----------------

• *Pleasure Island is an entire island of unique nighttime entertainment with restaurants, shops, movies, and six incredible clubs* •

ADDITIONAL ATTRACTIONS

	<u>Gate Price</u>	<u>Adult Price</u>	<u>Child Price</u>
Church Street Station (entertainment complex)	\$17.97	\$15.00	\$9.00 (3-9)
<i>Located in the heart of downtown Orlando, Church Street Station is your complete entertainment, dining and shopping complex. Five nightclubs, quality shops and boutiques, and some of Central Florida's best restaurants create an ideal atmosphere for you to enjoy an afternoon or evening of fun.</i>			
Sea World	\$40.95	\$40.95	\$33.90 (3-9)
<i>At Sea World of Florida, you'll experience a day of real life adventures. You'll embark on a bold journey through a world unknown to man. Encounter surprises at every turn while you enjoy live shows starring some of the waters most interesting creatures.</i>			
Universal Studios	\$42.14	\$42.10	\$33.90 (3-9)
<i>Florida's largest operating studio featuring famous rides like: Terminator 2 : 3-D, Back to the Future ...The Ride, Jaws, and Kongfrontation. Also, the home of Nickelodeon Studios. Wonderful dining and shopping, including the world-famous Hard Rock Cafe.</i>			

• **Prices subject to change without notice.** •

COUPON

Cancer & Leukemia Group B (CALGB)

November 18 - 28, 1997

\$4.00 Discount Off - Regular Round Trip Price Of: \$25.00
per person

Present this coupon to **MEARS MOTOR SHUTTLE BOOTH**
for round trip transportation to or from the
HILTON AT WALT DISNEY WORLD VILLAGE

SALES # 20

ORDER # 11599

A C
(for office use only)

MEARS MOTOR SHUTTLE



See reverse for booth locations

BOOTH COLLECTS PAYMENT

Ticket Must be Purchased at Airport Location for Discount. Gratuity not included.

MEARS MOTOR SHUTTLE BOOTH LOCATIONS

****2ND LEVEL****

- "A" TERMINAL: EXIT THROUGH THE DOORS IN FRONT OF
AMERICAN BAGGAGE CLAIM CAROUSEL #5
- "B" TERMINAL: EXIT THROUGH THE DOORS IN FRONT OF
UNITED BAGGAGE CLAIM CAROUSEL #8 OR
DELTA BAGGAGE CLAIM CAROUSEL #14

• **THANK YOU FOR USING MEARS TRANSPORTATION** •

ATM
Card



Credit
Cards



HILTON AT WALT DISNEY WORLD VILLAGE
HOTEL RESERVATION FORM
Cancer and Leukemia Group B (CALGB)
1997 Fall Group Meeting
November 21-23, 1997

Note: Hotel Reservation Deadline is October 23, 1997. Reservations received after this date will be accommodated on a space-available basis.

Please Print or Type:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Daytime Tel. No.: _____

Arrival Day/Date: _____ Departure Day/Date: _____
(Check-in time is 3:00 pm) (Check-out time is 11:00 am)

Name of person(s) sharing Accommodations: _____

Standard Category:

- \$109 single occupancy
 \$129 double occupancy

Alcoves Category:

- \$159 single/double occupancy

Towers Category

- \$179 single/double occupancy

- I request a non-smoking room I request a handicapped-accessible room
Please describe handicap:

Room rates are in effect for the entire duration of your stay, based on availability. All reservations must be received by the hotel no later than October 23, 1997. Room reservations will be available on a first-come, first-served basis until CALGB's hotel block is filled. The hotel will continue to make reservations after October 23, 1997, on a space-available basis.

Please enclose a check or money order for the first night's deposit or provide credit card information below to guarantee your room. Be advised that your credit card will be immediately charged toward 1st night's deposit.

Make your check payable to: Hilton at Walt Disney World Village

- My check is enclosed

Credit Card Information

- American Express VISA Master Card
 Diner's Club Discover En Route

Credit Card # _____

Exp. Date _____ Signature _____

MAIL (with check or credit card information) or FAX (with credit card information) this Hotel Reservation Form to:

Hilton at Walt Disney World Village
P.O. Box 22781
Lake Buena Vista, FL 32830
Attn: Reservations
FAX: 407-827-3888

CALGB GROUP MEETING REGISTRATION FORM

1997 Fall Group Meeting
November 21-23, 1997
Orlando, Florida USA

MEMBER INFORMATION

Name _____ Social Security # _____
Institution _____ Phone # _____
Address _____ Fax # _____
City, State, Zip Code _____

REGISTRATION

Advance Registration Deadline is October 23, 1997
Must be postmarked by deadline

Please check off your selections and then fill in the appropriate amounts under the "Fees" column. Add all the fees up, and put the amount in the "Total" box at the bottom. You may pay for all the items with one check.

	Fees
<input type="checkbox"/> Group Meeting \$40 advance/\$65 on-site	<input type="text"/>
<input type="checkbox"/> Agenda Book Only \$30 advance only	<input type="text"/>
<input type="checkbox"/> Donation to CALGB Foundation I wish to make a tax-deductible donation in the following amount: <i>You will receive an acknowledgement from the Foundation by mail.</i>	<input type="text"/>
Total	<input type="text"/>

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 the advance registration deadline.

AGENDA BOOKS: The registration fee for the meeting includes (1) Agenda Book. However, we cannot guarantee that the Agenda Books will be available if you register after the advance registration deadline. If you cannot attend the meeting and wish to obtain an Agenda Book, return this form (see above) with a check for \$30 made payable to the University of Chicago/CALGB by the advance registration deadline.

We cannot process registrations received by FAX and do not accept registrations by credit card. Return a photocopy of this completed form with your check payable to the University of Chicago/CALGB to:

Cancer and Leukemia Group B
Attn: Elmetrica Holman
208 S. LaSalle St., Suite 2000
Chicago, IL 60604-1104

**Deadlines for Fall Group Meeting
in Orlando, Florida,
November 21-23, 1997**

**Advance Registration Deadline:
October 23, 1997**

**Hotel Reservation Deadline:
October 23, 1997**

**Meeting Registration Cancellation/
Substitution Deadline:
October 23, 1997**

**Agenda Book Order Deadline
(if not attending meeting):
October 23, 1997**



*Church Street Station in Orlando, Fla. Orlando is the site of the
Fall 1997 Group Meeting.*

Note: All Fall Meeting registration forms appear in this issue. There will NOT be a separate mailing. For extra forms, contact Meachie at the CALGB Central Office, (773) 702-9163.

Mark your calendars to attend the CALGB's Spring Group Meeting, which will be held June 26-28, 1998, in Fort Lauderdale, Florida!

Cancer and Leukemia Group B
Central Office of the Chairman
208 South LaSalle Street, Suite 2000
Chicago, IL 60604-1104

First Class
U.S. Postage
PAID
Permit No. 16
Aurora, IL