THE CANCER LETTER

Vol. 8 No. 35
Sept. 10, 1982

Subscription $125 year North America/$150 yr elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

YARBRO PROPOSAL, CLINICAL RESEARCH SHOULD BE "FUN", DONE WITHOUT GRANTS/CONTRACTS, TO BE HEARD BY ACCC

In an era in which NCI support is considered almost mandatory for the conduct of cancer clinical trials, the Assn. of Community Cancer

(Continued to page 2)

In Brief

NEW NCAB MEMBERS BRIEFED AT ORIENTATION; WOGAN RESIGNS FROM BOARD; PARRY NAMED NCCP DEPUTY

ALL SIX NEW members of the National Cancer Advisory Board attended an orientation meeting last week at NCI. They were Chairman Tim Lee Carter, Richard Bloch, Angel Bradley, Victor Braren, Ed Calhoun, and Geza Jako. Bradley, Miami community and political activist, and Bloch, of the H & R Block income tax service, are lay appointees. Carter is a former congressman and community physician; Braren is a urologist and pediatrician at Vanderbilt Univ.; Calhoun is an Oklahoma surgeon and AMA delegate; and Jako is an otolaryngology professor and surgeon at Boston Univ. . . . **GERALD WOGAN** has resigned his membership on the NCAB, commenting that his duties as professor of toxicology in the Dept. of Nutrition & Food Science at Massachusetts Institute of Technology make it impossible for him to devote sufficient time to the Board. Wogan's departure cuts to two the number of Board members who are acknowledged experts in environmental, carcinogenesis, occupational cancer, or nutrition, as required by the Maguire amendment to the National Cancer Act. Those remaining members in that category are Irving Selikoff and Sheldon Samuels. President Reagan ignored the amendment in making the six appointments this year. . . . **STANLEY PARRY**, who has been associate director for administration of the Northern California Cancer Program, has been named deputy director to assure administrative leadership while a search committee works on finding a replacement for Stephen Carter. The search committee is chaired by Saul Rosenberg, who is also serving as principal investigator on the center's application for renewal of its core grant. . . . **SAUL ROSENBERG** will deliver the annual Bernard Schwartz Memorial Lecture at the Scripps Cancer Symposium in San Diego next month. The chief of oncology at Stanford Univ. and current president of the American Society of Clinical Oncology will discuss the hugely successful effort at Stanford in developing Hodgkin's disease therapy. Another speaker at the symposium will be Umberto Veronesi, director general of the Cancer Institute of Milan. The symposium is scheduled for Oct. 11-13, and will run concurrently with a Cancer Symposium for Nurses. . . . **GARY WITMAN** has left NCI as senior investigator and program director for clinical oncology to become vice president for medical affairs for Scott Laboratories and Oncology Laboratories, subsidiaries of Microbiological Sciences Inc.

ACCC COMMITTEE TO HEAR YARBRO PLAN; GRAND RAPIDS SYMPOSIUM SCHEDULED

(Continued from page 1)

Centers—or at least a component of that organization—may consider encouraging a program of clinical research in which one requirement is most emphatically that no outside support, especially from NCI, would be sought.

John Yarbro, professor of medicine at the Univ. of Missouri (Columbia) and former head of what is now NCI's Cancer Centers Branch, became chairman of ACCC's Clinical Trials Committee last spring when Edward Moorhead gave up that chore. Moorhead and the committee had played a major role in helping NCI put together the Community Clinical Oncology Program, which will channel $10 million a year into clinical trials at the community level.

Yarbro convened a meeting of the committee during the American Society of Clinical Oncology meeting in St. Louis and suggested that one project the committee might want to undertake would be to encourage oncologists to "get back to the good old days when research was fun." To do that, Yarbro said, would require that investigators write their own protocols and not ask for approval (except of course institutional review boards) or money from anyone.

Committee members were intrigued but no commitments were made. The subject will be brought up again when the committee meets at the ACCC Leadership Conference in Grand Rapids Oct. 1-2. Yarbro recently sent a letter to a number of "independent clinical investigators" on the subject, along with a questionnaire to find out if anyone is interested.

"What's Yarbro up to?

"This is the question I have been asked too many times recently to count. The answer is simple. I want to make research fun again. Mike Shimkin said it better than I can in his Presidential address to AACR in 1974:

"'Research is the most powerful thought and action process devised by man. . . Research needs unlimited vistas and unfettered dreams. Research is hampered by all limitations and all dogma, religious, philosophical, or political. . . . Research is a serious business, but it is also a form of play. The best playing, and the best research, is done when it is fun. . . . Factors that reduce fun in research reduce the quality of the research. Among such negative factors are too much planning, too many reviews, too many reports, and too many goals set by others.'

"Now, ladies and gentlemen, nothing is free. If we want to have fun at research we can't have a grant or contract pay for it because then we may be doing someone else's research. So, we will have to do our own paper work and pay for our own travel. On the other hand, these days it probably costs us more for our time to write grant-contract applications than we actually get back anyway, so we have little to lose. Besides, that's work!

"What I'm up to is simply this: I want to find out if there are enough people like me out there in cancer land to form a group of Independent Clinical Investigators to run each others' (our own) protocols on a voluntary basis, to answer our own questions, to collect our own data, to make our own decisions and to pay our own way. If there is such a group, we'll all have fun (and maybe do some good science as a spin-off). If not, too bad.

"A brief form is enclosed. Copy it for anyone you feel may be interested. Meanwhile, think about research questions you would like to ask. If you have a protocol you think ICI participants would like to try, don't be shy—you write it, you run it. For example, I would like to know whether operable small cell lung cancer patients do better if they are resected and given adjuvant RT/CT; or whether MOPP/ABVD is better than MOPP in Hodgkin's disease; or whether adjuvant liver perfusion with 5-FU works in resected colon cancer. You probably have even better questions.

"Join the fun!"

The questionnaire, to be returned to ACCC Executive Offices, 11600 Nebel St. Suite 201, Rockville, Md. 20852, follows:

INDEPENDENT CLINICAL INVESTIGATORS

Physician Name:
Address:
Phones:
Specialty:

1. How many new patients per year do you see in whom you control the therapy given?
2. How many do you think you could put on protocol?
3. Are you now in an organized group?
   Which group?
   How many patients do you put on study now?
   Any future obligations?
4. Are you willing to use your own funds for travel to meetings (one per year plus the ACCC annual)?
5. Do you have a special interest in a clinical research question our group might address?
   Would you like to lead a protocol on this?
   (Attach a concept summary if you feel like it.)
   (Attach a C.V. if you have one handy.)
6. Do you have any thoughts, ideas, or opinions you would like mailed to our small group? If so please enclose in a form suitable for us to xerox for distribution.

Tim Lee Carter, new chairman of the National Cancer Advisory Board, will be the luncheon speaker at the Leadership Conference, which will be held in the Amway Grand Plaza Hotel in Grand Rapids.

The conference will follow a three day symposium, "Cancer Care in the Community Hospital: Present

Problems, Future Prospects," sponsored by the Grand Rapids Clinical Oncology Program. This meeting also will be in the Amway Grand Plaza Hotel, Sept. 29-Oct. 1. Yarbro will be the luncheon speaker Sept. 30, with the topic, "Back to Square One." Peter Greenwald, director of NCI's Div. of Resources, Centers & Community Activities (soon to be changed to Div. of Cancer Prevention & Control), will speak at the Oct. 1 luncheon on "The Future of Cancer Control."

For registration and information, contact Diane VanOstenberg, Grand Rapids Clinical Oncology Program, 100 Michigan N.E., Grand Rapids, Mich. 49503, phone 616-774-1230.

SCHWEIKER APPROVES BRUCE CHABNER'S APPOINTMENT AS DIRECTOR OF DCT

HHS Secretary Richard Schweiker has approved appointment of Bruce Chabner as director of NCI's Div. of Cancer Treatment. Chabner has been acting director of the division since June, 1981, and was selected by NCI Director Vincent DeVita for the permanent appointment following a nationwide search for prospects.

Chabner, 42, received his BA from Yale and MD from Harvard, both with honors. He joined NCI in 1971, became chief of the Clinical Pharmacology Branch in 1976, and director of the intramural Clinical Oncology Program in 1981.

Another key DCT position remains to be filled, that of associate director for the Cancer Therapy Evaluation Program. It is a Senior Executive Service position, requiring national advertising of the vacancy and the work of a search committee. That process had almost been completed when new candidates were found, requiring reopening of the competition. That appointment probably will not be made final before the end of the year.

CAPIZZI SUCCEEDS SPURR AS DIRECTOR OF CANCER CENTER AT BOWMAN GRAY

Robert Capizzi, professor of medicine and pharmacology at the Univ. of North Carolina School of Medicine, has been named director of the Cancer Research Center at the Bowman Gray School of Medicine.

Richard Janeway, dean, announced Capizzi's appointment as director of the center and as professor of medicine (hematology/oncology). He also will be head of the school's Section on Hematology/Oncology. The appointment was effective Sept. 1.

Capizzi, who was co-director of the Div. of Hematology/Oncology at the UNC School of Medicine, succeeds Charles Spurr, who has been director of Bowman Gray's Cancer Research Center during its first 10 years of operation. Spurr will continue as professor of medicine and director of the Piedmont Oncology Assn. POA recently was awarded a $2.4 million grant by NCI as a regional cooperative group.

"Dr. Spurr deserves a great deal of credit for the development of the Cancer Research Center over the past decade," Janeway said. "We conducted a national search for the best possible person to direct the center as it enters what we expect to be a period of exceptional growth and productivity. We are fortunate to attract a person of Dr. Capizzi's reputation and proven leadership in this important field," Janeway said.

Capizzi formerly served as acting chief of the Section on Medical Oncology at Yale Univ. School of Medicine, where he also was an investigator with the Pharmaceutical Manufacturers' Assn. and the Howard Hughs Medical Institute. He has developed chemotherapy combinations, especially for acute leukemia, which are used worldwide.

Capizzi received a BS degree from Temple Univ. and the MD degree from Hahnemann Medical College.

SEARCH FOR MISSOURI CENTER DIRECTOR NARROWED TO WIERNIK, VINCENT

The search for a director of the Missouri State Cancer Center in Columbia has narrowed to two candidates.

The Missouri Cancer Commission is considering Peter Wiernik, former director of the Baltimore Cancer Research Center and Ronald Vincent, chief of thoracic surgery at Roswell Park Memorial Institute, according to state Rep. Joe Holt, who is chairman of the commission. Holt said the commission wants to make the final decision by the end of September.

Wiernik, interviewed by the commission Aug. 25, listed three "non-negotiable" conditions before he would take over as the center's director. He wants the Ellis Fischel hospital joined with the private Cancer Research Center next door, and part of one floor made a germ-free environment, along with in-room showers throughout the hospital to control infection.

Wiernik's third requirement is for a "lingering personnel problem" to be cleared up between the administration and chief medical physicist and radiation safety officer Clifford Richter.

The dispute began in 1978 when Richter reported to the Nuclear Regulatory Commission that radioactive seeds used for cancer treatment were accidentally left in a patient during surgery. The hospital reorganized the medical physics department eight months later, eliminating Richter's job.

Richter appealed the removal and was reinstated in April, 1981, after a court battle that reached the U.S. Supreme Court. Now Richter does not think the

center is complying with the Court's decision.

Acting Director Ned Rodes issued a memo Aug. 30 reaffirming radiation therapy department authority over medical physics.

Wiernik told the commission that specializing in areas not offered by other hospitals is the first step toward solving the hospital's problems.

NCI, NINCDS SEEKING PATIENTS FOR BREAST, BRAIN CANCER STUDIES

NCI and the National Institute of Neurological & Communicative Disorders & Stroke are asking for patient referrals for studies being conducted at the NIH Clinical Center in Bethesda.

The NCI study is a randomized comparison of mastectomy vs. excisional biopsy plus radiation and iridium implant with stage 1 and 2 breast cancer patients. Eligible are patients with biopsy proven breast cancer, stage 1-2, clinical T1, T2 and NO, NL. The surgery only group receives total mastectomy plus a complete axillary lymph node dissection. Those randomized to radiation therapy have a complete excisional biopsy (microscopic involvement at the excision margins in acceptable) and complete axillary dissection followed by external beam radiation and an iridium implant to the tumor bed.

For either treatment arm, patients receive one year of systemic adjuvant chemotherapy for any evidence of axillary lymph node involvement. Patients treated with total mastectomy are offered surgical reconstruction at a later date if they so desire.

The Surgical Neurology Branch of NINCDS needs patients with malignant brain tumors for two studies it is doing. In one, the use of intra-arterial delivery of BCNU to the tumors is being evaluated. The other will study the effects of CBSCA-platinum on rapidly spreading brain tumors. That agent, now completing phase 1 trials, seems to be less toxic than cisplatinum. It is administered intravenously on a monthly cycle.

Male and female patients in treatment stages before or after surgery, radiotherapy, chemotherapy, or immunotherapy are needed for both NINCDS studies.

Referrals for the NCI study may be made by calling Dr. Allen Lichter, 301-496-5457; Dr. Marc Lippman, 301-496-4150; or Dr. Ernest deMoss, 301-496-1533; or by writing to Lichter at the Clinical Center, Radiation Therapy Branch, NIH, Bethesda, Md. 20205.

Referrals for the NINCDS studies may be made by contracting Dr. Paul Kornblith, chief, Surgical Neurology Branch, NINCDS, Bldg. 10A, Rm 3E68, Bethesda, Md. 20205, phone 301-496-5728.

The government will pay expenses for all treatment carried out at the Clinical Center, as well as travel to and from Bethesda.

REST OF CCOP Q & A LIST PUBLISHED, WITH RESEARCH BASE NAMES, ADDRESSES

Questions and answers prepared by NCI explaining details of the Community Clinical Oncology Program were published in part in last week's issue of *The Cancer Letter*. The rest of the list appears below, followed by names, addresses and phone numbers of the clinical cancer centers and cooperative groups eligible to serve as research bases for CCOPs.

49. Why is it assumed that a patient gets better treatment on a clinical trial protocol than on a regular treatment regimen? Can it be documented?

It is assumed that a patient gets better treatment on a clinical trial because of the strict criteria for control. The diagnosis has to be specific, staging complete, pathology confirmed, and the needed laboratory work done. Monitoring is rigid and followup mandatory. Even if a patient is randomized to a standard therapy, he/she receives the same precisely ordered care under controlled conditions that patients receive on the investigational arm of the study.

50. What may be the effect of deaths or treatment complications affecting the quality of life of protocol patients and their families?

Some treatment complications and deaths can be anticipated. Community and family understanding is more likely if:

—A good information groundwork has been laid with professionals and the public about clinical trials in general;

—The community understands that clinical study protocols are not solely an individual physician's responsibility, but that they emanate from a nationally recognized center or cooperative clinical trials group and are, in addition, reviewed by the National Cancer Institute and the local hospitals' Institutional Review Boards;

—The patient and family have a clear understanding of the possible risks as well as benefits before the patient enters the study.

51. Who is responsible for research patient followup?

Consent of the patient to record access should be obtained at the time of entry into the clinical trial so that provisions can be made by the CCOP to assure a continued flow of information even if a participating physician leaves the CCOP. The CCOP must make treatment and followup information, from records or directly from patients, available to the research base.

Depending on the protocol and the patient's individual response to treatment, followup may be needed for a number of years.

52. What about patients who would best be referred to a center?

CCOPs will receive a credit of 1.25 per patient toward its total patient accrual goal for those patients with complicated problems referred by com-

munity physicians to centers for protocol studies, e.g., bone marrow transplantation in acute leukemia or special radiation therapy.

Multi-Disease Research Bases

1. NCI-funded comprehensive and clinical cancer centers
* – Comprehensive Cancer Center
** – Clinical Cancer Center

Comprehensive Cancer Center, Univ. of Alabama in Birmingham*; Dr. John R. Durant, Director; University Station, Birmingham, Ala. 35294, phone 205-934-5077.

Univ. of Arizona Cancer Center**; Dr. Sydney E. Salmon, Director; College of Medicine, Tucson, Ariz. 85724, phone 602-626-6044.

Univ. of Southern California Comprehensive Cancer Center*; Dr. Richard O'Brien, Acting Director; 2025 Zonal Ave., Los Angeles, Calif. 90033, phone 213-224-7126.

Jonsson Comprehensive Cancer Center, UCLA*; Dr. Richard J. Steckel, Director; 10833 Le Conte Ave., Los Angeles, Calif. 90024, phone 213-825-1532 or 5268.

Northern California Cancer Program**, Dr. Saul A. Rosenberg, 1801 Page Mill Rd., P.O. Box 10144, Palo Alto, Calif. 94303, phone 415-497-7431.

Cancer Research Center, City of Hope Research Institute**, Dr. Charles Mittman, Director; 1450 E. Duarte Rd., Duarte, Calif. 91010, phone 213-359-9711, ext. 2705.

Univ. of California (San Diego) Cancer Center**, Dr. John Mendelsohn; School of Medicine, La Jolla, Calif. 92093, phone 714-294-6930.

Yale Univ. Comprehensive Cancer Center*; Dr. Jack W. Cole, Director; 333 Cedar St., New Haven, Conn. 06510, phone 203-785-4095.

Georgetown Univ./Howard Univ. Comprehensive Cancer Center*:

–Vincent T. Lombardi Cancer Research Center, Dr. John F. Potter, Director; Georgetown Univ. Medical Center, 3800 Reservoir Rd., NW, Washington D.C. 20007, phone 202-625-7066.

–Cancer Research Center, Howard Univ. Hospital; Dr. Jack E. White, Director; 2400 Sixth St NW, Washington D.C. 20059, phone 202-636-7697.

Comprehensive Cancer Center for the State of Florida*, Dr. C. Gordon Zubrod, Director; Univ. of Miami Hospital & Clinics, PO Box 016960 (D8-4), Miami, Fla. 33101, phone 305-545-7707, ext. 203.

Cancer Center of Hawaii*, Dr. Lawrence H. Piette, Director; Univ. of Hawaii at Manoa, 1236 Lauhala St., Honolulu, Hawaii 96813, phone 808-548-8415, 8416.

Illinois Cancer Council*, Dr. Jan W. Steiner, Director; 36 S. Wabash Ave. Suite 700, Chicago, Ill. 60611, phone 312-266-5250. (Includes institutions listed, several other health organizations.)

–Northwestern Univ. Cancer Center, Dr. Nathaniel I. Berlin, Director; Health Sciences Bldg., 303 E. Chicago Ave., Chicago, Ill. 60611; phone 312-266-5250.

–Univ. of Chicago Cancer Research Center, Dr. John E. Ultmann, Director; 905 E. 59th St., Chicago, Ill. 60637, phone 312-947-6386.

Univ. of Iowa Cancer Center**, Dr. Richard L. DeGowin, Director; College of Medicine, 20 Medical Laboratories, Iowa City, Iowa 52242, phone 319-353-6595.

Ephraim McDowell Community Cancer Network Inc.**, Dr. D.K. Clawson, Acting Executive Director; 915 So. Limestone St., Lexington, Ky. 40503, phone 606-233-6582.

Johns Hopkins Oncology Center*, Dr. Albert H. Owens Jr., Director; 600 N. Wolfe St. Rm. 157, Baltimore, Md. 21205, phone 301-955-8822.

Sidney Farber Cancer Institute*, Dr. Emil Frei III, Director, 44 Binney St., Boston, Mass. 02115, phone 617-732-3555.

Cancer Center, Tufts-New England Medical Center**, Dr. Douglas J. Marchant, Director; Box 842, 171 Harrison Ave., Boston, Mass. 02111, phone 617-956-5406.

Comprehensive Cancer Center of Metropolitan Detroit*, Dr. Michael J. Brennan, Director; 110 E. Warren St., Detroit, Mich. 48201, phone 313-833-1088.

Mayo Comprhensive Cancer Center*, Dr. Charles G. Moertel, Director; 200 First St. SW, Rochester, Minn. 55901, phone 507-284-2511.

Norris Cotton Cancer Center**, Dr. O. Ross McIntyre, Director; Darmouth-Hitchcock Medical Center, Hanover, N.H. 03755, phone 603-643-4000, ext. 2535.

Memorial Sloan-Kettering Cancer Center*, Dr. Paul Marks, President; 1275 York Ave., New York N.Y. 10021, phone 212-794-6561.

Dept. of Neoplastic Diseases, Mt. Sinai School of Medicine**, Dr. James F. Holland, Chairman; Fifth Ave. at 100th St., New York, N.Y. 10029, phone 212-650-6361.

Roswell Park Memorial Institute*, Dr. Gerald P. Murphy, Director; 666 Elm St., Buffalo, N.Y. 14263, phone 716-845-5770.

Cancer Research Center, Albert Einstein College of Medicine**, Dr. Harry Eagle, 1300 Morris Park Ave., Bronx, N.Y. 10461, phone 212-430-2302, 212-792-2233.

Columbia Univ. Cancer Center*, Dr. Sol Spiegelman, Director; College of Physicians & Surgeons, 701 W. 168th St., New York, N.Y. 10032, phone 212-694-6900.

Cancer Center, New York Univ. Medical Center**, Dr. Vittorio Defendi; 550 First Ave., New York, N.Y. 10016, phone 212-340-5349.

Univ. of Rochester Cancer Center**, Dr. Robert A. Cooper Jr., Director; 601 Elmwood Ave., Richester, N.Y. 14642, phone 716-275-4865.

Comprehensive Cancer Center, Duke Univ. Medical Center*, Dr. William W. Shingleton, Director; Durham, N.C. 27710, phone 919-684-2282.

Cancer Research Center, Univ. of North Carolina**, Dr. Joseph S. Pagano, Director; Box 30, Clinical Science Bldg. 229H, Chapel Hill, N.C. 27514, phone 919-966-1183, 3036.

Oncology Research Center, Bowman Gray School of Medicine**, Dr. Robert L. Capizzi, Director; 300 S. Hawthorne Rd., Winston-Salem, N.C. 27103, phone 919-748-4464.

Ohio State Univ. Cancer Research Center*, Dr. David S. Yohn, Director; 410 W. 12th St. Suite 302, Columbus, Ohio 43210, phone 614-422-5022.

Fox Chase/Univ. of Pennsylvania Comprehensive Cancer Center*:

–Fox Chase Cancer Center, Dr. Alfred G. Knudson Jr., President; 7701 Burholme Ave., Philadelphia, Pa. 19111, phone 215-728-2490.

–Univ. of Pennsylvania Cancer Center, Dr. Richard A. Cooper, Director; 7 Silverstein Pavillion, 3400 Spruce St., Philadelphia, Pa. 19104, phone 215-662-3910.

Puerto Rico Cancer Center**, Dr. Angel A. Roman-Franco, Director; Univ. of Puerto Rico Medical Sciences Campus, G.P.O. Box 5067, San Juan, P.R. 00936, phone 809-763-2443, 809-765-2363.

Roger Williams General Hospital**, Dr. Paul Calabresi, Professor & Chairman, Dept. of Medicine, Brown Univ., 825 Chalkstone Ave., Providence, R.I. 02908, phone 401-456-2070.

St. Jude Children's Research Hospital**, Dr. Alvin M. Mauer, Director; 332 N. Lauderdale, Memphis, Tenn. 38101, phone 901-522-0301.

Univ. of Texas System Cancer Center*, Dr. Charles A. LeMaistre, President; 6723 Bertner Ave., Houston, Texas 77030, phone 713-792-6000.

Univ. of Texas Medical Branch Cancer Center**, Dr. John J. Costanzi, Director; Galveston, Texas 77550, phone 713-795-1862.

Vermont Regional Cancer Center**, Dr. Irwin H. Krakoff, Director; Univ. of Vermont, 1 So. Prospect St., Burlington, Vt. 05401, phone 802-656-4414.

MCV/VCU Cancer Center**, Dr. Walter Lawrence Jr., Director, Medical College of Virginia Box 37, Richmond, Va. 23298, phone 804-786-9322, 9323, 0448.

Fred Hutchinson Cancer Research Center*, Dr. Robert W. Day, Director; 1124 Columbia St., Seattle, Wash. 98104, phone 206-292-7545.

Univ. of Wisconsin Clinical Cancer Center*, Dr. Paul P. Carbone, Director; 600 Highland Ave., Madison, Wisc. 53792, phone 608-263-8610.

2. Cooperative Groups

Cancer & Leukemia Group B (CALGB), Emil T. Frei III, M.D., Chairman; Linda Hogan, Administrator, 44 Washington St., Brookline, Mass. 02146, phone 617-732-3676.

Eastern Cooperative Oncology Group (ECOG), Paul Carbone, M.D., Chairman; Barbara Miller, Administrator, Medical Sciences Center, Rm. 4765, 420 N. Charter St., Madison, Wisc. 53706, phone 608-263-7837.

North Central Cancer Treatment Group (NCCTG), James M. Ingle, M.D., Chairman, Carl T. Rider, Administrator, Administrative Services, Mayo Clinic, 200 First St. SW, Rochester, Minn. 55905, phone 507-284-7256.

Northern California Oncology Group (NCOG), Theodore Phillips, M.D., Chairman; Frank M. Torti, M.D., Executive Officer, 1801 Page Mill Rd. Bldg B, Suite 200, Palo Alto, Calif. 94304, phone 415-497-7512, 7431.

Southeastern Cancer Study Group (SEG), John R. Durant, M.D., Chairman; Rosalie Avent, Administrator, LBWTI–Rm. 225, Univ. of Alabama, University Station, Birmingham, Ala. 35294, phone 205-934-5270.

Southwest Oncology Group (SWOG), Charles Coltman Jr., M.D., Chairman; Debbie McGuire, Administrator, c/o Cancer Therapy & Research Center, 4450 Medical Dr., San Antonio, Texas 78229, phone 512-690-1080.

Mid-Atlantic Oncology Program–Georgetown Univ. (MAOP), Philip S. Schein, M.D., Chairman; James D. Ahlgren, M.D., Executive Officer, Lombardi Cancer Research Center, 3800 Reservoir Rd. NW, Washington, D.C. 20007, phone 202-625-6528.

Piedmont Oncology Assn. (POA), Charles L. Spurr, M.D., Chairman; Douglas R. White, M.D., Executive Officer, Bowman Gray School of Medicine, 300 S. Hawthorne Rd., Winston-Salem, N.C. 27103, phone 919-748-4397.

B. Special Category Research Cooperative Groups

Children's Cancer Study Group (CCSG), Denman Hammond, M.D., Chairman; Richard Honour, PhD., Administrator, Univ. of Southern California, School of Medicine, 1721 N. Griffin Ave., Los Angeles, Calif. 90031, phone 213-223-1373.

Pediatric Oncology Group (POG), Teresa J. Vietti, M.D., Chairman; Julie Myers, Administrator, 4386 Lindell Blvd., St. Louis, Mo. 63108, phone 314-535-5660.

Gynecologic Oncology Group (GOG), George C. Lewis Jr., M.D., Chairman; John R. Kellner, Group Manager, 1234 Market St., Suite 430, Philadelphia, Pa. 19107, phone 215-854-0770.

Radiation Therapy Oncology Group (RTOG), Luther W. Brady, M.D., Chairman, Lawrence Davis, M.D., Associate Chairman; Meg Keiser, Coordinator, 925 Chestnut St., Philadelphia, Pa. 19107.

National Surgical Adjuvant Project for Breast and Bowel Cancers (NSABP), Bernard Fisher, M.D., Chairman; Norman Wolmark, M.D., Executive Medical Officer, 914 Scaife Hall, 3550 Terrace St., Pittsburgh, Pa. 15261, phone 412-624-2671

Gastrointestinal Tumor Study Group (GITSG), Douglas Holyoke, M.D., Chairman, Philip Schein, M.D., Co-Chairman; Theresa Zentai, Administrator, ECTO Operations Office, The EMMES Corp., Suite 214, 11325 Seven Locks Rd., Potomac, Md. 20854, phone 301-299-8655.

Lung Cancer Study Group (LCSG), John Y. Killen Jr., M.D., Project Officer; Theresa Zentai, Administrator, ECTO Operations Office, address above.

NCI DESCRIBES REVIEW OF INTRAMURAL SCIENTISTS BY DIVISIONAL BOARDS

Executives of NCI and elsewhere at NIH, very much aware of criticism which suggests that NIH intramural scientists enjoy favored status in that they do not have to go through the same peer review process required of grantees, have attempted to develop review for intramural labs which is no less stringent than the extramural system.

NCI recently summarized the review process it requires. "We and the community we serve must be assured that we are supporting only the highest quality science in our intramural, as well as extramural, programs," Director Vincent DeVita said in the foreword to the summary. "Because our intramural programs are government laboratory facilities, they are by necessity operated differently than laboratories and clinics at universities and other institutions. However, there can be no semblance of a double standard for judging the quality of intramural research versus that funded under grants or contracts. To that end, we have developed a rigorous, standardized review process for the science performed in our own laboratories that is comparable to the NIH grant peer review system."

DeVita told the Div. of Cancer Treatment Board of Scientific Counselors that NCI's system "has created some controversy at NIH. We insisted that reviewers see all budgets. That was not well received elsewhere."

The summary, with some editing to conserve space, follows:

The intramural research programs are qualitatively and quantitatively evaluated in each division by a Board of Scientific Counselors, a group of nongovernment advisors who review the research and make critical peer judgments. Each of the four boards supervises, arranges, and conducts regularly scheduled site visits to each NCI intramural laboratory and branch every three to four years. Board members review and evaluate not only individual scientific projects but also the overall direction of the intramural research being conducted by the various divisions. Recommendations of the boards may range from suggested shifts in allocations of financial and personnel resources to changes in program emphasis or even major organizational changes. These recommendations are highly intrumental in shaping the intramural programs of NCI.

BOARD OF SCIENTIFIC COUNSELORS

In describing the evaluation of the quality of research being conducted by the NCI intramural programs it is necessary to appreciate the central and pivotal role that the boards of scientific counselors play in the entire process. NCI is unique among the NIH institutes in having multiple boards of scientific counselors (one for each operating division). These boards are constituted to reflect the mission and composition of the respective programs of each division and have between 15 and 20 members. The law requires that the chairman and at least 75 percent of board members be nonfederal employees. In practice, virtually all board members are drawn from outside the government, particularly from academic and other nonprofit institutions engaged in biomedical research. Appointees to the boards are carefully selected in accordance with departmental policy to ensure that members have the highest scientific qualifications and that each board has an appropriate balance of expertise, institutional, geographic and minority representation. Appointments to the boards range from two to four years and appointment terms are staggered so that one fourth of the membership of a group is replaced each year.

1. Responsibilities of the boards of scientific counselors

The boards of scientific counselors serve several functions within the NCI. Each board:

—Conducts an annual review of the entire divisional budget at the beginning of each fiscal year.

—Approves the concept of each new contract and contract recompetition proposed by the division for the fiscal year, as well as monies to be spent for grants which utilize the request for application (RFA) funding mechanism.

—Provides advice on all problems that have arisen which would have impact on the spending plans of the division.

—Provides advice on unusual management issues that confront each division.

—Provides peer review of the intramural programs through a process of site visiting. It is this responsibility which is addressed in detail in this document.

Schedule of intramural program reviews

The intramural research evaluation process begins with a schedule of site visit reviews for each of the laboratories and branches to be evaluated by a board of scientific counselors. This schedule is determined jointly by the director of each division and the chairman of the board of scientific counselors in consultation with board members. The boards consult with divisional officials primarily on matters such as the timing of the visit. Otherwise, the boards themselves virtually control the entire process. The review process is continuous. NCI has 41 intramural laboratories/branches and requires an in depth review of every unit during each three to four year cycle. When the schedule is completed the entire process is begun again. This is consistent with the usual period of time in which a grant application is renewed and reevaluated through the study section peer review system.

Selection of site visit team

Once a schedule has been determined and an approximate date for the site visit has been selected, the chairman of the board of scientific counselors then selects a member of the board to serve as site visit chairman, and usually several other board members with particularly relevant scientific background to serve on the team. The chairman of the site visit team chooses ad hoc consultants with highly specialized research expertise when they are needed on a case basis and when that expertise is not available from the board's membership. This approach expands the research experience base of the board and ensures a multidisciplinary team that is fully capable of reviewing in detail all of the science to be evaluated. The chairman of the team exercises absolute authority in the final selection of ad hoc advisors for the visit.

The intramural site visit

Usually, site visits require from one and a half to three days for the evaluations, depending upon the complexity and size of the laboratory/branch and the science to be reviewed. Typically, an evening session precedes the first business day of the site visit, allowing the visitors to convene as a group to discuss their first overall impressions of the background material and, as a group, to clarify areas of concern and questions regarding science and/or resources. The division director and/or the associate division director whose program falls within the purview of the site visit participate in this session.

The first day of the site visit usually begins with a formal orientation by the division director, relevant program associate director, and laboratory/branch chief. Attempts are made to familiarize the site visitors with the relative size and complexity of the laboratory/branch in comparison with others in the division, and to describe its mission within the context of the overall mission of the division. After this general orientation, the senior investigators of the laboratory/branch give oral presentations to the site visit team on the highlights of their individual research projects. In many cases reviewers also interview each senior investigator privately.

Site visit report

At the end of the site visit presentations, the visitors again convene as a group in executive session to discuss and critique the science, and based on that, the allocation of resources. The division director is present at this executive session and participates in the discussions. A consolidated report is prepared by the site visit team and is sent to the division director and each board member at least one month before

the next meeting of the board. The site visit report is then discussed and modified at the next full meeting of the board in closed session, and then declared by majority vote to be the board's recommendations for consideration by the division director.

IMPORTANT POLICY REQUIREMENTS IN THE INTRAMURAL REVIEW PROCESS

Specific intramural issues addressed by the boards of scientific counselors:

When conducting review of intramural programs each board is asked:

–To determine the relevance of the science of the NCI laboratories/branches to the mission of the division.

–To determine the necessity and/or desirability of ongoing intramural efforts in specific areas covered by the NCI laboratories/branches.

–To assess whether the quality of science is sufficient to warrant the current level of resource support of the organizational units, projects, and senior investigators devoted to these areas.

–To identify additional areas of science which should be addressed by NCI intramural laboratories/branches or programs based on evolving state of the art developments in cancer research as a whole.

Advance preparations by the site visitors

At least one month before the site visit is to take place the laboratory/branch submits a package of background review materials for the reviewers to read before the actual scientific presentations are made during the site visit. This written material is similar to that provided by a program project (P01) grant applicant and describes the past accomplishments of the laboratory/branch, its current activities, and its future plans. It addresses not only science but also resources including space, personnel, and funding. These packages include:

–A description of the division's organization and functions by laboratory/branch and section.

–Information describing current and future research activities by section and by project.

–A list of all personnel including curriculum vitae of all professional employees.

–A detailed compilation of resources for each laboratory/branch, (broken down to the section level where applicable) which includes space data–square footage, type of space, and floor plans; personnel resources–the number and types of personnel in a given laboratory; and operating costs–expenditures by major direct cost category such as personnel, supplies, equipment, travel, etc., and information on indirect cost.

Composition of the site visit report

Although the style and format of the site visit reports may vary slightly because of the preferences of each board, every report will have:

- A descriptive narrative that includes:

–A review of past, current, and proposed future research activities.

–A critique of each research project and senior investigator.

–A critical assessment of the resources allocated to the organization and projects under review.

- A qualitative judgment on the merits of each research project.
- Observations on the relevance and direction of the research under review, vis-a-vis the mission of the laboratory/branch, its parent division, and current cancer research developments outside of NCI.
- A summary of the board's major comments and observations. This summary is to include distinct, specific recommendations, for action by the division director, that flow from the board's judgmental evaluation of the items cited above. These recommendations obviously will vary from one laboratory/branch to another. Typically, they encompass things such as redirection, intensification or de-emphasis, as appropriate, for specifically identified segments of the research efforts that were reviewed; reallocations of resources; or possibly reorganization steps that might foster better collaboration between certain investigators whose research efforts are becoming highly related.

Division report to board on implementation of site visit recommendations

Approximately one year following receipt of the site visit report, a followup report is presented by the associate program director or division director to the board. This report demonstrates how the division has responded to the board's criticisms and recommendations.

CANCELLATION OF RFP N01-CM-25612-57

Title: *Technical support for review and evaluation of biological response modifiers*

The Small Business Administration has determined that this procurement be set aside for an 8(a) business.

CANCELLATION OF RFP N01-CM-25609-68

Title: *Preparation and supply of fresh and cultured mammalian cells.*

This RFP is hereby cancelled due to a change in program requirements.

The Cancer Letter Editor Jerry D. Boyd

Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston Virginia 22090. Also publisher of The Clinical Cancer Letter.