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Cancer Centers Could Form Network For Genetics Research, NCI Says

NCI is likely to use its network of designated cancer centers as the foundation for research in cancer genetics, Institute officials said at a meeting last week.

The plans outlined at the first meeting of the Cancer Genetics Working Group were tentative, and, officials emphasized, the network would be formed during the next fiscal year at the earliest.

However, a proposal that appeared to be favored by NCI leadership

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In Brief

Edward Sondik Named Director Of CDC's National Center For Health Statistics

EDWARD SONDIK, deputy director of the NCI Division of Cancer Prevention and Control, has been appointed director of the National Center for Health Statistics, a division of the Centers for Disease Control and Prevention. He plans to leave NCI early next month to join the center, located in Hyattsville, MD. Sondik, formerly an assistant professor of engineering at Stanford University, came to NIH in 1976 as chief of the Program Analysis and Evaluation Branch of the National Heart, Lung and Blood Institute. He also served as deputy director of the NIH Office of Program Planning and Evaluation. He joined NCI in 1982 as associate director for the Surveillance Program in DCPC, and in 1989 was named deputy director for the division. Sondik was acting deputy director of NCI in 1994 following the departure of Daniel Ihde. He served as acting NCI director for six months last year following the departure of Samuel Broder. Since last August, he also had the title of associate director for strategic planning. . . . **FAYE AUSTIN** was named director of the NCI Division of Cancer Biology. Austin has been acting director of the division since the NCI reorganization last October. Previously, Austin was associate director of the Extramural Research Program in the former Division of Cancer Biology, Diagnosis and Centers. . . . **AMERICAN ASSOCIATION FOR CANCER RESEARCH** will present its Public Service Award to **Sen. Tom Harkin** (D-IA), **Sen. Mark Hatfield** (R-OR), and **Rep. John Porter** (R-IL) at an event later this month on Capitol Hill marking the 25th anniversary of the signing of the National Cancer Act. The event coincides with the AACR annual meeting April 20-24 in Washington.

Centers Proposed As "Hubs" For NCI Genetics Research

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entailed broadening the centers program beyond the boundaries of NCI-designated cancer centers to include institutions with an expertise with genetics research and counseling.

The emerging system would be expanded further to include general practitioners, general surgeons, genetic counselors, urologists, gynecologists, nurses, and other health professionals who have rarely been involved in NCI programs.

"I will take from this that we should proceed with our planning to look into a cooperative-type network based upon hubs," NCI Director Richard Klausner said at the conclusion of the meeting.

"The way to build the network is to give each of the centers the responsibility of reaching out to the community, and to put this together through informatics," Klausner said.

Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers, said the proposed network would collect and analyze data, follow cohorts, participate in intervention trials, develop strategies for education, and address psychosocial issues.

"I haven't envisioned randomized trials, but longitudinal studies would be within the scope," Wittes said at the meeting.

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The advisory group did not address the specifics of how NCI's genetics research would be funded. However, several members said the issue of costs would be critical.

"There is one disincentive, which is the cost of conducting the trials, which used to be reimbursable, but no longer is," said Edison Liu, of the University of North Carolina Lineberger Cancer Center, referring to the limitations imposed by managed care. "That's the new wrinkle on it."

Judy Garber, of the Dana-Farber Cancer Institute's Division of Cancer Epidemiology and Control, agreed. "This can't work if it's going to be as underfunded as the [Breast Cancer] Prevention Trial," Garber said. "We want to make sure that there actually is a realistic expectation about costs."

Though funding mechanisms remain to be worked out, NCI officials said they believed the incentive to participate in nationwide clinical trials would attract institutions to genetics studies.

"I have no concern about the incentives," Wittes said. "I think the incentives are built into the nature of this activity. Our only concern is that if you fantasize about something close to 100 percent national participation, that we will never get. You won't even begin to approach it.

"But you will have enough to have a really healthy activity," Wittes said.

The network would not encourage genetic testing, but would instead serve individuals who request to be tested, Klausner said.

"The motivation is coming from the individual to seek this," he said. "Right now, a significant number of people who are going to self-identify to want testing are people who are thinking about cancer because its very close to them."

Alternative Structures

Wittes described three options for structuring the genetics clinical trials program.

The first option would involve NCI running the trials directly. Under the second proposal, the Institute would administer the trials through the cooperative groups. The third plan entailed launching the genetics trials by broadening the cancer centers program.

Wittes said Option 1, running genetics trials directly from NCI, with the help of a steering committee, has one advantage: the system would bypass all existing NCI support mechanisms and work directly with the participants.

"I am not terribly interested in this model," Wittes said. "The one thing that interested me initially was that the physicians and health care providers that we are going to loop into this effort are not people who are within NCI- supported clinical trials.

"They are much more likely to be family practitioners, internists, osteopaths, general surgeons.

"[Since] there is no affiliation between those people and cooperative groups and the cancer centers, there seemed to be virtue in considering a model that didn't actually depend on NCI-supported mechanisms," Wittes said.

Option 2, administering the trials by broadening the mandates of the existing cooperative groups, would be more practical than the first option, Wittes said.

Under the plan, principal investigators working in genetics would be added to the system that currently coordinates treatment and prevention trials.

"We would need an award structure that would create a series of institutional PIs who would be cancer genetics or genetics counselors, or behavioral psychologists," Wittes said.

"The advantage [is] that [cooperative groups] are functional structures already," he said. "It would seem that piggy-backing something like this onto something that already knows how to be a coordinating center or a data-collection center would be easier than building from the ground up.

"The other feature of this that's attractive is that because the groups are already doing intervention studies, it becomes much easier to consider how a genetics function might interact with an intervention function, because they are part of the same organization," Wittes said.

The proposal would greatly increase the workload—and the size—of the groups, and that could present a problem, Wittes said.

"The groups are already pretty big structures," he said. "I think it's worth some speculation whether big structures can be made both bigger and more efficient at the same time, while doing something that's quite different from what they have done in the past."

Just as important, cooperative groups may not be the best structures for attracting genetics investigators, Wittes said.

"Is it likely that family physicians and internists and primary care people in the community are going to feel a natural affiliation to organizations like this, which are heavily identified as cancer treatment organizations?" he said.

Option 3, building on the foundation of the NCI cancer centers program, would offer genetics investigators a more tangible link to clinical trials, Wittes said.

"Institutions, as opposed to cooperative groups, have natural affiliations in the community," Wittes said. "The primary care physicians, the internists, the general surgeons think of tertiary care centers the way they don't think of cooperative groups.

"Clustering around these institutions are large clusters of individuals who think of them as natural places to gravitate to when they have difficult problems, medically, and want help," Wittes said.

Francis Collins, director of the NIH National Center for Human Genome Research, said participation in the network should not be limited to NCI-designated cancer centers.

"There may be centers that do not happen to be called cancer centers that have great strength in medical genetics, and you would not want to lose the opportunity to lose those groups, because they may come into this better prepared than a lot of the cancer centers," Collins said.

Wittes agreed. "In setting up a structure like this, one would want the very best places, whether they happen to be designated cancer centers or not," he said.

Cancer Centers Best Suited?

"Cancer centers are more equipped to deal with things quickly and respond to change quickly," said Barbara Weber, of the University of Pennsylvania, co-chairman of the working group. The group's other co-chairman is Alfred Knudson, special advisor to the NCI Division of Cancer Epidemiology and Genetics.

"[Cancer Centers] are most able to respond to the infrastructure needs for informatics or hiring the right kind of people," said Barbara Rimer, of Duke University, member of the working group and chairman of the National Cancer Advisory Group.

Particularly, Rimer said, smaller organizations, including those that hold Community Clinical Oncology Program grants from NCI, do not have access to the highly specialized expertise required for psychosocial research in genetic counseling.

"I don't think CCOPs have been able to do the kind of counseling and other studies we are talking

about as one of the possibilities here," Rimer said. "I would be very concerned about the ability of CCOPs or the clinical trials groups in general to do this in the time frame that's required."

Collins cautioned that a plan to build a genetics testing program based at cancer centers would be likely to cause "anxiety and paranoia" among physicians who had not participated in trials in the past.

"When they hear that there is this program, they are going to say, That's just another plot here to take our patients away," Collins said.

Committees Formed

At the end of the all-day meeting Klausner appointed committees to consider the various aspects of the program. The national protocols writing committee is to be headed by Ken Offit, of Memorial Sloan-Kettering Cancer Center.

The informatics committee will be headed by Kenneth Buetow, of the Fox Chase Cancer Center Division of Population Science.

Another committee, charged with developing educational materials and establishing contacts with other groups involved in cancer genetics issues includes Reed Pyeritz, chairman of the Department of Human Genetics of the Allegheny-Singer Research Institute, Judy Garber of the Dana-Farber Cancer Institute's Division of Cancer Epidemiology and Control, and Mary Jo Kahn, of the National Breast Cancer Coalition.

At the meeting, Kahn requested that patients be represented on all committees, and offered to provide the list of prospective members.

Kahn said NBCC would support genetics trials as long as they provide adequate informed consent and appropriate counseling of patients.

Working Group To Review Clinical Trials Programs

NCI has established a working group to review the Institute's extramural clinical trials programs and make recommendations on the structure and functioning of the programs.

The Clinical Trials Working Group is the second of the advisory committees that are being convened by NCI Director Richard Klausner to evaluate the Institute's major programs. A group reviewing the cancer centers program was convened earlier this year.

Altogether, seven such committees are expected to be formed.

Besides reviewing NCI management of clinical trials programs, the working group is expected to assess potential threats to clinical research, including managed care, difficulties in recruitment of patients and physicians, funding problems, and challenges related to exchange of information.

"The charge to this group is to review clinical trials as a set of concepts, to use your imagination, to be creative," Klausner said at the group's first meeting April 8. "This is going to be a challenging and difficult area. I believe this report will be important in guiding the whole country."

Klausner asked the working group to prepare a report in nine to 12 months.

The group would report to the NCI Board of Scientific Advisors. Following the BSA review, the report would be presented to Klausner and, subsequently, to the National Cancer Advisory Board.

At its meeting, the working group decided to create subcommittees to gather information and report to the full group. The group plans to hold its next meeting in late June or early July, according to NCI staff.

"Do We Need New Paradigms?"

BSA Chairman David Livingston, professor of medicine at Harvard Medical

School, said the recruitment of young scientist-physicians was at the top of his list of concerns about the future of clinical cancer research.

"The supply [of young investigators] is falling to a level below which it is simply unacceptable. I think we are in a crisis," Livingston said to the working group.

Livingston asked the group to think about long-term goals for clinical cancer research. "Where should clinical cancer research be in 10 years? Is the US clinical trials program constructed in the way that will get there?" he asked. "How do we speed clinical research? Do we need new paradigms?"

Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers, asked the working group to examine the configuration of the cancer clinical trials system. His division administers the clinical trials cooperative group program. NCI budgeted $89.2 million for the cooperative group program this fiscal year.

"I'd like to see you deal with the fundamental

question of whether the current configuration of the clinical trials program best meets our needs and meets the scientific opportunities that exist today," Wittes said.

"One can find these organizational anomalies if one looks at the cooperative group program," Wittes said. "For example, we have two large pediatrics groups and several other pediatrics activities, and several groups that are largely medical oncology in their orientation.

"We have a surgically based group that deals with the adjuvant therapy of two diseases, a gynecology group, but no CNS group.

"This probably isn't the way you would set it up if you were setting it up today. That doesn't mean it isn't terrific. It doesn't mean it doesn't do its job.

"Evolution has a way of working in other contexts, and it may have worked very well here."

Wittes also asked the committee to consider whether modifications in structure, organization or funding policies might improve the functioning of the cooperative groups.

"We'd like you to take a look at the way the groups work," Wittes said. "The groups are large organizations. They do what they do very well, but very often they do them slowly.

"It's difficult for large organizations to turn on a dime, but what we are talking about is getting business done much more expeditiously than has been common practice in the past."

Other questions Wittes posed to the working group:

—What is the most effective funding structure to promote clinical trials activities?

—How might NCI coordination of the program be strengthened?

—How can the clinical trials program keep up with current trends in health care reform that will enable it to have access to patients and to retain partnerships with payers?

—How can NCI best integrate treatment trials activities with those in molecular or imaging diagnostics?

—What is the appropriate balance of activities in the clinical trials program, from pilot studies to phase III trials?

—Are procedures for working with the pharmaceutical and biotechnology industry well-suited to the task of developing new diagnostics and therapies?

—Is the frequency and focus of the site-visit monitoring program suited for its purpose?

—How can the clinical trials program benefit from state-of-the-art technology in informatics?

Several group members noted that the pharmaceutical and health insurance industries are not represented on the working group.

NCI officials said they felt that one or two individuals could not fully represent these industries, and the 30-member working group already was relatively large.

"Both industries are very diverse, and particularly managed care is going through all sorts of convulsions," Wittes said. "I doubt you could get a representative who would be recognized as such by HMOs and indemnity insurers."

The working group could invite representatives to one of its meetings, chairman James Armitage said.

Clinical Trials Working Group Members

Members of the Clinical Trials Working Group are: Chairman, James Armitage, University of Nebraska Medical Center.

Martin Abeloff, Johns Hopkins Oncology Center; Joseph Bailes, Physicians Reliance Network Inc.; Andrea Barsevick, Fox Chase Cancer Center; Archie Bleyer, M.D. Anderson Cancer Center; Clara Bloomfield, Roswell Park Cancer Institute; Malcolm Brenner, St. Jude Children's Research Hospital; Paul Bunn, University of Colorado Medical Center.

George Canellos, Dana-Farber Cancer Institute; Norman Coleman, Harvard Medical School; Charles Coltman, Cancer Therapy and Research Foundation of South Texas; Deborah Collyar, Clinical Trials Information Project; James Cox, M.D. Anderson Cancer Center.

Kay Dickersin, University of Maryland School of Medicine; Lawrence Einhorn, Indiana University Medical Center; John Glick, University of Pennsylvania Cancer Center; David Harrington, Dana-Farber Cancer Institute; David King, Greater Phoenix CCOP; Edison Liu, University of North Carolina Lineberger Cancer Center.

John Minna, Simmons Comprehensive Cancer Center, UT Southwestern Medical Center; Hyman Muss, Bowman Gray School of Medicine, Wake Forest University; Kenneth Olden, National Institute of Environmental Health Sciences; Richard O'Reilly, Memorial Sloan-Kettering Cancer Center; Etta Pisano, UNC Lineberger Cancer Center; Nicholas

Robert, Fairfax Hospital; Paul Sondel, University of Wisconsin Clinical Science Center; G. Marie Swanson, Michigan State University; Samuel Wells, Washington University School of Medicine; Carol Westbrook, University of Illinois; William Wood, Emory University School of Medicine.

Ex officio members: David Livingston, Dana-Farber Cancer Institute; Edward Harlow, Massachusetts General Hospital Cancer Center. Executive secretary: John Cole III, NCI Division of Cancer Biology.

NIH Consensus Panel Urges Wider Pap Test Use

Wider use of the Pap test and annual tests for women with one or more risk factors could prevent most of the 15,000 new cases of cervical cancer that occur each year in the US, a panel convened by NIH said in a report.

Greater efforts should be made to reach groups of women who have lower rates of screening with the Pap test and higher rates of cervical cancer, a panel of outside advisors said in a report following a two-day NIH Consensus Development Conference on Cervical Cancer.

Among the population groups least often receiving Pap tests are older women, the uninsured, ethnic minorities, especially Hispanics and older blacks, and the poor, particularly those in rural areas, the panel said in a report April 3.

Smoking, oral contraceptive use and sexually-transmitted diseases other than HPV also are risk factors for developing cervical cancer, the panel found.

"Needless Deaths" From Cervical Cancer

"Cervical cancer is a disease of the economically disadvantaged," said Patricia Braly, panel co-chairman and professor of gynecologic oncology at Louisiana State University. "Thousands of women continue to die needlessly from this disease."

The panel also advocated research to develop an effective HPV vaccine.

Cervical cancer is one of the most common malignancies in American women, accounting for nearly 5,000 deaths a year, the panel said. Half of all women newly diagnosed with cervical cancer have never had a Pap test and another 10 percent have not been screened in the past five years.

"If we could reach all the women in this country who are not getting regular Pap tests, we could eradicate this form of cancer," said panel co-chairman Allen Lichter, professor of radiation oncology at the University of Michigan.

The panel said that a principal cause of cervical cancer is the human papillomavirus (HPV), which is transmitted sexually. To prevent the infection, the panel stressed the need to educate adolescents and health care providers about the strong link between HPV and cervical cancer, to discourage early sexual intercourse, to encourage the use of barrier contraceptives and to develop a preventive vaccine.

Women who become sexually active in their adolescent years are far more likely to contract HPV and subsequently to develop cervical cancer, the panel said. It also strongly recommended that young people delay until adulthood the start of sexual activity.

"Typically, most every young woman now fits into the high risk category for cervical cancer" because of sexual activity and the common spread of HPV, Braly said.

HPV Vaccine Research Advocated

There are 70 types of HPV, but only six are associated with cervical cancer. About 30 million Americans, about half women, are infected with HPV. About 1 percent of the infected women will develop cervical cancer, said Richard Sweet, a panel member and a professor at the University of Pittsburgh, Magee Women's Hospital.

Sweet said the cellular structure of the reproductive tract of adolescent females makes them more likely to develop cervical cancer from an HPV infection than are women who delay sexual intercourse until post-adolescence.

The panel said additional research is needed to improve the detection, staging, treatment and quality of life for cervical cancer. "Included among these are the investigation into optimal pre- and post-treatment imaging, improved screening compliance and technical interpretation of Pap smears, prognostic markers to improve treatment selection, laparoscopic surgical techniques, radiobiologic investigations, and systemic chemotherapy trials," the panel's report said.

Copies of the Consensus Development Conference Statement on Cervical Cancer may be obtained from the NIH Office of Medical Applications of Research, tel: 301/496-5641.

New Phone, Fax Numbers For The Cancer Letter

The Cancer Letter has moved.

The new mailing address is: PO Box 9905, Washington, DC 20016. For overnight delivery, the street address is: 3821 Woodley Road NW, Washington, DC 20016.

The new telephone number is 202/362-1809. The new fax number is 202/362-1681.

E-mail addresses remain the same. Editor Kirsten Goldberg: kirsten@www.cancerletter.com. Editor Paul Goldberg: paul@www.cancerletter.com. Subscription manager Rena Guseynova: subscrib@www.cancerletter.com.

NIH Expands "Just-In-Time" Procedure For Two Awards

NIH plans to expand its "Just-in-Time" initiative that postpones the collection of certain information the grant applications that have a likelihood of funding.

In fiscal year 1995, four institutes (NICHD, NHLBI, NIAID, and NIA) issued requests for applications that incorporated JIT procedures. The results of the pilot demonstrations convinced the NIH to expand implementation of "just-in-time" procedures.

Beginning June 1, all unsolicited First Independent Research Support and Transition (FIRST) (R29) award and career award (K) applications must follow the JIT instructions below. All other requirements of the PHS 398 application remain in effect, as do the FIRST award and career award program guidelines.

The FIRST award guidelines may be requested from Grants Information of the NIH Office of Extramural Outreach and Information Resources by email at asknih@nih.gov or by phone on 301/435-0714.

In addition, beginning in FY1996, all NIH institutes and centers have been encouraged to incorporate JIT procedures routinely in RFAs.

JIT instructions for career and FIRST awards:

Budget Instructions—The total direct costs must be requested in accordance with the R29 and K program guidelines, following the budget instructions described below.

Detailed Budget for Initial Budget Period—Do not complete form page 4 of the PHS 398 (rev. 5/95). It is not required nor will it be accepted at the time of application. In some cases it may be requested prior to award.

Budget for Entire Proposed Period of Support—Do not complete the categorical budget table on form page 5 in the PHS 398 (rev. 5/95). Only the requested total direct costs for each year and total direct costs for the entire proposed period of support should be shown. Begin the budget justification in the space provided, using continuation pages as needed.

Budget Justification:

•List the name, role on project and percent effort for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on the project and proposed level of effort.

•Identify all consultants by name and organizational affiliation and describe the services to be performed.

•Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. No specific costs for items or categories should be shown.

•Indirect costs will be calculated at the time of the award using the institution's actual indirect cost rate. Applicants will be asked to identify the indirect cost exclusions prior to award.

•If consortium/contractual costs are requested, provide the percentage of the subcontract total costs (direct and indirect) relative to the total direct costs of the overall project. The subcontract budget justification should be prepared following the instructions provided above.

Biographical Sketch—A biographical sketch is required for all key personnel, following the modified instructions below. Do not exceed the two-page limit for each person.

•Complete the education block at the top of the form page;

•List current position(s) and those previous positions directly relevant to the application;

•List selected peer-reviewed publications directly relevant to the proposed project, with full citation;

•Provide information on research projects completed and/or research grants participated in during the last five years that are relevant to the proposed project. Title, principal investigator, funding source, and role on project must be provided.

Other Support—Do not complete the other support page (format page 7 of the PHS 398 (rev. 5/95)). Information on active support for key personnel will be requested prior to award.

Checklist—Do not submit the checklist page. For amended and competing continuation applications, applicants must complete the block in the upper right corner of the face page to indicate the previous grant number. A completed checklist will be required prior to award.

Beginning June 1, all unsolicited FIRST award and career (K series) award applications must follow the JIT procedures.

Failure to provide the requested information in the format required could result in the applications being returned as nonresponsive.

For those applications with a likelihood of funding, NIH grants management staff will contact the institutional business official prior to award to request information about active other support, the checklist page, and in some cases, a detailed budget for the project.

Inquiries: Questions about these JIT procedures should be directed to the grants management staff in any of the NIH awarding institutes or centers.

NIH Grants Information Office Changes Location, E-Mail

The NIH Grants Information Office, formerly with the Division of Research Grants and now a component of the Extramural Outreach and Information Resources Office, Office of Extramural Research, Office of the Director, NIH, has changed its e-mail address. The new e-mail address is: asknih@odrockm1.od.nih.gov.

The e-mail address is to be used when requesting single copies of grant application materials or program guidelines and for general questions regarding extramural grant programs.

The grants information telephone and fax numbers remain unchanged. Grant applications and other printed materials may be requested on 301/435-0714 or by fax on 301/480-0525.

The mailing address is: Office Of Extramural Outreach & Information Resources, NIH, 6701 Rockledge Drive-MSC 7910, Bethesda, MD 20892-7910.

All competing grant applications submitted to NIH must be sent to: Division of Research Grants, NIH, 6701 Rockledge Drive, Room 1040-MSC 7710, Bethesda, MD 20892-7710. For express/courier service, the Zip code is 20817.

ORI Says Study Coordinator Committed Misconduct

The HHS Office of Research Integrity has made final findings of scientific misconduct in the following case:

--Gail L. Daubert, R.N., Northwestern University: Based on an investigation conducted by its Division of Research Investigations, ORI found that Daubert, while serving as clinic coordinator for the Collaborative Ocular Melanoma Study (COMS) atNorthwestern University, committed scientific misconduct by falsifying clinical trial data.

The multicenter COMS involves research on the treatment of choroidal melanoma, a rare form of eye cancer. It is supported by the National Eye Institute. The study is still ongoing, and no results have been published.

ORI found that Daubert falsified 211 data items, including falsely stating that a radiation oncologist had evaluated patients prior to randomization, falsely reporting laboratory blood test results were normal when they were abnormal, falsely reporting that dates for patient visits or procedures had been performed within the specified protocol window when the actual date was outside the protocol window, and falsely reporting that a COMS certified examiner had performed an evaluation or procedure when a non-certified examiner had performed the task.

Daubert has entered into a Voluntary Exclusion Agreement with ORI in which she does not admit to any acts of scientific misconduct, but she has agreed to exclude herself voluntarily, for the three year period from federal grants and contracts.

The exclusion does not apply to Daubert's future training or practice of clinical medicine, unless that practice involves research or research training, ORI said.