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# New Phase III Trial Reviews Approve 25%; Should Trialists Worry? Not Yet, NCI Says

*By Kirsten Boyd Goldberg*

Traditionally, the process of starting a phase III trial involved a cooperative group sending a proposal to NCI and awaiting a ruling from institute officials.

A system now being phased in by the institute changes this schema by delegating review to scientists working in what amounts to grant review committees. The objective of this new system is to make review more open and rigorous, as well as to avoid duplication in cooperative group trials.

Over the past year, NCI formed two such "disease-specific steering committees" to review and prioritize proposed phase III trials. Altogether, the committees reviewed eight concepts for trials, approving two of them.

This batting average worried members of NCI's new Clinical Trials

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*Cancer Statistics:*

## President Bush Visits NIH, Marks Decline In U.S. Cancer Deaths For Second Year

*By Paul Goldberg*

President George W. Bush came to the NIH campus Jan. 17 to announce that the number of cancer deaths in the U.S. has declined for the second year in a row.

Bush characterized the decline as "the steepest drop ever recorded." Indeed, the number of actual deaths from cancer has either risen or remained the same year to year for over 70 years since record-keeping began.

Last year, the American Cancer Society reported that 369 fewer people had died of cancer between 2002 and 2003. And earlier this week, ACS reported that the trend continued, as the number of cancer deaths declined by 3,014 between 2003 and 2004.

"Obviously, we're all very concerned about cancer," said the President who has cut NCI budget in each of the past two years. "I'm pleased that we're funding cancer research. We're up about 25 percent or 26 percent since 2001; it's a commitment that I made when I first came to Washington, it's a commitment we're keeping. And the reason why it makes sense to spend taxpayers' money on cancer research is that we can make some good progress, and have."

It is correct that NCI budget has increased by about 25 percent from 2001, the year Bush took office. However, this benchmark includes two years during which Congress was deliberately doubling the NIH budget.

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## New Committees Approve Two Of Eight Protocols

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Advisory Committee, which met last week for the first time to review progress in reorganization of the Institute's clinical trials system.

"I'm alarmed by the disapproval rate," CTAC member Peter Adamson, professor of pediatrics and pharmacology at University of Pennsylvania, and chief of Clinical Pharmacology and Therapeutics at the Children's Hospital of Philadelphia, said at the Jan. 10 CTAC meeting.

The Gastrointestinal Cancer Steering Committee reviewed five phase III concepts and approved one—Radiation Therapy Oncology Group 0436, a phase III trial evaluating the addition of celuximab to paclitaxel, cisplatin, and radiation for patients with esophageal cancer who are treated without surgery.

The Gynecological Cancer Steering Committee reviewed three concepts and approved one—Gynecologic Oncology Group 0226, a randomized phase II trial of intraperitoneal chemotherapy regimens in ovarian and peritoneal primary carcinoma.

"I certainly think we should be alarmed if this continues," said Joel Tepper, co-chairman of the GI committee, and professor and chairman of radiation oncology at University of North Carolina at Chapel Hill. "We really should be in a position in the steering committees to disapprove very few protocols."

Two other steering committees only recently began their work and are yet to complete protocol reviews, NCI officials said. Those committees will cover head and neck cancer, and symptom management.

The steering committees were formed as a result of the June 2005 report by the Clinical Trials Working Group, which recommended that NCI involve more participants in trial design and prioritization.

Over the past year, NCI began to put in place the new organizational structures that the working group recommended. The disease-specific steering committees are responsible for prioritizing concepts for phase III trials, holding "state-of-the-science" meetings to identify strategies for future trials, developing concepts for new trials, and reviewing accrual and implementation issues.

The GI committee is the farthest along, because it evolved from the GI Intergroup, an informal gathering of clinical trialists from several of the NCI-supported cooperative groups, Tepper said. "But the GI Intergroup had no specific authority and no specific power," he said. Review was conducted by the NCI Cancer Therapy Evaluation Program.

Under NCI's new system, the cooperative group disease committees will continue to analyze phase I and II data to develop concepts for phase III trials, and work out logistical issues with industry partners, said Jeffrey Abrams, chief of CTEP's Clinical Investigations Branch. But instead of submitting the concepts to CTEP, they will go to the appropriate task force within the steering committee.

The task forces will refine the concepts, identify any gaps or opportunities, and send them forward to the steering committee. The committee's role is to provide formal evaluation and approval of phase III concepts, and prioritize among many concepts and diseases, Abrams said.

"Unfortunately, we had a high rate of initial turn-down," Tepper said.

The committee's task forces, which had existed within the old GI Intergroup, didn't fully understand their new role, Tepper said. "Previously, the task forces were very informal," he said. "It wasn't viewed as a very careful vetting process for protocols. Now, we are really asking the task forces to think about the protocols that are coming through.

"I think they are beginning to understand this, but it's still an evolving process."

The co-chairman of the GI committee is Daniel Haller, professor of medicine at the Abramson Cancer Center, University of Pennsylvania. The membership includes eight cooperative group GI committee

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chairmen, the former chairman of the GI Intergroup, a representative from the American College of Radiology cooperative group, two GI SPORE representatives, three R01/P01 scientists, a biostatistician, two community oncologists, two patient advocates, and three NCI staff. The meetings are held via monthly teleconferences. The committee has six disease task forces: colon, esophagogastric, pancreas, rectal-anal, hepatobiliary, and neuroendocrine.

"I understand the explanation that the task forces are in evolution, but I think other explanations that I assume you have discussed and considered are two-fold: one, there is a fundamental failure at the group level; and two, there is a major disconnect in the vision between the steering committee and the group committees," Adamson said.

Tepper said one concept was turned down because it was deemed more appropriate as a randomized phase II trial. Another was turned down because it contained too many contingency plans, which made it apparent that the task force pushed it forward too soon, he said.

"Some of this is related to the fact that the task forces didn't view their job as to critique these, but more just to discuss them," Tepper said. "That has changed. If we continue at this rate, we have every right to be seriously alarmed. I think it means that Dan and I are not doing our job properly if the task forces are not doing something the steering committee is going to accept. I think that right now—only concern, not alarm."

CTAC member Daniel Sargent, director of cancer center statistics at Mayo Clinic, Rochester, and a member of the GI steering committee, noted that the steering committee rejections are "much more public" than CTEP review. The list of approvals and disapprovals is emailed to cooperative group chairmen after each round. Previously, CTEP only announced the approvals.

"A group used to submit a concept to CTEP, and they are probably the only one who knows the true rate of being turned down," Sargent said. "We would have to know what that rate was to know whether this is high."

Under CTEP reviews, roughly a third of the concepts are disapproved, a third are approved, and a third are sent back for revisions, NCI's Abrams said at the meeting. "I wouldn't make too much of this initial [round]," he said. "I think, as with many review committees, cooperative groups gain experience about what they are looking for, and I suspect things will change."

The GI committee hopes to expand its work from reviewing phase III trials to serve as a coordinator for large, randomized phase II trial concepts from the cooperative groups, Tepper said. This coordination of group trials would "avoid the duplicative efforts of the past," Tepper said.

"We want to carry out all these initiatives without destroying the structure of the individual cooperative groups," Tepper said. "We still believe that the individual cooperative groups can bring an enormous amount to the table. It's a way to bring new people into the system; it's a way to get multiple, different ideas into the system. We think the cooperative groups are critical to make this happen, and so we want to have this collaboration."

However, resources will be "central" to making this new system work, Tepper said.

The GYN Steering Committee also will review both phase III and large, randomized phase II concepts, Abrams said. The co-chairmen are William Hoskins, of Memorial Health University Medical Center in Savannah, Ga., and Gillian Thomas, professor of radiation oncology at the University of Toronto.

The committee includes 12 representatives from the Gynecologic Oncology Group, other cooperative group representatives, a SPORE representative, three R01/P01 scientists, two community oncologists, two patient advocates, three NCI staff, and one NCI intramural scientist.

The committee is planning to form three disease task forces: ovary, cervix, and uterine corpus.

The Head and Neck Steering Committee is co-chaired by Arlene Forastiere, of Johns Hopkins University; P.G. Shankar Giri, of Eastern Virginia Medical School; and David Schuller, of Ohio State University.

Appointments to the Symptom Management and Health-Related Quality of Life Steering Committee are pending. The committee's primary responsibility will be to review symptom management intervention studies conducted in the Community Clinical Oncology Program. Also, it will develop and review studies with quality of life secondary endpoints in cooperative group treatment studies.

NCI will evaluate how the committees perform and then determine whether to form additional committees for other cancers, Abrams said.

"I think these [committees] are the crux of what we are trying to do, so I'm pleased to see progress," NCI Director John Niederhuber said at the CTAC meeting. "Are we better off?"

"I think we are," Tepper said. "I think the system is much better."

"Organizationally, we are better off, even though there has been a high rate of initial failure," said CTAC member James Abbruzzese, professor and chairman of GI Medical Oncology at M.D. Anderson Cancer Center. "I think the steering committee reflects how seriously we all take the charge to conduct the highest quality phase III trials in an environment in which we are constrained by resources. I think, ultimately, we are going to have to make a serious and critical assessment of the resources that are being applied to this effort.

"You can see how complex it is for a disease site like GI," Abbruzzese said. "Multiply that by a large number of other sites, and it's going to be a huge investment on the part of NCI. We have to be very critical at some point, but I think it's too early to really say. In terms of the interactions and gaining cooperation of and between the cooperative groups, with the idea of reducing redundancy, I think that's a very positive thing thus far.

"Is this better than the old system? I think we need some time to see exactly how this shakes out, and a real cost assessment after a period of a couple years."

CTAC member Carolyn Runowicz, chairman of the National Cancer Advisory Board and director of the Neag Comprehensive Cancer Center at University of Connecticut, said the clinical trials system needs more funding. "It seems to me the Clinical Trials Working Group worked really hard in trying to figure out how to re-do the system so that it could be a more effective, functioning system, and one of the conclusions was that it had to be adequately resourced," she said. "With the 2007 scenario of a 10 percent reduction in the cooperative group budget—it seems to me that we have gotten the ideal report, but we are in a circumstance where we can't fund that report. That puts us in an awkward situation as a board."

"You are right," Niederhuber said. "It puts all of us in an awkward position. I think that message, that story, shouldn't be underneath the bushel basket." The proposed 10 percent budget cut for the cooperative groups was "the worst scenario that we could possibly come up with," he said.

"I can't lobby for a change in this budget," Niederhuber said. "I'm supportive of the President's budget, but I need to give you the information, so that you can understand what impact certain changes would be. If we, all of us, advisors and various boards, the Executive Committee as it wrestles with the various lines on the budget, change their priorities, then the numbers will change.

"But, remember, there is no new money," Niederhuber said. "There is less money. So, if we decide that we must put more money into this, then that money has to come from at least one, two, or three other pots. That's the process we have been going through. We have been going through very rigorously to find as much of those dollars that are sitting in desk drawers and put them into the pot. Do we fund fewer SPOREs and take that money from the SPORE program because we have to address issues in clinical trials?

"This rabbit is skinny," Niederhuber said.. "There's no more fat in this rabbit, I can tell you."

**New NCI Organization For Clinical Trials**

In addition to the disease-specific steering committees, NCI has established other new organizational structures to govern the clinical trials system:

—**Clinical Trials Advisory Committee**: Established under the Federal Advisory Committees Act. Provides extramural oversight for the implementation of the Clinical Trials Working Group recommendations. Provides strategic advice for NCI's entire clinical trials portfolio, including resources associated with clinical trials. This would include an assessment of the funding distribution for clinical trials across NCI and review of disease-specific clinical trials portfolios. Provides advice on the use of new correlative science and quality of life funding.

—**Coordinating Center for Clinical Trials**: Sheila Prindiville directs this new office, which has five full-time employees and is located in the NCI director's office. Information about the office is available at http://ccct.nci.nih.gov.

—**Clinical Trials Operations Committee**: An internal committee formed in December 2005 to provide strategic oversight for NCI clinical trials programs. The NCI director serves as chairman of the committee. CTOC reviews and prioritizes clinical trial programs proposed by NCI divisions, evaluates infrastructure to reduce duplication, and evaluates all Requests for Applications and Program Announcements involving clinical trials prior to review by the NCI Executive Committee.

—**Investigational Drug Steering Committee**: provides external strategic input into the prioritization of phase I and II trials for new agents for which NCI holds the IND. Its responsibilities are to provide new strategies and directions for trials, review clinical development plans and Letters of Intent, and link developmental therapeutics activities with disease-specific clinical trial prioritization. Membership includes all principal investigators of NCI phase I U01 grants and phase II N01

contracts, representatives from the cooperative groups, and "content experts" in areas including biostatistics, industry, imaging, radiation oncology, pharmacology, and patient advocacy.

The IDSC elected two co-chairmen: phase I PI Mark Ratain, of University of Chicago, and phase II PI David Gandara, of University of California, Davis.

The committee decided that its input on drug development plans should occur prior to Letter of Intent solicitation, Adamson said at the CTAC meeting. The committee will designate a task force to review the plans depending on the nature of the agent.

The committee established working groups, issue-oriented task forces, and agent-oriented task forces. The Conflict of Interest and Confidentiality Working Group is chaired by Mace Rothenberg, of Vanderbilt University, and Sherry Ansher, of NCI. The group is working on developing a COI system that's analogous to FDA's. The Scientific Meeting Planning Working Group, chaired by Don Kufe and Dimitri Colevas, both of Dana-Farber Cancer Institute, will assist CTEP in planning the Early Drug Development Meeting.

The task forces and their chairmen include: Clinical Trial Design—Alex Adjei and Michaele Christian; Pharmacokinetics and Drug Metabolism—Ned Newman and Jerry Collins; Biomarkers—Michael Greaver and Janet Dancey; Signal Transduction—Razelle Kurzrock and John Wright; Angiogenesis—George Wilding and Percy Ivy.

*Cancer Statistics:*

## Decline In Deaths Coincides With Decrease In NCI Funding

(Continued from page 1)

Funding of federal biomedical research has been stumbling after that process concluded, with NCI facing the largest declines at NIH. The institute's budget dropped by an estimated $72 million from fiscal 2005 to fiscal 2007. Last year, Republican-led Congress adjourned without passing the spending bill that includes NIH, and the Democratic-led Congress now plans to fund the government via continuing resolution.

"There are tangible results as a result of the research that takes place around the country, and a lot of it focused here at the NIH," Bush said during his NIH appearance. The efforts noted by the President are being disrupted, scientists say. The payline for NCI grants was 12 percent last year, down from about 22 percent after the doubling of the budget was completed. And if the NCI clinical trials system is squeezed by 10 percent, as currently projected, the number of new trials would drop by 60 percent next year.

**ACS: Danger of Reversing Progress**

Plans for the rollout of the annual cancer statistics report were changed in order to make it possible for the President to take part in the rollout. Originally, the news releases had the embargo of Jan. 19, but the release date was pushed up to Jan. 17, apparently to fit the White House schedule.

Hours after his appearance at NIH, the President received a letter from the ACS chief executive John Seffrin.

"You have an opportunity, along with leaders in Congress, to rededicate our nation to conquering this feared and too often deadly disease," Seffrin wrote. "You can help to ensure that we greatly accelerate our remarkable progress against cancer, not jeopardize these gains. When you soon present your budget to Congress, we urge you to demonstrate your commitment to this effort by providing the resources required to reverse a recent trend of stagnant funding and cuts so we can expedite the war on cancer.

"The researchers you met with today at the National Cancer Institute and the thousands of their colleagues throughout the nation need the support of our government to carry out their heroic work. Without a sustained funding commitment that at least tracks the increased costs of this work from year to year, projects such as the expansion of the Cancer Genome Atlas, to which you referred, will not realize their full potential.

"The historic news announced today can be attributed in large part to the investment our nation has made in medical research. Between 1998 and 2003 our government doubled its investment in this area. However, in recent years our nation has scaled back its commitment to these lifesaving programs. We need our leaders at the highest levels of government to demonstrate their commitment by providing the resources to fund not only research, but early detection and prevention programs as well. Failure to do so would risk reversing our progress and would slow the day when we can conquer this disease once and for all."

**A Half-Percentage Point Decline**

The decrease in the number of deaths is modest, a bit more than half of one percent.

According to ACS, in 2004, there were 553,888 deaths from cancer, compared to 556,902 in 2003.

Projecting, ACS estimates that 1.44 million

Americans will be diagnosed with cancer this year, and 560,000 will die from it. (The numbers have been age-adjusted to the 2000 census.)

The figures are published in the January/February issue of CA: A Cancer Journal for Clinicians, as well in the 56th edition of Cancer Facts & Figures 2007. The report is posted at http://www.cancer.org/docroot/STT/stt_0.asp.

According to ACS, decreases in cancer deaths were seen in men and women with lung, breast, prostate, and colorectal cancers. Colorectal cancer showed the largest decrease in the number of deaths, and lung cancer among women had, in fact, increased.

The highlights from the report follow:

• Among men, cancers of the prostate, lung and bronchus, and colon and rectum account for more than half (54 percent) of all newly diagnosed cancers. Prostate cancer alone accounts for nearly a third (29 percent) of cases in men.

• The three most commonly diagnosed types of cancer among women in 2007 will be cancers of the breast, lung and bronchus, and colon and rectum, accounting for more than half (52 percent) of estimated cancer cases in women. Breast cancer alone is expected to account for one in four (26 percent) new cancer cases among women.

• Lung cancer surpassed breast cancer as the leading cause of cancer death in women in 1987. Lung cancer is expected to account for 26 percent of all female cancer deaths in 2007.

• Cancer incidence rates stabilized in men from 1995 to 2003 and increased in women by 0.3 percent per year from 1987 to 2003. Death rates for all cancer sites combined decreased by 1.6 percent per year from 1993 to 2003 in males and by 0.8 percent per year in females from 1992 to 2003.

• Mortality rates have continued to decrease across all four major cancer sites in men and in women except for female lung cancer, in which rates continued to increase by 0.3 percent per year from 1995 to 2003.

• Death rates from all cancers combined peaked in 1990 for men and in 1991 for women. Between 1990/1991 and 2003, death rates from cancer decreased by 16.3 percent among men and by 8.5 percent among women

• Lung cancer incidence rates are declining in men and appear to be plateauing in women after increasing for many decades.

• Colorectal cancer incidence rates decreased from 1998 through 2003 in both males and in females.

• Female breast cancer incidence rates leveled off from 2001 to 2003 after increasing since 1980, which may reflect the saturation of mammography utilization and dramatic reduction in hormone replacement therapy use that followed publication of the Women's Health Initiative in 2002.

• Among males under age 40 years, leukemia is the most common fatal cancer, while cancer of the lung and bronchus predominates in men aged 40 years and older.

• Among females, leukemia is the leading cause of cancer death before age 20 years, breast cancer ranks first at age 20 to 59 years, and lung cancer ranks first at age 60 years and older.

• From 2003 to 2004, the number of recorded cancer deaths decreased by 1,160 in men and by 1,854 in women. The largest change in number of deaths from the major cancers was for colorectal cancer in both men and women (decreased by 1,110 and 1,094, respectively).

• African American men have a 15 percent higher incidence rate and 38 percent higher death rate than white men. African American women have a nine percent lower incidence rate, but an 18 percent higher death rate than white women for all cancer sites combined.

• Among other racial and ethnic groups, cancer incidence and death rates are lower than those in whites and African Americans for all cancer sites combined and for the four most common cancer sites.

• Cancer is the second leading cause of death among children between ages one to 14 years in the U.S., after accidents. The five-year relative survival rate among children for all cancer sites combined improved from 58 percent for patients diagnosed in 1975 to 1977 to 79 percent for those diagnosed in 1996 to 2002.

*In Brief:*

## Mansukh Wani To Retire, Developed Taxol, Camptothecin

**MANSUKH WANI** of RTI International is retiring after a 44-year career, the institute said.

Wani is known, along with his late research partner, Monroe Wall, for developing Taxol and camptothecin. The compounds and their derivatives represent nearly one-third of all anti-cancer medications on the market.

"Drs. Wani and Wall are responsible for some of the most important research ever conducted at RTI International and the most prominent example of how our research improves the human condition," said **Ivy Carroll**, director of the RTI Center for Organic and Medicinal Chemistry.

## *Funding Opportunities:*

# RFAs, PAs Available

RFA-RM-07-006: Limited Competition for Supplements to CTSAs to Plan for Pilot Projects to Apply the National Clinical Research Associates Model in Their Community Engagement Activities. UL1. Application Receipt Date: Jan. 22. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-006.html. Inquiries: Anthony Hayward, 301-435 0791; haywarda@mail.nih.gov.

RFA-AI-07-002: Asthma and Allergic Diseases Cooperative Research Centers. U19. Letters of Intent Receipt Date: April 13; Application Receipt Date: May 14. http://www.grants.nih.gov/grants/guide/rfa-files/RFA-AI-07-002.html. Inquiries: Gang Dong, 301-496-8973; gdong@niaid.nih.gov.

RFA-DA-07-012: The Genes, Environment, and Development Initiative. U01. Letters of Intent Receipt Date: Feb. 15. Application Receipt Date: March 15. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-DA-07-012.html. Inquiries: Glen Morgan, 301-496-8585; gmorgan@mail.nih.gov.

PA-07-097: Chronic Illness Self-Management in Children and Adolescents. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-097.html. Inquiries: Ann O'Mara, 301-496-8541; Omaraa@mail.nih.gov.

PA-07-098: Chronic Illness Self-Management in Children and Adolescents. R03. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-098.html.

PA-07-099: Chronic Illness Self-Management in Children and Adolescents. R21. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-099.html.

PA-07-100: Prioritizing Molecular Targets for Cancer Prevention with Nutritional Combinations. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-100.html. Inquiries: Cindy Davis, 301-594-9692; davisci@mail.nih.gov.

PA-07-109: Cross-Disciplinary Translational Research at NIH. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-109.html. Inquiries: Mark Parascandola, 301-451-4587: paramark@mail.nih.gov.

PA-07-132: Pathophysiology of Bisphosphonates-associated Osteonecrosis of the Jaw. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-132.html. Inquiries: Roy Wu, 301-496-8866: wur@ctep.nci.nih.gov.

PA-07-106: Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships to Promote Diversity in Health-Related Research. F31. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-106.html. Inquiries: H. Nelson Aguila, 301-496-7344; Aguilah@mail.nih.gov.

PA-07-107: Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships to Promote Diversity in Health-Related Research. F32. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-107.html.

PA-07-140: Research on Sleep and Sleep Disorders. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-140.html. Inquiries: Ann O'Mara, 301-496-8541; ao45s@nih.gov.

PA-07-148: Understanding Mechanisms of Health Risk Behavior Change in Children and Adolescents. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-148.html. Inquiries: Amy Yaroch, 301-402-8425; yarocha@mail.nih.gov.

PA-07-165: Pathogenesis And Treatment Of Lymphedema And Lymphatic Diseases. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-165.html. Inquiries: Suresh Mohla, 301 435 1878; mohlas@mail.nih.gov.

PA-07-172: Ruth L. Kirschstein National Research Service Awards for Individual Senior Fellows. F33. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-172.html. Inquiries: Nancy Lohrey, 301-496-8580; lohreyn@mail.nih.gov.

PA-07-173: Research on Malignancies in AIDS and Acquired Immune Suppression. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-173.html. Inquiries: Elizabeth Read-Connole, 301-496-6085; bconnole@mail.nih.gov.

PA-04-174: Testing Tobacco Products Promoted to Reduce Harm. R01. Full text: Inquiries: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-174.html. Mirjana Djordjevic, 301-496-8584; djordjev@mail.nih.gov.

PA-07-175: Diet, Epigenetic Events, and Cancer Prevention. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-175.html. Inquiries: Sharon Ross, 301-594-7547; rosssha@mail.nih.gov.

PA-07-176: Studies of Energy Balance and Cancer in Humans. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-176.html. Inquiries: Virginia Hartmuller, 301-594-3402; hartmulv@mail.nih.gov.

PA-07-177: Correlative Studies with Specimens from Multi-Site Trials. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-177.html. Inquiries: Heng Xie, 301-496-8866; xiehe@mail.nih.gov.

PA-07-178: In Utero Exposure to Bioactive Food Components and Mammary Cancer Risk. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-178.html. Inquiries: Cindy Davis, 301- 594-9692; davisci@mail.nih.gov.

PA-07-179: Protein Biomarkers of Infection-Associated Cancers. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-179.html. Inquiries: Karl Krueger, 301-435-1594; kruegerk@mail.nih.gov.

PA-07-180: School-based Interventions to Prevent Obesity. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-180.html. Inquiries: Amy Yaroch, 301-451-9530; yarocha@mail.nih.gov.

PAR-07-145: Tools for Zebrafish Research. R01. Letters of Intent Receipt Date: Aug. 19. Application Receipt Date: Sept. 19. Full text: http://www.grants.nih.gov/grants/guide/

pa-files/PAR-07-145.html. Inquiries: Lorette Javois, 301-496-5541; lj89j@nih.gov.

PAR-07-160: Innovations in Biomedical Computational Science and Technology Initiative. SBIR [R43/R44]. Application Receipt Date: Feb. 9; May 24; Sept. 24; Jan. 24; May 24; Sept. 24; Jan. 24, 2009. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-160.html. Inquiries: Peter Lyster, 301-451-6446; lysterp@mail.nih.gov.

PAR-07-161: Innovations in Biomedical Computational Science and Technology Initiative. STTR [R41/R42]. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-161.html.

PA-07-186: Diet-Induced Changes in Inflammation as Determinants of Colon Cancer. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-186.html. Inquiries: Young Kim, 301-496-0126; yk47s@nih.gov.

PA-07-187: Stem Cells and Cancer. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-187.html. Inquiries: R. Allan Mufson, 301-496-7815; am214t@nih.gov.

PA-07-201: Characterization, Behavior and Plasticity of Pluripotent Stem Cells. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-201.html. Inquiries: Neeraja Sathyamoorthy, 301-435-1878; ns61r@nih.gov.

PA-07-203: Decision Making in Cancer: Single-Event Decisions. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-203.html. Inquiries: Wendy Nelson, 301-435-4590; nelsonw@mail.nih.gov.

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PA-07-206: The Effect of Racial and Ethnic Discrimination/Bias on Healthcare Delivery. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-206.html. Inquiries: Vickie Shavers, 301-594-1725; shaversv@mail.nih.gov.

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PA-07-260: Understanding the Effects of Emerging Cellular, Molecular, and Genomic Technologies on Cancer Health Care Delivery. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-260.html. Inquiries: Louise Wideroff, 301-435-6823; wideroff@nih.gov.

PA-07-266: Networks and Pathways Collaborative Research Projects. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-266.html. Inquiries: Karl Krueger, 301-594-1044; kruegerk@mail.nih.gov.

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PAS-07-267: The Role of Nuclear Receptors in Tissue and Organismal Aging. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAS-07-267.html. Inquiries: Neeraja Sathyamoorthy, 301-435-1878; ns61r@nih.gov.

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