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NCI And SPORE PIs Discussing Potential Changes To Grant Program Guidelines

By Kirsten Boyd Goldberg

NCI is holding discussions with leaders of the Specialized Programs of Research Excellence to consider potentially extensive changes to the $123-million translational research grant program.

Some of the changes being discussed include:

—Broadening the program's organ-site focus to permit research in other areas such as AIDS-related or pediatric malignancies.

—Eliminating a requirement to move projects into human studies within five years.

—Reducing the maximum number of projects required for each SPORE.

—Eliminating required projects involving screening, detection, or

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In the Cooperative Groups & Cancer Centers:

NSABP Donates Sculpture To NIH To Commemoriate 50th Anniversary

NATIONAL SURGICAL ADJUVANT BREAST AND BOWEL PROJECT, to commemorate its 50th year of conducting clinical research studies, donated a sculpture to NIH to honor the thousands of women and men who have participated in the group's breast and colorectal cancers research.

The sculpture, "Emergence," by John Jayson Sonnier, will be on permanent display at the NIH Clinical Center as a tribute to the volunteers who have given their time and devotion by being involved in a clinical study. A limestone sculpture of two leaves gently emerging from the hard, rough pedestal with a marble base, *Emergence* recognizes the research patients' decisions to participate in clinical trial research and the vital role they play in advancing medical science.

"The NSABP is grateful that we can contribute such a beautiful and profound piece of artwork to the NIH campus in this one-of-a-kind recognition that celebrates our 50th Anniversary," said NSABP Chairman **Norman Wolmark**. "On behalf of the thousands of doctors, nurses, and clinical research associates who conduct NSABP studies, we would like to thank the thousands of men and women who have tirelessly and relentlessly given themselves to research studies that have improved the quality of cancer care so that one day there may be a cure."

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NCI To Consider Change To SPORE Grant Program

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prevention.

"We are in middle of a very intensive information-gathering process," James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis, said at a Sept. 8 meeting of the National Cancer Advisory Board. "All SPORE investigators will have input into this process."

The discussions, which NCI officials began in August and plan to continue through the fall, follow the institute's organizational changes to the SPORE program over the past several months.

The Organ Systems Program, which oversees the SPOREs, was moved from the NCI director's office to Doroshow's division, DCTD, and renamed the Translational Research Program. Toby Hecht was named acting chief of the program.

The move of the program to DCTD "does not mean that the SPORE program will have greater emphasis on treatment," Doroshow said.

The program's move was a result of a review by the Translational Research Working Group. The TRWG report recommended that the SPOREs make better use of NCI's system of programs and resources, such as cancer centers and cooperative groups. The report also urged NCI to find out exactly how much it spends on translational research, and then to try to prioritize research and find ways to enhance support of translational research.

Doroshow and Hecht began to meet with SPORE principal investigators last month to discuss the SPORE program guidelines. They visited or held teleconferences with four cancer centers that together hold 31 out of 61 active SPORE grants—M.D. Anderson Cancer Center, Mayo Clinic, Johns Hopkins Oncology Center, and Harvard Cancer Center.

Also, the SPORE Directors Executive Committee began monthly teleconferences to bring issues to the attention of the NCI director.

NCI's Clinical and Translational Research Advisory Committee is reviewing guidelines of the SPORE program as well as guidelines for cancer centers and cooperative groups, Doroshow said. The goal is to "enhance clinical and translational research coordination."

"Why should we revisit the guidelines for a program that is already very strong?" Doroshow said. "We have been engaged in ways to integrate and incentivize collaboration across cancer centers, cooperative groups, and SPOREs with respect to clinical trials."

DCTD is undergoing a reorganization to align the guidelines with NCI goals for translational science that were outlined in the TRWG report, Doroshow said. Also, the institute's "fiscal reality"—a flat budget—may make some of the current guideline requirements "onerous," he said.

This fall, NCI will hold teleconferences with the SPORE programs that weren't visited, Hecht said. "We will have as many sessions as it takes to get the information that people want to comment on," she said.

After those sessions, the Clinical and Translational Research Operating Committee and the Clinical Trials Advisory Committee will develop formal recommendations, and the suggestions of the SPORE directors would be presented. The recommendations would go to the NCI Executive Committee for approval.

In the initial discussions with SPORE principal investigators last month, five major guideline issues came up, NCI officials said.

—The requirement to move projects into human studies within five years. It's difficult to move from laboratory observation to patients within five years without outside sponsorship. A possible change would be to implement milestones and evaluate whether benchmarks are being met (GMP production, toxicology, IND submission). However, loosening the requirement might cause loss of the program's translational focus.

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Founded Dec. 21, 1973, by Jerry D. Boyd.

—The requirement of four independent projects to build a critical mass and a translational research culture at the institution. The problem is that with a flat budget, investigators can do less per project. A possible change could be to require four projects for submission and three for funding.

—One of the required projects must be in early detection, screening, prevention, or population sciences. Many outstanding studies have come from this requirement, Hecht said. However, not all the organ sites have this requirement, and the project may not be the strongest an investigator could propose. Also, population studies often require a larger budget than SPORE grants can provide. This project could be optional, or required only for breast, prostate, GI, and lung cancers.

—The program currently requires an organ-site focus, which allows for easier collaboration between SPOREs and for progress in a disease. However, broadening the focus would permit other research groups to compete for SPOREs, including those working on AIDS-related and pediatric malignancies and pathways of disease common to different organ sites.

NCI officials also are looking at ways to keep "science first" in peer review and scoring of SPORE grant applications, Hecht said. In fiscal 2009, reviewers were asked to ignore paylines. Each review element was rated with a numerical score, and reviewers were told to focus on the scientific projects scores and to use the programmatic or procedural elements to move the scores up or down.

This resulted in scores that were better spread across the range, Hecht said.

"The new leadership has done a wonderful job," said NCAB member Bruce Chabner, clinical director of the Massachusetts General Hospital Cancer Center. "They came to us and asked us questions, and I have the greatest confidence in this. They are reducing the number of restrictive guidelines and making science the first priority."

Commentary:

Professional Fundraiser Poses Eight Questions For SU2C

By Harry A. Freedman

I've lost many friends and family members to cancer. So, understandably, as I watched Stand Up 2 Cancer, a star-studded benefit broadcast by the three major networks on Sep. 5, I felt a powerful urge to give money.

I called the number that appeared on the screen, but got a busy signal. I tried again and again, every 10 minutes, and for half an hour after the show ended. Still, I could not get through. The SU2C website didn't give me a chance to contribute either. Finally, I gave up.

As a professional fundraiser and the author of three books on producing profitable charity special events, I am disappointed, indeed embarrassed, that an event of this magnitude, with a goal of netting over $250 million was so disorganized. As I look back, I wonder whether the SU2C organizers had consulted a professional fundraiser.

I am sure that the celebrities, news anchors, sponsors and underwriters—and, most importunately, contributors—participated in this event in good faith. I think that now the organizers of this benefit have the duty to assure the public that all these good-faith efforts weren't wasted.

The Cancer Letter and The Chronicle of Philanthropy have attempted to get answers to some very important questions about this event, but the answers, alas, were not informative, and, in my opinion, disingenuous and evasive.

How can the organizers claim to be unaware of how much money they spent and how much they brought in? Jerry Lewis, at the end of his telethon, announces exactly how much was raised, and within a few days, the net proceeds are reported to the public. The same holds true for St. Jude's Children's Research Hospital and many other high-profile fundraisers. The answer we have seen so far—that SU2C has raised "more than" $100 million—isn't good enough.

I hope that cancer advocacy groups will demand that the SU2C organizers make a full accounting of the costs, the revenues and the plans for distributing the net funds raised through the Sept. 5 event. After years of helping national charities hold profitable events, I would like to see answers to the following questions:

1. How much money was raised before the telethon started? How much was raised during the telethon?

2. What was the dollar value of in-kind donations, and how were they used?

3. What were the overall costs, including production, entertainment, parties and travel by the SU2C organizers and the American Association for Cancer Research?

4. Responding to questions from The Cancer Letter, the SU2C organizers suggest that two pots of money were used. One of these accounts was said to disburse corporate contributions to pay for the show's expenses. How much money was placed into this account and how was it used?

5. What are the administrative costs? How much

will be charged by AACR to administer the grants? How much will be charged by the Entertainment Industry Foundation? Responding to questions from The Cancer Letter, the SU2C organizers said the EIF administrative costs have been paid through corporate donations. Were these donations solicited in a separate fundraising effort, and how are they reported?

6. What portion of the gross proceeds of SU2C is available for immediate disbursement? How much of it represents multi-year commitments?

7. How does the EIF plan to spend the 10 percent earmarked for maintenance of ongoing operations? How will the disbursement of these funds be reported? Will the public be able to monitor how this money is spent?

8. Have you secured a multi-year commitment from the network to continue the effort? Are they pleased with the ratings? What are the assurances that this is not a one-time televised event?

The author is a fundraising consultant who organizes and produces special events for corporations and non-profits. He is the author of three books on fundraising, most recently, "Black Tie Optional; A Complete Special Events Resource for Non-Profit Organizations."

In the Cancer Centers:

OSU Names Byrd To Lead Clinical Translational Research

(Continued from page 1)

OHIO STATE UNIVERSITY Comprehensive Cancer Center-James Cancer Hospital and Solove Research Institute named **John Byrd** to the new position of associate director of clinical translational research. Byrd is director of hematologic malignancies, the D. Warren Brown professor in leukemia research, professor of medicine and medicinal chemistry, co-director of the Division of Hematology-Oncology, and member of the OSUCCC Immunology and Experimental Therapeutics programs. In his new position, he will accelerate translational cancer research throughout the OSU cancer program and facilitate grant applications and awards for translational research, said **Michael Caligiuri**, CEO of the James Cancer Hospital and director of the Ohio State Comprehensive Cancer Center. The center also recently expanded its urology team with the addition of three surgical oncology specialists: **Ronney Abaza**, **Ahmad Shabsigh**, and **David Sharp**. Abaza, of the University of Toledo and founder of the Robotic and Minimally-Invasive Urologic Institute of Northwest Ohio, was named director of robotic urologic surgery. Shabsigh, who completed his fellowship at Memorial Sloan-Kettering Cancer Center, has clinical interests that include genitourinary malignancies. Sharp was trained in laparoscopic and robotic techniques for urologic cancers at Memorial Sloan-Kettering Cancer Center.

UNIVERSITY OF ARKANSAS for Medical Sciences Winthrop P. Rockefeller Cancer Institute received a $2.5 million grant to provide colorectal cancer education and screenings in St. Francis and Mississippi counties. The five-year grant from NIH's National Center on Minority Health and Health Disparities will fund the Colorectal Cancer Education and Screening Program, a community-based research program. **Ronda Henry-Tillman** is principal investigator of the program and professor of surgery in the UAMS College of Medicine. The funding will provide home test kits to be distributed to residents of St. Francis and Mississippi counties.

HOAG MEMORIAL Hospital Presbyterian has partnered with the University of Southern California Keck School of Medicine to establish a breast fellowship program at Hoag Breast Care Center. The USC Breast Fellowship Program will be expanded to include Hoag Hospital as a third rotation, placing Hoag alongside Los Angeles County-USC Medical Center and USC Kenneth Norris Comprehensive Cancer Center, teaching hospitals that are current rotations in the program. Under the direction of **Melvin Silverstein**, medical director of Hoag Breast Care Center, fellows will gain experience in oncoplastic surgery and new technologies.

NEVADA CANCER INSTITUTE received its second gift from the Engelstad Family Foundation. The $20 million donation will fund the Ralph and Betty Engelstad Cancer Research Building, under construction on the NVCI campus. The 183,378-square-foot research facility will have 36 laboratories on three floors, as well as a core laboratory for clinical research and expanded basic and translational research. In 2006, the institute received a $15 million gift from the foundation for scientific research, screening and treatment in lung cancer. Three named chairs and fellowships focusing on the prevention and the therapy of lung cancer will be created from an endowment, said **Nicolas Vogelzang**, institute director.

MEMORIAL SLOAN-KETTERING Cancer Center announced awards and appointments. **Marcel**

van den Brink was named head of the Division of Hematologic Oncology in the Department of Medicine. A physician-scientist working in allogeneic blood stem cell transplantation for adult cancer, van den Brink also heads a laboratory in the Sloan-Kettering Institute Immunology Program that focuses on the immunology of bone marrow transplantation and the role of T cells in graft-versus-host disease. **Jason Lewis** was named chief of the Radiochemistry Service in the Department of Radiology and an associate member in MSKCC. He also holds an appointment in the Molecular Pharmacology and Chemistry Program and is director of the Cyclotron-Radiochemistry Core facility. Lewis was assistant professor of radiology at Washington University School of Medicine, St. Louis. **Isabelle Rivière**, cellular and molecular biologist, was named director of the newly created Cell Therapy and Cell Engineering Facility. The facility will merge the cell and vaccine production handled by the Adoptive Immune Cell Therapy Facility, the Immunobiology Facility, and the Gene Transfer and Somatic Cell Engineering Facility, which Rivière has co-directed since 1998. **Victor Reuter**, vice chairman of the Department of Pathology and co-director of the MSKCC Pathology Core Facility, was appointed president of the U.S. and Canadian Academy of Pathology. Reuter has been at MSKCC since 1983 and involved in studies linking cell proteins to clinical characteristics tumors of the bladder, kidney, and testes.

UNIVERSITY OF FLORIDA Office of Research, UF College of Medicine and Moffitt Cancer Center have created a $4 million research fund to finance collaborative pilot research projects at the two institutions. The fund would promote scientific endeavors of researchers while helping them prepare for the development of a consortium-style NCI-designated cancer center. Each $100,000, one-year grant is meant to kick-start joint projects that lead to publications or grant applications prior to the resubmission of the cancer center grant from the NCI that Moffitt and UF will be a part of, said **Joseph Simone**, director of the UF Shands Cancer Center and physician-in-chief of cancer services for Shands at UF medical center.

OMER KUCUK, prostate cancer scientist, was appointed professor of hematology and medical oncology at Winship Cancer Institute, Emory University. He was professor and co-leader of the population sciences and prevention program, and member of genitourinary and head and neck cancer multidisciplinary groups at Karmanos Cancer Center at Wayne State University.

Foundations & Societies:

MMRF Names Susan Kelley As Chief Medical Officer

MULTIPLE MYELOMA Research Foundation and the Multiple Myeloma Research Consortium appointed **Susan Kelley** to the new position of chief medical officer. She was vice president of global clinical development for Oncology at Bayer Healthcare Pharmaceuticals. Also, **Louise Perkins** was promoted to chief scientific officer. Perkins was director of Cancer Research at Bayer Pharmaceuticals. Both Kelley and Perkins will serve on the MMRF and MMRC Executive Committee and will report directly to **Kathy Giusti**, founder and CEO of MMRF and MMRC. "Their expertise in drug discovery and development, combined with executive committee members' expertise in drug commercialization and strategic planning, will enable the MMRF and MMRC to serve as an end-to-end solution for the development of new myeloma therapies," said Giusti.

ALISON MARTIN was named president and CEO of the Melanoma Research Alliance, a public charity formed in November 2007 under the auspices of the Milken Institute, with the initial support of **Debra** and **Leon Black**. Martin was most recently head of Genitourinary Cancers and Melanoma Therapeutics in the Clinical Investigations Branch of the Cancer Therapy Evaluation Program at NCI. She has served as liaison to three of NCI's cooperative groups and been a senior investigator in the Investigational Drug Branch of CTEP. Martin was a team leader in the FDA Office of Oncology Drug Products.

LANCE ARMSTRONG FOUNDATION made appointments to two new leadership positions: **Morgan Binswanger** as chief of staff and **Philippe Hills** as Executive Vice President for Development. Binswanger was director of the Jimmy Carter Work Project, Habitat for Humanity's international building effort. Hills was vice president of development for the Robert W. Woodruff Health Sciences Center of Emory University.

AMERICAN CANCER SOCIETY and the **National Medical Association** announced a three-year collaboration to educate the public and health professionals about best practices to achieve optimal outcomes in cancer prevention and early detection, and treatment among ethnic minority and underserved

population groups. Initial goals for the collaboration include developing and distributing culturally relevant consumer and professional materials that focus on prevention, early detection, and treatment of breast, prostate, and colorectal cancer, as well as proper nutrition and physical activity. The effort will also target faculty and alumni of Historically Black Colleges and Universities, NMA clinical specialty sections, regions, states and local members, community-based organization leaders in the African-American and Hispanic/Latino communities, and large African-American and Hispanic/Latino church congregations nationwide.

AMERICAN SOCIETY for Therapeutic Radiology and Oncology promoted two staff members of its Government Relations Department. **Dave Adler**, government relations representative, was named assistant director of government relations. **Richard Martin**, legislative and regulatory analyst, was promoted to senior legislative and regulatory analyst.

NCI News:

Abrams Named CTEP Director

JEFFREY ABRAMS was selected as associate director of the NCI Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program. Abrams, who served as CTEP's acting associate director for the past year, joined DCTD in 1993 as a clinical research scientist to oversee the breast cancer treatment trials portfolio and conduct clinical trials at the NIH Clinical Center and the National Naval Medical Center.

JAMES TATUM was named associate director of the DCTD Cancer Imaging Program. Tatum joined CIP in 1998 as a special assistant to the associate director. In 2006, Tatum assumed leadership of CIP's Molecular Imaging Branch. Since July 2007, he has served as acting associate director of CIP.

TOBACCO MONOGRAPH: NCI issued its 19th monograph in a series of tobacco control monographs. "The Role of Media in Promoting and Reducing Tobacco Use" is the first comprehensive distillation of the scientific literature on media communications in tobacco promotion and tobacco control.

It synthesizes the science across the disciplines of marketing, psychology, communications, statistics, epidemiology and public health. More than 1.5 million American children began smoking in 2005 and close to half a million Americans died prematurely from diseases caused by tobacco use or secondhand smoke exposure, so it is hoped that the key lessons from this monograph can inform policymakers as well as scientists and practitioners.

Some of the conclusions the monograph addresses are the role of advertising in recruiting young smokers which expands the market for tobacco products by reinforcing smoking, discouraging quitting, and appealing to health concerns; the integration of marketing communications across a broad range of channels to promote tobacco; consumer marketing themes are effective in targeting consumers; and how stakeholder marketing aimed at retailers, the hospitality industry and policymakers impedes tobacco control interventions. The monograph is available at http://cancercontrol.cancer.gov/tcrb/monographs.

Research Policy:

National Academies Updates Stem Cell Research Guidelines

The National Academies released amended guidelines for research involving human embryonic stem cells, revising those that were issued in 2005 and updated in 2007.

One reason for the 2008 modifications is to provide guidance on the derivation and use of new human stem cells that were first developed last year. These "induced pluripotent cells" are made by reprogramming nonembryonic adult cells into a stem-cell-like state, in which they can be manipulated to form a wide array of specialized body cells.

Although induced pluripotent stem cells can be derived without using embryos, the ethical and policy concerns related to their potential uses are similar to those pertaining to human embryonic stem cells. For example, issues arising from mixing human and animal cells in a single organism are relevant for stem cells from both embryonic and nonembryonic sources. However, derivation of induced pluripotent stem cells does not require special stem cell expertise and is adequately covered by current Institutional Review Board regulations, the report says.

At this time it is still undetermined which stem cell types will prove the most useful for regenerative medicine, as most likely each will have some utility, noted the committee that wrote the report. Therefore, the need for research with human embryonic stem cells still exists despite the availability of new cell sources.

The amended guidelines also clarify that "direct expenses" for reimbursement to women donating their

eggs for use in stem cell research may include costs associated with travel, housing, child care, medical care, health insurance, and actual lost wages. This language extends the 2005 guidelines.

Copies of the report, "2008 Amendments To The National Academies' Guidelines For Human Embryonic Stem Cell Research," are available at www.nap.edu.

Funding Opportunities:

NIH Offers $250 Million Over Five Years For New T-R01s

NIH intends to invest more than $250 million over the next five years to foster bold and creative investigator-initiated research through a new transformative R01 (T-R01) Program.

While R01 grants support the bulk of mainstream NIH investigator-initiated efforts, the structure and review of R01 proposals can discourage submission of the most bold, creative, and risky research proposals. In response to these challenges, the NIH has created the T-R01 Program.

"The T-R01 Program will pilot novel approaches to peer review to facilitate identification and support of the most ground-breaking, high impact research and augment the existing Pioneer and New Innovator Awards programs," said NIH Director Elias Zerhouni.

The purpose of the T-R01 Program is to support exceptionally innovative, original or unconventional research that will allow investigators to seize unexpected opportunities and cultivate bold ideas regardless of the anticipated risk. T-R01 funding will support inventive and innovative studies intended to transform current paradigms in biomedical or behavioral sciences. The TR01 program is a trans-NIH effort coordinated by the Office of Portfolio Analysis and Strategic Initiatives (OPASI) as part of the NIH Roadmap for Medical Research.

"The new TR01s follow years of discussion as to how to encourage thinking outside of the box. This new mechanism is designed to encourage the generation of new scientific paradigms or the disruption of old ones," said Alan Krensky, director of OPASI.

The NIH aims to achieve T-R01 program goals by supporting original studies that will:

—Forge the synthesis of new paradigms for biomedical or behavioral sciences.

—Reflect an exceptional level of creativity in proposing bold and ground-breaking approaches to fundamental problems.

—Promote radical changes in a field of study with a profound impact in other scientific areas.

—Be evaluated by new procedures being piloted by the NIH Center for Scientific Review that are distinct from the traditional NIH peer review process.

"Conventional wisdom says that R01 applications of this sort are 'dead on arrival.' The hope is that the T-R01 Program will liberate scientists to unveil extraordinary ideas and approaches, and that novel review and support procedures will select the best for funding," said Keith Yamamoto, of University of California, San Francisco, and co-chair of the Advisory Committee to the Director Working Group on Enhancing Peer Review.

NIH encourages T-R01 applications from scientists from all disciplines relevant to the NIH mission, including the biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences. Areas of highlighted need that have been identified through an NIH strategic planning process include:

Science of Behavior Change, Protein Capture, Functional Variation in Mitochondria, Complex 3-D Tissue Models, Acute to Chronic Pain Transition, and Pharmacogenomics.

Applications for new five-year grants are now being accepted. Review criteria will focus on a project's transformative potential. NIH plans to fund the first cohort of T-R01 awards in 2009, and hopes to announce the T-R01 program again in 2010 if funds are available.

Further information is available at: http://www.nihroadmap.nih.gov/grants/index.asp.

RFPs Available

RFP S08-221: Chemical Biology Consortium. Response Due date: Oct. 27, 5:00:00 PM. Full text: http://www.fbodaily.com/archive/2008/09-September/18-Sep-2008/FBO-01672543.htm. Inquiries: Melissa Borucki; cbcsubs@mail.nih.gov.

RFP N02-RC-91002-56: Retroviral vector Encoding Anti-Tumor TCR Genes. Response Due date: Oct. 31. Full text: http://www.fbodaily.com/archive/2008/09-September/14-Sep-2008/FBO-01668919.htm. Inquiries: Michael Marino, 301-435-3801; marinomic@mail.nih.gov.

RFP N02-CM-91008-48: Operation and Support of the Cancer Therapy Evaluation Program's Protocol and Information Office. Full text: http://www.fbodaily.com/archive/2008/09-September/18-Sep-2008/FBO-01671877.htm. Inquiries: John Manouelian, 301-435-3813; manouelj@mail.nih.gov.

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The University of Maryland Marlene and Stewart Greenebaum Cancer Center was recently selected as a **National Cancer Institute (NCI)-designated cancer center**, a distinction shared by only the top cancer centers in the country. The NCI bestows this special designation on the nation's top cancer centers in recognition of their scientific excellence and outstanding patient care.

At the University of Maryland Marlene and Stewart Greenebaum Cancer Center, we're proud to be recognized as a national leader for our innovative approaches to cancer diagnosis, treatment and research. Our NCI designation is a tremendous honor and achievement, as well as a new benchmark in our shared goal of defeating cancer.

The University of Maryland Marlene and Stewart Greenebaum Cancer Center has also been ranked as one of the nation's top cancer centers in the 2008 list of "America's Best Hospitals" by *U.S. News & World Report.*

For more information call us at 1-800-373-4111 or visit us at www.umgcc.org.

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