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New Policy On Minor Changes In Trials Requires Halt In Patient Enrollment

By Kirsten Boyd Goldberg

In a bout of regulatory wrestling over human subject protections, NCI seems to have lost to the Department of Health and Human Services.

The result has the institute's cooperative groups and cancer centers scrambling to minimize interruptions in the enrollment of patients on clinical trials.

Under a ruling by the HHS Office of Human Research Protections, ongoing clinical trials must be halted to patient enrollment even if minor changes that affect the risk-benefit ratio for new patients are made to the protocol. The trials must be stopped to await review and approval of the changes by Institutional Review Boards.

Previously, changes of this sort didn't require interruption of trial

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Conflicts of Interest:

AACR Journal Publishes A Henschke Letter Without Disclosure Of Conflicts Of Interest

By Paul Goldberg

Something was missing in a letter to the editor from the lung cancer researcher Claudia Henschke, who in recent months found herself in the center of a controversy over failure to disclose her numerous conflicts of interest.

The letter published in the April 15 edition of Clinical Cancer Research contained no disclosure.

Three months earlier, the editors of the journal published by the American Association for Cancer Research were first informed by The Cancer Letter that the Weill Cornell Medical College radiologist was listed as an inventor on numerous patents covering screening technology and was receiving royalties from General Electric (The Cancer Letter, Jan. 18).

The New England Journal of Medicine, the Journal of the American Medical Association, The Oncologist, and the American Cancer Society journals Cancer and Cytopathology have since published corrections, clarifications, and editorials on the subject of disclosures left out from the articles by Henschke and collaborator David Yankelevitz, also of Weill Cornell.

"I guess the editors of Clinical Cancer Research don't read The New York Times and don't read The Cancer Letter," said Shannon Brownlee, Schwartz Senior Scholar at the New America Foundation and author of a

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Minor Changes To Protocols May Slow Patient Enrollment

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enrollment. NCI allowed accrual to continue as long as doctors explained the information to new participants verbally. Once the IRB approved the protocol amendment, the new participants would sign a revised informed consent document.

"Clinical trials are difficult enough to complete without putting these enormous restrictions in place that will cause enormous difficulties in our ability to accrue patients and complete trials that will improve cancer treatment and prevention," said Norman Wolmark, chairman of the National Surgical Adjuvant Breast and Bowel Project and chairman of the Department of Human Oncology at Allegheny General Hospital. "It seems to be a reinterpretation of previous, longstanding policy."

OHRP, NCI, and FDA have been negotiating the policy over the past year. NCI originally objected to the change and was overruled, institute officials said.

On March 20, the NCI Cancer Therapy Evaluation Program sent a memorandum to the cooperative groups outlining the new procedures that would need to be put in place.

"We were informed by OHRP about the requirement that we modify our procedures regarding how newly discovered risks for an ongoing trial are communicated to new patients being enrolled on the study," Jeffrey Abrams, acting associate director of CTEP, said in an email. "We initially tried to have OHRP reconsider their ruling, but were unsuccessful.

"We then worked with representatives of OHRP and FDA to develop a procedure that would, in most cases, avoid the necessity of closing clinical trials to new enrollments each time an informed consent document needs to be modified for newly discovered risks," Abrams said. "As new risks are detected fairly frequently for investigational agents in oncology, we were very concerned that repeated closings of trials, even if only temporary, would have a very negative impact on patient enrollment.

"In an attempt to avoid this, we were able to reach agreement with OHRP that local IRBs could perform an expedited review when the modifications to the risk section were deemed to represent no more than a minor change in the risk-benefit profile for patients," Abrams said.

"Expedited review should help to minimize the impact of this OHRP requirement, assuming local IRBs agree that the changes are minor," he said. "CTEP has recently instituted an approach to enable rapid generation of protocol amendments and consent form changes for expedited local IRB review when new risks are detected.

"However, it is a very labor-intensive process for the cooperative groups and cancer centers, and I remain very concerned that this process will result in a slow-down in our ability to enroll patients," Abrams said. "We will carefully monitor this new process to determine its impact."

"A Huge Step Backward For Cancer Patients"

Cancer patients hoping for access to experimental therapies and willing to go on clinical trials could be turned away unnecessarily, said Richard Schilsky, chairman of Cancer and Leukemia Group B, and professor of medicine in the Biological Sciences Division at University of Chicago.

"I think all the groups agree, as do many of our institutions and our patient advocates, that this requirement is a huge step backward for cancer patients," Schilsky said. "These procedures will increase the regulatory paperwork for the groups and for every IRB in America and, more importantly, will interrupt patient accrual to important trials and, potentially, prevent patients from being enrolled on studies."

Even a short delay of a few days could result in eligible patients choosing not to enroll in a trial, Schilsky said. "Take the example of a patient who has been screened and determined to be eligible for a trial when

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an amendment comes out that requires interruption of accrual until it receives IRB approval," he said. "Even for an efficient, responsive IRB, it might take three to five working days to complete the IRB review. By then, the window of opportunity for the patient to be enrolled may have closed, either because they don't want to delay treatment or their pre-treatment testing is no longer valid.

"OHRP seems to have missed the point on risk-benefit," Schilsky said. "The real risk to cancer patients is missing the opportunity to participate in a clinical trial of a new treatment that might improve their outcome—not missing the opportunity to receive notification in writing of a minor change in the toxicity profile of a treatment program."

Ivor Pritchard, OHRP acting director, said the agency hasn't changed its policies.

"OHRP has not changed the regulations for the protection of human subjects or its policies related to procedures in clinical trials," Pritchard said in an email. "Rather, NCI has revised the procedures of the Cancer Therapy Evaluation Program for implementing protocol changes in these clinical trials, because it has become aware of a discrepancy between those procedures and the long-standing requirements of the regulations.

"In particular, NCI is appropriately correcting its procedures related to institutional review board review of these protocol changes," Pritchard said. "With regard to expressed concerns that satisfying the regulatory requirements through the revised procedures would have a major impact on the length of trials, we believe those concerns are mistaken.

"OHRP has advised CTEP staff that many of the protocol and informed consent changes that need to be made in response to new or modified risk information representing minor alterations in the overall risk-benefit to subjects may be eligible for expedited review by an IRB chairperson," Pritchard said. "This OHRP advice is also reflected in Dr. Abrams's memorandum. IRBs should be able to approve most of these amendments expeditiously, and the impact on the time to complete these clinical trials should be minimal."

Joyce Mull, director of regulatory affairs at NSABP, said the cooperative group tested the new procedure soon after NCI's March 20 memo. The group's B-40 study had a change that fell into the category of "minor alteration in the overall risk-benefit ratio," she said.

"The sites were instructed to inform their IRBs of the new information, and any new patient would not be allowed to be accrued to the study without IRB approval of the amendment," Mull said. "We allowed for expedited IRB review according to the NCI directive."

Reactions have varied among hundreds of institutions affected. For example, one site, a large Community Clinical Oncology Program, said its procedures would require full IRB review and it would be unable to accrue patients for six weeks. However, other sites completed their expedited IRB approval in about three days, Mull said.

"We think we have been able to maintain safety for patients in our studies all along," said Lawrence Wickerham, associate chairman of NSABP and associate professor of human oncology at Drexel University School of Medicine. "Major changes in safety have always resulted in trials being shut down until we can make changes in informed consent documents."

A copy of an NSABP memo describing the policy change is posted at www.cancerletter.com/publications/special-reports.

NCI's Memo To Cooperative Groups

The text of the March 20 memo from NCI to the cooperative groups follows:

This memorandum is in reference to discussions between the Cancer Therapy Evaluation Program (CTEP) at the National Cancer Institute (NCI), the Office of Human Research Protections (OHRP), and the Food and Drug Administration (FDA) regarding changes in informed consent documents in NCI/CTEP-sponsored clinical trials and the continued enrollment of new participants to those trials.

OHRP has advised the NCI/CTEP staff that when new or modified risk information is discovered that requires an amendment to satisfy the requirements for informed consent under U.S. Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(a)(2), enrollment of new participants must cease until the designated Institutional Review Board (IRB) has reviewed and approved the changes to the informed consent and protocol documents.

CTEP's procedures have been in compliance with OHRP regulations with respect to modifications to the informed consent and protocol documents for new or modified risk information for clinical oncology trials that it sponsors when the information represents a **major** alteration in the overall risk-benefit for new participants. In those situations, CTEP has required immediate suspension of accrual to the trial until an amendment that includes that information and a revised informed consent document is reviewed and approved by the IRB.

In situations in which new or modified risk

information was considered to represent a **minor** alteration in the overall risk-benefit for new participants, CTEP's past procedures have not been in compliance with OHRP regulations. In those situations, CTEP allowed continued enrollment of new participants, before review and approval of a protocol amendment by the designated IRB, if the new information was verbally conveyed to new participants, the verbal communication was documented in the new participants' medical record, and the new participants signed a revised informed consent document once the appropriate IRB approved the protocol amendment.

In order to comply with OHRP regulations, CTEP has now revised its procedures to ensure that new or modified risk information that represents a minor alteration in the overall risk-benefit is conveyed to new participants appropriately. This information will be disseminated to sites participating in the clinical trial with an amended protocol and revised informed consent document. The sites will be instructed that new participants cannot be enrolled on the study until the amended protocol and informed consent document have been reviewed and approved by the designated IRB. However, since the changes to the protocol and informed consent document represent a minor alteration in the overall risk-benefit for participants, the participating sites will be notified that the amendment can undergo expedited review at the discretion of the Chair of the designated IRB (i.e., if the IRB Chair agrees that the new or modified risk information is minor with respect to the overall risk-benefit for participants in the trial, the Chair may review and approve the amendment via an expedited review procedure).

Per NCI/CTEP's discussion with OHRP, expedited review by the IRB Chair in this situation would be in compliance with OHRP's interpretation of the regulations. New or modified risk information may be considered to represent a minor alteration in the overall risk-benefit for participants in oncology trials since participants enrolled on these trials already incur significant risks because of the potential lethality of their disease. Many treatment interventions in oncology are known to cause serious adverse events. If new or modified risk information provides additional detail on the risks of the treatment intervention under study without changing, in a major way, the overall weight given to the risks versus benefits for participants, a protocol amendment, including a revised informed consent document, containing this information may be subject to an expedited review procedure at the discretion of the IRB Chair.

Conflicts of Interest:

AACR Journal Says Policy On Conflicts Was In Transition

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recently published book, "Overtreated." A story about Henschke accepting $3.6 million from the parent company of the cigarette maker Liggett Group appeared concurrently in the two publications on March 26.

AACR publisher Kathleen Case explained that Henschke's letter ran without a disclosure because the journal is in the process of implementing updated policies on conflicts of interest. The journal would run a correction, she said.

"AACR has recently changed our conflict of interest policy for our journals to make more explicit the kinds of conflicts that need to be disclosed and to require publication of the conflicts disclosed, or the fact that none were disclosed," Case said in an email.

The change was made in two phases. A version of a conflict of the policy that went into effect last August left it to the editor-in-chief to decide whether disclosures made by authors should be published. After the Henschke controversy came to light, the society adopted a policy that requires publication of all disclosures submitted by authors.

"We are not publishing disclosures for articles that were already in our system prior to this decision," Case said. "Therefore, for much of 2008, some journal articles will have disclosures and some will not, depending on when papers were first submitted."

Henschke's letter was a response to two other letters, by Peter Bach, of Memorial Sloan-Kettering Cancer Center, and Gerard Silvestri, of Medical University of South Carolina. Bach and Silvestri were seeking clarification on claims Henschke had made in an editorial published by CCR on Sept. 1, 2007.

"Three letters to the editor in the April 15 issue of Clinical Cancer Research, from Drs. Bach and Silvestri and the response from Dr. Henschke were received, typeset, and then held pending revision after the decision had been made to publish all disclosure forms, although we had requested and received signed disclosures from all of these authors," Case said. "Dr. Henschke acknowledged no conflicts on our form. We have since learned that Dr. Henschke had items to disclose, and she has provided us with a list of disclosures, not all of which are relevant to the topic of the letter. In the interests of complete transparency, however, we have mutually agreed to publish the disclosures of all of the authors of these letters that reference Dr. Henschke's previous

commentary published in Clinical Cancer Research."

The disclosures will appear in the June 15 issue of the journal, said Case, who will be retiring next week.

Though an earlier version of the journal's conflict rules was less specific than the current version, it still required disclosure of "actual, potential, or apparent conflicts of interest." The new rules posted on the CCR website require disclosure of conflicts for all submissions. Other letters to the editor published in the April 15 issue included disclosure.

Now, CCR authors sign the following statement: "I understand that failure to complete this form will disqualify my manuscript from consideration for publication. Failure by any author to disclose a conflict that later comes to light will result in a ban on that author publishing in any AACR journal for a period of 3 years."

"The invited letter-response was written prior to the expanded disclosure policy," Jonathan Weil, a spokesman for Weill Cornell, said in an email. "Disclosure has already been supplied to the journal."

Robert Erwin, president of the Marti Nelson Cancer Foundation, an advocacy group, said publishers should be aggressive in enforcing disclosure requirements.

"Any published manuscript from a medical professional has the potential to influence the opinions of other professionals and even change the practice of medicine," Erwin said. "How can it not be obvious to both authors and journal publishers that failure to disclose such conflicts of interest is a blow to the field of medicine and the framework of trust and objectivity patients expect to rely upon in dealing with serious treatment decisions?"

A proper disclosure by Henschke et al. requires a significant commitment of space. The version of disclosure published as a correction by The Oncologist took up 929 words. Henschke's letter to CCR stands at 516 words.

In the Courts:

Former BMS Executive Bodnar Indicted By Federal Grand Jury

By Paul Goldberg

Andrew Bodnar, a former Bristol-Myers Squibb Co. executive, was indicted by a District of Columbia grand jury on charges of making a false statement to the Federal Trade Commission.

The indictment filed on April 24 stems from Bodnar's role in negotiating a 2006 agreement between the Canadian firm Apotex Corp. in an effort to settle litigation over a generic version of the blood thinner Plavix, which was marketed by a BMS in a partnership with Sanofi.

The Plavix scandal led to the firing of the BMS CEO Peter Dolan (The Cancer Letter, Sept. 15, 2006).

The indictment alleges that Bodnar, then a senior vice president at BMS, reached an oral agreement in face-to-face negotiations with Apotex chairman Bernard Sherman and didn't reveal those agreements to Federal Trade Commission, which at the time was monitoring the company. The agency and the state attorneys general were given the authority to review Bristol's agreements as part of a settlement of a 2003 criminal case.

In April 2006, antitrust officials nixed a deal in which BMS agreed to allow Apotex to manufacture a generic version of Plavix two months before the patent's expiration date, promising to refrain from introducing an authorized generic version of the drug for six months.

After the regulators jettisoned the original deal, Bodnar and Sherman hammered out another deal and submitted it for approval, court documents state. However, Apotex also submitted a letter that disclosed that the companies had reached an oral agreement over the very same issues that FTC found unacceptable in an earlier version of the deal.

The indictment states that "on or about June 12, 2006, in the District of Columbia and elsewhere, the defendant Andrew Bodnar did knowingly and willfully make a materially false, fictitious and fraudulent statement and representation in a matter within the jurisdiction of FTC." Bodnar faces up to five years in prison and a $250,000 fine.

"The charges in the indictment against Dr. Bodnar are legally and factually unsupportable," said his attorney Elkan Abramowitz. "He will plead not guilty to those charges and vigorously contest them at trial."

A copy of the indictment is posted at http://www.cancerletter.com/publications/special-reports/bodnarindictment.pdf.

In the Cancer Centers:

Masons Give $65 Million To Minnesota Cancer Center

UNIVERSITY OF MINNESOTA Cancer Center received $65 million from Minnesota Masonic Charities for cancer research. The pledge brings Masonic support of cancer research and care at the University of Minnesota to $100 million over the past 53 years. In

recognition, the UM Cancer Center will now be called the Masonic Cancer Center, University of Minnesota. The new funds will allow the center to expand its work, including bringing research to clinical practice for cancer prevention, diagnosis, and treatment. Researchers also will be able to expand studies of cancer survivorship. "Our continued partnership with Minnesota Masonic Charities and this extremely generous gift will allow us to take the Masonic Cancer Center to the next level," said **Douglas Yee**, director. "We will be able to significantly expand our capabilities in cancer research and treatment." . . . **UNIVERSITY OF SOUTHERN CALIFORNIA** opened its Epigenome Center on April 11 with an inaugural symposium hosted by USC Epigenome Center Director **Peter Laird**. Housed in the ground floor of the Harlyne J. Norris Cancer Research Tower on the USC Health Sciences Campus, the Epigenome Center is the first large-scale academic center dedicated to epigenomic research, the university said. A $10 million gift from the Kenneth T. and Eileen L. Norris Foundation provided the infrastructure and technology to enable USC researchers to join an international effort to map the human genome. "This center is important because it gets USC on the ground floor of an international research initiative," said **Peter Jones**, director of the USC/Norris Comprehensive Cancer Center at the Keck School of Medicine. . . . **CITY OF HOPE** Graduate School of Biological Sciences received a $1 million gift from **Norman** and **Melinda Payson**. Norman Payson is a member of the City of Hope national board of directors and was chairman and CEO of Oxford Health Plans Inc. Half of the gift will establish the Dr. Norman and Melinda Payson Graduate Studies Center. The remaining $500,000 will endow the Dr. Norman and Melinda Payson Graduate Student Fellowship, an annually awarded graduate student fellowship. City of Hope also announced new nursing leadership for patient care services. **Shirley Johnson** was named chief nursing and patient services officer and **Sharon Steingass** was named vice president of ambulatory services. Johnson was executive director of the Siteman Cancer Center, Barnes-Jewish Hospital and Washington University School of Medicine in St. Louis. Steingass was interim chief nursing officer at City of Hope. . . . **HOLLINGS CANCER CENTER** at the Medical University of South Carolina dedicated the Edwin and Barbara Pearlstine Healing Garden, which was endowed with a $1 million gift from **Edwin Pearlstine Jr**. in memory of his wife Barbara, who died of cancer. The ceremony also celebrated the opening of the Hollings expanded building, said **Andrew Kraft**, cancer center director. . . . **NEAL FLOMENBERG** was named chairman of the Department of Medical Oncology at Jefferson Medical College of Thomas Jefferson University, Thomas Jefferson University Hospital and the Kimmel Cancer Center at Jefferson. He has been interim chairman since 2006. Flomenberg is clinical deputy director at the Kimmel Cancer Center and professor of medical oncology and microbiology and immunology at Jefferson Medical College. Prior to his appointment as interim director, he was director of the Division of Medical Oncology from 2003 to 2006, and acting director from 2001 to 2003. He has been director of the Hematologic Malignancies and Hematopoietic Stem Cell Transplant Program at Thomas Jefferson University Hospital and the Kimmel Cancer Center since coming to Jefferson in 1994. . . . **LAWRENCE MARKS** was appointed chairman of the department of radiation oncology at the University of North Carolina at Chapel Hill School of Medicine. He succeeds **Carolyn Sartor**, professor of radiation oncology. Marks has been a member of the radiation oncology faculty at Duke University since 1989. Marks is a member of UNC Lineberger Comprehensive Cancer Center. "Larry Marks is a nationally renowned radiation oncologist who brings to UNC strong research accomplishments, with particular interests in clinical trials in breast and lung cancer, as well as in enhancing our understanding of the mechanisms behind radiation-related lung injury," said **William Roper**, dean of the UNC School of Medicine and chief executive officer of UNC Health Care. . . . **EDDIE REED** was appointed professor of oncologic sciences and the Abraham Mitchell Distinguished Investigator at the University of South Alabama Mitchell Cancer Institute. Reed was director of the Division of Cancer Prevention and Control at the Centers for Disease Control. From 2001 to 2005, he was director of the Mary Babb Randolf Cancer Center, University of West Virginia. From 1985 until 2001, Reed was at NCI, where he served as chief of the Medical Ovarian Cancer Section and chief of the Clinical Pharmacology Branch, Division of Cancer Treatment.

CORRECTION: An item in the March 28 issue incorrectly identified the chairman of the Department of Neurosurgery at the University of California, San Francisco. **Mitchel Berger** serves in that position. He also is the Kathleen Plant Distinguished Professor and director of the Brain Tumor Research Center. The UCSF Brain Tumor Program received a pledge of $10 million from Champion Charities for a new Brain Tumor Research Center.

In Brief:

Komen Awards $100 Million In Research Grants For 2008

SUSAN G. KOMEN for the Cure awarded $100 million in research grants for 2008. The 143 grants represent the largest single-year investment in research in the foundation's 26-year history and a 30 percent increase over last year's award total of $77 million.

The foundation began its new Promise Grants, designed to promote collaboration between basic and clinical researchers and different institutions. The awards provide up to $1.5 million per year over five years for breast cancer research.

The seven Promise Grants will fund research in estrogen-negative breast cancer, inflammatory breast cancer, the effects of obesity on the progression of breast cancer, molecular targets of treatment response, the development of hormonal therapies tailored to individual tumor, and patient characteristics and the treatment of HER2-driven breast cancer.

Also, Komen started the Career Catalyst Research grants to support young investigators in the transition from training to scientific independence in breast cancer research. The awards offer $300,000 per year for two years, with option of an additional, performance-based award of $150,000 in year three. Komen is funding $10.8 million in Career Catalyst Research grants for 2008.

The organization said it continues to offer its Post-doctoral Fellowships and Investigator Initiated Research projects. Komen awarded a grant to the American Association of Clinical Oncology to create programs and grants to support improvements in access and delivery of cancer care.

ADVISORY COMMITTEE ON RESEARCH on Women's Health, NIH Office of the Director, announced three new committee members at its semiannual meeting March 17: **Linda Giudice**, the Robert B. Jaffe, M.D., Endowed Professor and chairman of the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco; **Nancy Nielsen**, senior associate dean, State University of New York at Buffalo School of Medicine and Biomedical Sciences, and president-elect of the American Medical Association; and **Debra Toney**, president of the National Black Nurses Association and administrator, Rainbow Medical Centers, Las Vegas. . . **HAROLD P. FREEMAN** Patient Navigation Institute said representatives from the Leukemia & Lymphoma Society and the Ralph Lauren Center for Cancer Care and Prevention were among the first to be certified in patient navigation. Representatives from the Cleveland Clinic were also trained in patient navigation. The Institute offers the only certification program in patient navigation. Patient navigation, a concept pioneered by Harold Freeman in 1990, helps remove barriers to timely cancer screening, treatment and supportive care. To earn certification, the representatives participated in a three-day course at the institute.

Obituary:

Edward Kuff, NCI Researcher

EDWARD KUFF, a researcher at NCI from 1952 until his retirement in 1992, died April 2 of respiratory failure at Suburban Hospital in Bethesda, Md. He was 83. Kuff became deputy chief of NCI's biochemistry laboratory in 1981. He was known for his early research on the structures of cancer cells, his work with electron microscopy, as well as mouse tumor cells. Born in Baltimore, Kuff graduated from Johns Hopkins University in 1943 and received a medical degree from the Johns Hopkins School of Medicine in 1947. He did his medical residency at Washington University in St. Louis, where he received a doctorate in 1952. Later that year, he joined NCI. His wife Suzanne Seff Kuff died in 2006. Survivors include a daughter, Karen Duff-Demico of Binghamton, N.Y., and two grandsons.

Funding Opportunities:

PA-08-151: Midcareer Investigator Award in Patient-Oriented Research. K24. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-08-151.html. Inquiries: Lester Gorelic, 301-496-8580; gorelicl@mail.nih.gov.

PA-08-152: Academic Career Award. K07. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-08-152.html. Inquiries: Shannon Lemrow, 301-496-8580; lemrows@mail.nih.gov.

PA-08-156: Biomarkers of Infection-Associated Cancers. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-08-156.html. Inquiries: Victoria Moncada, 301-435-1594; vmoncada@mail.nih.gov.

PA-08-157: Biomarkers of Infection-Associated Cancers. R21. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-08-157.html.

NOT-CA-08-013: Administrative Supplements to Study Economic Impact of Interventions Targeting Cancer Survivors and/or their Families. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-CA-08-013.html. General Inquiries: Julia Rowland, 301-402-2964; rowlandj@mail.nih.gov.

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