

THE

# CANCER LETTER

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## NCAB Working Group Is Not Subject To Open Meetings Law, NCI Official Says

An advisory committee formed to examine the NCI intramural research program is not subject to federal law requiring open meetings, a senior NCI official said in an interview with **The Cancer Letter**.

The National Cancer Advisory Board Working Group on NCI Structural Organization was scheduled to meet Dec. 7 in closed session. A search of the Federal Register revealed that the meeting was not announced.

No part of the meeting was to be open to the public, Marvin Kalt, director of NCI's Div. of Extramural Activities and executive secretary of  
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### *In Brief*

#### **Baltimore Named ACS Research Professor; Currie, Sachdeva Lead Education Association**

**DAVID BALTIMORE**, Nobel Prize winning biologist at the Massachusetts Institute of Technology, was named an American Cancer Society Research Professor at the society's Board of Director's meeting last month. The Research Professorship, the society's most prestigious award, frees recipients from academic tasks such as heavy teaching and administrative duties, allowing concentration on research. Baltimore will receive ACS support for the duration of his career, subject to scientific review every five years. He received an initial award of \$250,000 for the next five years. He was awarded an ACS Research Professorship in 1973 but was required to relinquish the position in 1982 when he took an administrative position as director of the Whitehead Institute for Biomedical Research, according to an ACS statement. Baltimore became eligible to reapply after returning to a primarily investigative role on the MIT faculty.

... **ACS BOARD** funded 161 new research grants totalling nearly \$24.5 million and the renewal of 131 grants for nearly \$12.7 million at its November meeting. In fiscal 1994, the society spent about \$94 million on extramural research. ... **JOHN CURRIE**, of the Sinai Hospital of Baltimore, was elected president of the American Association for Cancer Education at the association's annual meeting last month in Louisville. **Ajit Sachdeva**, of Medical College of Pennsylvania, was elected president-elect. Other new officers are: secretary, **Robert Chamberlain**, of M.D. Anderson Cancer Center, and treasurer, **Charles Kupchella**, of Southeast Missouri State Univ. At the meeting, **Edward Creagan**, of Mayo Medical School, gave the annual Samuel C. Harvey Memorial Lecture. The

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## NCI Closes Meeting Of Group Examining Institute Structure

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the working group, said to **The Cancer Letter**.

Kalt declined to release the meeting's agenda to a reporter.

The working group does not fall under the Federal Advisory Committee Act "because it is an ad hoc advisory body that is not issuing its own final report," Kalt said to **The Cancer Letter**. "The final report will be issued by the NCAB."

The working group is "a group of independent advisors in executive session," Kalt said.

### Second Closed Meeting

In a statement this week, **The Cancer Letter** disputed Kalt's interpretation of federal open meetings law.

"The editors of **The Cancer Letter** believe that the NCAB working group is in fact an advisory committee, as defined by FACA," the statement read. "This is the second example in recent months of NIH officials illegally closing meetings conducting the review of the intramural program. We find it intolerable that a publicly funded institution is demonstrating such contempt for the law and the public."

**The Cancer Letter** has retained legal counsel to pursue the matter.

"It appears that [NCAB] is improperly delegating its authority to a working group, with plans to rubberstamp whatever decision the working group reaches," said Rebecca Daugherty, an attorney with the Reporters Committee for Freedom of the Press.

"The only reason they are doing this is to avoid

the requirement to meet in public that FACA imposes," she said.

Daugherty said the NCI action bears resemblance to a recent case in which a Federal District Court judge found that the Clinton Administration had improperly closed meetings of the working groups of the task force that drafted the health care reform proposal.

"You would think the Administration would mend its ways," Daugherty said to **The Cancer Letter**.

### NCI: Group Needs Freedom to Explore

"The entire ad hoc advisory nature of this is such that it does not fall under FACA," NCI's Kalt said of the upcoming meeting.

"But, applying the standards we would usually apply, the reason [the meeting] is not open is the confidential nature of the information being discussed," Kalt said.

The committee will discuss intramural site visit reports and will be "interviewing individual scientists," Kalt said.

"The working group has the freedom to go in any direction it sees fit. Therefore, it is impossible to predict when they would get into information that is not accessible to the public," he said.

The working group, whose members were selected by NIH Director Harold Varmus, is reviewing the NCI intramural research program. Other institutes are expected to undergo similar review.

At the upcoming meeting, the working group was expected to hear presentations from NCI division directors and chairmen of each division's Board of Scientific Counselors, sources said. Former NCI director Vincent DeVita also was invited to address the group, sources said.

The group is expected to meet once a month for the next four months. Portions of some of the remaining meetings may be open to the public, Kalt said.

The working group is expected to present a draft report to the NCAB in May, after which discussion of the document will be conducted in open session of the board, Kalt said.

In a statement, the editors of **The Cancer Letter** pointed out that consideration of personnel matters involving intramural scientists--a legitimate reason for closing a meeting--was not part of the mission of the working group.

"The group's stated mission is not to conduct

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review of individual scientists, but to consider how NCI programs came to exist and how they fit into the Institute's administrative structure and scientific mission," the statement read.

"Finally, the working group is expected to recommend whether any of the programs ought to be altered or eliminated," the statement read. "FACA was written to ensure that discussion of the use of public funds be conducted in public."

### "Misreading of FACA"

In a Nov. 29 letter to Anne Thomas, NIH associate director for communications, **The Cancer Letter** protested an earlier decision by NIH to close a meeting of the chairmen of the NIH Boards of Scientific Counselors.

That committee met in an unannounced closed session on Aug. 1 (**The Cancer Letter**, Aug. 5). Part of the meeting was opened after reporters from **The Cancer Letter** arrived to cover the meeting.

The letter requested that **The Cancer Letter** be informed of any subsequent meetings of the chairs or their representatives.

NIH has argued that public access to the group's meetings can be curtailed where the purpose of the meeting is to obtain the advice of individual attendees and not to seek consensus or recommendations.

"In our view, this is a misreading of FACA, and one that we will challenge if applied to any subsequent gathering of any of the boards, their representatives, designees, or persons acting on their behalf," the letter said.

"The distinction suggested by the agency's position is at best metaphysical, practically unworkable, and entirely inconsistent with the letter, spirit, and case law interpreting FACA," the letter said.

### NCI Roundup

## Varmus Pools \$13.4 Million To Fund Priority Projects; NCI's Donation Is \$2.6 Million

NIH Director Harold Varmus has transferred \$2.607 million from the NCI fiscal 1995 appropriation to fund projects of other institutes, NCI Director Samuel Broder said last week.

In the fiscal 1995 appropriation, Congress gave Varmus the authority to transfer 1 percent from any

institute's budget to fund projects the NIH director deems deserving.

Varmus implemented that authority by pooling \$13.4 million from all of the institutes to fund projects at five institutes, Broder said to the National Cancer Advisory Board at its meeting this week.

Among the institutes receiving funding are:

- Human Genome Project, DNA sequencing technology development, \$1.5 million.

- National Heart, Lung & Blood Institute construction of genetic map of the rat genome, \$3.2 million.

- National Institute of Child Health & Human Development, adolescent health study, \$5 million.

- National Center for Research Resources and National Institute for General Medical Sciences small angle x-ray scattering and spectroscopy, \$3.7 million.

NCI will not receive any of the funds, Broder said.

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NCI's FY 1995 budget of \$2.136 billion is only worth 1 percent more in purchasing power than the institute's FY 1980 budget of \$1 billion.

Since 1980, the NCI budget has grown 1 percent, using 1980 constant dollars, Broder said to the NCAB.

Over the same time, the NIH budget grew approximately 15 percent in purchasing power, using 1980 as the base. This includes some adjustments to bring the institutes for mental health, drug abuse and alcoholism back into NIH.

The non-AIDS portion of the NCI budget fell by 10 percent in constant dollars over the same period, while NIH non-AIDS spending grew about 2 percent.

The NCI budget fell in purchasing power during the early 1980s, a period of rapid inflation and austere budgets, Broder said. The NCI budget then rose slightly and held steady for several years.

Only in FY 1992, when Congress gave the Institute its largest single increase, did the NCI budget achieve the same purchasing power as it had held in 1980.

Since FY92, the NCI budget has fallen off in purchasing power from the 1992 level, but it has not fallen below the 1980 level, Broder said.

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**Leon Rosenberg**, president of Bristol-Myers Squibb Pharmaceutical Research Institute, has been added to the NCAB Working Group on Structural Organization, Broder said this week. The committee is reviewing the NCI intramural research program.

Also formally added to the committee was David Baltimore, of Massachusetts Institute of Technology.

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**Vice President Albert Gore** will honor the NCI International Cancer Information Center at an awards ceremony this week for agencies that are "reinventing" government.

NCI is one of several agencies that will receive Gore's "Hammer Award" for "successfully enacting President Clinton's goal of making a government that works better and costs less."

The ICIC will receive the award for several innovations that make it easier for health professionals to access information on cancer biology, prevention and treatment available from NCI.

Last January, the ICIC began the Information Associates Program to provide one-stop access to NCI's scientific information resources, including the Journal of the National Cancer Institute, monographs, and on-line databases.

After an evaluation in 1990, the ICIC determined that its products were underutilized due to fragmented production, promotion and distribution, according to an NCI statement. The office receive the authority to restructure its operations.

In January 1994, NCI awarded a contract for the Information Associates Program. The contract provides customer service, marketing and production and delivery of all ICIC publications.

In response to an executive order requiring executive agencies to identify its customers and survey them to assess their satisfaction with services, ICIC applied to the Office of Management and Budget for clearance to conduct customer surveys. It was the first component of NIH to receive clearance to conduct customer surveys.

## **Clinical Center Director Gallin Plans Better Communication, Training, For Clinical Research**

NIH Clinical Center Director John Gallin announced a new initiative aimed at revitalizing clinical research at the Institutes.

The plan, which Gallin described to Advisory Committee to the Director of NIH last week, includes enhanced clinical research training for NIH clinical associates, enhanced communication between intramural and extramural scientists and extensive use

of telecommunications technology.

Central to completion of these goals is the design and construction of the new, smaller, 250-bed Clinical Center, Gallin said.

The advisory committee endorsed the plans.

"The Warren G. Magnusen Clinical has been a vibrant center for clinical research," Gallin said. "However, since being built in the early 1950's the use of the facility by the institutes has declined over the years, and the physical structure has begun to show signs of deterioration."

### **New \$380 Million Center**

Having resolved that revamping the existing structure would cost more than construction of a new one, NIH has begun the process of planning the new \$380-million facility.

The new Clinical Center will house a contiguous day hospital, ambulatory care facilities, laboratory space and state-of-the-art surgery suites, Gallin said.

Funding for the project will come from current and future intramural budgets. The facility is expected to be completed at the turn of the century.

Downsizing for the smaller center is already taking place, as the center's capacity is being reduced from 416 beds to 325, Gallin said to the advisory group. As it stands, the NIH Clinical Center accounts for nearly 40 percent of all US hospital beds dedicated exclusively to research, as opposed to billable patient care, Gallin said.

The space will be turned into offices for researchers whose offices are currently located in their laboratories at the Clinical Center. The former office space, in turn, will be converted to laboratory space that NIH Director Harold Varmus would allocate.

With the consolidation of patient beds, the Institutes will have to share patient care units, Gallin said.

"This is going to result in a major change in the NIH culture," he said. "Although the Institutes are somewhat nervous about the changes, they are viewing with excitement a new level of intellectual cross-fertilization."

### **Improving Communications**

Also, Gallin said, the changes will include modernization of information systems at the Clinical Center.

"Major innovative changes are planned in terms

of the information system in the Clinical Center," Gallin said. "Digitalization of X-rays, retinal photographs and electrocardiograms will be readily accessible by computer. We intend to have computer terminals available in all patient care units."

Computerization of the data would allow referring physicians to access patient records by computer. Also, NIH researchers would be able to use telecommunications to review information on clinical trial candidates.

"I believe that we are in the unique position helping to define the role of such technology in clinical research," Gallin said. The information infrastructure could also be used to monitor clinical trials, he said.

### **Formal Clinical Research Training**

The majority of clinical researchers receive no formal training in conducting research involving human subjects, Gallin said.

"The lack of formal training for clinical researchers at NIH and nationally, in my opinion, has contributed to some of the problems with clinical studies that we have read about in newspapers this past year," he said.

The intramural clinical research core curriculum about to be offered to NIH clinical associates will consist of four "modules" which will include lectures and practical experiences, including mock data safety monitoring boards and internal review boards.

The NIH training program for clinical researchers will include:

- Training in epidemiology, study design and development, and biostatistics;
- A review of ethical, regulatory and legal issues. Subjects will include the importance of racial diversity and scientific conduct.
- Quality assurance, monitoring of clinical trials and relations with FDA will make up the third part of the course.
- Finally, students will be asked to write research protocols, analyzing the infrastructure and resources needed for clinical research and issues of technology transfer.

The training program is scheduled to start later this winter, and the entering class of clinical associates will be offered the course next summer.

NIH is considering offering the training materials through the "information super highway," Gallin said.

"It would be a nice addition to the program," he said.

## **NCI, Groups Still Disagree On Repayment For Misconduct**

NCI and the chairmen of the clinical cooperative groups still have not resolved the question the Institute's authority to recover research funds in the event of scientific misconduct.

Over the past several months, NCI staff and the cooperative group chairmen have reached agreement on most of the new requirements, or "terms of award," for cooperative agreements that fund the headquarters of the groups (**The Cancer Letter**, Oct. 7).

These include procedures in the event of scientific misconduct, auditing procedures, and procedures for informing patients about adverse events of therapy.

"Serious problems remain" on the issue of NCI recovery of funds, Ross McIntyre, chairman of the cooperative group chairmen's committee, wrote in a Nov. 21 letter to Richard Ungerleider, chief of the Clinical Investigations Branch in the Div. of Cancer Treatment.

NCI officials have said the Institute has the authority to recover funds provided to the cooperative group headquarters in the event that any member of the cooperative group has been found guilty of scientific misconduct.

Cooperative group chairmen have said their institutions would not allow them to accept the headquarters grants if they had to accept liability for misconduct that might happen at subcontract institutions.

### **Term Raises "Red Flag"**

The issue remained unresolved after a meeting last month of the cooperative group chairmen.

"The grants administration point of view is that money spent for activities that are subsequently deemed to represent scientific misconduct are unallowable costs, and in such cases we would seek to recover the funds," Ungerleider said to **The Cancer Letter**. "The argument from NCI's point of view is that we already have this authority and that the term of award is just a consciousness-raising thing, so that institutions know that we have this authority."

According to McIntyre, not all legal counsel to the groups agree that NCI has this right.

"If NCI has the authority, then it doesn't have to be in the terms of award as a 'red flag' that will cause our institutions to refuse to accept the awards," McIntyre wrote in the letter. "If NCI is insisting on

this section, I suspect that some or all of our institutions will turn down the awards.

"You should understand that we support the idea that we should not pay for work that is unacceptable," McIntyre continued. "How to guarantee that we can achieve 100 percent on this is the issue."

### **Examine Relationship Of Groups To NCI**

In a letter to National Cancer Advisory Board Chairman Barbara Rimer, McIntyre suggested that the board examine the role of the cooperative groups and their relationship with NCI.

In the letter dated Nov. 18, McIntyre, whose term as chairman of the group chairs ended last month, noted that he presided over the committee during the crisis over the National Surgical Adjuvant Breast & Bowel Project.

"As reported in **The Cancer Letter** [Nov. 4], Dr. [Harold] Varmus [NIH director] has commented that the several departures from leadership positions within NCI offers the opportunity for a re-examination of the organization and programs within the Institute," McIntyre wrote.

"This would also be an excellent time for a thorough and frank discussion concerning the organization and conduct of clinical trials under the leadership of NCI."

### **Group Chairs "Greatly Disturbed"**

"It is no secret that a number of cooperative group chairs have been greatly disturbed by the recent course of action NCI has set in motion," McIntyre continued. "Our community is concerned because of steps that NCI has taken to increase or threaten to increase the level of control over extramural science and in particular to direct it.

"Although these measures have been put in place in response to what NCI genuinely regards as its 'oversight responsibility,' the net result has been a serious erosion of morale both within the NCI as well as the extramural community," he wrote.

"There is probably no better time for those of us who have witnessed these events to sit down for a constructive discussion with the parties involved in hopes that a thorough review of the program and its organization will be a benefit to all concerned," McIntyre wrote.

**Sharon Murphy**, of Northwestern Univ., chairman of the Pediatric Oncology Group, was elected to replace McIntyre as chairman of the group chairs.

## **Leukemia Society Accepting Applicants For New Grants**

The Leukemia Society of America is accepting research grant applications for a new program in translational research.

The program was developed as a result of a workshop earlier this year sponsored by the society and NCI (**The Cancer Letter**, Jan. 21). The objective of the program is the early stage support of novel clinical therapeutic research on leukemia and its related cancers, emphasizing innovative strategies, firmly grounded on laboratory observations.

The society has set aside \$1.5 million for the first-year funding for up to 10 awards. Awards will be made for a two-year period, and a third year of funding may be provided for projects of high promise.

The program is designed to foster interactions between basic scientists in a variety of disciplines and clinicians performing clinical trials in leukemia and related cancers, to expand the opportunities for bringing innovative basic research findings to the clinic.

Applications are sought proposing novel approaches relevant to the treatment of hematopoietic malignancies. Proposals must be conceptually innovative and rationally based on molecular, cellular, or pharmacological laboratory studies.

Examples of research areas that proposals might focus on include, but are not limited to: regulation of apoptosis, gene-directed therapies, cell adhesion factors, angiogenesis, tumor targeting, differentiating agents, signal transduction regulators, and novel cytotoxic agents.

The program is intended to provide support over an initial two-year period. Projects which demonstrate promise over this time frame will, through the involvement of an NCI coordinator, be directed to seek further funding from traditional NIH funding sources for clinical therapeutic research. In certain instances, funding may be available for a third year from the Leukemia Society.

NCI has agreed to assign a project coordinator to each awardee to provide assistance and consultation to the investigator and to keep the investigator informed about NIH policies and procedures that will enhance the investigator's subsequent ability to successfully compete for NIH funding.

Applications may be submitted by domestic and

foreign non-profit organizations, public and private. Applications from minority and women investigators are encouraged.

Awards will be limited to an annual maximum of \$100,000 in direct costs and 30 percent overhead. Budget requests should be carefully justified and commensurate with the needs of the project.

Scientific peer review will be conducted by the society's Translational Research Grant Review Committee. A second level of review by the society's Committee on Medical and Scientific Affairs will consider the recommendations of the grant review committee and propose funding awards to the society's National Board of Trustees. Awards will be made by vote of the trustees.

#### **Inquiries:**

Instructions for proposal submission are contained in the Translational Research Grant application packet, available from: Research Program Administrator, The Leukemia Society of America Inc., 600 3rd Ave., New York, NY 10016, Tel: 212/573-8484, Fax: 212/972-5776.

Applications must be received at the society's New York office by 5 p.m. on March 1. Award announcements will be made in July and funding activated on Sept. 1.

#### ***In Brief***

### **Hill Wins Edwards Medal; Fowble Moves To Fox Chase**

(Continued from page 1)

Margaret Hay Edwards Medal for Excellence in Cancer Education was presented to **George Hill**, of New Jersey Medical School. The 1995 AACE annual meeting is scheduled for Nov. 9-12, in Tampa, FL. Abstracts are due April 15. Forms and instructions are available in the Journal of Cancer Education. . .

**BARBARA FOWBLE** was appointed staff radiation oncologist and associate director of the Fox Chase Cancer Center's breast cancer program. She was professor of radiation oncology and co-director of the breast cancer evaluation center at the Hospital of the Univ. of Pennsylvania. She is conducting research in breast cancer in younger women. . . **DAVID SCHAPIRA** has been appointed director of the Louisiana State Univ.-Stanley S. Scott Cancer Center and professor and chief of the section of hematology/oncology at LSU Medical Center. Schapira was director of the cancer prevention program at the H.

Lee Moffitt Cancer Center & Research Institute. . . **COMPUTER PROGRAM** for teaching newly diagnosed breast cancer patients about the disease and surgical options has been developed at M.D. Anderson Cancer Center. Using interactive videodisc technology, the program allows video images to appear on a computer monitor as part of the individualized, self-paced instruction. "We developed this program to help alleviate some of the fears associated with a diagnosis and to enable breast cancer patients to make informed decisions—with the surgeon—regarding surgical treatment options," said **Eva Singletary**, chief of breast surgery. The program may not reduce the time health care providers spend with patients, but it helps patients better articulate questions about treatment, she said. The program will be available to other hospitals and cancer centers in a few months.

### **NIH Defines Misconduct, Lists Awardee Responsibilities**

NIH has issued a statement on the responsibilities of NIH and awardee institutions for the responsible conduct of research. The statement was issued in the Dec. 2 NIH Guide to Grants and Contracts:

The responsible conduct of research is an important public policy issue. Cases of misconduct in science present a serious threat to continued public confidence in the integrity of the scientific process and the stewardship of Federal funds. The Public Health Service has set forth regulations and policies (42 CFR Part 50, Subpart A) for handling misconduct in science. The purpose of this notice is to provide guidance on the responsibilities of awardee institutions under current regulations when misconduct in science affects the design, conduct, or reporting of research funded by the NIH.

**Definition:** Misconduct in science is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgements of data. Copies of the regulation pertaining to misconduct in science are available from the Office of Research Integrity.

#### **Policy:**

1. It is the policy of PHS to maintain high ethical standards in research and investigate and resolve

promptly and fairly all instances of alleged or apparent misconduct. NIH places responsibility on awardee institutions to assure that each NIH funded program, function, or activity is progressing toward its respective goals (45 CFR Part 74.81) and that awarded funds are expended solely for the purpose of the award in accordance with the approved application and budget, applicable regulations, the terms and conditions of the award, and the applicable cost principles. These responsibilities must be carried out with extra care where misconduct in science has been found or where a misconduct in science investigation has been initiated.

2. Where a misconduct in science investigation has been initiated that involves alleged misconduct affecting an ongoing project, the awardee institution, consistent with its responsibilities under applicable regulations, is responsible for taking whatever steps are necessary to protect the scientific integrity of the project; protect human or animal subjects; provide reports to ORI; ensure that awarded funds are properly expended; and ensure the continuation of the project, to the extent such continuation is consistent with the foregoing objectives and the need to ensure a prompt, fair investigation. Affirmative obligations are imposed in each of these areas by 42 CFR 50.103 and 50.104. The institution should consult with the ORI and the funding agency as necessary to accomplish these objectives. Appointment of a qualified institutional official not previously connected with the research project to oversee the scientific and/or financial aspects of the project is an example of an action that may be necessary, depending upon the circumstances.

3. When a finding of misconduct in science has been made against an individual or individuals working on the funded project by the ORI, the awardee institution must assess the effect of that finding upon the qualifications of the Principal Investigator or other staff named in the application. Proposed changes must be reported promptly to the awarding agency. In accord with 42 CFR Parts 52.2 and 52.5(a), the awarding agency may withdraw its approval of the PI or other staff named in the application against whom a finding of misconduct has been made, and require the appointment of acceptable substitutes before the project may continue. If PHS or HHS has imposed administrative actions based on an ORI finding of misconduct, such as debarment of an investigator from Federal funding, the awardee institution is expected to make any changes necessary on the funded project to comply with such actions.

4. A finding of misconduct in science that has a significant effect upon the conduct of a funded project may constitute grounds for the withholding of additional awards and the suspension and/or termination of current funding under 45 CFR Parts 74.114 and 74.115.

5. Under 45 CFR 74.170, et seq., and the cost principles referenced therein, expenditures of awarded funds for research that is invalid or unreliable because of misconduct in science may be considered unallowable costs for which the awardee institution is liable for repayment to the awarding agency. This is decided on a case-by-case basis. This and any other determination of unallowable costs is appealable under 42 CFR Part 50, Subpart D and 45 CFR Part 16.

6. Where the validity or reliability of data has been affected by misconduct in science, the awardee institution and its employee authors are responsible for submitting a correction or retraction of data to a journal, as appropriate, and/or for republishing the corrected data. Such corrections or retractions may be required as a PHS administrative action. If the institution does not meet its responsibilities, the awarding agency may invoke its rights to access the data (45 CFR Part 74.211) and to use copyrightable material developed under the award (45 CFR Part 74.145), have the data reviewed, and submit the correction.

**Cooperation and Technical Assistance:** Staff of the ORI are available to assist awardee institutions in responding to misconduct in science. Staff of the NIH awarding agencies are available to provide technical assistance to protect funded projects from the adverse effects of misconduct in science. The joint responsibilities of the awarding agencies and the awardee institutions are the protection of human and animal subjects, proper stewardship of public funds, and ensuring the integrity of the scientific data from the project.

**Inquiries:** Questions concerning technical assistance to protect funded projects should be directed to: NIH Agency Extramural Research Integrity Officer, NIH Bldg 1 Rm 152, Bethesda, MD 20892, Tel: 301/496-5356, Email: gg9i@nih.gov. Questions concerning the conduct of institutional or ORI inquiries or investigations should be directed to: Division of Research Investigations, Office of Research Integrity, 5515 Security Ln., Suite 700, Rockville, MD 20852, Tel: 310/443-5330, FAX: 301/594-0039, Email: dmacfarlane@oash.ssw.dhhs.gov.