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Medicare Will Cover Patient Care Costs For All Phases Of Cancer Treatment Trials

After several fits and starts, the Clinton Administration has unveiled a Medicare clinical trials reimbursement policy that appears to be consistent with demands of cancer researchers and advocates.

The new "national coverage decision" published by the Health Care Financing Administration in August mandates reimbursement of routine costs associated with participation in clinical trials for all diseases.

Sources said the policy is expected to take effect in mid-September. The HCFA document is posted at http://www.hcfa.gov/quality/8d1.htm.

The document is certain to resolve the controversy that erupted over

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In Brief:

Neuro-Oncologist Schold Leaves Duke For UPCI; Rosner Leads Institute At Chicago

CLIFFORD SCHOLD, director for neurosciences at Duke Clinical Research Institute at Duke University, was appointed director of the University of Pittsburgh Cancer Institute Neuro-Oncology Program. Schold will coordinate the program's current and new efforts in neuro-oncology, neurology, neurosurgery, neuropathology, neuro-imaging, radiation oncology, and translational research. Schold will co-direct the UPCI Brain Tumor Center with **Ian Pollack**, and hold appointments as professor in the division of hematology/oncology and in the departments of medicine and neurology at the UP School of Medicine. Schold is expected to assume additional clinical trials responsibilities over time in Pittsburgh. . . . **UNIVERSITY OF CHICAGO** Cancer Research Center appointed **Marsha Rosner** director of the Ben May Institute for Cancer Research and deputy director of the UCCRC. Rosner was director of cancer education and chairman of the Cancer Biology Training Program. She replaces **Jeffrey Bluestone,** who was named head of the Diabetes Institute at the University of California, San Francisco. **Michelle LeBeau**, head of the Cancer Molecular Genetics Program at UCCRC, was appointed chairman of the Cancer Biology Training Program. **Glenn Steele** was reappointed to another five-year term as dean of the Biological Sciences Division. . . . **DAN IHDE**, of Washington University in St. Louis, Moffit Cancer Center and NCI, will receive the Bristol-Myers Squibb Award for Excellence in Lung Cancer Research at the 9th World Conference on Lung Cancer in Tokyo, Sept. 11. The award is presented every three years to a researcher who has made seminal and sustained

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All Phases Of Treatment Trials To Be Covered By Medicare

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HCFA's earlier efforts to implement President Clinton's June 7 executive memorandum mandating Medicare coverage for patient care costs. Interpreting the President's wishes, HCFA produced an earlier draft policy that could have in effect curtailed reimbursement (**The Cancer Letter**, June 9, June 18, July 28).

The definition of clinical trials in the final HCFA policy includes all phases of treatment trials. The regulation would not cover prevention trials and toxicity trials conducted in healthy volunteers. The definition of "covered services" includes everything but the cost of the experimental agents and the cost of collecting and managing the data.

The federal government will not create a review board for establishing eligibility trial by trial. Instead, coverage will be extended automatically to trials sponsored or reviewed by government agencies. Under the policy, principal investigators would be required to enroll the trial in the Medicare clinical trials registry for tracking purposes.

In cancer, coverage will be extended to NCI-funded trials, NCI-designated cancer center trials, as well as trials conducted under IND licenses from FDA and IND-exempt trials.

"The vast majority of cancer trials will be covered under this provision," said Richard Pazdur, director of the FDA Oncology Drug Products Division. "The federal agencies, including FDA and NCI, worked together with advocacy groups and professional societies to eliminate this obstacle to clinical trials accrual."

HHS plans to convene an advisory board to develop the criteria for trials that are not automatically deemed eligible for coverage of patient care costs.

The Cancer Leadership Council, a patient-led group, is preparing a detailed response to the HCFA document. While the council's response will ask the administration to clarify some fine points, for the most part, the policy gives patient advocates what they wanted, said Ellen Stovall, executive director of the National Coalition for Cancer Survivorship.

"We at NCCS applaud officials at HCFA for drafting a comprehensive document that implements, in a very thorough manner, the national coverage decision announced by President Clinton in June," Stovall said.

In formal comments to HCFA, CLC members are expected to ask for a clarification of language on eligibility of privately-sponsored trials.

This appears to be a technical point:

The document states that trials conducted under INDs or IND exemptions would be deemed covered. However, elsewhere, the document states privately-sponsored trials would be covered only after HHS officials and their outside advisors derive criteria for assessing privately sponsored trials.

"The cancer advocacy community is united in its comments back to HCFA to tighten the language around extending 'deemed' coverage status to privately sponsored trials that occur under an IND exemption from the FDA," Stovall said. "We feel confident that this one remaining point of clarification will result in an excellent benefit for Medicare eligible patients who want to participate in cancer clinical trials."

The final policy appears to be consistent with the recommendations of a recent Institute of Medicine report that reviewed reimbursement for patient care costs in cancer clinical trials.

The IOM report, titled "Extending Medicare Reimbursement in Clinical Trials," defines routine costs as "care that would be received by a patient undergoing standard treatment. This would include such items as room and board for patients who are hospitalized, diagnostic and laboratory tests and monitoring appropriate to the patient's condition, post-

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World Wide Web: http://www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-362-1681
PO Box 9905, Washington DC 20016
E-mail: kirsten@cancerletter.com or paul@cancerletter.com

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surgical care when indicated, [and] office visits."

The report is available at http://www.nap.edu/books/0309068886/html.

The IOM report recommends that coverage should include all costs except the cost of the investigational agents and protocol-induced costs. Protocol-induced costs are defined as "patient care costs incurred in a clinical trial for services necessary solely to satisfy data collection needs of the clinical trial, such as monthly CT scans for a condition usually requiring only a single scan. Care that would be required under standard treatment—even if it also is required by the trial protocol—would not be considered protocol-induced."

The following is an edited text of the HCFA decision:

Previously, Medicare has not paid for items and services related to clinical trials. One result of this policy has been a lack of information about the safety and effectiveness of medical interventions for the Medicare population. Only a small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease.

On June 7, the U.S. President issued an executive memorandum directing the Secretary of HHS to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials."

Definition of Routine Costs of Clinical Trials

For purposes of this national coverage decision, routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (e.g., hospital services, physician services, diagnostic tests) that are provided in a clinical trial *except:*

* the investigational item or service, itself,

* items and services provided solely to satisfy data collection needs (protocol induced costs); and

* items and services provided by the trial sponsor without charge.

For further clarification, routine costs that will be covered in clinical trials include:

* Items or services that are typically provided absent a clinical trial (e.g., conventional care);

* Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

* Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications.

In its recent report, "Extending Medicare Reimbursement in Clinical Trials," the Institute of Medicine defines routine costs of clinical trials as "care that would be received by a patient undergoing standard treatment.

"This would include such items as room and board for patients who are hospitalized, diagnostic and laboratory tests and monitoring appropriate to the patient's condition, post-surgical care when indicated, office visits, and so on."

The IOM report specifically recommends excluding from Medicare coverage the investigational item or service, itself, and protocol-induced costs.

The IOM defines protocol-induced costs as "patient care costs incurred in a clinical trial for services necessary solely to satisfy data collection needs of the clinical trial, such as monthly CT scans for a condition usually requiring only a single scan. Care that would be required under standard treatment—even if it also is required by the trial protocol—would not be considered protocol-induced."

Thus, our proposed policy is consistent with the IOM's definition.

Definition of Clinical Trial for Purposes of Medicare Coverage

In order to implement this proposed coverage policy for routine costs in clinical trials, Medicare must define the clinical trials for which payment should be made. Therefore, we must develop a way to identify trials that meet an appropriate standard of quality and for which it is appropriate for Medicare to pay for associated routine costs.

We propose that all clinical trials must meet certain requirements in order for Medicare to pay for associated routine costs. As with Medicare coverage for any item or service, the subject of the trial must evaluate an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

Trials that are designed exclusively to test such things as toxicity levels or basic disease biology are excluded from coverage of routine costs. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers.

Trials funded by certain Federal agencies, as described below, will be automatically deemed to receive Medicare coverage of routine costs as soon as this NCD takes effect.

Other types of trials will be included later as the principal investigators certify that the trials meet criteria developed by a Federal multi-agency group that are based on the desirable characteristics that follow. The certification process will be simple and not pose a significant burden to the sponsors and investigators in the trials that are not deemed.

The proposed desirable characteristics of a trial are:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

3. The trial does not unjustifiably duplicate existing studies;

4. The trial design is appropriate to answer the research question being asked in the trial;

5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

6. The trial is in compliance with federal regulations relating to the protection of human subjects; and

7. The trial is conducted according to appropriate standards of scientific integrity.

For trials that do not have deemed approval status, we propose that a Federal multi-agency group, external to HCFA, identify criteria that indicate that a trial is likely to have these desirable characteristics. We propose that the Agency for Healthcare Research and Quality convene a multi-agency Federal group composed of representatives of the Department of Health and Human Services research agencies, NIH, Centers for Disease Control and Prevention, AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense, and the Department of Veterans Affairs. [Sources said FDA will also be involved in these meetings.]

This multi-agency group would develop qualifying criteria that indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria should be easily verifiable, and where possible, dichotomous. The multi-agency group will not approve trials. Trials that meet the qualifying criteria developed by the multi-agency group would receive Medicare coverage of their associated routine costs.

The qualifying criteria would be developed under the authority found in §1142 of the Social Security Act (cross-referenced in §1862(a)(1)(E) of the Act).

A trial's principal investigator would submit a certification form indicating which of the qualifying criteria the trial meets and a copy of the trial protocol to a Medicare clinical trials registry. If the completed certification form demonstrates that the trial meets the criteria, the registry would assign a trial identifier to it. This identifier would allow the routine costs of the trial to be billed to Medicare. The Medicare clinical trials registry will be designed to protect patient confidentiality.

The multi-agency group would meet periodically to review and evaluate the program and recommend any necessary refinements to HCFA. HCFA would fund the administrative costs of this multi-agency group and the development and maintenance of the clinical trials registry through an interagency agreement with AHRQ.

Certain trials are presumed to be of sound quality and would automatically be deemed to receive Medicare coverage of their associated routine costs. Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA, trials conducted at NCI cancer centers, and all trials of patients that are either conducted under an investigational new drug application or are exempt from having an IND under 21 CFR 312.2(b)(1) would have deemed status.

[Trials of FDA-approved drugs are exempt from the IND requirement if the following three conditions apply:

(i) "The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling of a drug;

(ii) "If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

(iii) "The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product."]

The trials' principal investigators would be required to enroll the trial in the Medicare clinical

trials registry for tracking purposes. All other trials would be required to meet the qualifying criteria established by the multi-agency group.

This approach of automatically including certain trials and establishing a self-certification approval process for others will avoid the administrative burden that a trial-by-trial review would impose on the Federal government and trial investigators.

A significant percentage of trials have already gone through an intensive peer-review process to obtain approval or funding by other entities.

HCFA would accept all approvals arising from this self-certification process unless HCFA's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries. We anticipate that such disapprovals would be rare.

Should HCFA find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain approval for Medicare payment of its associated routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §1879, §1842(l), or §1834(j)(4) of the Act, as applicable.

In such cases, the billing providers would be held liable for the costs. Trial sponsors and principal investigators may contractually handle liability issues. Where appropriate, fraud investigations of the billing providers and the trial's principal investigator may be pursued. Billing providers, of course, may avail themselves of existing procedures to appeal any adverse HCFA action.

We are soliciting comments about what qualifying criteria might be appropriate and adequate to capture the desirable characteristics of a trial. The criteria should be easily verifiable and, where possible, dichotomous (that is, objective yes/no responses). Some examples might be:

Is the trial approved by an investigational review board (IRB)?

Does the trial have a written protocol?

Has the trial been approved by a Federal agency?

Has the trial received any external, non-Federal funding?

Has the trial been reviewed by any external, non-Federal group?

Does a data safety and monitoring board provide independent oversight of the trial?

The qualifying criteria suggested by commenters on this NCD will be forwarded to the multi-agency group once it is convened.

Details on coding and payment methodology where current claims processing systems are inadequate to support implementation of this NCD will accompany publication of the final NCD. Proper implementation of such payment methodologies may require rulemaking. Moreover, we intend to initiate a rulemaking to make the category A and B investigational device exemption (IDE) policy consistent with this NCD once it is finalized. Rulemaking will ensure that trials studying category A devices will be able to receive coverage of routine costs, as defined by this NCD.

Following final publication of this NCD, we will provide further clarification about how to identify properly which costs are routine patient care ones and which costs are protocol-induced ones. As part of that clarification, we may require that a trial's principal investigator and sponsors submit further material to the Medicare clinical trials registry.

Examples of what we may request are a declaration of protocol-induced costs and a list of items and services being provided by the trial sponsor. For tracking purposes, will will probably also require a list of Medicare beneficiaries enrolled in the trial. Such information would be handled to ensure beneficiary confidentiality.

Impact on Medicare+Choice

Medicare regulations (42 C.F.R. §422.101(b)) require Medicare+Choice (M+C) organizations to follow HCFA's national coverage decisions. This proposed NCD would establish Medicare coverage for certain items and services furnished as part of clinical trials that have the characteristics described above.

Except under certain specific circumstances (e.g., emergency care), M+C organizations furnish, or pay for, items and services covered under original Medicare only within the limits of a plan's rules governing the plan's network of providers and out-of-network referrals. For example, M+C organizations are not required to pay for services covered under original Medicare if a plan enrollee obtains covered services outside a plan's network without obtaining a pre-approval or referral required by the plan.

This NCD raises special issues that require some modification of the usual rules governing provision of items and services in and out of network in the M+C organization context. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials.

However, an M+C organization typically will not have in its network all of the providers that participate in the clinical trials that are described in this NCD. To the extent that providers participating in clinical trials are within an M+C organization's network, the M+C organization can and should provide items and services within its network in accordance with this NCD. However, because an M+C organization is obligated to cover the items and services covered under this NCD, if a provider that participates in a clinical trial is not part of the M+C organization's network, the M+C organization must provide items and services out-of-network in accordance with this NCD.

At the same time, we recognize the essential role of plans in the appropriate management and coordination of beneficiary health care. Thus, plans may have reporting requirements when enrollees participate in clinical trials that allow them to coordinate care appropriately. Plans are free to use their current tracking systems or develop new ones but they cannot require prior approval or prior authorization such services.

Medicare regulations (42 C.F.R. §422.109) also provide that, if HCFA were to determine that an NCD meets the criteria for "significant cost," M+C organizations would not be required to bear the risk for the costs of the items and services covered under an NCD until the capitation rates are re-determined on a basis that incorporates those costs.

Rather, the M+C organizations would be required to furnish, arrange, or pay for the items and services in the interim period, and obtain reimbursement from the Medicare fiscal intermediary and/or carrier in accordance with the original Medicare payment rules, methods, and requirements.

HCFA's Office of the Actuary is analyzing whether this NCD meets the criteria for "significant cost." In determining whether this NCD meets the criteria for "significant cost," HCFA will take into account the additional costs to M+C organizations deriving from the requirement to pay for the items and services covered under this NCD outside of plan networks.

NCI Programs:

Seven Organizations To Use NCI-Army Coding System

Seven organizations that fund cancer research said this week that they would join NCI and the U.S. Army Medical Research and Materiel Command in adopting a standard coding system to describe research projects.

The new system, called the Common Scientific Outline, will enable the organizations and the federal government to better compare and coordinate research efforts, NCI officials said.

"The CSO helps to lay a framework for better coordination among research organizations," NCI Director Richard Klausner said. "It puts everybody on the same page as they evaluate their scientific portfolios, helping to point to areas of possible collaboration and suggesting areas of duplicated or undersupported study."

The organizations that agreed to use the new system were: American Cancer Society, California Cancer Research Program, California Breast Cancer Research Program, Cancer Research Campaign of the United Kingdom, CaP CURE, Susan G. Komen Breast Cancer Foundation, and Oncology Nursing Society.

The CSO was designed for easy accessibility to scientists and the public, NCI said. Organized around seven broad areas of scientific interest in cancer research, these categories include: biology; etiology; prevention; early detection, diagnosis, and prognosis; treatment; cancer control, survivorship, and outcomes research; and scientific model systems.

NCI is developing a Web-accessible database, expected to be available by the end of the year, that will let users look up NCI-supported research by type of cancer and by scientific area, the Institute said.

NIH Consensus Conference Agenda, Registration Online

Speakers and topics for the NIH Consensus Development Conference on Adjuvant Therapy for Breast Cancer have been announced and are available online at http://odp.od.nih.gov/consensus.

Registration for the Nov. 1-3 conference in Bethesda, Md., is also available online. The conference is free and open to the public.

Like other NIH consensus conferences, the meeting will culminate in recommendations for clinical practice. Conference speakers will consider

data on chemotherapy, hormonal therapy, and other aspects of post-surgical (adjuvant) treatment that have emerged in recent years. A panel of experts from outside the NIH will use this information to address seven major questions:

--Which factors should be used to select systemic adjuvant therapy?

--For which patients should adjuvant hormonal therapy be recommended?

--For which patients should adjuvant chemotherapy be recommended? Which agents should be used and at what dose or schedule?

--For which patients should postmastectomy radiotherapy be recommended?

--How do side effects and quality-of-life issues factor into individual decision-making about adjuvant therapy?

--What are promising new research directions?

Sponsors of the conference are the NIH Office of Medical Applications of Research and NCI.

Funding Opportunities:
NIH RFAs Available

RFA CA-01-013: Cancer Care Outcomes Research and Surveillance Consortium

Letter of Intent Receipt Date: Oct. 15, 2000

Application Receipt Date: Jan. 24, 2001

NCI Division of Cancer Control and Population Sciences invites applications from domestic institutions for cooperative agreements to support a new collaborative research consortium that would conduct cancer care outcomes research and surveillance. Research institutions are invited to apply for primary data collection and research site awards that would support the conduct of prospective studies in newly diagnosed cohorts of lung and colorectal cancer patients. These prospective studies will collect information about medical care practices used to manage patients over the course of their disease, various outcomes associated with these practices, and information about patient and provider behaviors and perceptions.

This RFA is the first major step by NCI to support the development of a system for obtaining details about cancer care beyond the initial diagnosis and limited treatment data that are now routinely collected in high quality population-based cancer registries. This research will help build the information base needed for measuring and improving the quality of cancer care in the US.

This RFA cooperative agreement will fund individual grantees who will be formed into the CanCORS Consortium whose purpose will be to collaboratively collect and analyze process-outcome relationships in patients newly diagnosed with lung or colorectal cancer. Applicants must propose specific research hypotheses to serve as the scientific foundation of this data collection system. In addition, separate applications are invited to support a CanCORS Statistical Coordinating Center (SCC). The primary objectives of the SCC will be to develop and support the collection of standardized, core data across individual research sites, and to serve as the central repository for the analysis of pooled data.

A CanCORS website includes answers to frequently asked questions: http://www-dccps.ims.nci.nih.gov/ARP/cancors.html. See the full RFA: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-01-013.html.

Inquiries: Arnold Potosky, Division of Cancer Control and Population Sciences, NCI, 6130 Executive Blvd., Rm 4005, MSC 7344, Bethesda, MD 20892-7344, phone 301-496-5662; fax 301-435-3710; e-mail potosky@nih.gov

RFA CA-01-014: In Vivo Cellular and Molecular Imaging Centers

Letter of Intent Receipt Date: Oct. 17, 2000

Application Receipt Date: Nov 28, 2000

The Biomedical Imaging Program, NCI Division of Cancer Diagnosis and Treatment, invites applications for P50 Research Center Grants for the establishment of in vivo cellular and molecular imaging centers. The initiative is designed for studying cancer non-invasively, and in many cases, quantitatively due to recent advances in molecular imaging modalities, as well as molecular and cellular biology. The initiative will facilitate the interaction of scientists from a variety of fields such as, but not limited to: imaging sciences, chemistry, radiopharmaceutical chemistry, cellular and molecular biology, pharmacology, computer science, biomedical engineering, immunology and neuroscience, and provide resources to conduct multidisciplinary research. The RFA is available at: http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-01-010.html.

Inquiries: Anne Menkens, Bomedical Imaging Program, NCI, Executive Plaza North, Suite 800, Bethesda, MD 20892; phone 301-496-9531; fax 301-480-5785; e-mail am187k@nih.gov

RFA CA-01-012: Small Animal Imaging Resource Programs

Letter of Intent Receipt Date: Oct. 19, 2000

Application Receipt Date: Nov. 28, 2000

NCI invites grant applications from extramural and intramural investigators to support shared imaging research resources to be used by cancer investigators, research related to small animal imaging technology, and training of both professional and technical support personnel interested in the science and techniques of small animal imaging. Small Animal Imaging Resource Programs will be supported by the resource-related research projects R24 mechanism.

Inquiries: Barbara Croft, Diagnostic Imaging Program, NCI, 6130 Executive Blvd., Rm 800, Rockville, MD 20892-

7440, phone 301-496-9531; fax 301-480-5785; e-mail bc129b@nih.gov

RFA AT-00-004: Botanical/Drug Interactions

Letter of Intent Receipt Date: Nov 10, 2000

Application Receipt Date: Jan 12, 2001

The objective of this National Center for Complementary and Alternative Medicine initiative, which will use the NIH R01 and the NCCAM R21 award mechanisms, is to encourage biomedical research to prevent adverse botanical/drug interactions during therapy or anesthesia, to establish possible synergistic combinations of botanicals with pharmaceutical drugs, and to increase our knowledge of the mechanisms of action of botanicals.

Inquiries: Neal West, program officer, National Center for Complementary and Alternative Medicine, Bldg 31/Rm 5B58, Bethesda, MD 20892-2182, phone 301-402-5867; fax 301-402-4741; e-mail westn@od.nih.gov or Jeffrey White, director, Office of Cancer Complementary and Alternative Medicine, NCI, Executive Plaza North Suite 102, Bethesda, MD 20892, phone 301-435-7980; fax 301-480-0075, e-mail: jeffreyw@mail.nih.gov; Web site http://occam.nci.nih.gov

RFA DK-01-008: Role of Hormones and Growth Factors in Prostate Cancer

Letter of Intent Receipt Date: Feb. 27, 2001

Application Receipt Date: March 27, 2001

The RFA, which will use the NIH research project grant R01 and pilot and feasibility R21 award mechanisms, is designed to explore the underlying mechanism(s) of action of hormones and growth factors in the regulation of prostate development, growth, and tumorigenesis. The focus will be on fundamental studies of hormone and growth factor action including the mechanisms of action of nuclear hormones, the role(s) of nuclear accessory proteins and the signal transduction pathways important for nuclear hormone action in prostate. Focus will also be on growth factor action in prostate, including growth factors, binding proteins, receptors and signal transduction pathways.

Inquiries: For NCI—Suresh Mohla, chief, Tumor Biology and Metastasis Branch, Division of Cancer Biology, NCI, 6130 Executive Blvd, EPN Suite 5000, Rockville MD 20892-7364, phone 301-435-1878; fax 301-480-0864; e-mail sm82e@nih.gov

RFA CA-01-016 Development of High Yield technologies for Isolating Exfoliated Cells in Body Fluids

The initiative will promote the development of high yield technologies for capturing, enriching and preserving exfoliated tumor cells in body fluids. The preserved cells should be suitable for molecular, genetic, and biochemical studies.

Inquiries: Sudhir Srivastava, Cancer Biomarkers Research Group, Division of Cancer prevention, phone 301-496-3983; e-mail ss1a@nih.gov

In Brief:

Hood's ISB Gets $5 Million From Merck, Hires Scientists

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contributions to research that will have an major impact on the prevention and/or treatment of lung cancer. . . . **INSTITUTE FOR SYSTEMS BIOLOGY** of Seattle, received a $5 million from Merck & Co. Inc. for its work in molecular biotechnology and genetics. "This generous gift will provide the institute with critical discretionary resources for attacking leading-edge technical, biological and medical projects that otherwise might be difficult to fund from generally conservative federal sources," said **Leroy Hood**, president and director of ISB. In a related development, the institute appointed four scientists to the research staff. The new faculty members, who will bring another 30 scientists and researchers from the University of Washington, are: **Alan Aderem**, an expert in immunology and cell biology; **Ruedi Aebersold**, a leading protein biochemistry and proteomics researcher; **George Lake**, an astrophysicist with computational methods expertise; and **Ger van den Engh**, a multi-parameter high-speed cell sorting specialist. Aderem and Aebersold are institute co-founders along with Hood. . . . **LAWRENCE TABAK**, director of the Center for Oral Biology, Aab Institute of Biomedical Sciences, University of Rochester, was appointed director of the National Institute of Dental and Craniofacial Research at NIH beginning Sept. 1. "As NIH focuses on racial and ethnic health disparities, we are fortunate to have someone who has designed and managed a successful training program aimed at recruiting and developing minority investigators," said NIH Acting Director **Ruth Kirschstein**. . . . **NATIONAL MARROW DONOR PROGRAM**, of Minneapolis, appointed **Jeffrey Chell** as chief executive officer. Chell was president and chairman of the board of the Allina Medical Clinic and system vice president for clinical services of the Allina Health System. . . . **ALAN SANDLER**, associate professor of medicine, division of hematology-oncology at Indiana University Medical Center, was named medical director of thoracic oncology at Vanderbilt-Ingram Cancer Center in Nashville and director of its Affiliate Network Program. Sandler is a member and principal investigator for of the Thoracic Oncology Committee of the Eastern Cooperative Oncology Group.

INTERNATIONAL PEDIATRIC CANCER RESEARCH ORGANIZATION SEEKS:

SCIENTIFIC WRITER

Will write/edit: scientific manuscripts on results of clinical trials for peer-reviewed medical & scientific journals, grant applications, study protocols & scientific articles for newsletter. Will collaborate with statisticians & investigators to achieve high quality, original scientific publications. Ph.D. in the life sciences. 8+ years of research training in immunology, molecular biology, cancer research, or related. Knowledge of clinical research & statistical methods. Writing experience including published manuscripts, grants, or other doc's related to scientific research. Work collaboratively with investigators. Please submit a writing sample with your resume.

REGULATORY COMPLIANCE MANAGER

Responsible for ensuring regulatory compliance, directing on-site & internal audit program, adverse event reporting, training & conducting continuing education, reporting on institutional performance & all aspects of regulatory compliance. BS required; MS preferred. 6 years professional experience in clinical research setting, thorough knowledge of good clinical & research practice. Strong regulatory background, especially NCI, NIH & Code of Federal Regulations/Human Subjects. Detailed knowledge of hospital & research chart elements, statistical reporting & team management skills. Computer literate: Microsoft Suite.

Send cover letter and resume, with salary history, to National Childhood Cancer Foundation at HR@NCCF.org or fax to (626) 447-6359. EOE

You can learn more about the organization by logging on to www.nccf.org

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