

Publication: T. M Sissung *et al.* Association of ABCB1 genotypes with paclitaxel-mediated neutropenia and peripheral neuropathy. To be submitted to *Clinical Pharmacology and Therapy*.

Patent Status: U.S. Provisional Application No. 60/807,453 filed 14 Jul 2006 (HHS Reference No. E-237-2006/0-US-01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: David Lambertson, PhD; 301/435-4632; lambertsond@od.nih.gov.

Collaborative Research Opportunity: The NCI Medical Oncology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize ABCB1 genotyping to predict paclitaxel toxicity. Please contact Betty Tong, PhD at 301-496-0477, tongb@mail.nih.gov for more information.

Use of Grape Skin Extracts as Anti-Cancer Agents

Description of Technology: The invention describes anti-tumor effects of extracts from grape skins. Grape skin extract and derivatives may therefore be useful as preventive or therapeutic agents against tumor development.

Literature indicates that grape and red wine consumption may be inversely associated with prostate cancer risk. Moreover, to date there are no known grape skin extract-associated toxicities described. The current invention discloses that grape skin extract, or purified fractions thereof, inhibited metastatic growth in human prostate transformed cell lines. Specifically, grape skin extract induced cellular apoptosis via inhibition of the phosphatidylinositol 3-kinase (PI3-K)/Akt survival pathway.

Historically, anti-tumor effects of grapes were mainly attributed to resveratrol, a phytoalexin present in grapes, nuts and wild berries. However, resveratrol's mechanism of anti-tumor action is distinct from that of grape skin extract, in that it arrests cell cycle division without significant induction of apoptosis.

The current invention also provides for methods of treating patients with prostate cancer or persons at risk for developing prostate cancer with compositions that include grape skin extract or active anti-tumor fractions thereof.

Development Status: Pre-clinical stage.

Inventors: Tamaro Hudson and Jeffrey E. Green (NCI).

Patent Status: U.S. Provisional Application No. 60/789,181 filed 03

April 2006 (HHS Reference No. E-179-2006/0-US-01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: David A. Lambertson, PhD; 301-435-4632; lambertsond@od.nih.gov.

Collaborative Research Opportunity: The NCI's Laboratory of Cell Regulation and Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Patrick Twomey, PhD at 301-496-0477 or twomeyp@mail.nih.gov for more information.

Dated: August 23, 2006.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E6-14353 Filed 8-29-06; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, September 11, 2006, 5 p.m. to September 13, 2006, 5 p.m. Doubletree Hotel Bethesda, 8120 Wisconsin Ave., Bethesda, MD, 20814 which was published in the **Federal Register** on July 25, 2006, 71 FR 42099.

The meeting notice is amended to reflect the change in hotel from the Doubletree Hotel, 8120 Wisconsin Ave., Bethesda, MD 20814 to the Clarion Hotel, 8400 Wisconsin Ave., Bethesda, MD 20814. The meeting is closed to the public.

Dated: August 22, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06-7228 Filed 8-29-06; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, September 11, 2006, 5 p.m. to

September 13, 2006, 6 p.m., Doubletree Hotel, 8120 Wisconsin Ave., Bethesda, MD, 20814 which was published in the **Federal Register** on July 25, 2006. 71 FR 42098.

The meeting notice is amended to reflect the change in hotel from the Doubletree Hotel, 8120 Wisconsin Ave., Bethesda, MD 20814 to the Clarion Hotel, 8400 Wisconsin Ave., Bethesda, MD 20814. The meeting is closed to the public.

Dated: August 22, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06-7229 Filed 8-29-06; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Minority Health and Health Disparities, September 12, 2006, 8:30 a.m. to September 12, 2006, 5 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on August 18, 2006, 71 FR 47817.

The meeting location changed to the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, Maryland 20814. The meeting is partially closed to the public.

Dated: August 23, 2006.

Anna Snouffer

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06-7227 Filed 8-29-06; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute, NEI Conference Application Review.

Date: August 31, 2006.

Time: 4:30 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892; (Telephone Conference Call).

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute; 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892; 301-451-2020; haraj@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: August 23, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06-7226 Filed 8-29-06; 8:45 am]

BILLING CODE 4141-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): Proposed Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)

ACTION: Notice.

SUMMARY: The NIH is seeking comments regarding a proposed policy for NIH supported or conducted Genome-Wide Association Studies (GWAS). A genome-wide association study is currently defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. The proposed policy addresses (1) data sharing procedures, (2) data access principles, (3) intellectual property and (4) issues regarding the protection of research participants through all phases of GWAS. Many of the principles contained in the policy reflect and extend existing NIH policies (e.g., the

2003 data sharing policy¹) and other recent NIH discussions.²

DATES: Responses must be received by October 31, 2006 in order to ensure that the NIH will be able to consider the comments when developing new policies.

FOR FURTHER INFORMATION CONTACT:

Inquiries will be accepted at: http://grants.nih.gov/grants/guide/rfi_files/NOT-OD-06-094_rfi_add.htm or GWAS@nih.gov. Comments can be mailed to NIH GWAS RFI Comments, National Institutes of Health, Office of Extramural Research, 6705 Rockledge Drive, Room 350, Bethesda, MD 20892-7963.

SUPPLEMENTARY INFORMATION:

Background

The NIH is interested in advancing GWAS to identify common genetic factors that influence health and disease. Whole genome information, when combined with clinical and other phenotypic data, offers the potential for increased understanding of basic biological processes affecting human health, improvement in the prediction of disease and patient care, and ultimately the realization of the promise of personalized medicine. In addition, rapid advances in understanding the patterns of human genetic variation and maturing high-throughput, cost-effective methods for genotyping are providing powerful research tools for identifying genetic variants that contribute to health and disease. For these reasons, the NIH announced this spring that it has planned to: (1) Update the NIH data sharing policy for research applications involving GWAS data; (2) initiate a public consultation process to inform policy development activities; and (3) track GWAS applications and awards at a central level (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-071.html>). This RFI serves as the first step in the public consultation process referenced in the May 15, 2006 Notice.

Protecting Research Participants. The potential for public benefit to be achieved through sharing GWAS data is significant. However, genotypic and phenotypic information generated about individuals, such as data related to the presence or risk of developing particular diseases or conditions, and information regarding paternity or ancestry, may be

sensitive and substantial. Therefore, it is critically important that the privacy and confidentiality of the participants be protected. Risks to individuals, groups, or communities should be carefully balanced with potential benefits of the knowledge to be gained through GWAS. The nature of GWAS information about participants and the broad data distribution goals of the NIH GWAS data repository highlight the importance of the informed consent process to this research. In order to protect research participants, the NIH will establish mechanisms to oversee the repository and monitor GWAS data use practices.

The NIH recognizes that there are evolving scientific, ethical and societal issues relevant to this proposed policy and will revisit and revise the policy as appropriate.

Proposed Policy for Genome-Wide Association Studies (GWAS)

Principles

Consistent with both the NIH mission to improve public health through research and its longstanding legislative mandate to make available to the public the results of the research activities that it supports and conducts, the NIH believes that the full value of GWAS to the public can be realized only if the genotype and phenotype datasets are made available as rapidly as possible to a wide range of scientific investigators. Rapid and broad data access is particularly important for GWAS because of the significant resources involved; the challenges of analyzing large datasets; and the extraordinary opportunities for making comparisons across multiple studies.

Protection of research participants is a fundamental principle underlying biomedical research. The NIH is committed to responsible stewardship of data throughout the research process, which is essential to protecting the interests of study participants and to maintaining public trust in biomedical research.

Applicability

This draft policy is proposed to apply to active research applications identified by applicants or NIH staff as GWAS per NOT-OD-06-071.

Data Management

Data Repository. To facilitate broad and consistent access to NIH-supported GWAS datasets, the NIH proposes the development of a central GWAS data repository, at the NIH (National Center for Biotechnology Information [NCBI], National Library of Medicine). The repository will provide a single point of

¹ The 2003 NIH Data Sharing Policy applies to investigators seeking \$500,000 or more in direct costs in any year (http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm).

² Request for Information on Modifications to the NHLBI Policy for Distribution of Data from Clinical Trials and Epidemiology Studies (<http://www.nhlbi.nih.gov/funding/policies/rfi-genome.htm>), 2006.